HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Public Consultation on
Annual Review and Proposal for Fees – For Financial Year 2018

Medical Devices

8th May 2018

CONTENTS

1 INTRODUCTION

The HPRA as the competent authority for medical devices has a key role to play in the protection of public health in respect of medical devices. Increasingly innovative and complex medical device technologies afford patients and health systems new diagnostic and therapeutic possibilities, conferring additional benefits with consequent changes in risk profile. The medical device regulatory model is based on comparatively early market access and iterative development of new technologies, recognising that the safety and performance of a medical device must be demonstrated over its lifetime when exposed to different patient groups and user practices. Consequently, one of the HPRA's key roles is to ensure robust market surveillance of the ongoing safety and performance of medical devices in Ireland and the EU throughout the product lifecycle. The provision of a market surveillance system for medical devices is a key public service obligation of member states and is fundamental to the regulatory approach for protection of public safety. These requirements and obligations on the HPRA are increased with the introduction of new European Regulations on medical devices[1]. This surveillance function, both proactive and reactive, is not amenable to transaction based funding like many of the HPRA's other assessment activities in other health product areas.

Up until 2016, in recognition of the public health remit, medical device activities at the HPRA were funded by Government subvention. In 2017, a new fee regime was introduced to cover the cost associated with all of our market surveillance activities for medical devices. The purpose of this document is to review the success of the fee model and to propose a fee model for 2018.

2 REVIEW OF THE 2017 FEES

2.1 The 2017 fees

In 2017, the HPRA introduced a new fee model with the aim of making medical devices fully self-funding. The model proposed for 2017 involved a fee levied to all companies responsible for manufacturing or placing devices on the market in Ireland – primarily medical device manufacturers, authorised representatives and medical device distributors. These fees were stratified based on the size of the companies (with the number of employees used as a measure for manufacturers and turnover as a measure of a distributors operations). During previous consultations stratification based on turnover was not favoured by the manufacturing industry, as they were concerned that this would be perceived as a tax.

Despite extensive consultation with the medical device industry associations and a public consultation, it was acknowledged that the model was being developed in the absence of complete information of the structure and operation, across the full medtech sector in Ireland.

[1] Regulation (EU) 745/2017 and Regulation (EU) 746/2017

This is because companies and medical devices, other than self-declared devices (such as class I devices), are not required to register with the HPRA. Consequently, we do not have access to reliable data on the full profile of the industry based here, particularly those operating as small or very small enterprises and/or SMEs. In addition, while the HPRA extensively engaged and consulted with the industry representative bodies in advance, only limited information on the industry profile was made available.

In respect of the 2017 fees, the HPRA has always recognised the difficulty of developing a model without exact knowledge of the market place and we have always committed to revising the fees if they are incorrect or not properly aligned with the market place. Prior to invoicing for the 2017 fees the HPRA did an exercise identifying all the medical device companies in Ireland that fall under the new fee regime. The companies were then invited to provide information on their company so that we could classify them appropriately under the fee classifications. Following that exercise, relevant invoices were issued. The outcome of this work indicated that:

- The majority of companies operating in Ireland appear to fall into the small and SME categories.
- While the medical device industry has an annual turnover of €12 billion, a significant portion of this turnover is centred on a relatively small number of companies.
- Many companies are not members of industry associations and thus may have had limited awareness of the public fee consultation.
- Some companies have limited awareness of the role and activities of the HPRA in the regulatory system for medical devices.
- Many manufacturing companies expressed concern that the fees were excessive in relation to the size of their business.
- Authorised representatives contacted the HPRA to outline the impact of the new fee on their business model, which was not sustainable in some cases.

While these comments came in as part of the fee invoicing process, to reflect our commitment to engage and to ensure that our fee model is fair and transparent, we have treated these comments as being consultative in nature.

2.2 The 2018 fees

In relation to the 2018 fees, the proposal has been reviewed based on the comments in respect of the 2017 fees. As a result of this review, we attach a proposal which will better align the fees for smaller manufacturers with the size of their activity. There are also proposed reductions to the authorised representative fee and some of the distributors. While the fees for the very large manufacturers remain unchanged, all other fee categories are reduced.

In addition to the revision to the new fee model, some changes are proposed to the existing medical device fees which are outlined in section 6.

2.3 Risks and uncertainties in relation to the fee model

While the HPRA has sought to reflect the data received to date, some companies have still not provided complete information to the HPRA on their size and nature of their activities. While we have much information now on the size and nature of the sector, we recognise that further adjustments may be needed. We therefore propose to have an ongoing engagement with the industry and propose to review the fees again in 2018 based on further experience of the industry and the fee model.

3 THE FEE MODEL

The fee model for 2017 was based on the medical device industry funding medical device regulation in Ireland. The reductions proposed for 2018, reflecting the concerns expressed by industry, will result in the fee income being insufficient to cover the costs of meeting the legal responsibility of competent authority for medical devices, under the medical device EU legislation. Exchequer funding will therefore be required to make up the shortfall.

4 FINANCIAL CHALLENGES IN 2018

In addition to ongoing work on medical devices, the implementation of the new EU Regulations for medical devices will be a priority task for 2018. This will be the most significant driver on resources particularly as a result of our increased responsibilities and obligations under that regulation. To ensure we are appropriately resourced to fulfil these obligations we will continue to optimise our activities and resource utilisation. The impact of Brexit, while uncertain, is likely to increase the work load for 2018. Additionally, the HPRA is investing in new IT systems for the management of medical device oversight and the reversal of the Haddington road pay cuts impacts on the cost base. We are therefore predicting an increase in our costs for 2018. The increase in costs combined with the reduced fees will result in the need for exchequer funding for 2018.

5 PROPOSED FEES

As noted above, we have reviewed the fee model introduced in 2017 and we are reducing the fees for the smaller entities to better align the fees with the size of the business.

6 DETAILED CHANGES TO FEES

6.1 General changes to fees

Organisations that have multiple manufacturing sites based in Ireland will be charged a fee per site based on the size of each. This fee will be capped at a maximum of €60,000.

Finished product manufacturers (who manufacture devices for other organisations) will be subject to the manufacturer fee. An organisation which acts as the legal manufacturer for a device, which is manufactured by another party, will be subject to the manufacturer fee in accordance with their size.

Entities which act as authorised representatives, without being a medical device manufacturer, are charged a fee up to a maximum of €5,000 a year.

Organisations that only act as suppliers, component manufacturers and critical subcontractors/service providers will not be subject to the fee model.

6.1.1 Medical Devices

(a) New proposed fee model for 2018

Category	2017 Fee	Proposed 2018 Fee	Change
Manufacturers - more than 150 employees	€30,000	€30,000	-
Manufacturers - 100-150 employees	€25,000	€20,000	(€5,000)
Manufacturers - 50-99 employees	€25,000	€15,000	(€10,000)
Manufacturers - 16-49 employees	€15,000	€5,000	(€10,000)
Manufacturers - 5-15 employees	€5,000	€1,250	(€3,750)
Manufacturers - less than 5 employees /turnover less than €500k	€250	€250	-
Legal Manufacturer/Authorised Representative, where also a Manufacturer	€1,000	-	(€1,000)
Authorised Representative	€5,000	€1,250	(€3,750)
Distributors - turnover greater than 15 million	€5,500	€4,500	(€1,000)
Distributors - turnover €3-€15 million	€3,500	€2,500	(€1,000)
Distributors - turnover under €3 million	€1,250	€1,250	-
Distributors - turnover less than €500,000	€250	€250	-

7 CONSULTATION

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

Contributions to the consultation on this proposal may be provided to the HPRA by 25 May 2018. Contributions should be sent by e-mail to feesconsultation@hpra.ie.

APPENDIX I SERVICE LEVELS – MEDICAL DEVICES

The activity levels seen during 2017 continued to increase, across all of the teams involved in medical devices at the HPRA. There continued to be a high number of vigilance cases and an increasing number of resultant field actions (recalls, device modifications etc.) relating to devices on the Irish market. These cases are increasing in complexity and significance in terms of impact on public health.

In addition, the HPRA continued to develop its medical device market surveillance activities, increasing the level of technical and clinical focus for these assessments. Another key area of focus during the past year has been our contribution to development of the European regulatory system for medical devices and to the new European legislation on medical. During 2017, the HPRA also commenced an organisational review to ensure that we can optimise effectiveness of our activities and resources in preparation for the new EU Regulations. Further details on these issues are outlined below.

New EU legislation on medical devices and other regulatory developments and initiatives

Two new Regulations on medical devices were published in the *Official Journal of the European Union* in May 2017. This agreement follows four years of intense negotiation and development of these complex regulatory proposals involving over 100 meetings of the European Council's Working Party on Pharmaceuticals and Medical Devices. Throughout the negotiation, the HPRA provided regulatory and technical support to the Department of Health (DoH) for the purposes of representing the national position at the European Council Working Party and in other fora.

This new European legislation will replace the existing Directives. Some elements will become legally binding from the end of 2017 while the remainder will be applicable from 2020 for medical devices and 2022 for *in-vitro* diagnostic devices. During 2017, the HPRA commenced work on implementation of the new legislation at organisational and national level. In November 2017, the first provisions of the new Regulations, for example, those relating to notified bodies, became fully applicable. The HPRA developed its internal procedures, systems and resources to be ready in time for application of these provisions. In addition, the HPRA assisted the Department of Health (DoH) in preparing relevant national legislation (SI 547 of 2017) to nominate authority to the HPRA and to clarify language provisions for applications under the new Regulations.

The HPRA has identified different groups of stakeholders that are affected by the new Regulations and plan to tailor its communications on the new Regulations to each of these groups to help ensure stakeholders are aware and ready to comply with the new requirements. It is critical that medical manufacturers, notified bodies, distributors and other stakeholders affected by these Regulations start to plan now for these substantial changes which will come into place between 2017 and 2022.

With publication of the new Regulations, the HPRA encouraged establishment of an EU level taskforce of the EU Competent Authorities for Medical Devices (CAMD) network to allow opportunity for discussion and agreement on interpretation of the Regulations and to help coordinate EU level implementation work. This taskforce, under the leadership of the HPRA, published a roadmap during 2017 of EU-level priorities for implementation from a competent authority perspective. In addition, the CAMD participated in collaboration with the Commission in two EU-level stakeholder workshops on implementation.

Also at a national level, the HPRA has placed specific focus on engagement with health services and healthcare professionals. The approach has focused on three inter-related areas of the dissemination of safety information, the development of the role of 'designated person/vigilance officer' and the encouragement of user reporting. In 2017, the HPRA met with key personnel within the Health Service Executive (HSE)'s various hospital groups to support and enhance the work completed to date in this area.

The HPRA continued its commitment to the Competent Authorities for Medical Devices (CAMD) network (www.camd-europe.eu) which promotes coordination and joint working between authorities. . This network also promotes partnership and allows for close cooperation between all of the device authorities and the European Commission. The HPRA continued to serve on the Executive Group of the CAMD (along with Austria, France, Germany, Sweden, Switzerland and the UK).

The HPRA participated across all of the different working groups of the European Commission. In particular the HPRA has provided co-chairs for the Clinical Investigation and Evaluation Working Group, the Compliance and Enforcement Working Group (COEN) and the Notified Body Operations Group (NBOG).

Over the last number of years the HPRA has also been contributing to the development of regulatory systems for medical devices at the International Medical Device Regulators Forum (IMDRF) with a view to promoting harmonisation of international regulatory systems and consistency and cooperation between device regulatory authorities across the globe. This helps to improve regulatory systems and practices, and increases consistency and predictability for the regulated industry. In addition, participation in these activities also helps to build confidence, recognition and reliance on the European system in other global territories.

During 2017, the HPRA continued its membership of the IMDRF's Management Committee as part of the European delegation (along with France, Germany and the EU Commission).

During 2017, HPRA continued its support to the medical device single audit program (MDSAP) acting as an active auditor for the consortium and observing the scheme on behalf of the European Union. The HPRA also made active contribution to the IMDRF working group on Regulated Product Submissions (RPS).

In addition, the HPRA continued its role as the international secretariat for the IMDRF's NCAR Exchange programme which it has undertaken since 2014. This scheme allows for the exchange of information between international regulatory authorities on identified or emerging safety issues relating to medical devices.

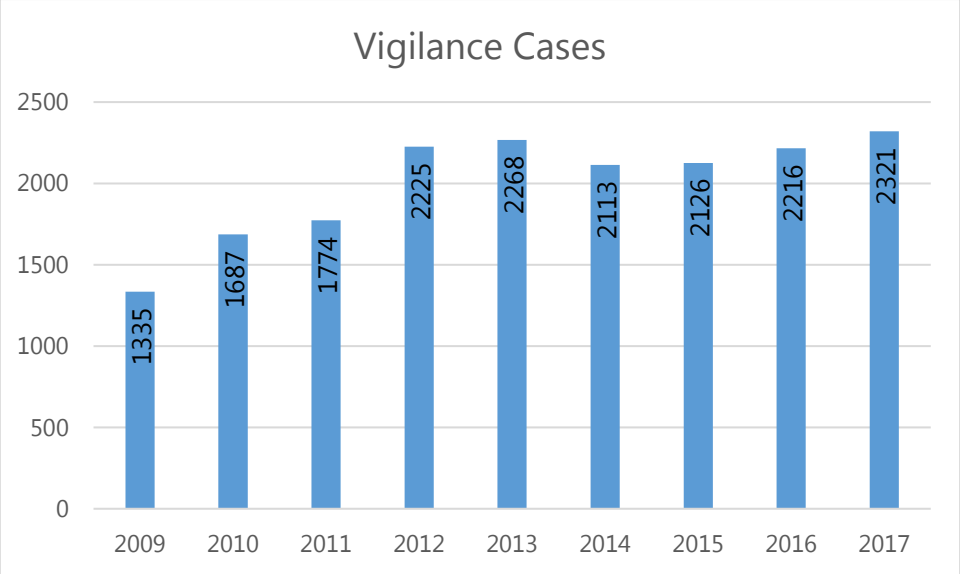
Case Workloads

Vigilance & Compliance

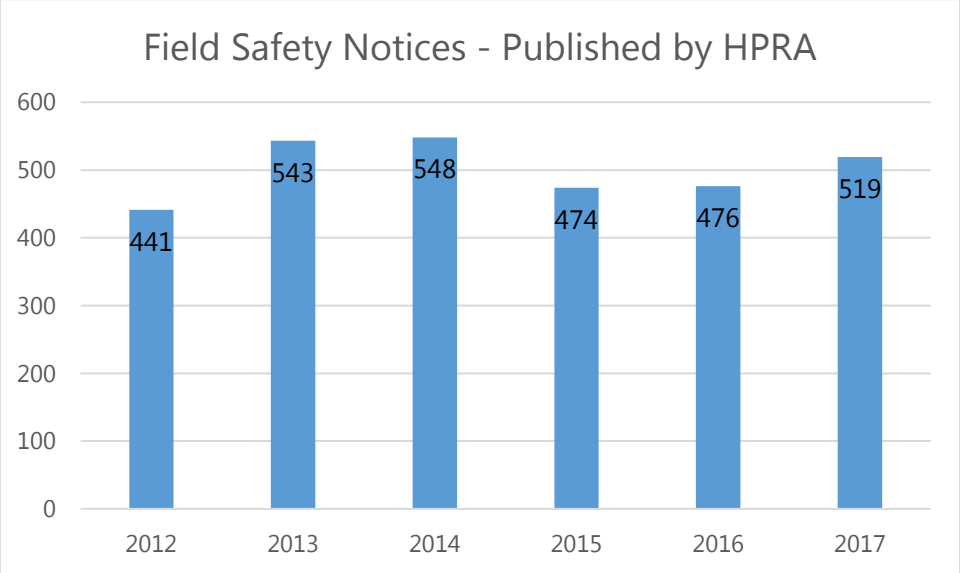
Several significant medical devices issues resulted in significant workload over the period 2013 to 2017. These include issues with implantable cardiac devices such as implantable cardiac defibrillators (ICD) and transcatheter aortic valve implants (TAVI), defibrillators (AEDs and professional), intraocular lenses, hip and knee implants, infusion pumps both implanted (for example for diabetes and pain management) and hospital pumps and heater cooler cardioplegia systems). There has been significant ongoing work with the Health Service Executive (HSE) and with various National Incident Management Teams.

In 2015 and 2016 work has been undertaken 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.

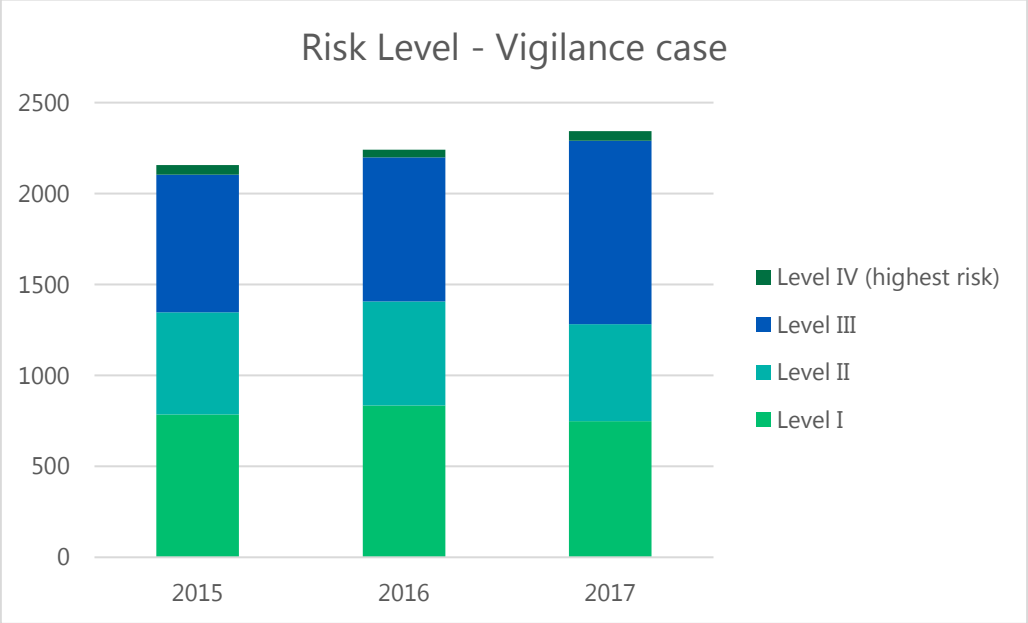
See charts showing activity levels as follows.



Graph 1: Number of Vigilance Reports Received (2009 to 2017)



Graph 2: Number of Field actions affecting Irish Market (2012 to 2017)



Graph 3: Risk level assigned to cases (2015 to 2017)

Designation and monitoring of Notified Bodies

In 2017, we conducted 2 on-site surveillance assessments of the Irish Notified Body, the National Standards Authority of Ireland (NSAI) as a follow up to its re-designation review in 2016. Two observed assessments of NSAI auditors undertaking assessments at manufacturing sites were also conducted. During 2017, the HPRA acted in an observed role for two MDSAP witnessed audits.

During 2017, the HPRA dedicated significant support to the development of relevant documents and European systems in time for the full application of the notified body requirements and designation process from November 2017. The HPRA also provided support and guidance to notified bodies at national and EU level in relation to the requirements in the new Regulation.

The HPRA ensured that its internal systems, processes and resources were ready in time for full application of the requirements relating to notified bodies. From the 26th November onwards, organisations are allowed to apply to become notified bodies under the new EU Regulations. Following on from that date the HPRA received a number of applications for designation from Irish based organisations.

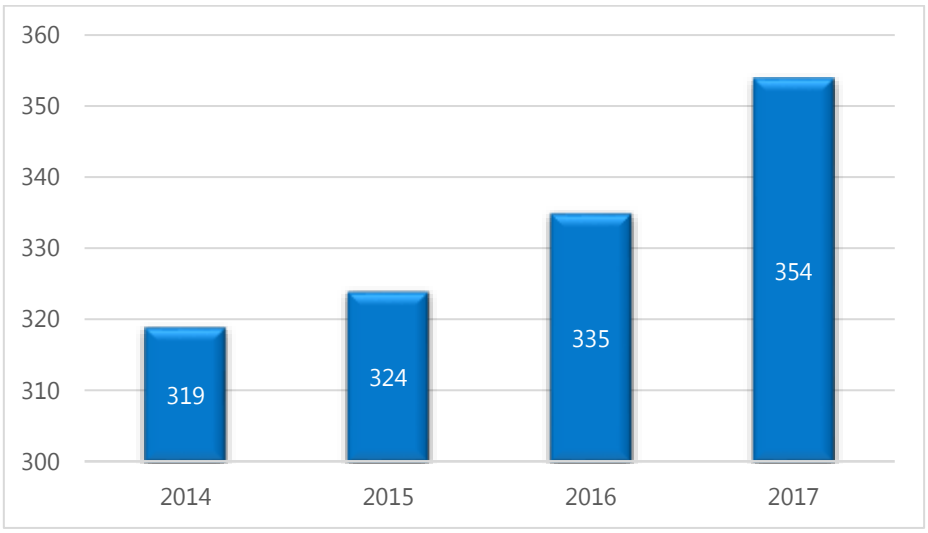
During 2017, the HPRA continued its commitment to the EU joint assessment scheme for notified bodies. It provided expert assessors to participate in 4 joint assessments over this time period.

Market Surveillance

Since 2012, the HPRA placed significant focus on its market surveillance activities and has continued to increase the number of cases it assesses on an annual basis, with an emphasis on proactive rather than reactive surveillance activities.

During 2017, the HPRA continued its lifecycle approach to market surveillance and investigated 354 market surveillance cases.

The new Regulations place additional responsibilities and obligations on the activities of regulatory authorities in market surveillance. The HPRA has continued to develop its market surveillance processes and systems to prepare to meet these requirements. The new Regulations also place increased emphasis on authorities conducting market surveillance inspections of manufacturing sites. The HPRA are contributing to EU joint actions to develop training and best practice schemes for these at European level.



Graph 4: Annual numbers of market surveillance cases

Joint action on market surveillance of medical devices (JAMS) project

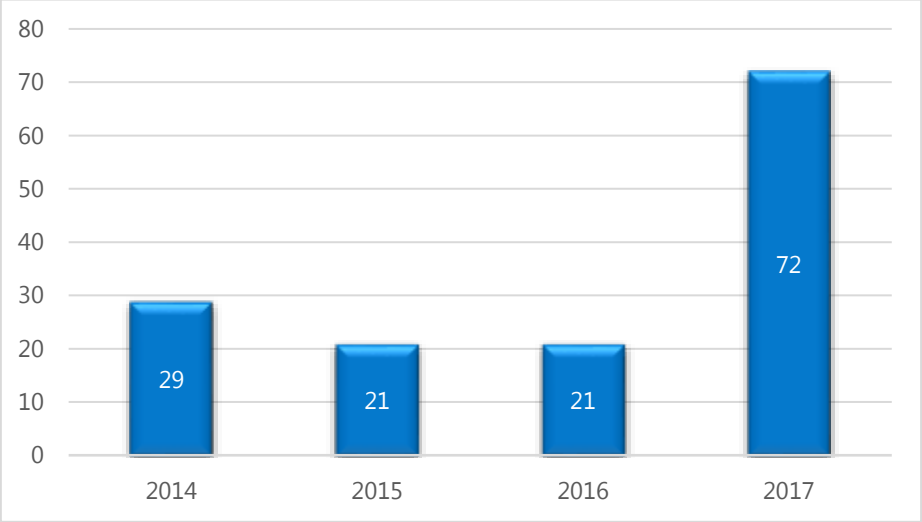
During 2017, the HPRA contributed significantly to the EU JAMS project. This initiative funded by the EU Health Programme is aimed at developing best practices, capacity and consistency across EU competent authorities. The project is led by the UK's MHRA, the Dutch IGZ and the HPRA. During 2017 the HPRA led the technical work package on clinical resource development at authorities. This package includes participants from 13 national device authorities across Europe. Work in 2017 focussed on developing common communication mechanisms/platforms for medical device issues and also on developing a proposed procedure for prioritisation and selection of devices for development of common specifications. Also during 2017, due to unforeseen circumstances, the HPRA took on leadership (on a temporary basis) of the technical work package relating to manufacturer audits. This work package produced a best practice guidance for authorities and aims to develop common procedures, templates and coordinating mechanisms for authority audits of manufacturers.

Certificate Notifications

During 2017 there were 844 notifications from Member State authorities relating to certificate refusals, withdrawals and suspensions by notified bodies. The number of these notifications have been levelling off over the last number of years potentially as a consequence of the joint assessment process for notified bodies which has increased the consistency and performance of notified bodies across the EU. The HPRA investigated those certificate notifications with implications for the Irish market, those arising from identified safety concerns and major non-compliances, and those arising from a reduction in the designation scope or de-designation of notified bodies.

Technical file reviews

In 2017, the HPRA continued its increased focus on detailed review of technical documentation both in the context of market surveillance activities and notified body oversight. A total of 72 technical file reviews were completed in 2017. A significant number of these were in relation to the European joint action on re-usable instruments and on provision of scientific advice for drug-device combination products.



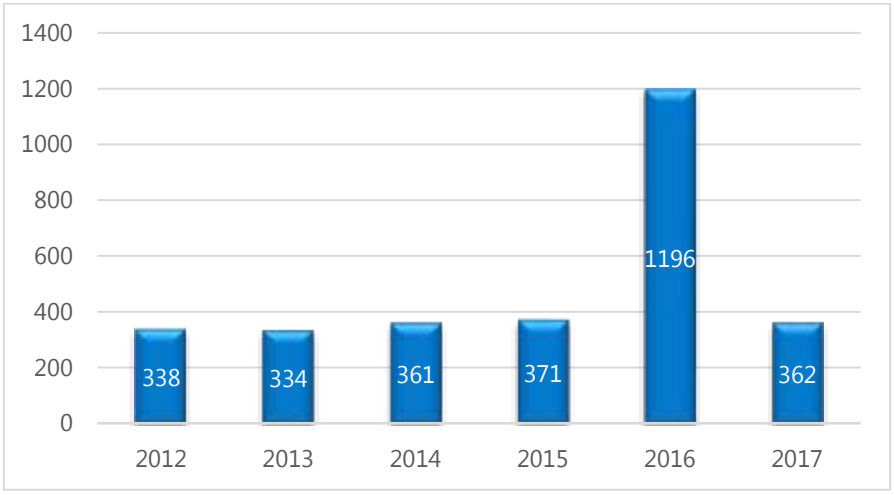
Graph 5: Technical file reviews as part of market surveillance activities

Clinical Evaluation Review

During 2017, the HPRA increased its activities further in the assessment of clinical data, presented by manufacturers to support the safety and performance of their device. This work was conducted as part of proactive market surveillance activities, in some cases as part of broad reviews of specific product ranges. Clinical evaluations were also triggered as a result of a number of specific device issues.

Product registrations

The HPRA received 362 notifications of new medical devices to the medical device register in 2017. These registrations apply to self-declared class I, *in-vitro* diagnostic and custom made medical devices and to system and procedure packs. Registration of these devices is required in the Member State in which the manufacturer or their authorised representative is based.

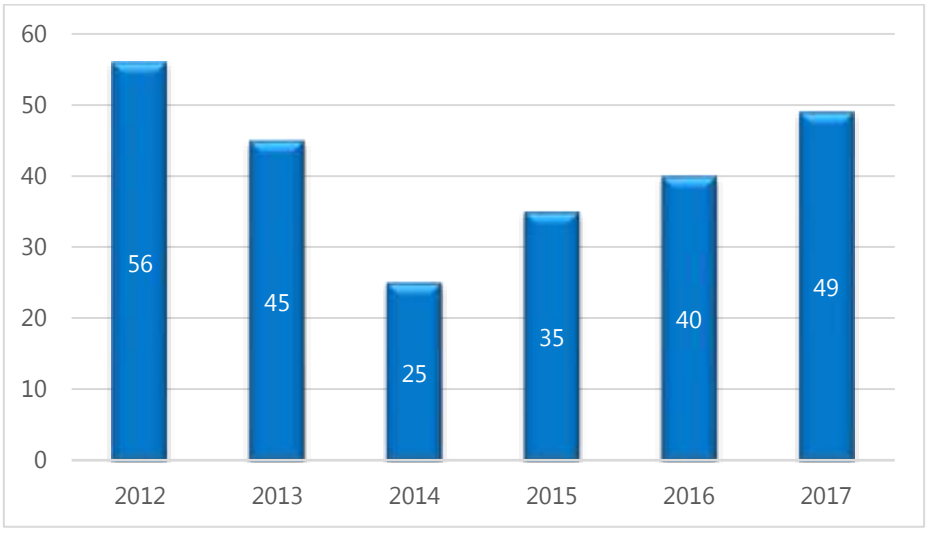


Graph 6: Device registrations

During 2017, 34 organisations registered with the HPRA as Irish based manufacturers or authorised representatives of class I, custom-made, *in-vitro* diagnostic medical devices, as manufacturers of system or procedure packs, or as sterilisers of medical devices.

Classification Requests

The HPRA received 49 applications for classification of medical devices or other products queried as medical devices in 2017.



Graph 7: Classification of medical devices

Clinical Investigation Applications

The HPRA received 15 applications for clinical investigations of a medical device during 2017. The HPRA hope that this continuation of an upward trend in the number of applications reflects increased levels of clinical research of devices in Ireland and will continue as the new Regulations approach.

During 2017, the HPRA received five applications to use medical devices in Ireland on compassionate use grounds but anticipate further increases in such applications over the coming years.

Queries

During 2017, the HPAR medical devices team received 496 queries relating to medical devices, increasing by almost 15% over 2016. The majority of the queries related to the provision of guidance and interpretation of the legislation, registration, labelling, qualification and classification of devices and distribution

It is expected that, with the advent of the new Medical Device legislation, the numbers of queries relating to medical devices will increase further over the coming years.