HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Public Consultation on

Annual Review and Proposal for Fees – Financial Year 2026

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

OCTOBER 2025

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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[1] of the HPRA. Since 2004, the HPRA has implemented a policy of annual fee reviews following consultation with industry. For medical devices, cosmetics, blood, tissues and cells, the HPRA receives a partial subvention from the Department of Health but also commits to ensure that the income received matches the costs of those functions.

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 2026.

2 THE OPERATING ENVIRONMENT

In 2025 the HPRA operating environment stabilised after a number of challenging years following the COVID-19 pandemic. Hybrid working is established within the organisation, enabling nearly 500 staff to return to the office while continuing to facilitate homeworking. While the hybrid model continues to be reviewed, the organisation has adapted to the new way of working.

2025 was a busy year where the activity levels reached or exceeded the previous year. Volumes of transactions were high across all areas of the organisation, and this was combined with significant project work and the implementation and development of significant new legislative packages. For human medicines, we managed the regulatory transition arising from the expiry of the Brexit exemptions at the end of 2024 and the requirements from the commencement of the Windsor framework in January 2025. This work will be finalised in October 2025, and we will return to business as usual. For veterinary medicines we are preparing for the expiry of the Brexit

[1] 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.

exemptions. Shortages remained a feature of both the national and European market and continue to consume considerable resources. Preparing for the inquiry into sodium valproate and preparing a review of codeine containing medicines were also resource intensive in 2025 and will continue to be in 2026. A very significant piece of work in 2025 related to contributing to the new pharmaceutical legislative package at Europe. While the DOH was responsible for the Member State position and led on policy matters, the HPRA was able to contribute on technical matters and attended all Council working parties. As the legal text extended to beyond 500 pages this was a resource intensive work and preparatory work for its implementation will commence in 2026. Overall, human medicine income and other income categories are performing well in 2025. In 2026, authorisation and inspection volumes are expected to be consistent with 2025 and costs are expected to increase. Payroll costs were significantly less than planned in 2025 due to delays in approvals which meant that positions were unfilled for a large part of the year. In 2025, we experienced significant payroll increases arising out of the national State sector pay deal which will also impact 2026. In 2026, we also expect substantial increases in the cost of payroll related to increases in staff numbers particularly as we are expecting an uplift of 5% in staff in Q3/4 2025 and further increases in 2026. Increased staff numbers reflect delays in recruiting in 2025 and further staff requirements. Additional staff are also required to reflect the increased volume of activity and increased complexity of regulation. For 2026 we will start to implement our new strategic plan, we expect significant updates to the Clinical Trial Regulation, the Medical Device Regulation, new responsibilities under the Critical Medicines Act, the AI Act, NIS2, starting preparatory work for implementing the new pharma package and hosting over 20 meetings under the EU presidency. We must continue to address the level of Mutual Recognition Procedures (MRP) and Decentralised Procedures (DCP) in the system and the need for more centralised assessors to support the EMA. The medical device department continues to need additional staff as the Medical Device and *In Vitro* Medical Device Regulations (MDR and IVDR) are rolled out across Europe. General inflation has stabilised and is expected to be around 1.9% in 2026 but we are experiencing increases closer to 3% reflecting cost of living increases and wage inflation is 3.5% in 2025.

Pensions continue to be a growing cost and for the single service scheme, the employer contribution is up to 17% of the payroll cost of those employees. By its nature, this cost 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 all staff in this scheme will have their pension funded from the central exchequer. However, staff from pre 2013 are part of the local government superannuation scheme which is an unfunded pension scheme, and 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, availability and access to innovative therapies.

3 STRATEGIC DIRECTION OF THE HPRA

The HPRA has commenced the process of developing its new strategy for the period 2026 to 2028. We continue to deliver under our current strategic plan for the years 2021-2025. The new strategic plan is in draft and reflects extensive stakeholder engagement. As it has not yet been approved by the Minister, we cannot include it in this fees consultation but the high-level strategic goals from the current plan will be reflected in the new strategic goals.

The strategic plan for 2026-2028 will be published in Q4 2025. Projects for 2026 will include:

Public Health Priorities
- Contribute to the State Sodium Valproate inquiry.
- Progress activities in line with the HPRA strategic proposal for medicines availability/shortages.
- Deliver the final report for the codeine classification review.

Regulatory Priorities
- Work at national level with the Department of Health to develop proposed statutory instruments on the implementation of the new EU pharmaceutical legislation and build internal plans for implementation.
- Ensure regulatory preparedness and successful implementation for new legislation, e.g. NIS2, the EU AI Act, SoHO, CER-D.
- Lead on EU work packages for EU coordinated assessment of clinical investigations, performance studies and combination CTR studies.

Engagement and Collaboration Priorities
- Support the Department of Health and Permanent Representation in Brussels in relation to hosting the Presidency of the Council of the EU and prepare for hosting the 22 plus meetings in the regulatory network under the EU presidency.
- Host information campaigns and events to continue to promote the HPRA's visibility and value to the health sector.
- Participate in the EU presidency council working party in relation to the anticipated Commission proposals on medical devices and work with the DOH in agreeing the IE position to support the IE Presidency in the latter six months of 2026.

Business Priorities
- Develop our workforce planning processes by improving forecasting, role clarity, and cross-functional collaboration.

- Continue to work on initiatives to support the People Strategy, especially focusing on the career and capability framework project, implementation of the L&D roadmap to enhance organisational capabilities, succession planning and an updated Performance review process.
- Complete the onboarding of processes and data to Eolas and assess options for the upgrade or migration to an enhanced enterprise platform.
- Review IT system needs in areas such as pharmacovigilance, legal, enforcement and interfaces with EUDAMED, and deliver an organisation wide 'time recording' solution.
- Advance an organisational data strategy focusing on data optimisation and its utility linked to opportunities for identification of sources of risk. Pilot the conversion of the HPRA's unstructured data records to structured data sets using AI technologies.

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

4 THE OUTLOOK FOR 2026

Operating environment for 2025
While inflation has stabilised, the volume of work has increased and the need for additional resources has resulted in a challenging operating environment.

New legislation
As noted above there is extensive new legislation being negotiated/completed which will require preparation for implementation. This includes the new pharma package, the update to the MDR, the Critical Medicines Act, the SoHo regulation, update to the CTR, the Bio Tech act, NIS2 and the AI Act. In 2026 Ireland has the presidency for the last six months of the year, this means that there will be considerable support provided to the work in Brussels in relation to legislation in health products and supporting the 22 meetings hosted by the HPRA.

Medical Devices
The workload of the medical device department continues to increase significantly. The importance of the role that medical devices play in healthcare delivery, and the related challenges in their regulation is recognised. The MDR and IVDR are both applicable although transitional provisions still apply. Significant work remains in providing support to stakeholders to aid their understanding and support their implementation of the regulations. In addition, the Commission has announced an update to the MDR which is due to start shortly.

The new regulations place very explicit obligations on regulatory authorities in relation to their activities, resources and capabilities. Furthermore, the HPRA is to be appointed the competent authority under the EU AI Act which will have a particular focus on medical devices. 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 further staff increases in 2025/2026 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. The 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 outturn for 2025
The outturn for 2025 will be positive. This reflects the income levels operating as expected or above expectations and significantly lower costs, principally around payroll caused by the inability to bring the expected levels of staff on board in the first half of 2025.

Financial impacts on 2026
It is expected that there will be a substantial increase in costs for 2026. This reflects the high level of recruitment in Q3/Q4, planned additional staff in 2026 and a continuing increase to costs reflecting the increased workloads. Income levels are expected to be similar to those of 2025.

Payroll
The key driver of payroll increases in 2026 will be the impact of the new pay deal which was finalised in January 2024 and resulted in pay awards in 2024, 2025 and 2026 as follows:

Year 2024
- 2.25% or €1,125 whichever is higher in January 2024
- 1% in June 2024
- 1% or €500 whichever is higher to be paid in October 2024

Year 2025
- 2% or €1,000 whichever is higher to be paid in March 2025
- 1% to be paid in August 2025
- 1% to be paid in September 2025 (local bargaining)

Year 2026
- 1% or €500 whichever is higher to be paid in February 2026
- 1% in June 2026

The impact of these pay increases is to increase payroll by 3% in 2026.
There will also be additional staff numbers related to expanded functions, increased levels of work and increased pension costs.

Other costs
Inflation is running at 1.9% and we broadly expect other costs to increase by a similar amount. The HPRA expects that 2026 will be another challenging year in managing costs 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 2025. The nature of regulatory income is that it is dictated by industry activity, which can change significantly over a period of time.

As with previous years, the HPRA commits to review the proposed fees during the planning cycle in 2026 and further amend the fees and fee structure, if required, for 2027.

5 PROPOSED FEES

The HPRA proposes to increase fee by 2.5% to reflect wage and general inflation.

6 DETAILED CHANGES TO FEES

6.1 General change to fees

As outlined above, there will be a 2.5% adjustment to fees for the year 2026.

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 National Office fee

A single fee is charged by Ireland (the HPRA and the National Office for Research Ethics Committees ('National Office')) for each clinical trial application or substantial modification (previously known as substantial amendment). The sponsor pays the total fee to the HPRA at the time of application and following validation the HPRA transfers the corresponding portion to the National Office.

The HPRA proposes to increase the current CTR fees (see section 6.2.2 below). The National Office intends to review its fees and conduct an independent consultation on clinical trial fees that may impact the total single fee for CTR clinical trials. Following the National Office consultation, the HPRA will publish any changes to the single fee for CTR clinical trials in our fee documents. For information on the National Office fees, see https://www.nrecoffice.ie/apply/fees/

The National Office and the HPRA will continue not to charge for non-commercial/academic clinical trials to encourage non-commercial research.

6.2.2 Clinical trial fees

The HPRA proposes to increase the following clinical trial fees as follows to align with other Member States and to ensure clinical trials are sufficiently resourced. However, it is proposed not to increase the RMS fee for new clinical trial applications.

New clinical trial applications

Fee code	Description	Current HPRA fee	Proposed fee	Increase
1001	Applications with IMPD: Mono-national applications (i.e. Ireland only)	2,110	2,425	315
1003	Applications with IMPD: IE is a concerned member state for initial, or additional applications	1,870	2,150	280
1007	Mono-national (no IMPD, simplified IMPD or low interventional CT)	995	1,145	150
1009	IE is a concerned member state for initial, or additional applications (no IMPD, simplified IMPD or low interventional CT)	700	805	105

The general increase will apply to all other clinical trial fees.

6.3 Other proposed adjustments to fees – Human

6.3.1 National Scientific Advice

It is proposed to restructure the scientific advice fees, aligning existing fees with the required service and increasing those fees where complex advice is sought across a number of areas. Fee codes 240 and 246 only incorporate the general fee increase and fee code 248 and the new code are increased to reflect the range of advice sought.

Fee code	Description	Current HPRA fee	Proposed fee
240	Swift National Scientific Advice	2,865	2,935
246	One area (Quality/Clinical/Non Clinical/Regulatory)	3,655	3,745
247	Two areas (Quality/Clinical/Non Clinical/Regulatory)	4,575	5,245
248	Three areas (Quality/Clinical/Non-Clinical/Regulatory)	5,875	6,745
New	Four areas (Quality/Clinical/Non-Clinical/Regulatory)		8,245

6.3.2 Booking fees for DCP applications where Ireland is the RMS

It is proposed to increase the booking fee for DCP applications where Ireland is the RMS from €1,000 to €5,000 due to the high volume of these applications being cancelled.

This fee is non-refundable but will be credited against the application fee provided the application is received within the agreed time slot.

6.3.3 Variations – Type II reference member state (RMS) supplement

It is proposed to correct an anomaly in the current fee for type II standard RMS supplement. The current fee for type II RMS supplement is lower than the supplement for type IB RMS supplement which does not reflect the complexities of the variations.

Fee code	Description	Current HPRA fee	Proposed fee
205	Type II standard – Mutual recognition /Decentralised RMS supplement	440	490

6.3.4 Restructure of fees for new product applications

The HPRA is considering applying a single fee for new product applications. A single fee will apply to an application for a marketing authorisation and the fee will cover all strengths and pharmaceutical forms. The proposed combined fees have been restructured on a cost neutral

basis. In other words, we have taken the average income received per application for all strengths and pharmaceutical forms and have proposed a single fee to reflect this new approach. The benefit for both the industry and HPRA is that it simplifies the application process and gives certainty on the fee. It will result in lower or higher fees depending on the number of line extensions, but over time should be cost neutral, but also allows companies add additional strengths at no additional cost.

Complex Dossier – New Active Substance

Fee code	Description	Current HPRA fee	Proposed fee
	National Applications		
111	National Application	23,700	25,000
112	Each additional form (at the same time)	8,295	0
113	Each additional strength (at the same time)	1,180	0
	Mutual Recognition – Concerned Member State		
114	Mutual Recognition – CMS	16,590	18,500
115	Each additional form (at the same time)	5,925	0
116	Each additional strength (at the same time)	1,180	0
	Mutual Recognition – Reference Member State		
117	Mutual Recognition – RMS Supplement	17,770	17,770
124	Mutual Recognition – RMS Supplement – within 12 months of national procedure	17,770	19,230
	Decentralised Concerned Member State		
119	Decentralised CMS	23,700	25,000
120	Each additional form (at the same time)	8,295	0
121	Each additional strength (at the same time)	1,180	0
	Decentralised Reference Member State		
122	Decentralised RMS	59,245	62,000
120	Each additional form (at the same time)	8,295	0
121	Each additional strength (at the same time)	1,180	0

Reduced Dossier - Complex

Fee code	Description	Current HPRA fee	Proposed fee
	National Applications		
131	National Application	17,770	18,900
132	Each additional form (at the same time)	8,295	0
133	Each additional strength (at the same time)	1,180	0
	Mutual Recognition – Concerned Member State		
134	Mutual Recognition – CMS	11,850	13,000
135	Each additional form (at the same time)	5,925	0
136	Each additional strength (at the same time)	1,180	0
	Mutual Recognition – Reference Member State		
137	Mutual Recognition – RMS Supplement	17,770	17,770
144	Mutual Recognition – RMS Supplement – within 12 months of national procedure	11,850	13,330
	Decentralised Concerned Member State		
139	Decentralised CMS	17,770	18,900
140	Each additional form (at the same time)	8,295	0
141	Each additional strength (at the same time)	1,180	0
	Decentralised Reference Member State		
142	Decentralised RMS	47,390	50,000
140	Each additional form (at the same time)	8,295	0
141	Each additional strength (at the same time)	1,180	0

Reduced Dossier - Standard

Fee code	Description	Current HPRA fee	Proposed fee
	National Applications		
151	National Application	11,850	13,500
152	Each additional form (at the same time)	8,295	0
153	Each additional strength (at the same time)	1,180	0
	Mutual Recognition – Concerned Member State		
154	Mutual Recognition – CMS	8,295	9,500
155	Each additional form (at the same time)	4,735	0
156	Each additional strength (at the same time)	1,180	0
	Mutual Recognition – Reference Member State		
157	Mutual Recognition – RMS Supplement	11,850	11,850
164	Mutual Recognition – RMS Supplement – within 12 months of national procedure	7,110	8,650
	Decentralised Concerned Member State		
159	Decentralised CMS	11,850	14,000
160	Each additional form (at the same time)	8,295	0
161	Each additional strength (at the same time)	1,180	0
	Decentralised Reference Member State		
162	Decentralised RMS	30,805	34,000
160	Each additional form (at the same time)	8,295	0
161	Each additional strength (at the same time)	1,180	0

The overall general increase in fees will be applied to the proposed fees stated above.

6.4 Other Proposed adjustments to fees – Medical Devices

6.4.1 Certificates of free sale or letters confirming the location of a manufacturing facility in Ireland

It is proposed to introduce a reduced fee for digital certificates of free sale and letters confirming the location of a manufacturing facility in Ireland.

Fee code	Description	Current HPRA fee	Proposed fee
New	Digital signature and sent digitally – Certificates of free sale/letter confirming the location of a manufacturing facility (four certificates per request)	275	200

6.4.2 Determination of classifications within the medical device regulations

It is proposed to align the medical device classification fees with the human classification fees.

Fee code	Description	Current HPRA fee	Proposed fee
481	Determination not requiring a complex technical review (one device per request)	300	335
492	Complex classification requests	1,085	1,210

6.5 Other Proposed adjustments to fees – Compliance

6.5.1 New authorisations for nominated INNs or identified national vulnerabilities

It is proposed to apply the service item fee of €795 for these applications.

6.5.2 Inspection cancellation fees

It is proposed to charge any costs incurred in preparing for the inspection along with 50% of the planned inspection days if the inspection is cancelled within 15-30 days and 100% of the planned inspection days if cancelled within 15 days of the inspection date.

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 31 October 2025. Contributions should be sent by email to feesconsultation@hpra.ie.

APPENDIX I SERVICE LEVELS – HUMAN PRODUCTS AUTHORISATION, REGISTRATION AND SAFETY MONITORING

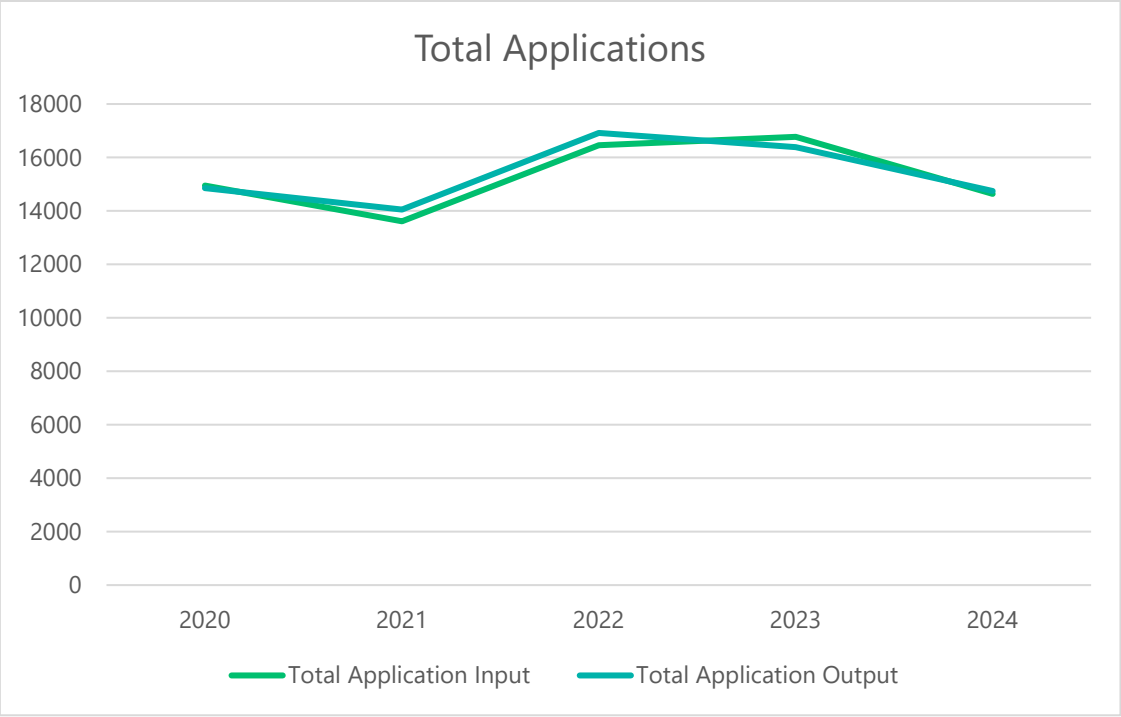
The most significant projects undertaken by the HPRA in the last number of years were driven by the requirement to maintain and further improve patient safety, protect access to medicines and service levels to industry.

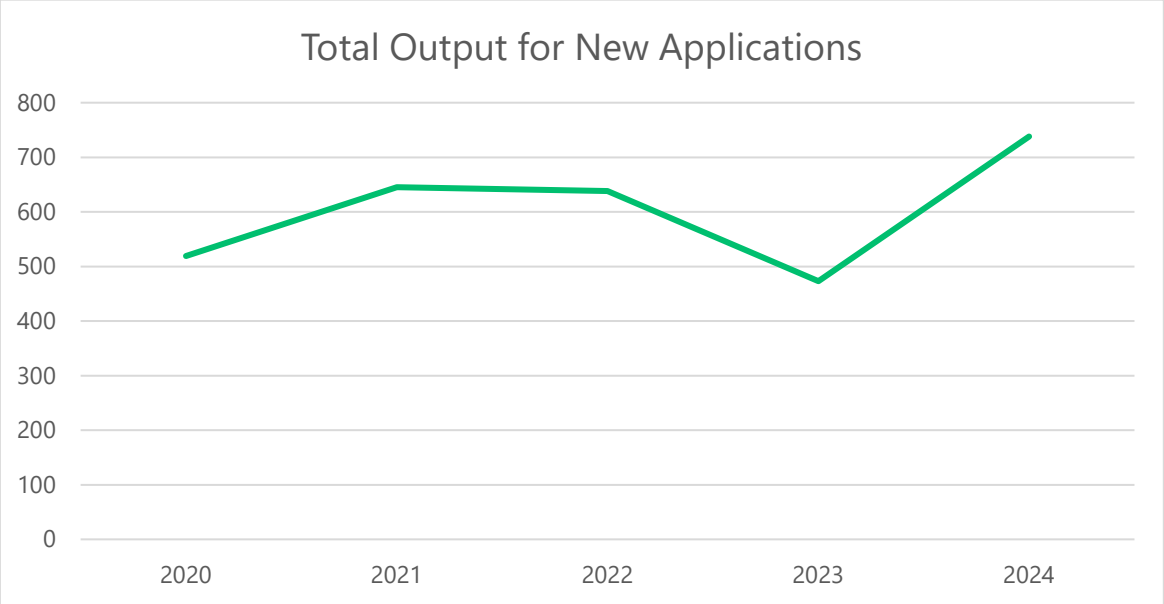
These projects include in summary:

- Readiness to operate as Reference Member State for both MRP and DCP new procedures.
- Introduction of a booking system for MRP, DCP and national procedures to better plan resource utilisation.
- A national scientific advice procedure was introduced in 2016 and was expanded to include a swift national scientific advice procedure in 2023. 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. The process for national scientific advice has been further refined in 2024 and the introduction of defined areas of advice for which applicants can submit requests will be introduced.
- The development of a new HPRA workflow system has been completed. 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. Key performance indicators have been identified and introduced to allow for more effective monitoring of timelines, which 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 healthcare professionals. Further streamlining of adverse reaction processing procedures is also underway to improve efficiency in this area. This work supported the significant increase in adverse reaction reports related to vaccines and therapeutics which were submitted directly to the HPRA arising from the COVID-19 pandemic.
- 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 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 new requirements from the CTR and MDR.
- 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.
- Establishment of a dedicated Pharmacovigilance Risk Communication section with a focus on educational material and DHPC assessment and partnership with the health system to facilitate clinical readiness as regard to risk management of medicines in clinical use.

The following graphs outline the output across all application types up to the end of 2024.

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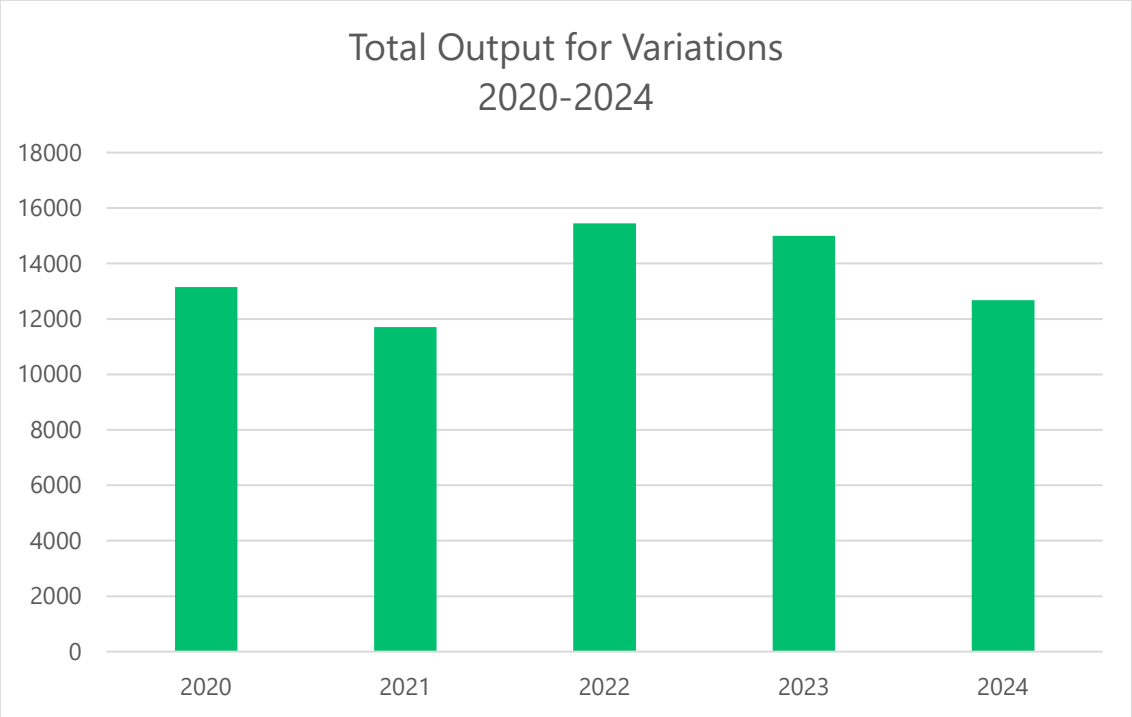
2020
2021
2022
2023
2024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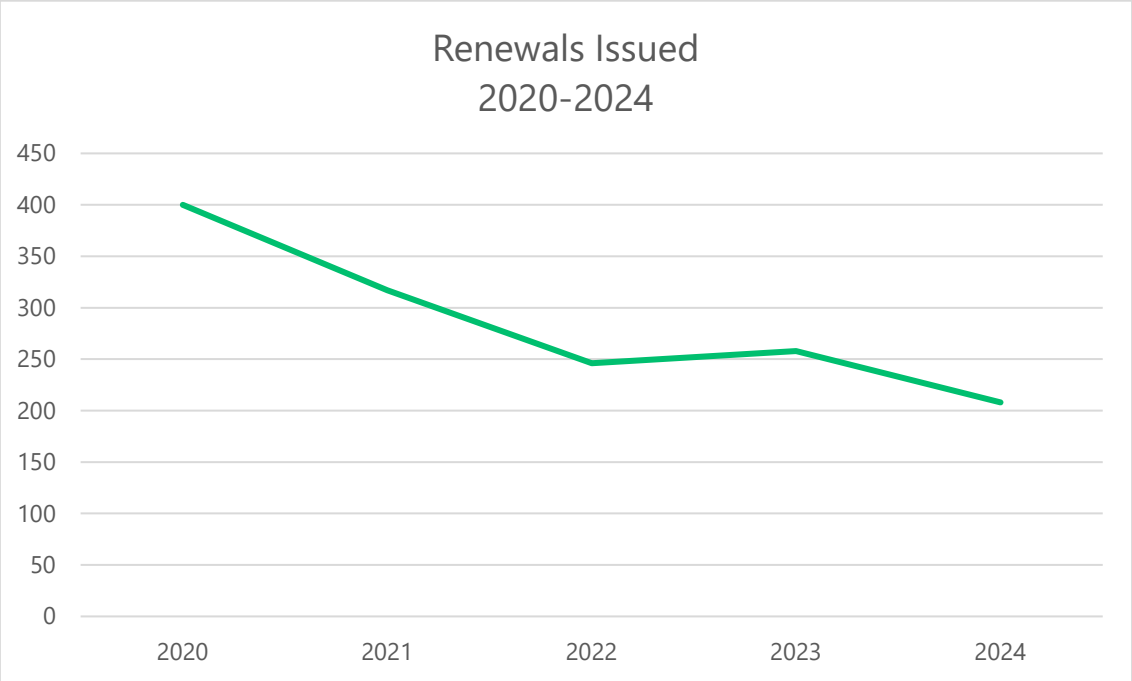
2022
2023
2024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2022
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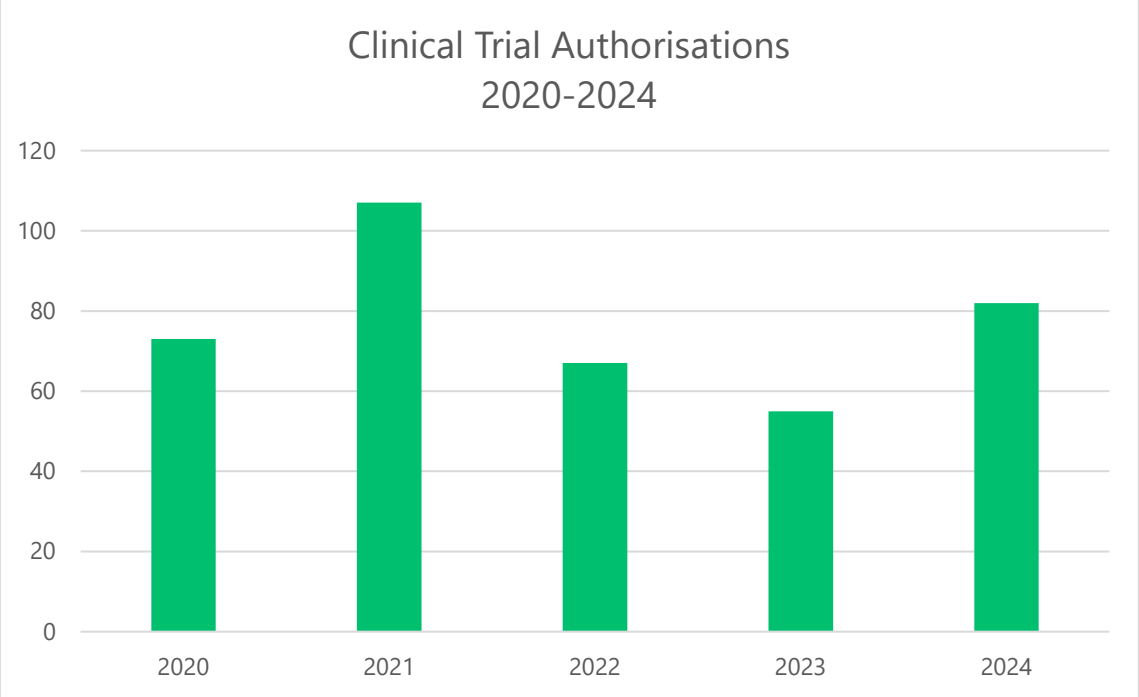
2024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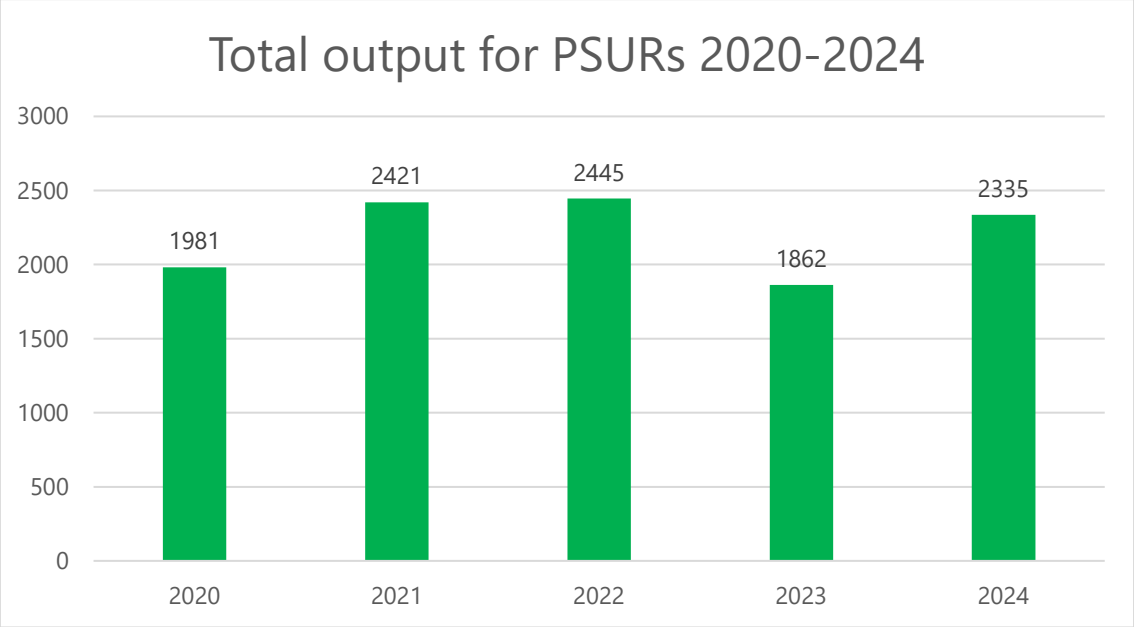
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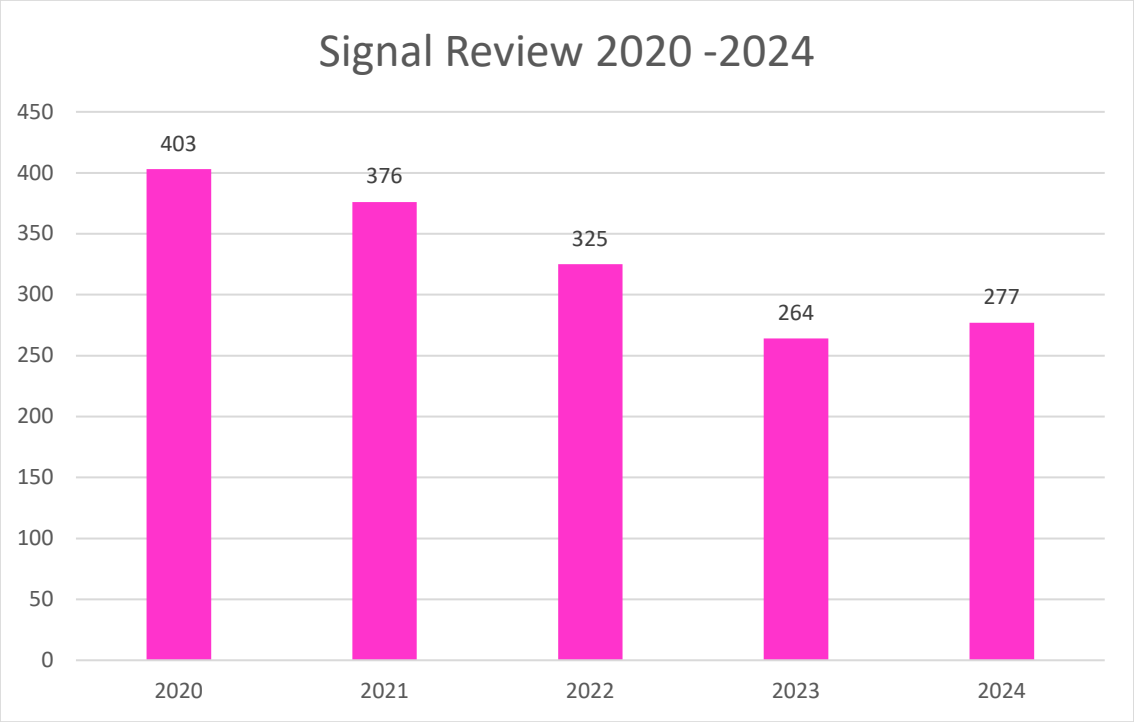
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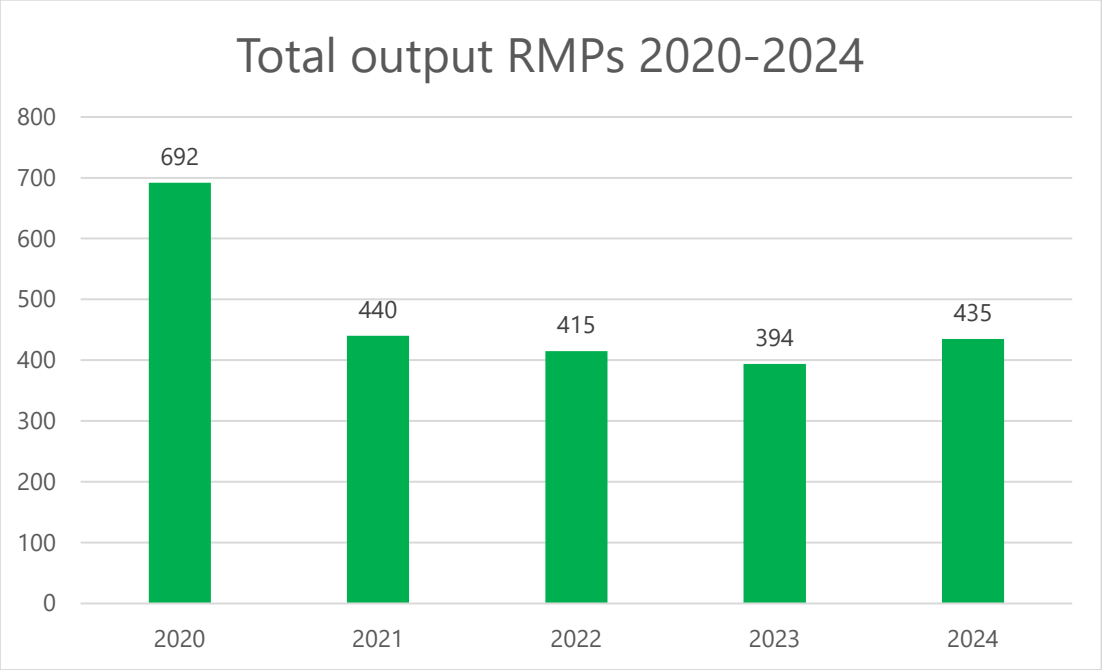
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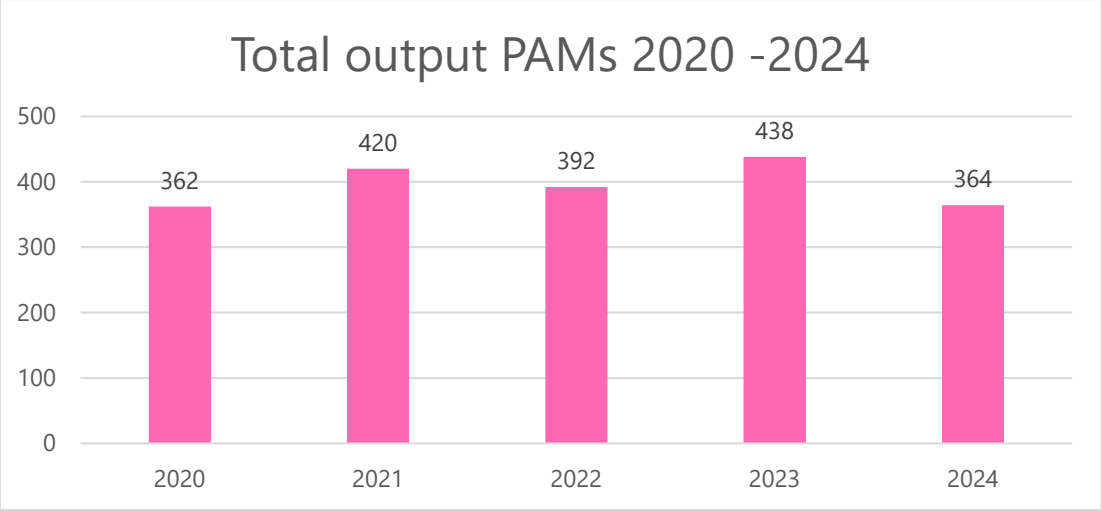
2024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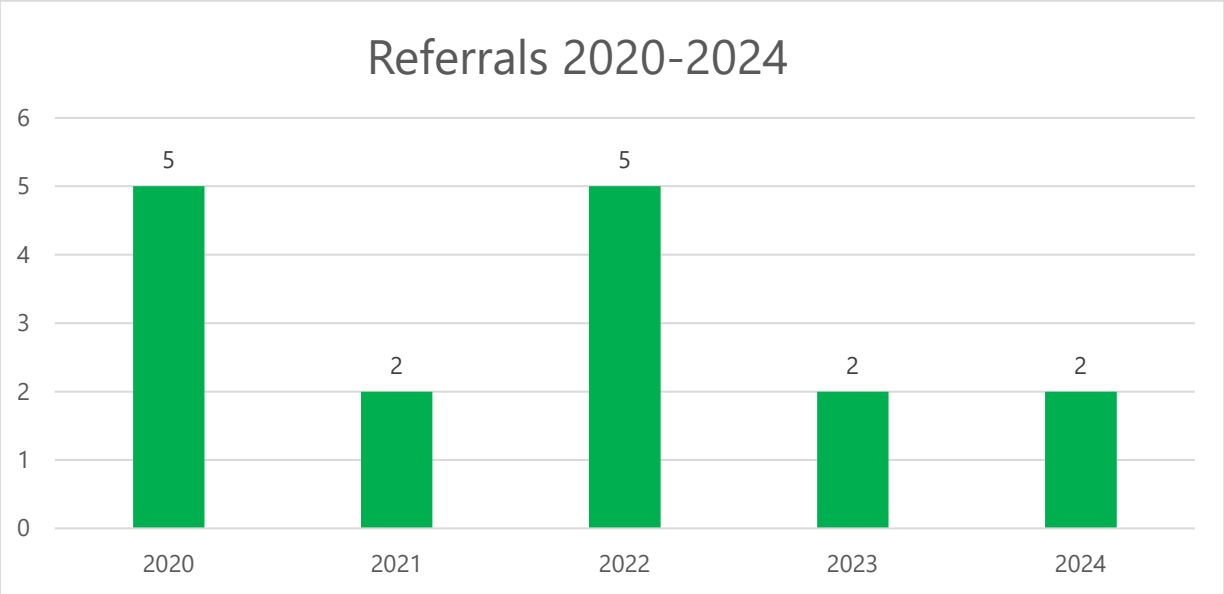
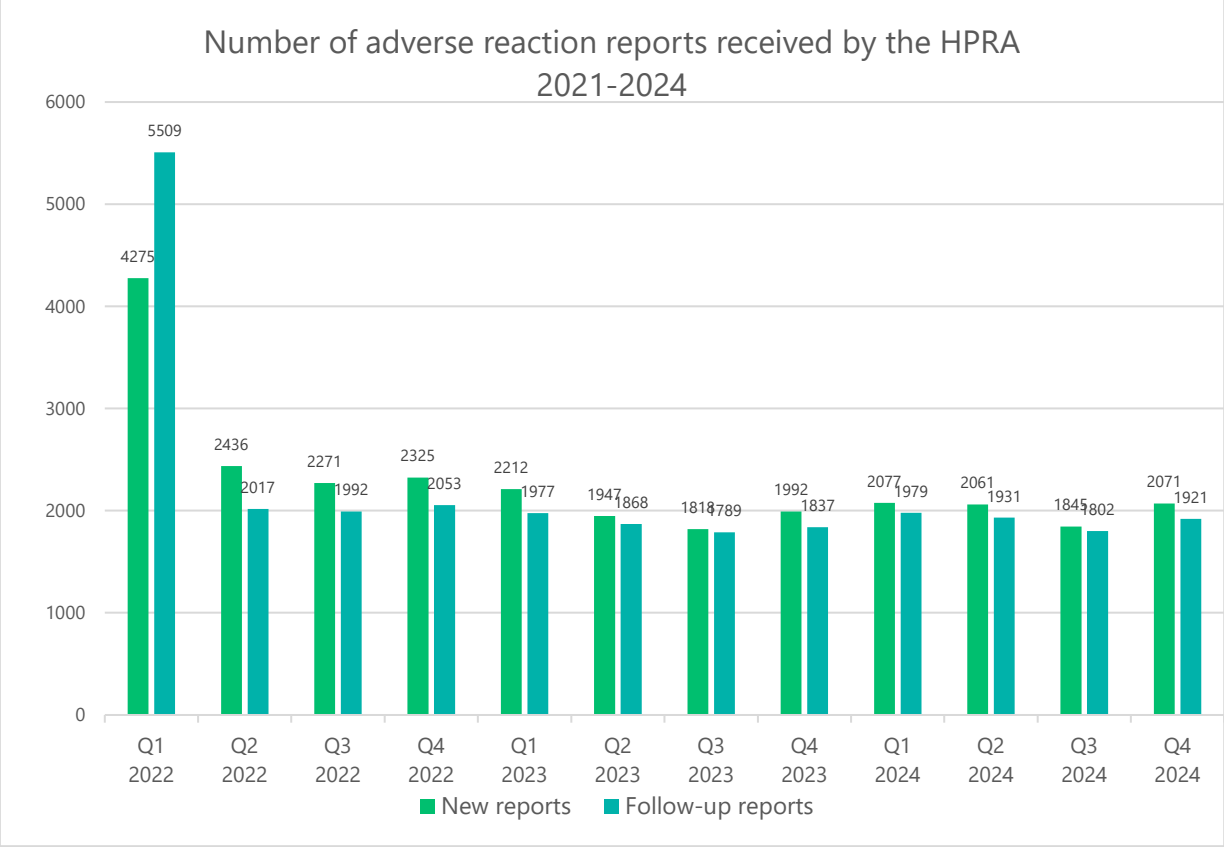
2020
2021
2022
2023
2024


Referrals 2020-2024
6
5
4
3
2
1
0
5
2
5
2
2
2020
2021
2022
2023
2024


Number of adverse reaction reports received by the HPRA 2021-2024
6000
5000
4000
3000
2000
1000
0
4275
5509
2436
2017
2271
1992
2325
2053
2212
1977
1947
1868
1818
1789
1992
1837
2077
1979
2061
1931
1845
1802
2071
1921
Q1 2022
Q2 2022
Q3 2022
Q4 2022
Q1 2023
Q2 2023
Q3 2023
Q4 2023
Q1 2024
Q2 2024
Q3 2024
Q4 2024
New reports
Follow-up reports

APPENDIX II SERVICE LEVELS – COMPLIANCE DEPARTMENT

Initiatives undertaken/further developed in 2024/2025 included:

- Preparations for the end of certain derogations arising from Brexit and preparing for the implementation of Regulation (EU) 2023/1182 arising from the Windsor Framework have included:
  - Continued engagement with stakeholders with the primary purpose of maintaining supplies of health products.
  - Continued meetings with companies to discuss their Brexit related plans and to clarify issues arising. Such meetings and liaison will continue to be an important focus.
  - Meetings with industry representative bodies, and attendance at workshops organised by some of those bodies, to consider and clarify Brexit related questions.
  - Advising potential applicants for authorisations and licences of the requirements and processing of a number of new applications.
  - Provision of support to the Department of Health and the Department of Agriculture, Food and the Marine (DAFM), including participation in regular meetings of the Brexit Operations Group and the Brexit Medicines Review Group, both convened by the Department of Health.
  - Liaison with other agencies, including the HSE and Revenue's Customs Service, on issues of mutual interest.
- Annual updates to registrations of manufacturers, importers and distributors of active substances and brokers of medicines for human use were processed during 2024 and 2025. Continued provision of regulatory support to the Irish Medicines Verification Organisation (IMVO) in relation to operating the national repository for safety features data in relation to human medicinal products. (This repository, which is a database for batches of human medicines bearing safety features that are placed on the Irish market, coupled with the scanning of 2D barcodes on packs of medicines, is one of a number of regulatory tools aimed at preventing the entry of falsified medicines into the legal supply chain. It became operational on 9 February 2019 via the national implementation of EU Directive 2011/62/EU (the Falsified Medicines Directive) and its associated EU Commission Delegated Regulation, 2016/161.) In 2024 and in 2025 to date, the HPRA made significant use of the national competent authority reporting functionalities associated with the repository data, and it liaised with the IMVO when investigating a number of safety feature alerts. While these reporting functionalities continue to be useful, the HPRA has made a number of suggestions for their improvement to the relevant EU working group. While the HPRA is not part of the governance structure of the IMVO, we continue to liaise closely with the organisation. The HPRA also has an oversight role in relation to the repository and has taken the lead role of the EU working group on supervision of the national repositories. The HPRA also continues to participate in a National Safety Features Oversight Group made up of key governmental and regulator stakeholders and chaired by the IMVO. In 2024, the HPRA and IMVO joined a number of other EU national competent authorities and their national medicines verification organisations to run a pilot project to examine the feasibility of implementing an EU-wide IT

solution for addressing safety feature alerts on packs of medicinal products that are known to be authentic and where the reasons for the alerts are known. The HPRA contributed significantly to the risk assessment elements of the project before the pilot began, and it continued to support and operate the pilot into 2025.
- Continued upload of wholesale distribution authorisations and post-inspection good distribution practice (GDP) certificates to the EudraGMDP database.
- Continued upload of manufacturers and importers authorisations and post inspection good manufacturing practice (GMP) certificates to the EudraGMDP database.
- The NVR (2019/6) was implemented in January 2023. Work continues with colleagues from the Veterinary Sciences department, the legal section and the DAFM 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 the HPRA is 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 from 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.
- 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.
- Continued provision of support to the Department of Health in relation to the access programme for cannabis for medical use. The HPRA continues 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 GMP and GDP requirements, Good Clinical Practice (GCP) and Good Pharmacovigilance Practice (GvP) standards, and of the required controls relating to controlled drugs and precursor chemicals.
- Monitoring, via inspections, of the activities of MAH 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 European Medicines Agency (EMA) working groups and the Pharmaceutical Inspection Co-operation Scheme (PIC/S) Committee and its Expert Circle meetings.
- 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 has continued to lead on an initiative within the Heads of Medicines Agencies (HMA) Group on developing the risk-based approach to the sampling and analysis of mutual recognition, decentralised and centralised medicines.

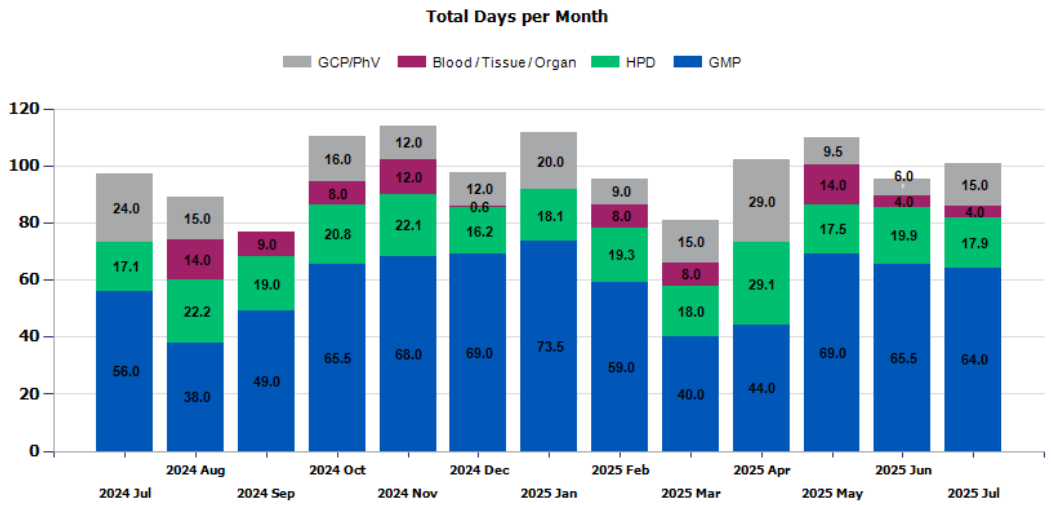
- The HPRA continues to participate in optimisation of the processes used by EEA medicines competent authorities for the management of quality defects, recalls and rapid alerts. This includes implementation of revised (more risk-based) versions of the relevant EEA procedures.
- The HPRA continues to work with the EMA Compliance Management procedure as outlined in the Compilation of Procedures, implemented locally in 2023.
- Continued focus on the advertising compliance programme which includes regular liaison with industry to outline HPRA requirements and 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 and on-going public communication regarding the risks of purchasing prescription medicines on-line.
- In its role as the designated competent authority, the Cosmetics team continues to uphold strong and effective working relationships with key national stakeholders, including Government Departments. Leveraging our technical expertise, the HPRA is actively contributing to several European Commission Working Groups, notably in areas such as Nanomaterials, the Cosmetic Products Notification Portal (CPNP), Borderline Classification, and Sunscreen Recommendations.
- In 2024/25 the National Cosmetics Surveillance Forum was continued by the HPRA, the HSE and the Public Analyst Laboratories for the purpose of sampling, analysis and review of the safety of cosmetic products available within the Irish marketplace. The forum develops the market surveillance programme in line with risk-based principles and takes account of new legislative and technical progress, driving a coordinated national approach to market surveillance and testing of cosmetics.

Other activities included:

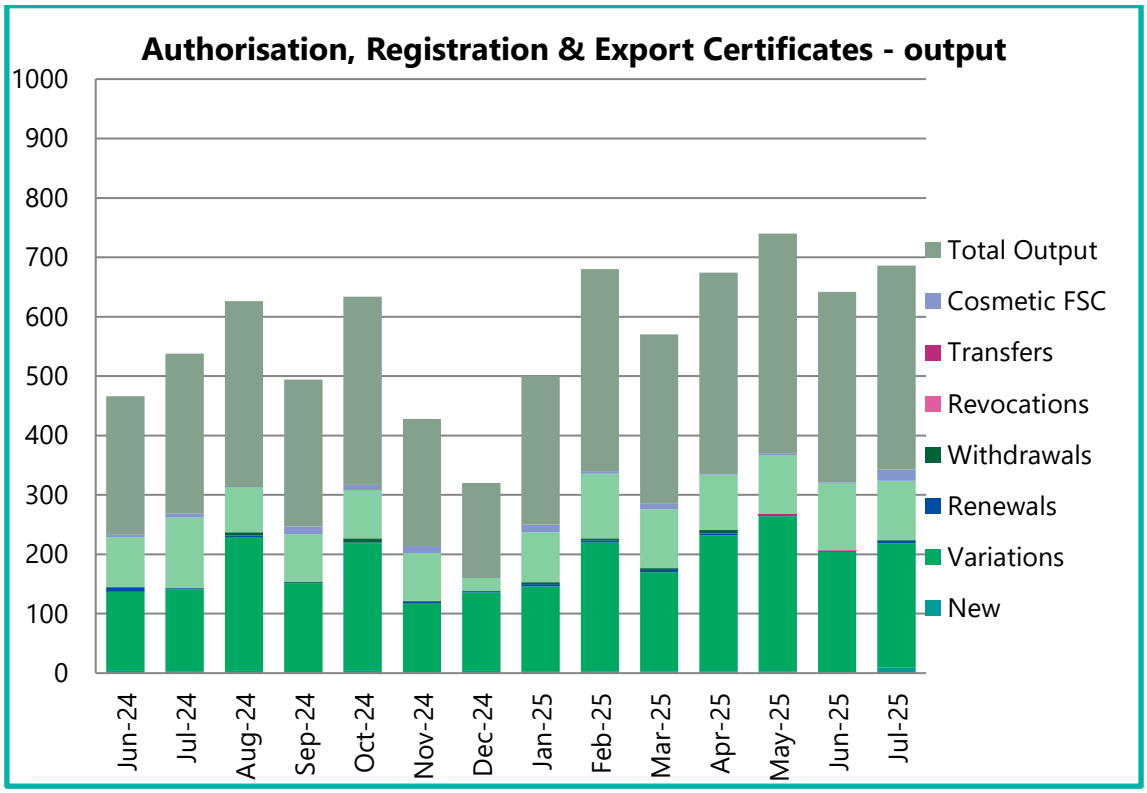
- Continued interaction and communication with stakeholders, including industry and other representative groups. These included meetings (virtual) with industry representative bodies and individual companies.
- Continued provision of support to the Department of Health in processing controlled drugs licence applications and collation of associated statistics.
- 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.
- Processing 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.

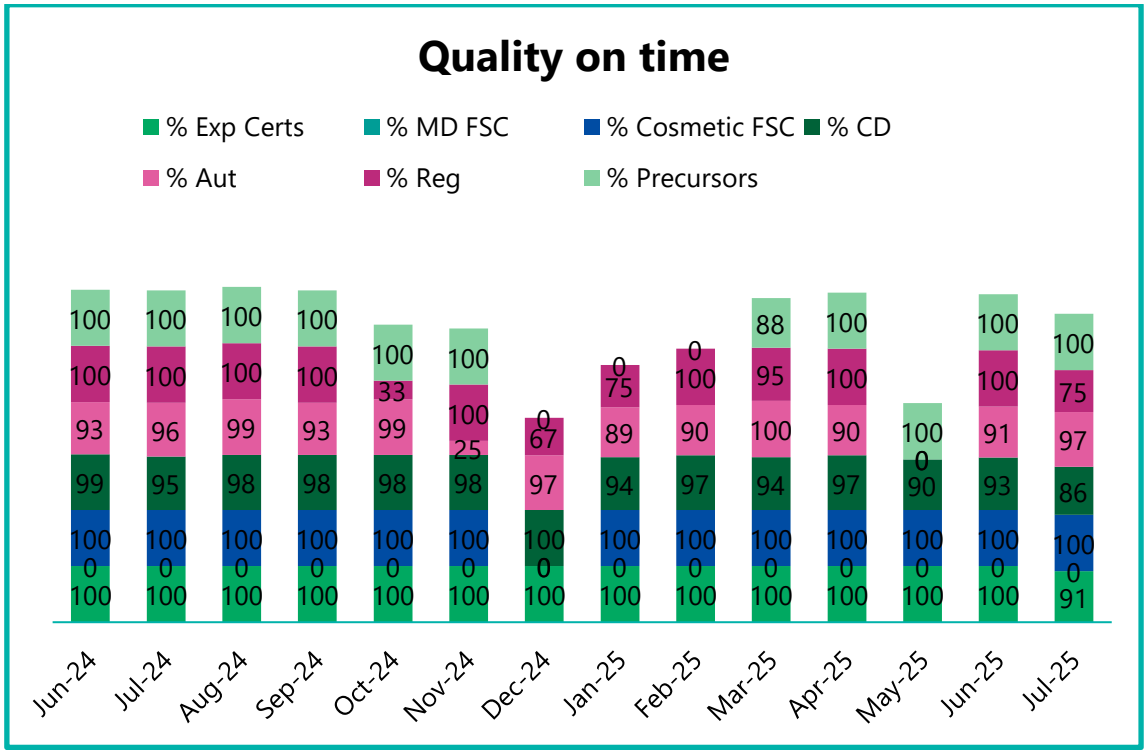
- Focus on illegal trade in and the development of associated cyber surveillance has continued.
- In co-operation with Revenue's Customs Service, ongoing detection and detention of illegal supply, including mail-order importations of prescription-only medicines and a focus on associated information to members of the public.
- 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 considered to present a risk to human health.
- Co-operation with An Garda Síochána and the Pharmaceutical Society of Ireland (PSI) 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 2024 to July 2025 inclusive. HPD refers to Health Product Distribution inspections which includes GDP, cosmetics and Controlled Drugs inspections.

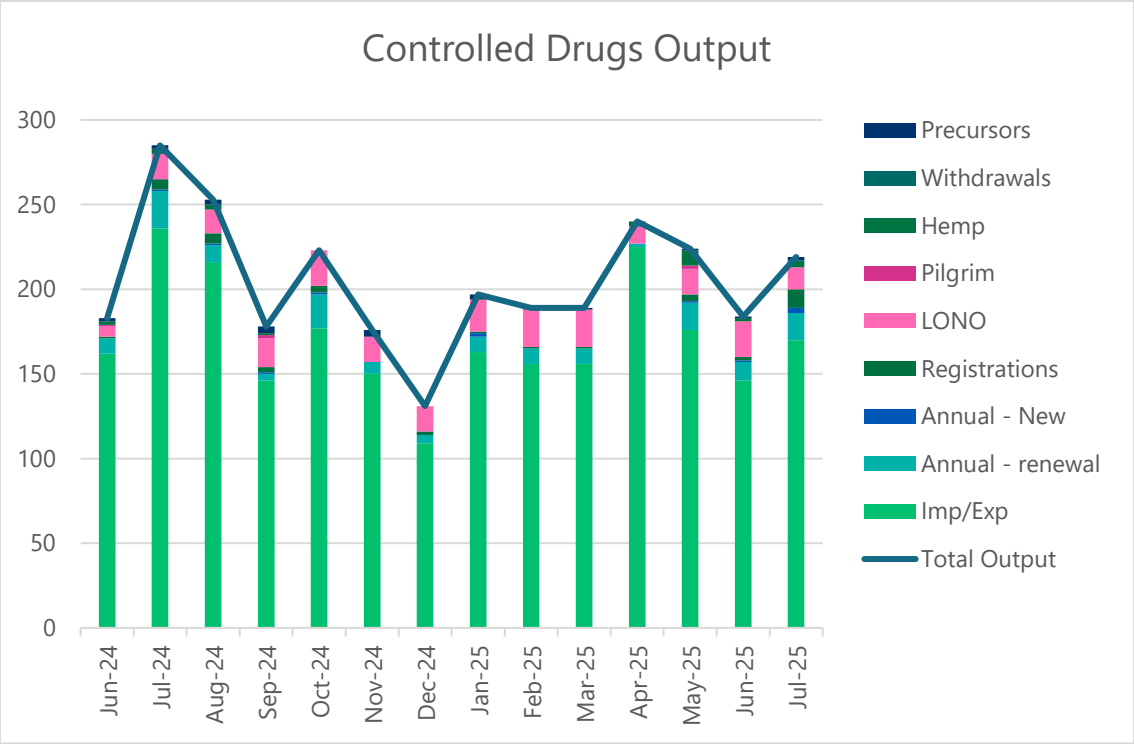


The following graphs show the numbers issued and the percentages issued on time, for export certificates, controlled drugs licences and GDP, GMP and IMP licences, over the period July 2024 to July 2025, inclusive.

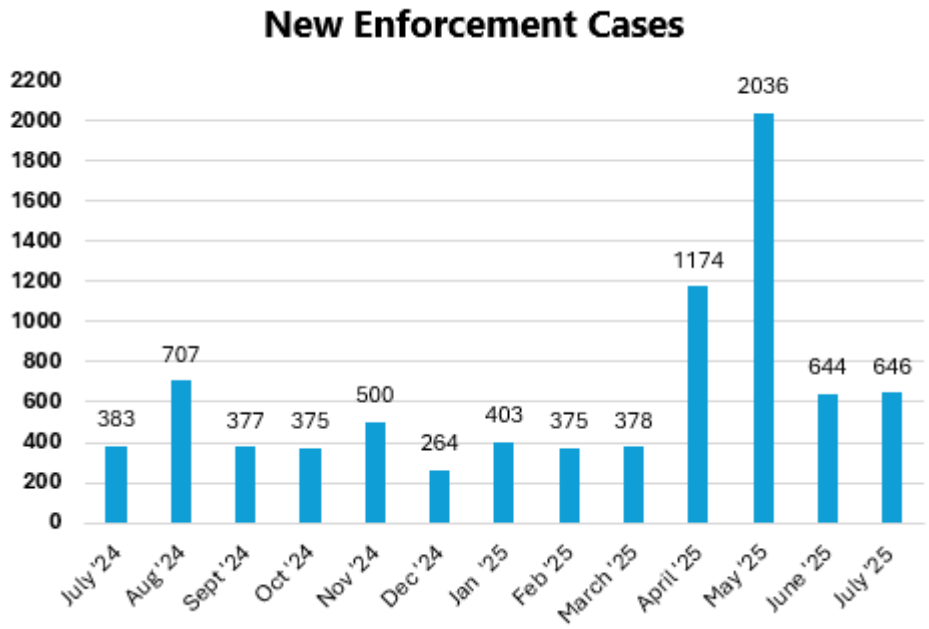




The graph below shows the output of licensing of controlled drugs, by category of licence.



The graph below shows the number of enforcement cases for the period July 2024 – July 2025 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 falsified medicines and prescription-only medicinal products which are authentic, but diverted from the legal supply chain.



Blood, tissues and cells

During 2024 and 2025 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 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 continued to operate the tissues and cells vigilance system and participates in 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 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 and this requires the schedule to a statutory instrument to be amended. Inspections related to import, export and holding of controlled drugs and drug precursors continue.

Exempt medicinal products

Notifications of importation of exempt (unauthorised) medicines continued through 2024 and 2025, to date. The HPRA has an electronic system for notifications and continues to work closely with notifying companies to ensure data has been uploaded correctly. The notifications are an important source of information, mainly 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, and the authority responsible for notified bodies in Ireland, we, as the HPRA, carry out a range of activities. Our aim is to ensure that medical devices, including *in-vitro* diagnostic medical devices (IVDs), perform as intended and do not compromise the health and safety of the patient or the person using them.

The HPRA's medical devices department carries out a range of functions including:
- Registration of economic operators
- Qualification and classification of medical devices
- Supporting innovation and research of new technologies
- Review of clinical investigations, compassionate use applications and derogations
- Inspections of economic operators including manufacturers, importers, distributers and authorised representatives
- Engagement with health services and healthcare professionals to raise awareness of the regulatory framework for medical devices
- Communication initiatives to raise awareness of the impact and requirements arising from the new EU device regulations
- Assessment of vigilance issues including incident reports and field safety corrective actions (FSCAs)
- Market surveillance activities at both national and EU level, including investigation of activities associated with non-compliant supply and manufacture of devices
- Active involvement in several EU working groups, task forces and coordination groups
- Contribution to the implementation and application of EU medical device regulations at national and European level.

Authorisation and registration

Designation and oversight of notified bodies at national and European level:

In 2024, we:
- Continued our schedule of oversight of the notified body in Ireland based on ongoing assessment and audits (surveillance and observed). This included several monitoring activities, an on-site surveillance assessment in June and the initiation of assessment for redesignation to the MDR.
- Following on from the oversight of IVDR designation, a decision in accordance with article 42.4 of the IVDR was taken.
- Contributed a national expert as part of a European Joint Assessment Team (JAT) for a designation application under the MDR in Sweden.
- Participated in the EU Notified Bodies Oversight (NBO) group and the Medical Device Coordination Group (MDCG).

- Continued to work with the European Commission and the Competent Authorities for Medical Devices (CAMD) to gather data on notified body capacity and certification workload associated with MDR/IVDR.

Supporting innovation and research of new technologies is a key strategic priority. In 2024, this support included:
- Review of clinical investigation applications under the MDR.
- Review of clinical investigations for innovative devices from both multi-national and academic sponsors with 11 new applications, 17 amendments to ongoing investigations and 11 post-market clinical investigations.
- Review of 11 performance studies under IVDR.
- Offering of pre-submission meetings (16 total) with innovators to discuss potential clinical investigation or performance study applications for new devices.
- Provision of technical, clinical and regulatory support for queries received from the Innovation Office.

Registration:
In 2024, the HPRA validated 128 economic operators on EUDAMED, and 153 new organisations were registered nationally.

Certificates of Free Sale:
A review of our process and application forms was conducted including engagement with stakeholders through a dedicated focus group to improve our service level and apply process efficiencies.

Safety and quality

Market surveillance activities:
- 30 proactive and 'for-cause' inspections of manufacturers, notified bodies, importers, distributors and authorised representatives.
- These inspections resulted in significant market action being initiated including a recall of automated external defibrillator (AED) pads which were found with unauthorised expiry labels applied outside of the manufacturer's control.
- 403 market surveillance cases.
- Proactive market surveillance includes documentation and labelling checks, sampling and analysis of products from the marketplace and detailed reviews of technical and clinical documentation.
- Further development of the lifecycle market surveillance strategy and planning mechanism with emphasis on proactive actions.
- A total of 11 notifications were sent by the HPRA to the European network relating to compliance issues.
- Participation in the Market Surveillance Working Group, leading on an initiative to develop common evaluation principles for market surveillance.

Vigilance activities:

- There were 3,672 vigilance cases.
- Of the individual reports, manufacturers accounted for 80%, 4% from users and 12% from other competent authorities.
- Of the 2,570 individual serious incident reports received, 6% came from users, including members of the public.
- There were 608 FSCAs associated with the national market.
- 146 national competent authority reports (NCAR) were issued to other European authorities.
- 5 HPRA safety notices and 42 direct-to-healthcare professional communications were issued.
- Infusion devices, surgical devices, vital signs monitoring, implants and IVDS together accounted for 70% of the total individual vigilance reports received.
- The HPRA continued the role of co-chair of the European Working Group on Post-market Surveillance and Vigilance (PMSV), a subgroup of the MDCG.

Legislation and regulation

Our work during 2024 focused on progressing implementation and application of MDR and IVDR at national and EU level. This included:

- Working with the Department of Health on identifying and proposing solutions for effective implementation of the regulations.
- Supporting the Department of Health in preparing for EPSCO interventions and multi-lateral non-papers calling out the need for targeted solutions.
- Engagement with key stakeholders to ensure awareness of the impact of the regulations.
- The development of guidance and information sessions/webinars on MDR/IVDR implementation, including the impact of the MDR Article 10a provisions.
- Participating and providing input into the EU4Health initiatives on medical device availability as part of our role as MDCG members.
- Participating in EU Working Groups and task forces established to develop guidance and gather data.
- The orphan taskforce led by the HPRA published the first definition of an orphan device and focused guidance on principles for clinical evidence for orphan devices.
- Continued participation in the Executive Group of the CAMD network.
- Participation in the IMDRF Management Committee as part of the European delegation (along with the EU Commission).
- Contributing to discussions and development of the Medical Device Single Review Programme.
- Co-chair of the Adverse Event Terminology working group at IMDRF on behalf of the EU.
- Participation in the clinical evaluation working group of the IMDRF.

Stakeholders and partners

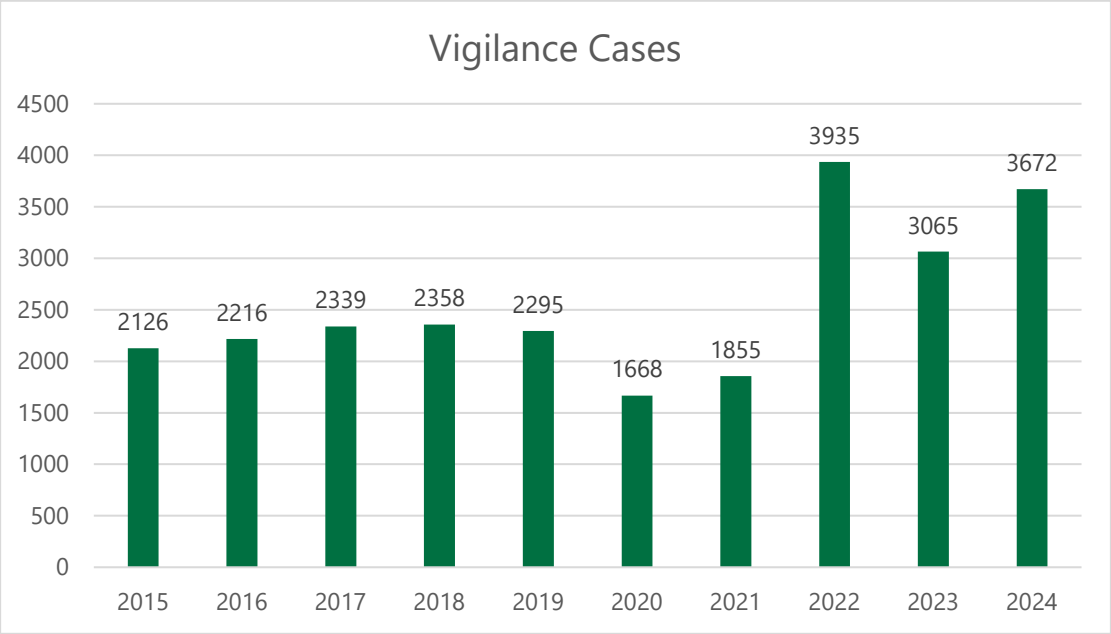
Our work to encourage direct reporting of incidents and medical devices issues by users and members of the public continued throughout 2024. We continued our engagement with health services and healthcare professionals to raise awareness of the regulatory framework for medical devices, the roles and activities of the HPRA and encourage reporting.

The HPRA undertook several communication initiatives to raise awareness of the impact and requirements of the MDR/IVDR. During 2024, we:

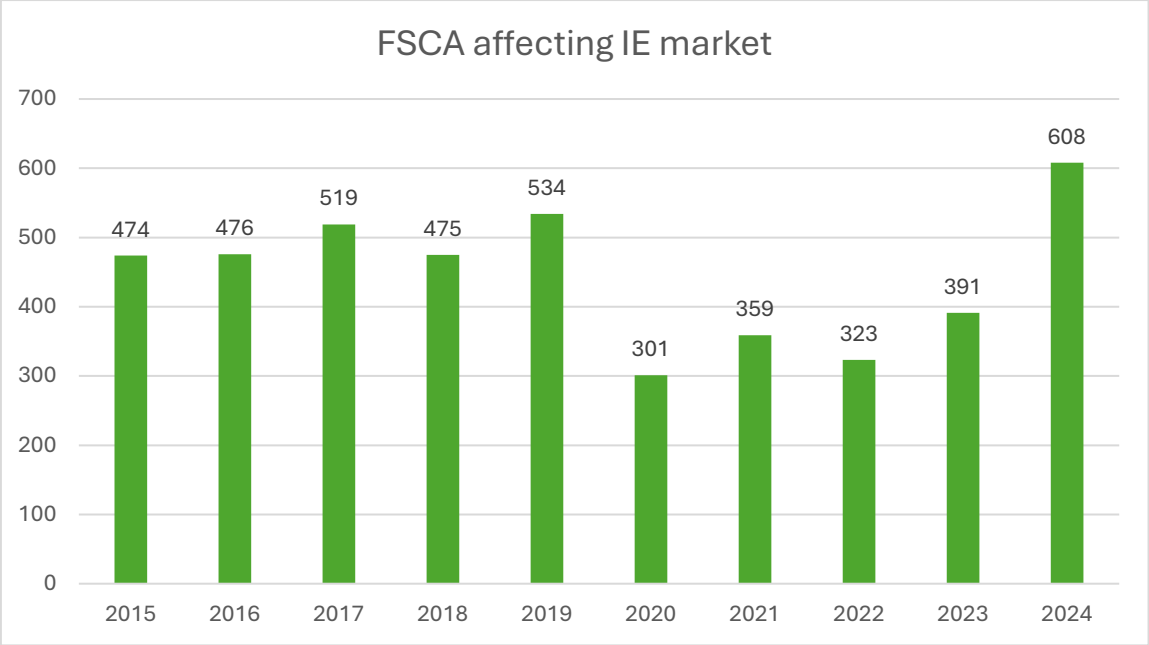
- Hosted webinars for health institutions on new MDR requirements, including notification requirements for reporting disruptions or discontinuations in supply of medical devices
- Updated the HPRA website and social media channels to provide information and guidance
- Launched a dermal fillers social media campaign highlighting the risks of dermal fillers for the public and those administering them
- Delivered briefings, advice and workshops on the new Regulations to a range of stakeholders including the HSE, industry and clinical associations.

The HPRA continues to deliver a programme of presentations, workshops and talks to external stakeholders. A full list of all presentations delivered during 2024 is provided in the Annual Report 2024.

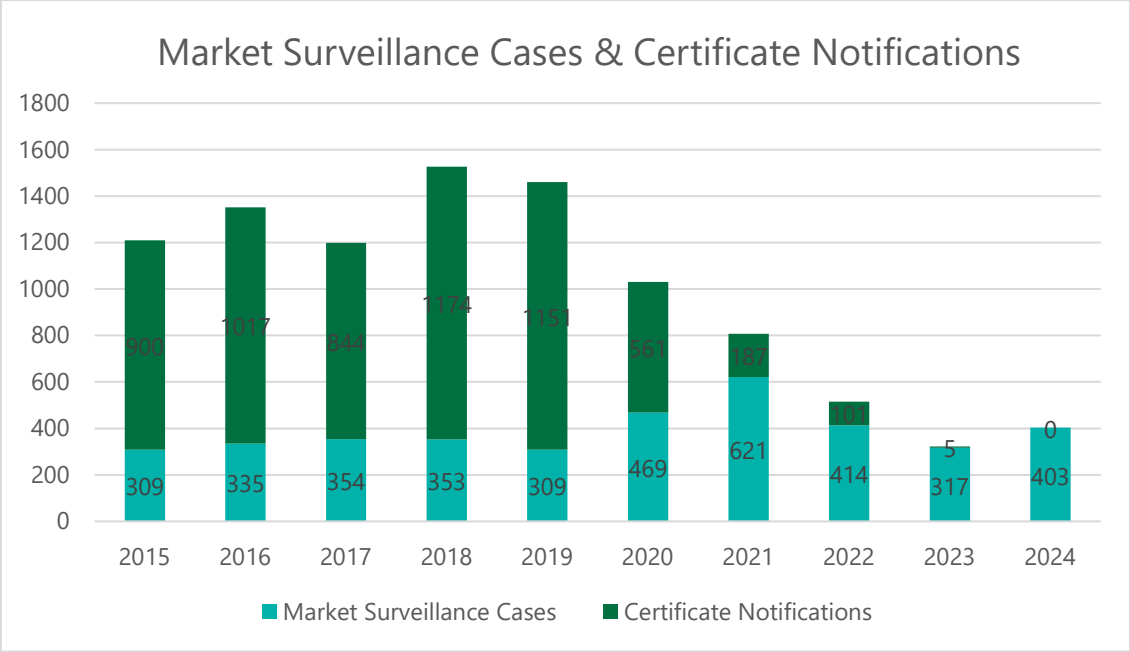
The medical devices team has initiated a work package at the EU clinical investigation and evaluation subgroup of the MDCG to review the outputs from the CORE-MD project for adaptation into regulatory guidance in the EU.



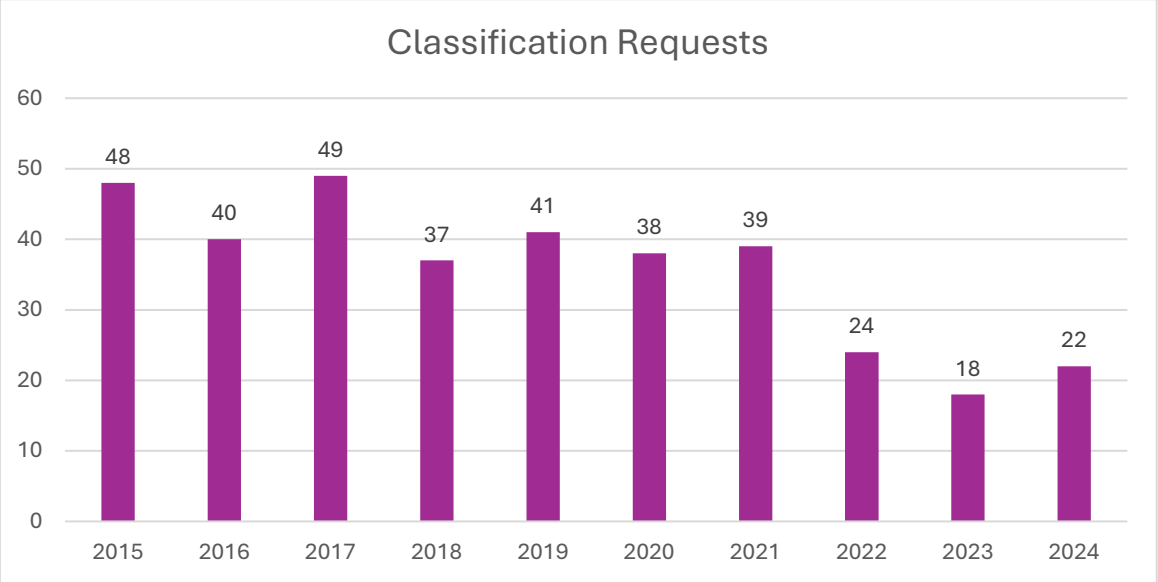
Graph1: Number of vigilance reports received (2015 to 2024)



Graph 2: Number of field safety corrective actions affecting the Irish market (2015 to 2024)



Graph 3: Number of market surveillance cases and certificate notifications (2015 to 2024)



Graph 4: Number of classification requests annually (2015 to 2024)