HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Public Consultation on
Annual Review and Proposal for Fees – Financial Year 2021

Medical Devices

01 OCTOBER 2020

CONTENTS

1 INTRODUCTION

In 2017, the HPRA introduced fees for the first time for the regulation of the medical devices sector. Following extensive dialogue with industry stakeholders, the original fee funded model was amended and a co-funded model adopted in 2018. The HPRA received a subvention from the Department of Health which facilitated a reduction in the fees. 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 and from the co-funding model with current work volumes and to plan for future activity. Also, in respect of fee income, an additional priority is to provide predictability, consistency 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 2021.

2 THE OPERATING ENVIRONMENT

2020 has been a challenging year for both the HPRA and the medical device industry. As with all companies, the COVID-19pandemic has resulted in the HPRA adapting to a different way of working and providing a wide variety of support to the Government and Health Services. Brexit has continued to bring considerable uncertainty to the regulatory framework and both industry and the HPRA have expanded their resources in preparation for Brexit.

In terms of costs, the Haddington road reductions have been re-instated and salaries are subject to general public service pay increases of approximately 2% per annum. General inflation remains low although the COVID-19 crisis has caused uncertainty in relation to costs and income. While the impact of Brexit is unknown, it is becoming clear that regulatory alignment and a free trade agreement are unlikely and 2021 will see the real impact of a hard Brexit.

For 2020, one of the biggest challenges for medical devices has been managing the unprecedented demand for medical devices because of COVID-19 and the worldwide shortage in relation to ventilators, protective equipment and diagnostic testing capacity. The medical device department completed the restructuring project that resulted from the review that was conducted during 2018-2019. The department also continues to implement a detailed programme to ensure that appropriate systems, resources and procedures are in place to ensure effective and timely implementation of the new Medical Device Regulation (MDR) and *In-Vitro* Diagnostic Regulation (IVDR) which go live in May 2021 and 2022 respectively. We have focused on optimising our processes relating to existing activities as well as preparing for the new activities in which we will be involved as a result of the new MDR and IVDR. Preparing for

Brexit under the withdrawal agreement and the Northern Ireland protocol (NIP) is an additional strand of work in 2020. These issues have hugely increased the workload of the Medical Devices department and a number of high profile safety issues have further contributed to a challenging year.

For the reasons outlined above, staff numbers have increased to meet the additional responsibilities of MDR and IVDR and further increases are planned to reflect the new Department structure implemented and meet the requirements of the MDR and the IVDR.

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 would make 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, both on the personal injury side and judicial review. Over recent years, significant resources have been dedicated to a significant increase in the number of FOI requests and legal queries. An unfortunate result of this is increased costs and resources dedicated to work which delivers nothing under our public health remit.

3 STRATEGIC DIRECTION OF THE HPRA

The HPRA has commenced the process of developing its new strategy for the period 2021 to 2025. We continue to deliver under our current strategic plan for the years 2016 – 2020. The high-level strategic goals under the current plan are as follows:

- **Access to medicines** (enhancing regulatory support to patient access to medicines)
- **Better informed users** (providing current information to inform choices and decisions made by patients and their healthcare professional)
- **Optimised regulatory system** (keeping pace with product, manufacturing and supply chain developments)
- **Supporting innovation** (providing regulatory support and advice to research and development centres)
- **Internal capabilities** (ensuring strong internal systems, resource and expertise)

The next strategic plan covering the period 2021 to 2025 will be published in Q4 of 2020. The new strategic plan will reflect our activities and will reflect changes to the regulatory environment past and future, identified over the last five years. While this plan is still undergoing consultation, key projects for 2021 will include:

- Managing the public health crisis arising from COVID-19 as it relates to medicines and medical devices
- Increasing collaboration and engagement with health services and health care professionals
- Enhancing the post authorisation systems in response to any COVID-19 vaccines
- Managing the impact of Brexit across all our strategic initiatives and in particular with our stakeholders, seeking to minimise the impact of Brexit at 31 December 2020
- Dedicated project and resources to manage medicines and medical device shortages from a regulatory view point, incorporating both the impact of COVID-19 and Brexit
- The further development of the innovation office and support for early innovation on a global basis
- Enhancing communication and dialogue with patients and members of the public on health product issues
- 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
- Working with our European counterparts to help develop the medical device network
- Increasing our regulatory offering both centrally and in the decentralised system
- Implementation of the clinical trials directive
- Implementation of the Medical Devices and IVD regulations

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

4 PROPOSED CHANGES FOR 2021

The HPRA is operating in a challenging environment, particularly in light of COVID-19, Brexit and the MDR and IVDR. As outlined above, we committed proactively to addressing the public health consequences relating to COVID-19 and Brexit, supporting its work in this area and on implementation of the new MDR and IVDR, and to support the industry to manage its regulatory obligations under the EUDR.

As noted above, the work load of the Medical Devices department has increased significantly in 2020 without additional income. The significance of the role that the medical devices play in healthcare delivery and the related challenges in their regulation were highlighted by the COVID-19 pandemic. The implementation of the Medical Device Regulation (MDR) has been deferred until 2021, which was necessary due to the COVID-19 crisis. Significant work remains and it is now due for implementation in 2021. The IVDR to be implemented in May 2022, will make a profound change to the regulatory system for diagnostics and significant work will be necessary in this area at national and international level. 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 and development of our staff. This, combined with a continuing impact from Brexit and COVID-19, means that staff increases in 2021 are required to manage this increased workload. This will impact on the funding model, which is currently subvented by the Department of Health.

However, despite the additional workload as a result of COVID-19, costs have not accrued as expected in 2020. The HPRA offices have been largely closed since March 2020 and consequently many consumables in relation to a large office building have significantly reduced. Other costs such as travel, training and meetings are also significantly reduced as meetings were cancelled or delivered online. Predicted staffing levels are also below expected levels as recruitment was put on hold. While recruitment has recommenced, it is challenging and it will take some time to achieve optimal staffing levels.

Despite the positive impact on costs arising from COVID-19, overall the HPRA cost base is expected to increase. As noted in previous submissions, payroll remains the most significant part of HPRA being up to 82% of total costs. Payroll costs have increased over the last number of years but will again increase in 2021 for the following reasons:

- The impact of the new Public Service Pay increases will result in pay awards of approximately 2%
- HPRA receives no funding for pensioners under the local government superannuation scheme (LGSS). Previously as a 'young' agency, this did not impact significantly but we have seen significant increases in pension costs in the last two years and it now accounts for 4% of payroll.
- The implementation of the MDR and IVDR will require additional staff in the medical device department to address the resulting increase in responsibility for the medical device department

The HPRA expects that 2021 will be challenging for the reasons outlined above. However, in recognition of the cost savings in 2020, we propose a general fee freeze for 2021. However, a number of medical device fees are being amended to reflect new responsibilities under the MDR or to better match the cost of providing the service with the fee.

General fee proposal

- No general fee increase

Amendments to the Medical Device Fees

- Application of fees for Medical Devices certificates of free sale to requests for letters confirming the location of the manufacturing site in Ireland
- Application of the Medical Devices Manufacturing fees to both manufacturers defined by EU legislation (legal manufacturers) and manufacturing facilities (manufacturing site) located in Ireland
- Restructure of the Medical Device Authorised Representative fees
- Application of the Medical Device Distribution fees to Medical Device Importers
- Application of the Clinical investigation fees to the MDR regulation and introduction of new fees for performance studies

- The fees for Medical Device assessments under Article 11.13 to include Article 59 of the MDR and Article 9.12 of IVDD, and the application of these fees to be based on the class of device
- Alignment of the Medical Device search fee with the human products search fee

5 PROPOSED FEES

As outlined above there will be a freeze on fees for the year 2021 but with a number of changes to Medical Devices fees due to the introduction of new legislation.

6 DETAILED CHANGES TO FEES

6.1 General change to fees

It is proposed that there will be no general increase applied to any fees.

6.2 Other proposed adjustment to fees – Medical devices

6.2.1 Certificates of Free Sale and Letters confirming the location of a manufacturing site in Ireland

It is proposed to apply the current certificate of free sale fees to applications for letters confirming the location of a manufacturing site in Ireland. These letters are provided to manufacturers to facilitate the export of products from Ireland.

Certificates of free sale and letters confirming the location of the manufacturing site in Ireland	Fee
Medical Device Certificates or Letters confirming the location of a manufacturing site in Ireland. (four certificates/letters per request)	€255
Additional certificates/letters (available at the time of the initial request)	€25

6.2.2 Annual fees for Manufacturers

It is proposed to apply the existing manufacturers fees to both manufacturers defined by the EU legislation (legal manufacturers) and manufacturing facilities (manufacturing site) located in Ireland.

Annual fee for a manufacturer (as defined by the EU legislation) and/or a manufacturing facility (manufacturing site) located in Ireland	Fee
More than 150 employees	€30,600
100- 150 employees	€20,400
50- 99 employees	€15,300
16- 49 employees	€5,100
5- 15 employees	€1,275
Fewer than 5 employees or with annual turnover of less than €500,000	€250

6.2.3 Annual fees for Authorised Representatives

It is proposed to apply the following annual fees to Authorised Representatives. The new Regulations place significant additional responsibility on authorised representatives and the changes below are to account for additional anticipated HPRA activities from mid-2021 onwards in relation to authorised representatives in Ireland. The fee is intended to reflect the nature/complexity of an authorised representatives responsibilities and so have been stratified according to both the number of entities represented and the risk class of products involved.

Annual fee for Authorised Representative	Fee
Type I AR - representing an non EU manufacturer that manufactures low risk devices (fee per manufacturer)	€1,100 per manufacturer capped at €5,500
Type II AR - representing an non EU manufacturer that manufactures high risk devices or a mix of high and low risk devices (fee per manufacturer)	€1,500 per manufacturer capped at €7,500

Type I AR - An authorised representative that represents non EU-Manufacturers that manufacturer class I general medical devices (MDD/MDR) and/or general category IVDs (IVDD)/Class A (IVDR).

Type II AR - An authorised representative that represents non EU-Manufacturers that manufacturer Class IIa, IIb, III general medical devices (MDD/MDR), active implantable medical devices, self test IVD, Annex II IVD(IVDD) or class B, C and D (IVDR).

Where an authorised representative represents non EU-Manufacturers with both low and high risk medical devices, the Type II high risk fee will apply.

Where an authorised representative represents both non EU manufacturers with low risk devices and non EU manufacturers with high risk devices the authorised representative will be charged either the Type I AR or Type II AR fee for each non EU manufacturer. This fee will be capped according to the Type II AR fee.

6.2.4 Annual fees for Distributors and Importers

It is proposed to apply the existing annual distribution fees to medical device importers, as importers will also be covered under the new Medical Devices Regulations.

Annual fee for Distributors and Importers	Fee
Large Distributor/Importer (turnover greater than €15 million)	€4,590
Medium Distributor/Importer (turnover €3 - €15 million)	€2,550
Small Distributor/Importer (turnover under €3 million)	€1,275
Distributor/Importer with annual turnover of less than €500,000	€250

Entities acting as both a distributor and importer located in Ireland will be charged the applicable distributors fee and an additional €1,000 to reflect the dual responsibilities. However, where the entity has a turnover of less than €500,000, the additional fee will be reduced to €250.

Where entities also act as an importer and/or distributor of medical devices to the Irish market for the purpose of intercompany distribution (from other EU and non EU sites) and distribution of third party devices, the fees outlined above shall apply.

The Importer fees will only be charged to entities operating in the context of the new Medical Device Regulations (Regulation (EU) 2017/745 on medical devices (MDR) and Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices (IVDR)).

Where an entity is recognised as a Manufacturer (manufacturers defined by the EU legislation (legal manufacturers) and manufacturing facilities (manufacturing site) located in Ireland), Authorised Representative and/or a Distributor/Importer, separate fees will be charged. There will be cap on total annual fees charged to an entity of €61,200.

6.2.5 Clinical Investigations and Performance Studies

It is proposed to amend the structure for clinical investigation fees and introduce new fees for IVDR performance studies. There are a number of changes affecting clinical investigations under (EU) 2017/745 on medical devices (MDR) and there is a requirement for the HPRA to review Performance Studies under the IVDR (EU) 2017/746 on *in vitro* diagnostic medical devices (IVDR).

Clinical Investigations and IVDR Performance Studies	Current fee	Proposed fee
Active implantable medical devices clinical investigations	€4,300	€4,300
Class III and Class IIb medical devices, including relevant MDR Annex XVI clinical investigations	€4,300	€4,300
Class IIa and Class I medical devices, including relevant MDR Annex XVI clinical investigations	€1,900	€1,900
PMCF investigation notifications in accordance with MDR Article 74(1)	€0	€310
Application for authorisation of In vitro diagnostic medical device (IVD) performance study under IVDR Article 58(1) (first submission)	€0	€2,500
Notification of Performance study involving Companion Diagnostic IVD using left-over samples (IVDR Article 58(2))	€0	€265
PMPF study under IVDR Article 70	€0	€2,500
Substantial modifications and technical amendment to a previously approved clinical investigation/performance study	€1,240	€1,240
Administrative amendment to a previously approved clinical investigation/performance study	€225	€225
Resubmission of a clinical investigation/performance study following a withdrawal or objection or if the application has lapsed	€1,900	€1,900
Resubmission of a clinical investigation/performance study – Academic Sponsor	€510	€510

6.2.6 Assessments under Article 59 of the MDR and Article 9.12 of the IVDD

It is proposed to restructure the fees to include assessments under Articles 59 of the MDR, Article 9.12 of the IVDD and apply the fees based on medical device class. For compassionate use applications made by clinicians under Article 59.1 of MDR and Article 9.12 of the IVDD no fee will be applicable. In relation to applications made under Article 59.2 this fee will be applied to the product rather than to all products covered by an existing notified body certificate.

Assessments under Article 59 of the MDR and Article 9.12 of IVDD.	Fee
Assessment relating to Class I (MDD/ MDR).	€1,000
Assessment relating to Class IIa and IIb (MDD/ MDR) and General Category IVD.	€2,000
Assessment relating to Class III, Active implantable (MDD, AIMD, MDR), Self test and Annex II list A and B IVDD).	€4,000

6.2.7 Determination of classifications within the medical device regulations

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

Determination of Classification within the medical devices regulation	Current Fee	Proposed Fee
Determination not requiring a complex technical review (one device per request)	€255	€280
Complex classification requests	€1,020	€1,020
Arbitration Fee	€5,000	€5,000
Appeal of a classification decision	€600	€600

6.2.8 Search Fee

It is proposed and agreed to increase the search fee to align with the Human fees

	Current fee	Proposed fee
Search fee of medical devices database	€60	€65

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 2020. Contributions should be sent by email to feesconsultation@hpra.ie.

APPENDIX I SERVICE LEVELS – MEDICAL DEVICES

As the national competent authority for medical devices, the HPRA carries out a range of classification, registration, surveillance, monitoring and compliance activities. Our aim is to ensure that these health products perform as intended and do not compromise the health and safety of the patient or the person using them.

Caseload volume continued in line with recent trends observed since 2015 in medical devices across the HPRA. 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 DOH, the HSE and industry in managing medical device relates 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 2019, we:
  - Assessed applications from organisations seeking to be designated as notified bodies in Ireland under the new EU Regulations on medical devices;
  - Continued our schedule of oversight of the notified body in Ireland based on ongoing assessment, surveillance and observed audits;
  - Provided expert assessors to participate in joint assessments of notified bodies based in other European countries;
  - Continued to support development of EU coordination of notified body designation and oversight through participation in the EU Notified Body Operations Group (NBOG) and the Medical Device Coordination Group (MDCG);

- Supporting innovation and research of new technologies is a key strategic priority for the HPRA medical devices team. In 2019, this involved:
  - The review of applications to conduct clinical investigations of medical devices in Ireland. Five new applications for clinical investigations and 10 amendments to ongoing investigations were assessed. The HPRA anticipates that these numbers will increase when the new EU Regulations are implemented;
  - continued focus on this area to ensure regulatory requirements and processes are clear and accessible to potential applicants;
  - Encouraging engagement during product development and innovation of medical technologies. We met with 19 groups of innovators to discuss potential clinical investigation applications in 2019;

  - Supporting the work of the HPRA Innovation Office on medical devices queries received;
  - Presenting and participating in innovation sessions at a variety of conferences and workshops including the Euro PCR conference.
- Manufacturers of certain medical devices and *in vitro* diagnostics are required to register with the HPRA. In 2019, the HPRA registered 99 new organisations. A total of 6,037 medical devices were also registered. This represented increased registrations when compared to previous years, some of which is attributable to the UK's exit from the European Union.

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 2019:
  - We utilised a lifecycle market surveillance strategy and planning mechanism to ensure continued safety and performance of devices throughout their lifetime;
  - We led and participated in various elements of both technical work packages of the EU Joint Action on Market Surveillance (JAMS) of medical devices initiative which is funded by the European Health Programme and aims to develop market surveillance activities;
  - A total of nine COEN notices were sent to the European network relating to medical device compliance concerns;
  - There were 1,645 market surveillance cases undertaken in 2019, a slight increase compared to 2018. Key areas of focus for market surveillance review included transvaginal mesh implant devices and breast implant associated anaplastic large cell lymphoma (BIA-ALCL).

- We continued to focus our vigilance activities during 2019 on the areas of user reporting and dissemination of HPRA medical device safety communications. This included:
  - The receipt and assessment of 2,295 medical device vigilance cases, similar to numbers received in 2018. Of the 1,105 incident reports notified to the HPRA, 13% came from users of medical devices. Manufacturers accounted for 60% of all reports received in 2019 while 32% came from other competent authorities;
  - There were 409 field safety corrective actions (FSCA) associated with the national market including 128 product removals conducted in Ireland during 2019;
  - We issued 84 national competent authority reports, eight notified body forms and four vigilance enquiry forms;
  - We also issued 33 safety notices in relation to medical device issues and 63 direct to healthcare professional communications;
  - Surgical devices, orthopaedic devices, implants and infusion devices accounted for 52% of the total vigilance reports. Reports continue to be received relating to in vitro diagnostic devices in the area of clinical biochemistry and medical devices in the areas of diagnostic imaging and vital signs monitoring. During the year, we also continued development work on signal detection of medical device issues.

COVID-19 PANDEMIC

The COVID-19 crisis highlighted the essential role that medical device technologies play in the diagnosis and treatment of disease. The availability for supply of medical devices, including accurate diagnostic tests for SARS-CoV-2, intensive care equipment such as ventilators and basic protective equipment for healthcare workers such as surgical masks, gloves and gowns came under intense and sustained pressure in response to unprecedented demand across the globe.

The Medical Devices Department has worked closely with the Department of Health and the Health Service Executive to assist in the national response to COVID-19 (SARS-CoV-2) in Ireland. The HPRA devices team worked as part of the Medical Devices Criticality Assessment Group (CAG), a subgroup of NPHET to provide regulatory advice and input on relevant medical devices. The devices team were also members of the NPHET subgroup on diagnostic testing approaches.

The HPRA also worked directly to provide guidance to manufacturers and suppliers on regulatory requirements for medical devices and IVDs and the HPRA continues to provide support on the regulatory framework to HSE and to manufacturers/distributors to ensure confidence in the long-term supply chain.

The regulatory support provided by the Devices Department during this pandemic has also resulted in cross-agency cooperation and collaboration with regulatory peers. The HPRA worked with HIQA in the area of Rapid Health Technology Assessment of alternative diagnostic testing for coronavirus 2 (SARS-CoV-2), as well as working with the Health and Safety Authority (HSA), the Competition and Consumer Protection Commission (CCPC) and the National Standards Authority of Ireland (NSAI), in relation to products such as face masks, gowns and gloves.

At a European level, the HPRA participated in the EU Commission established taskforce of the Medical Device Coordination Group (MDCG) market surveillance working group to share and exchange information on the challenges presented by COVID-19 in different EU countries. The devices team also participated in an international forum with regulators from Australia, Brazil, Canada, EU, Japan, Singapore, South Korea and the US to exchange experiences on emerging issues with essential devices on the market place.

The devices team working along with colleagues from the enforcement team continued to conduct surveillance of new devices coming on to the market in Ireland. The HPRA, working with customs colleagues and other stakeholders detected a number of falsified and counterfeit devices as well as incorrectly CE marked devices. Examples of falsified devices included fake or counterfeit tests and non compliant thermometers. Safety notice and social media have been used to highlight these issues and to ensure the information reaches the stakeholders concerned.

To reflect the needs of internal and external stakeholders, a number of COVID-19 specific webpages have been published on the medical devices webpage to facilitate consolidation of key information and resources.

LEGISLATION AND REGULATION

- We continued our work during 2019 to help ensure an effective and timely implementation of the EU Device Regulations[1] (EUDR) at national and European level. This included:
  - Implementing a HPRA programme plan for development of appropriate resources, process and systems to meet our obligations under the new EUDR;
  - Preparing detailed information relating to the new requirements with respect to the need for national legislation, the timelines and impact on existing national legislation;
  - Contributing to the European Commission's development of the secondary legislation involving implementing and delegating acts;
  - Participating in the new 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.

  We continued to engage with the Department of Health throughout 2019 on policy and legislative issues arising from implementation of the new EU Regulations. 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 2019 to streamline the approach and address some of the comments and feedback received following its initial introduction.

- 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. This included:
  - Re-election to the Executive Group of the Competent Authorities for Medical Devices (CAMD) network. This group has successfully worked in partnership with the EU Commission over the last number of years to help develop the regulatory system in Europe;
  - Participation in the CAMD's Implementation Task Force (ITF) and Transition Subgroup (TSG) which aim to improve co-ordination and consistency of implementation of the new EU Regulations and published guidance on what it means to be compliant by the date of application of the Regulations as well as proposing key areas for the Joint Plan on MDR Implementation;
  - Continuing to lead the work of the clinical investigation and evaluation working group (CIEWG), acting as the co-chair with the EU Commission.

[1] Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices

- We continued to participate actively in initiatives to promote regulatory convergence and harmonisation of medical devices globally through the International Medical Device Regulators Forum (IMDRF). This involved:
  - Participation in the IMDRF Management Committee as part of the European delegation (along with the EU Commission, France and Germany);
  - Continuing to act as the IMDRF secretariat for the National Competent Authority Report (NCAR) Exchange programme. We also participated in a number of different IMDRF working groups including the group on Medical Device Single Audit Programme (MDSAP);
  - Contributing to discussions and development of the Medical Device Single Review Programme, which relates to product review;
  - Contributing to briefings for the EU Commission for the purposes of the MDSAP Regulatory Authority Committee discussions and also encouraging discussions at EU level to further Europe's future engagement in the programme.

BREXIT PREPARATIONS

Preparations for Brexit, in conjunction with cross organisational departments, have continued in 2019 and 2020 and have included participation in stakeholder meetings, development of website and guidance material, registering new organisations establishing in Ireland as a result of Brexit. The HPRA has continued to have extensive communication with manufacturers and authorised representatives at national level to ensure appropriate awareness of the implications of a no-deal Brexit for medical devices. We have also led on EU work with other competent authorities to promote awareness and to prevent adverse impacts on medical devices used in Ireland. HPRA has provided support to the HSE and the Department of Health in the Brexit operations groups.

STAKEHOLDERS AND PARTNERS

- Our work to further developing our stakeholder engagement and communication with medical devices stakeholders continued throughout 2019. This included the promotion of direct reporting of incidents and medical devices issues by device users and members of the public. 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. We again promoted the adoption and communication of the HPRA step-by-step guide to user reporting which is targeted at healthcare providers.

- The HPRA undertook a number of communication initiatives to raise awareness of the impact and requirements arising from the new EUDR. During 2019, we:
  - Supported the TOPRA 2019 symposium on medical devices for manufacturers in Dublin. The event, which included a number of presentations from HPRA staff members, was attended by approx140 medical device participants;

- Developed and delivered a new workshop on medical devices for the IPPOSI Patient Education Programme Module on Regulatory Affairs;
- Continued to update the HPRA website and social media channels to provide information and guidance regarding EUDR;
- Provided briefings, advice and workshops on the new Regulations to a range of different stakeholders including notified bodies and distributors.

- Throughout the year, we engaged in ongoing strategic, operational and communication initiatives on a bilateral and multilateral basis with European and international authorities, and the EU Commission. We also further developed our bilateral partnerships with a number of those authorities. In addition, we participated in operational and strategic discussions on developing cooperation between the CAMD and the Heads of Medicines Agencies (HMA) networks.

- The HPRA continues to deliver a programme of presentations and talks to a range of external stakeholders.

- The HPRA also continued, during 2019, on the development of the medical devices department with the further introduction of organisational improvement and efficiencies. These included the seamless introduction of remote working for the majority of the team during the COVID-19 crisis.

Fee based funding

Fees for medical devices were introduced in January 2017 following extensive consultation with industry to cover the costs of the HPRA's medical device regulatory activities. The model was amended during 2018 to reflect feedback received from affected stakeholders and is now based on a cost recovery model which relies on subventions from the Department of Health.

Case Workloads

Vigilance and Compliance

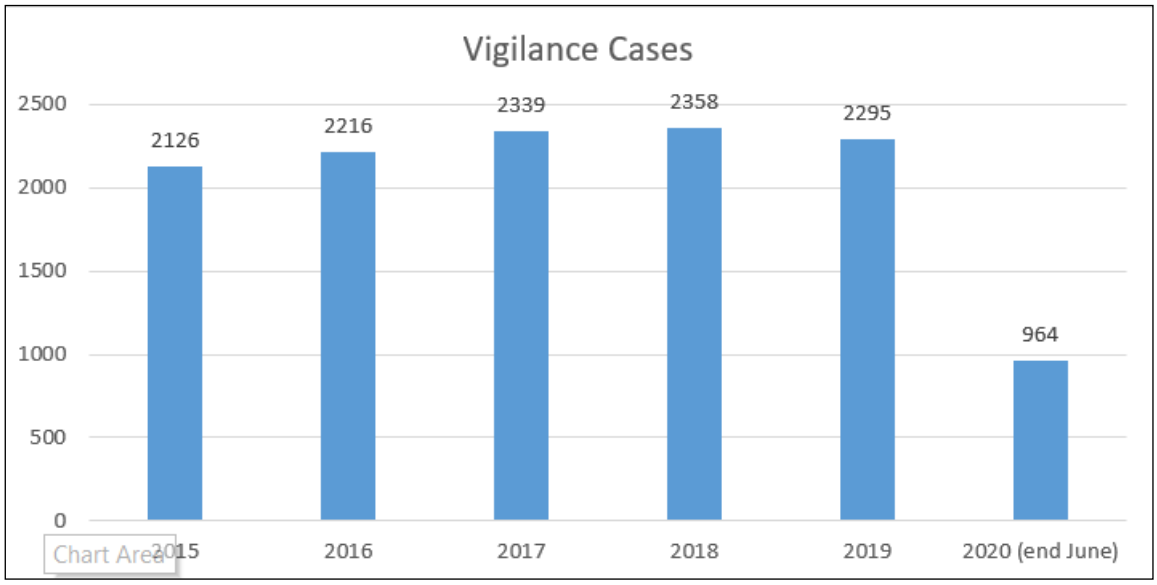
There has been ongoing work with the HSE in various National Incident Management Teams during 2018 – 2019 and case work continues to lead to the identification of significant issues that require increased monitoring and oversight by HPRA.

To date in 2020, the vigilance workload continues at consistent levels, with an increase in complexity in relation to vigilance cases. Year to date (January to end June), 964 vigilance cases were opened and reviewed. Also in this period, among other communications, 8 HPRA safety notices and 59 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.

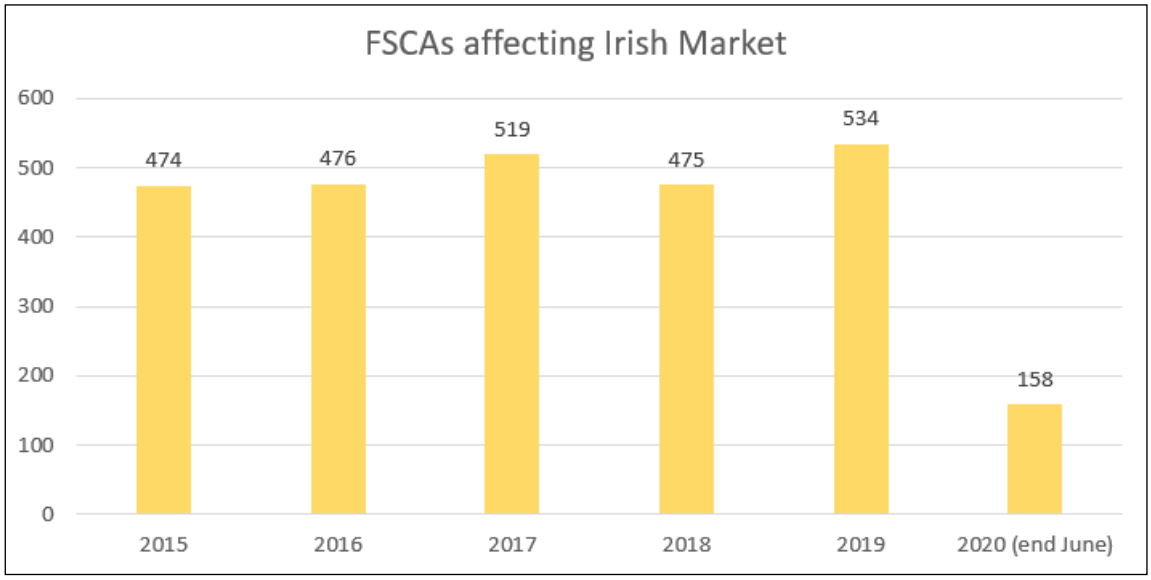
Work has continued to enhance the vigilance function through the introduction of a signal

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 2020)



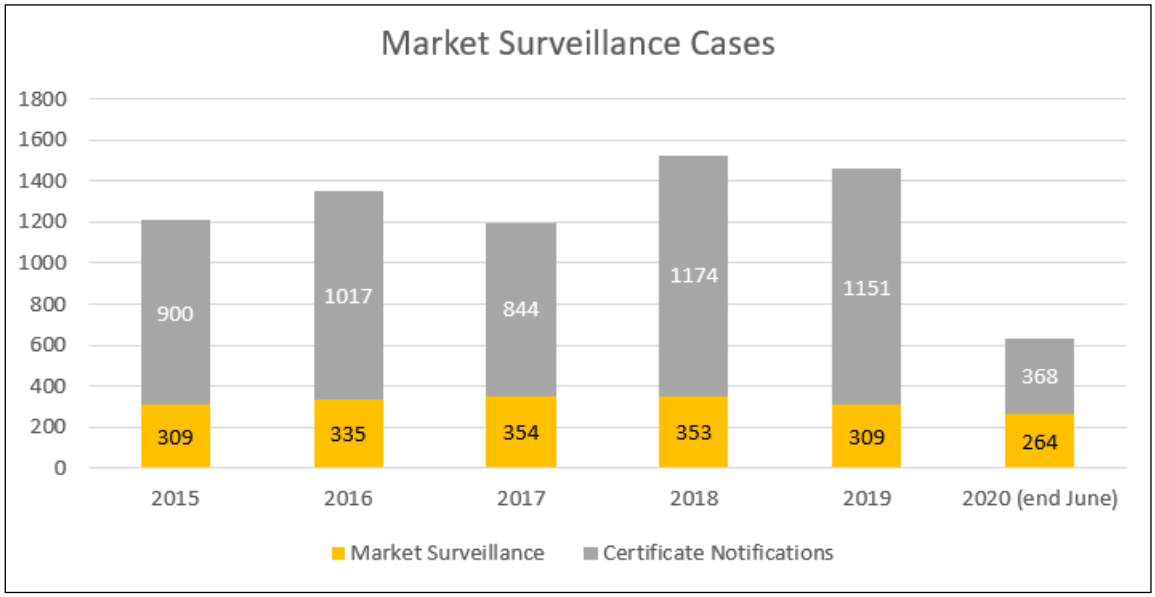
Graph 2: Number of Field Actions affecting Irish Market (2015 to end of June 2020)

Designation and Monitoring of Notified Bodies

Surveillance Cases

In line with the EU Commission's 2012 Joint Plan for Immediate Actions, the HPRA has, over recent years, been developing and reinforcing its market surveillance activities for medical devices. The HPRA has implemented a lifecycle approach to surveillance focused on protecting the health and safety of those who use medical devices by ensuring that all devices on the Irish market comply with the relevant European directives.

During 2019, the HPRA continued to develop its lifecycle approach to market surveillance and investigated 309 market surveillance cases.



Graph 3: Number of Market Surveillance Cases (2015 to end of June 2020)

The HPRA has, in particular since 2014, 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 market place 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.

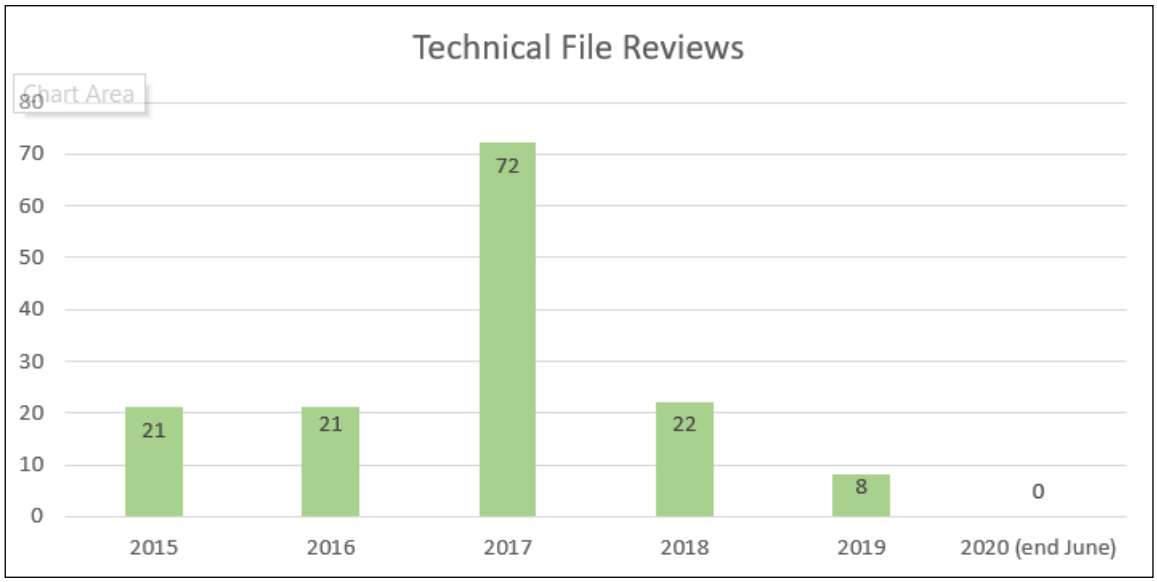
In addition, a significant number of queries for advice on regulatory issues have been processed. In 2019, we conducted nine audits relating to medical devices. These were comprised of one for cause audit and eight were based on proactive market surveillance projects and notified body surveillance/assessment.

<u>Technical file reviews</u>
A total of eight technical file reviews were initiated in 2019. Technical file reviews require input across the assessment and clinical teams and are related to proactive surveillance work. Reactive cases were also initiated due to concerns raised by external stakeholders regarding products where the manufacturer with legal responsibility for the product is based

in Ireland or the product has been certified by the Irish Notified Body.

Clinical Evaluation Review

Since 2015, 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 reactively in response to a number of specific device issues highlighted during the year 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 level and European level as part of EU joint assessment activities.



Graph 4: Number of Technical File Review Cases created (2015 to end of June 2020)

Product registrations

In 2019, the HPRA received 5414 notifications of new medical devices to the medical device register, with 500 device amendments received. In addition, 65 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. Registration of these devices in the Member State in which the manufacturer or its authorised representative is based is required by legislation as there is a self-declaration of conformity made by the manufacturer.

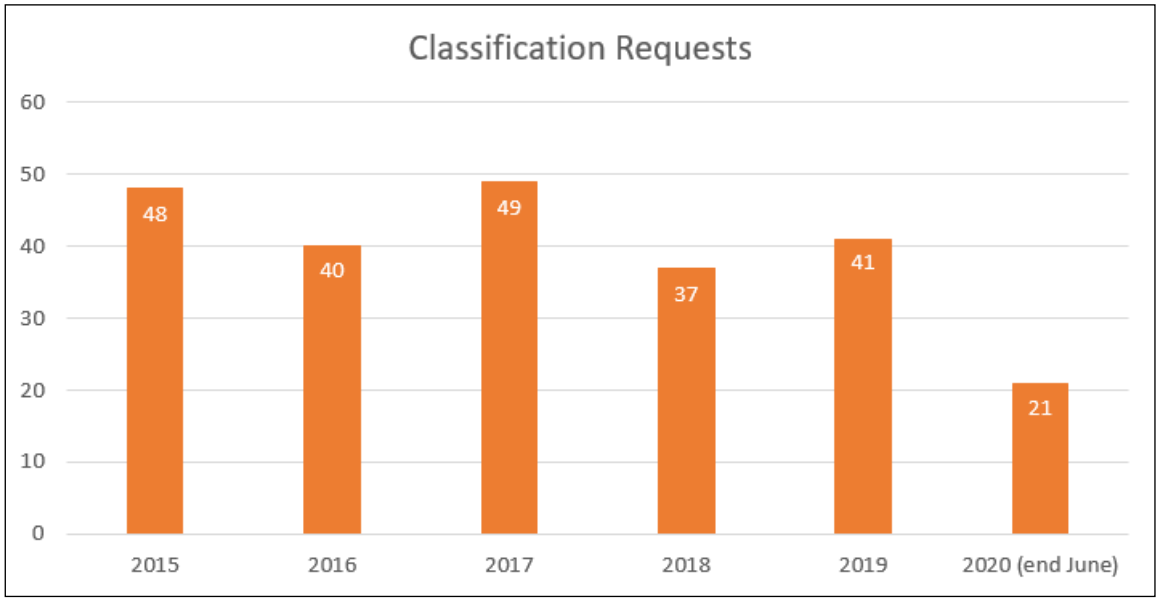
This increase in new organisations registering has already impacted on the number of market surveillance activities undertaken with regard to the register and it is expected that it will continue to be an ongoing focus of the market surveillance activity.

In the first six months of 2020, 48 medical device economic operators have registered with the HPRA under the MDD/IVDD and 32 medical device economic operators have registered under the MDR/IVDR.

Classification Requests

The HPRA received 41 applications for classification of medical devices or products queried as medical devices in 2019. 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 5: Classification Requests (2015 to end of June 2020)

Clinical Investigation Applications

The HPRA received five applications for clinical investigations of a medical device to be conducted in Ireland in 2019.
In addition, 24 compassionate use procedures were completed in this period.

Queries

During 2019, the HPAR medical devices team received 857 queries relating to medical devices. The majority of the queries related to the provision of guidance and interpretation of the legislation, registration, labelling. In addition, a large number of queries have been received in the first six months of 2020 the department received 1121 queries, 42% of these have been related to COVID-19 related matters.