

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

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

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## CONTENTS

1	INTRODUCTION	3
2	REVIEW OF THE 2017 FEES	5
2.1	The 2017 fees	5
3	SUMMARY OF PROPOSED CHANGES FOR 2018	5
3.1	Risks and uncertainties in relation to the fee model	5
4	FINANCIAL POSITION IN 2017	6
5	FINANCIAL CHALLENGES IN 2018	6
6	PROPOSED FEES	7
7	DETAILED CHANGES TO FEES	7
7.1	General change to fees	7
7.2	Other proposed adjustments to fees - human medicines	7
8	CONSULTATION	9
APPENDIX I	SERVICE LEVELS - HUMAN PRODUCTS AUTHORISATION, REGISTRATION AND SAFETY MONITORING	10
APPENDIX II	SERVICE LEVELS – COMPLIANCE DEPARTMENT	17

## 1 INTRODUCTION

The HPRA (formerly the Irish Medicines Board (IMB)), since its establishment in 1996, has successfully run its core 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 IMB Act and a stated objective of the Authority<sup>1</sup> of the HPRA. Since 2004, the HPRA has implemented a policy of annual fee reviews following consultation with industry.

After a period during which the country experienced an economic crisis, there are signs of an economic recovery. However, despite the projected growth in the economy, the effects of the economic crisis and the resulting difficult economic environment are still being experienced by both the HPRA and stakeholders. The HPRA continues to face increased workloads arising from both European and new national legislation. In addition, the predicted economic recovery has been thrown into turmoil with the United Kingdom vote to leave the EU. The UK commenced the negotiations to leave the EU on March 28 2017 and the negotiations must be complete by 2019. While there is considerable uncertainty as to the impact of Brexit, there is no doubt that it will significantly impact on the HPRA and the industry we regulate.

The impact of new legislation continues to be rolled out across the organisation and the preparation for the new Clinical Trials regulation commenced in 2017 for implementation in 2018/2019. The regulatory model is becoming more complex, there are more complex medicines and the Pharmacovigilance legislation has led to an increase in the number of referrals and regulatory action arising from the outcome of these referrals. Compliance activity, particularly outside of Ireland, is also increasing and the HPRA expects staff levels to increase across all areas in 2018. As noted in previous consultations the HPRA has absorbed the cost resulting from additional requirements and greater regulatory complexity for falsified medicines, pharmacovigilance and generic substitution without increasing its fees. In 2018 HPRA will become the competent authority for controlled drugs and will also commence the rollout resulting from the new medical device legislation (subject to a separate consultation).

During 2015 the HPRA developed a new strategic plan for the years 2016 – 2020 which also aligns with the EMA and HMA joint strategic plan. Following extensive consultations, detailed review of the environment within which we operate and management discussions, we have identified the themes and activities which we believe are relevant to the development of our regulatory activities over the next five years. High-level strategic goals have been determined as follows

- **Access to medicines** (enhancing regulatory support to patient access to medicines)

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

- **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).

While the strategic plan expands on each of these strategic goals, key projects for 2018 include:

- Dedicated project and resources to manage medicines shortages from a regulatory view point.
- The further development of the virtual innovation office and support for early innovation.
- The rollout of a new regulatory work flow system 'Eolas' across the entire organisation which will put the HPRA at the cutting edge in Europe in respect of its IT capabilities.
- European and international projects in pharmacovigilance, crisis management and GMP.
- Managing the impact of Brexit across all our strategic initiatives.

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

As previously stated, it is a priority for the HPRA to match resources from fee income with current work volumes and 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 2017 review of fees and it also sets out the current service levels and activities and expected changes in service levels and activities for 2018.

## **2 REVIEW OF THE 2017 FEES**

### **2.1 The 2017 fees**

In 2017 the HPRA kept fees at 2016 levels and continued to absorb the additional costs of the new European legislation without increasing the fee base.

## **3 SUMMARY OF PROPOSED CHANGES FOR 2018**

The HPRA, like all its stakeholders, is operating in a difficult economic environment particularly in the light of Brexit. We are committed to supporting the industry and to manage its regulatory obligations in Europe following the outcome of their Brexit negotiations.

A review of income levels across all categories has shown both increases and decreases in various income categories. Overall income levels are relatively stable although it is premature to understand what impact Brexit may have on those income levels. Given the increased responsibilities, the planned increases to staff numbers, increased payroll costs due to the reversal of Haddington road, future pension liabilities and the fact that we have not increased fees since 2010 and have reduced fees in 2011 and 2012, HPRA require a modest general fee increase for 2018. We have also reviewed individual fee categories to ensure that they are appropriate in relation to the service offered. The proposed key changes are:

- General fee increase of 2%;  
Amended/new fees for some clinical trial applications – amendments and annual drug safety updates.
- Increased fees for registration of an API Manufacturer.

### **3.1 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 2017. The nature of regulatory income is that it is dictated by industry activity which can change significantly over a period of time. In addition, the uncertainty being experienced by both the Irish and worldwide economies and uncertainty from Brexit means that forecasting is extremely difficult and subject to change.

The HPRA has been able to freeze fees due to the continued management of our cost base. However, as noted above, we are experiencing increased workloads and increased costs due to increased staff levels and a reversal of some of the pay costs that arose during the economic down turn. Consequently the HPRA is seeking a modest fee increase and the HPRA therefore commits to review the proposed fees during the planning cycle in 2018 and further amend the fees and fee structure, if required, for 2019.

#### **4 FINANCIAL POSITION IN 2017**

There has been a decrease in all new applications since last year. There has also been a decrease in national variations but the DCP/MR variations have remained the same as last year. We are still seeing a small reduction in parallel import applications to date. However there has been an increase in manufacturing and wholesale variations and inspections. Overall income levels are as expected. General costs have stabilised which reflects the fact that the HPRA had negotiated costs downwards to reflect the prevailing economic climate. However, our cost base is approximately 70% staff costs and in recognition of the additional responsibilities undertaken by the HPRA in 2016 and 2017 we have increased staff numbers and have absorbed these additional costs without increasing fee levels. It is no longer feasible to increase staff numbers and to fund increased salary levels due to the reversal of the Haddington road without seeking a fee increase. It should also be recognised that the salary cost of the HPRA has been artificially suppressed with substantive pay cuts across all grades for the last five years and with a recovering job market the HPRA is already starting to lose key senior members of staff as salaries are falling below the market place. It should also be noted in relation to payroll costs that the HPRA has a significantly unfunded pension liability which, while not reflected in the accounts, is a cost of the business. If the HPRA is to continue to deliver the service industry requires we will need to be in a position to recruit staff with the relevant expertise at the appropriate salary level. Although we hope to break even at year-end, we have substantial financial commitments. Following an IT strategic review of the organisation's needs and existing IT framework, we have commenced a very significant IT project 'EOLAS. Our existing workflow systems are now over 10 years old and can no longer be supported. Given the importance of IT in our service delivery we started a three-year programme in 2016 to replace all the workflow and stakeholder facing systems to continue providing a 'best in class' service. The investment in IT and infrastructure has delivered and will continue to deliver long-term savings and efficiencies.

#### **5 FINANCIAL CHALLENGES IN 2018**

The HPRA will face further financial challenges in 2018.

As noted above, government restrictions on pay and employment ceilings have artificially reduced the HPRA payroll and staff numbers and some of these reductions have reversed and more are due to reverse in 2018. We have been working closely with our parent Department and will be in position to increase staff numbers in 2018 with a corresponding increase in our cost base. As outlined in the introduction, the impact of Brexit, the increased complexity of the European regulatory model, the ongoing implementation of new directives such as the falsified directive, the implementation of the new clinical trials directive and expanded deliverables under the strategic plan mean that the HPRA continues to require additional resources to deliver our goals and objectives. The HPRA also has increased activity in areas funded by the state but there has been considerable pressure on exchequer funding over the last number of years. A further side effect of the ongoing economic recovery is a projected increase to certain

cost levels. While inflation remains low, certain costs were artificially low during the crisis, particularly in the service industries, as companies sought to survive and we predict increases above the expected inflation rates for 2017 in some of the categories. The impact of Brexit on the economy is a further unknown which needs to be managed.

The HPRA continues to manage the requirements under the Health (Pricing and Supply of Medicinal Goods) Act, 2015 where the HPRA is responsible for developing the list of interchangeable medicinal products. While the legislation provides for a fee, much of this work, by direction of the Department of Health, is not funded.

Despite the challenges arising from the economic climate and the increased regulatory responsibilities, the HPRA must also continue to invest in and deliver services to stakeholders. As outlined above, in 2017 the HPRA have made substantive investments in our new 'best in class' IT systems and will continue to do so in 2018. We will also use our resources to maintain and improve our existing levels of service to all stakeholders across a range of areas.

## **6 PROPOSED FEES**

As outlined above there will be a general increase of 2% in HPRA fees in 2018.

## **7 DETAILED CHANGES TO FEES**

### **7.1 General change to fees**

It is proposed that there will be a **2%** increase applied to all fees.

### **7.2 Other proposed adjustments to fees - human medicines**

#### **7.2.1 Transfers of MAH – Divestments and Bulk Transfers**

It is proposed to charge a fee for the transfer of HPRA's role from concerned member state to reference member state as this will create additional administration work.

It was agreed that a fee of €146 per procedure would be charged for these applications where it arises from commercial decisions. However for companies who change RMS as a result of BREXIT, no charge will arise.

#### **7.2.2 Clinical Trials**

##### **(a) Amendments**

As noted in previous years, it was agreed to reconsider an increase in the existing fee for clinical trial amendments. It was proposed to increase the existing fee for clinical trial amendments from €84 to €100 as the fees for clinical trials are considerably lower than the

cost of delivering the service. The HPRA continues to charge no fees for academic trials, consistent with our desire to support clinical trials in Ireland.

**(b) Amendment to include a new Investigational medicinal product dossier**

It was proposed to introduce a new fee of €800 for IMPD applications as these applications require significant work.

**(c) Annual Drug Safety Update Report**

It was proposed and agreed to increase the annual drug safety update report from €170 to €500.

**In Summary**

	<b>Fee Type</b>	<b>Current Fee</b>	<b>Proposed Fee</b>
340	Notice of Amendment under Regulation 21 of Clinical Trial Regulations	84	100
New	Amendments to include a new investigational medicinal product dossier.	0	800
347	Review of Annual Safety Data/ Drug Safety Update reports submitted for clinical trials.	170	500

**7.2.3 Controlled Drugs**

The HPRA is possibly to become the competent authority for controlled drugs in 2018 and it is proposed that a new fees structure will be put in place (fees for controlled drugs are unchanged from the 1980s).

It is proposed that the current fees will be reviewed during 2018, once the legislation is enacted.

**7.2.4 Registration for API Manufacturers**

It is proposed and agreed to increase the registration fee for API Manufacturers from €250 to €450 as the current fee is disproportionate to the application for a distributor registration.

	<b>Registration Fee</b>	<b>Current Fee</b>	<b>Proposed Fee</b>
	Registration fee, per activity	250	450



### 7.2.5 Centralised Inspections

It is proposed and has been agreed to charge the national inspection fees for centralised inspections where the HPRA do additional work in respect to inspections involving national products.

### 7.2.6 Inspections of Good Clinical Practice (Clinical Research Facilities)

It is proposed to reduce the inspection fees for clinical research centres that have a mixture of commercial and non-commercial trials. It was agreed to reduce the current reduction given to these facilities from 50% to 80%.

## 8 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 31 October 2017. Contributions should be sent by e-mail to [feesconsultation@hpra.ie](mailto:feesconsultation@hpra.ie).

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

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

These projects include in summary:

- Continued refining of the HPRA's operations to more effectively meet the needs of our stakeholders. Use of lean six sigma processing and capacity based resource allocation has facilitated improved management and increased efficiency of the assessment processes. Objectives included:
  - o improved efficiency with maintenance of quality
  - o streamlined procedures and processes
  - o improved transparency and standardisation of approach
  - o ongoing increased productivity and the continued management and reduction of backlogs

As a result of meeting these objectives, the Human Products Authorisation and Registration (HPR) department has seen faster turnaround times and a considerable reduction in the number of human medicine applications overdue.

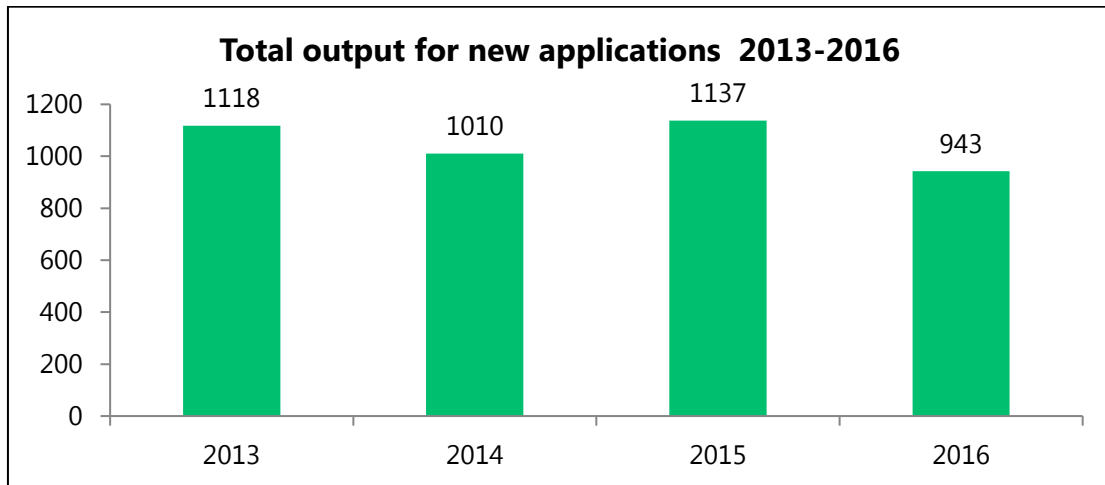
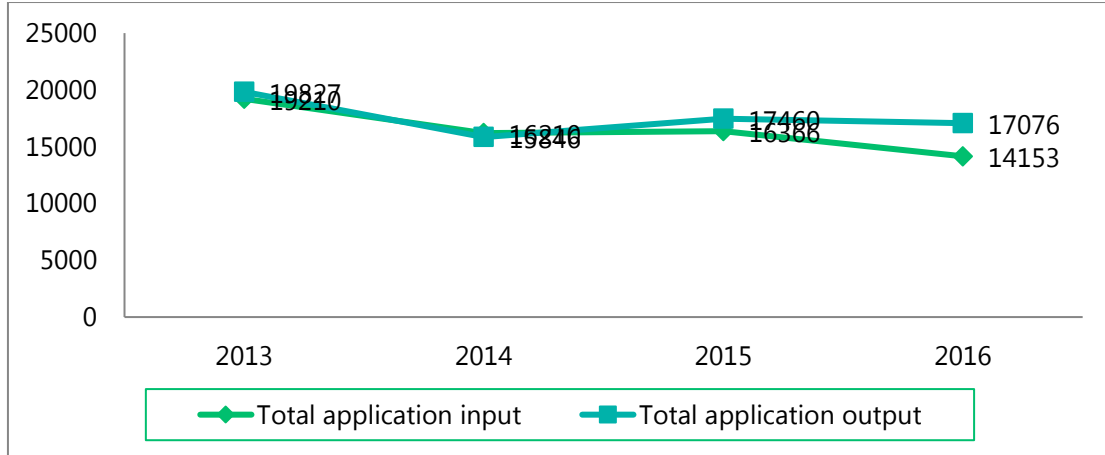
- A national scientific advice procedure was introduced in 2016. This is to assist applicants in the development of new or existing human medicinal products by taking into account the current knowledge of a given condition, targeted patient population, existing treatment modalities and specificities of the product being developed.
- Significant progress has been made in the development of a new HPRA workflow system. Our focus is on improving and extending our current workflow technology to ensure ongoing delivery of benefits to the organisation in the tracking and managing of workloads. Further development of capabilities in using key performance indicators to allow for more effective monitoring of timelines will improve utilisation of resources and drive further efficiencies.
- Introduction of online reporting for adverse drug reactions and quality defects, accessible to patients, health care professionals and industry.
- Continued customer-focused approach.
- The work on the development of interchangeable medicines to support generic substitution by pharmacists in line with the Health (Pricing and Supply of Medical Goods) Act 2013, has progressed very well. Of the 65 priority substances identified by the Minister for inclusion 59 are now incorporated on the list. The remaining six will be addressed as a matter of priority. The development of the interchangeable list will continue as a routine component of our assessment work whereby industry can proactively make applications to have their

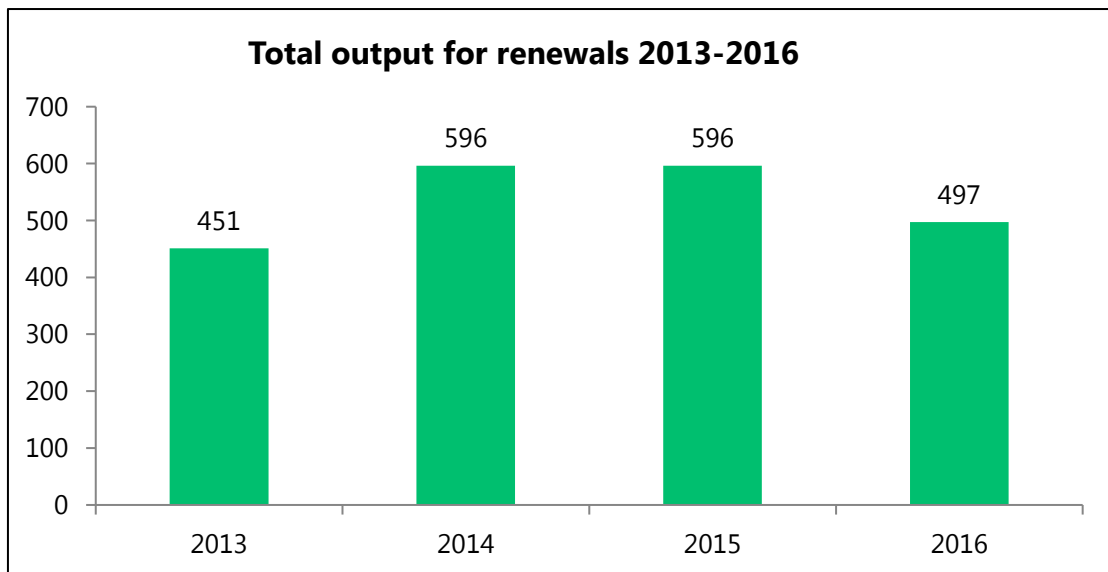
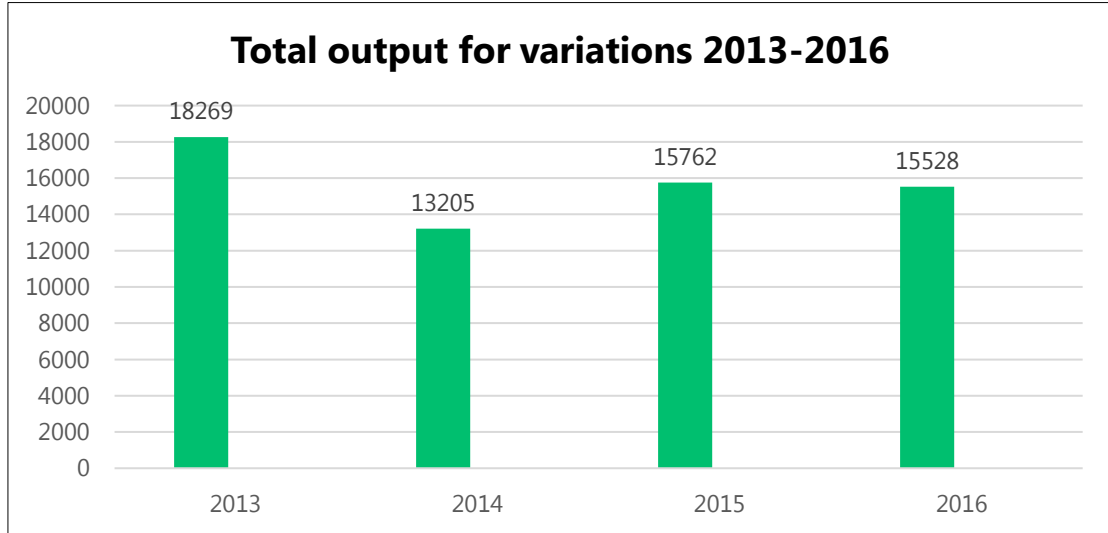
product incorporated on to the list; we will also continue to work to include further substances as may be requested by the Department of Health or the HSE. Further efficiencies will be introduced during 2017-2018 to allow marketing authorisation holders, where appropriate, to incorporate an application for inclusion on the list as part of the submission to have the product licensed for the Irish market.

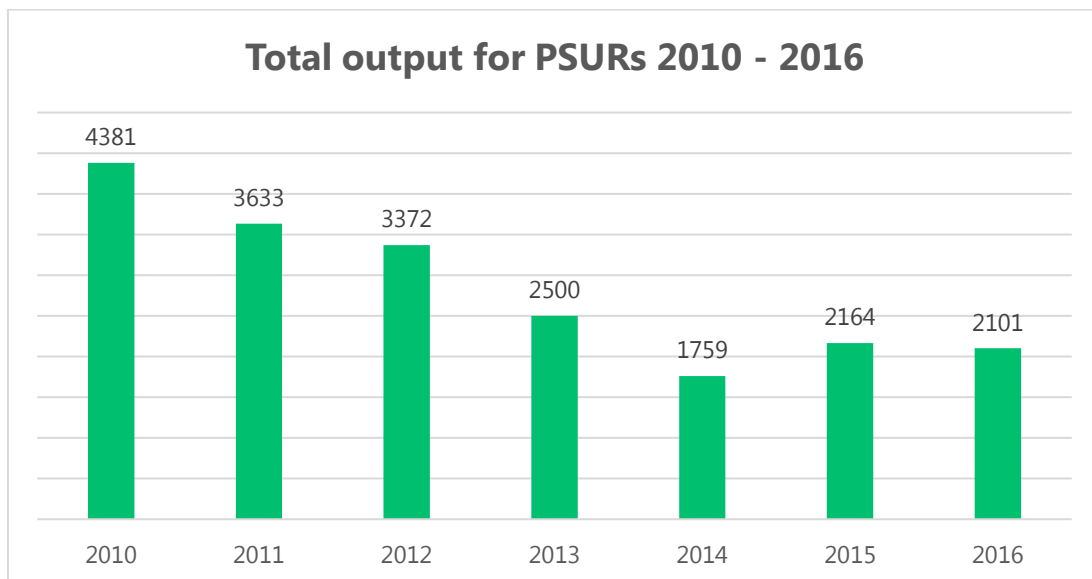
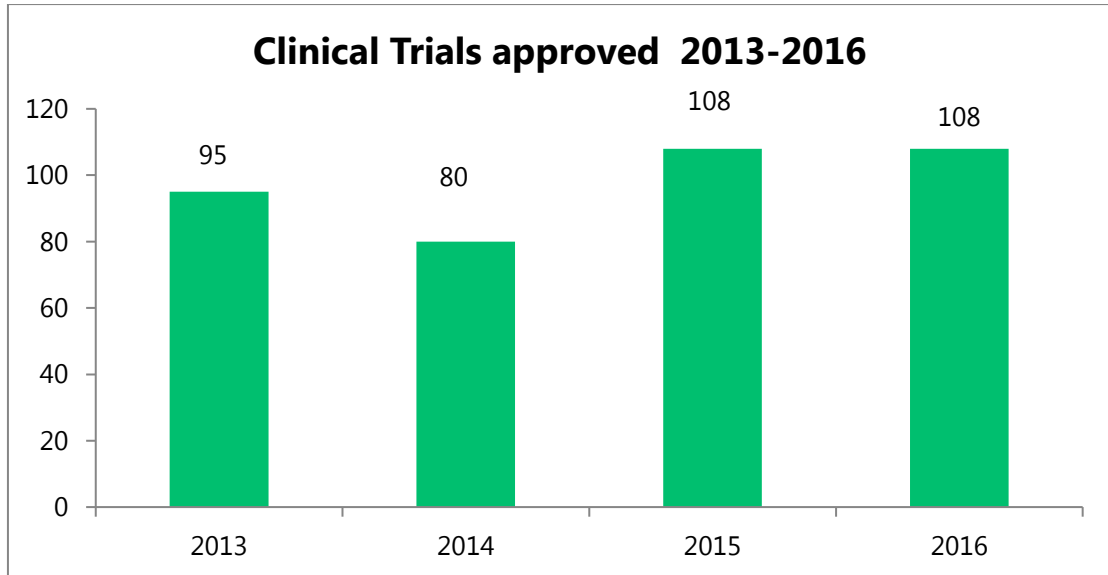
Focus on the continued provision of guidance and support to industry stakeholders in areas undergoing evolving regulatory development, including:

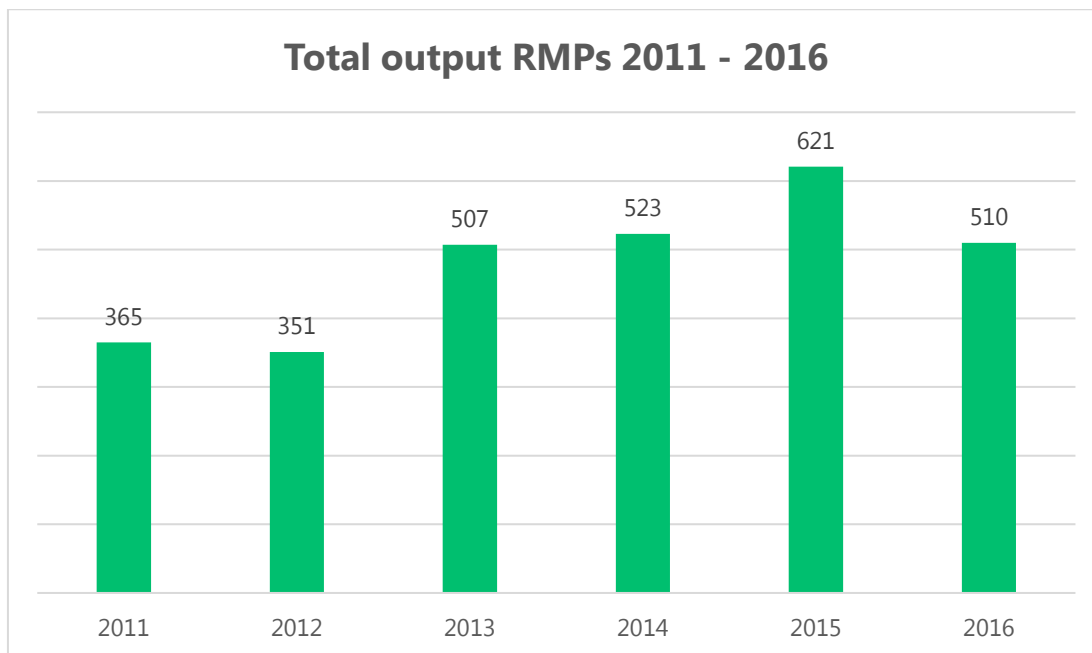
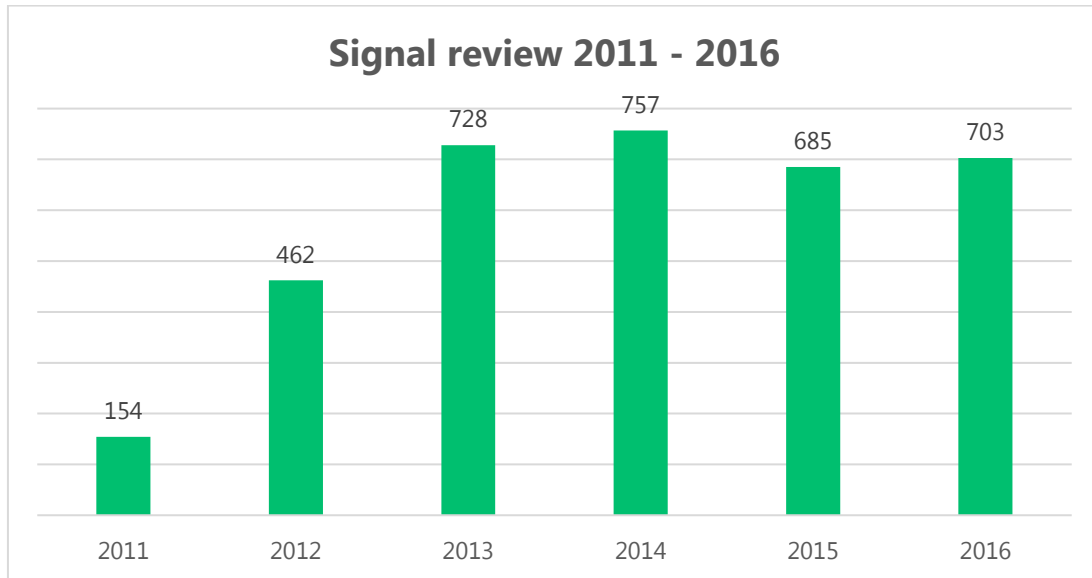
- the new requirements of the Clinical Trials Regulation
  - the new requirements of the Medical Devices Regulations
  - the registration of traditional herbal medicinal products
- Continued progression of a public health initiative focused on providing important online information about all medicines licensed by the HPRA. This includes maintaining publication of the summary of product characteristics document, patient information leaflets, ATC codes, interchangeable lists and the legal classification status of all human medicines on the HPRA website ([www.hpra.ie](http://www.hpra.ie)). Since December 2015 all educational materials are published on the website.
- A proactive approach to switching is ongoing. Following a review of policies in this area, and after liaison with the Department of Health, the HSE Health and Wellbeing Directorate and healthcare professionals, the HPRA has taken a proactive approach to the reclassification of medicines since 2014. This has included the publication of a list of active substances currently classified as prescription-only medicines which the HPRA considers could be safely switched from prescription-only medicine to over the counter (OTC) pharmacy sale (not subject to medical prescription). The response from the marketing authorisation holders to this initiative has been disappointing, commercial reasons cited most often. In 2016 the HPRA continued to engage directly with the industry to establish their interest in submitting applications for the reclassification of prescription medicines and reclassification of medicines currently available for sale through pharmacies, to make these available, where it is considered safe to do so, in general retail outlets.
- Raising awareness of the regulation of medicines and important safety considerations via publications and contributions to undergraduate programmes in the medical and paramedical fields.

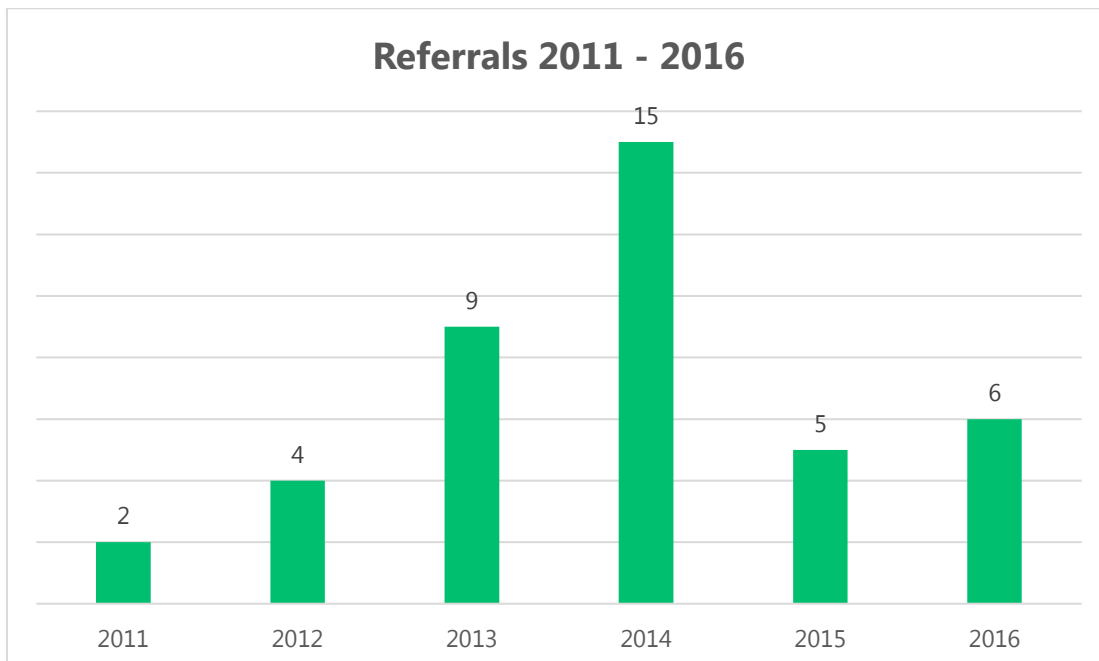
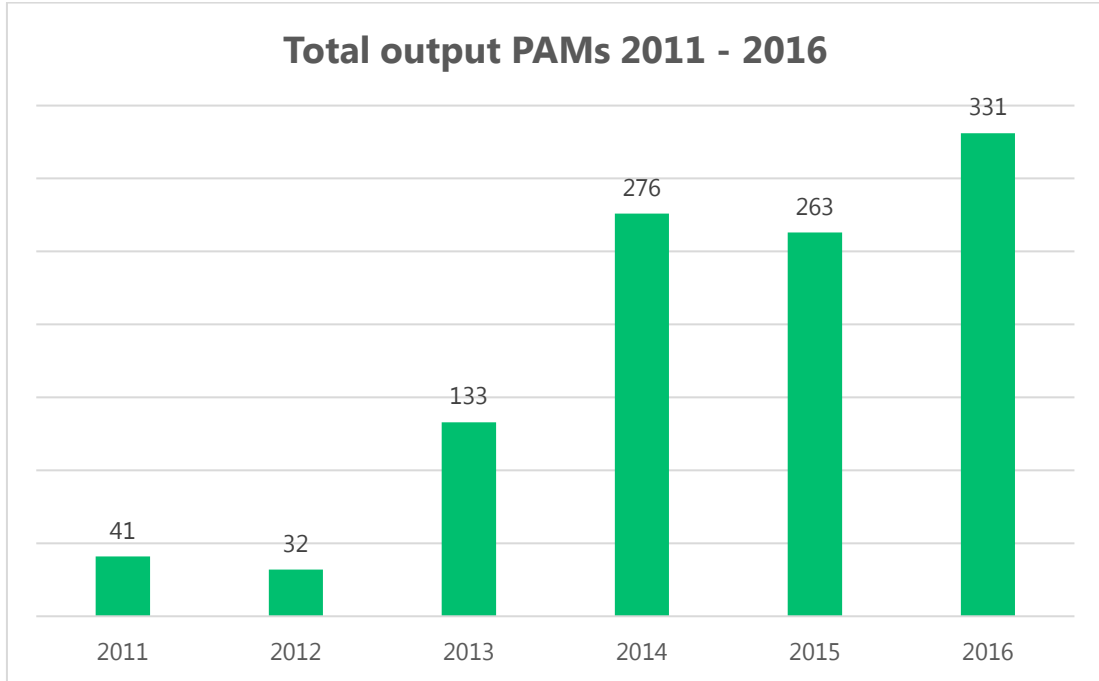
The following graphs outline the output across all application types up to the end of 2016.













## **APPENDIX II SERVICE LEVELS – COMPLIANCE DEPARTMENT**

### **Compliance Department General Activities**

Initiatives undertaken / further developed in 2016/2017 included:

- Continued development of a workflow database for compliance case management to improve efficiency in processing of authorisations/licences/registrations, organisation and follow-up of inspections, quality defects and recall management and other compliance monitoring cases.
- Continued provision of support to the Department of Health on the implementation of national legislation aimed at preventing the entry of falsified medicines into the legal supply chain – transposition of Directive 2011/62/EU ('Falsified Medicines Directive' (FMD)).
- Under the FMD, annual updates to registrations of manufacturers, importers and distributors of active substances and brokers of medicines for human use were processed during 2016 and 2017.
- Also under the FMD, HPRA staff continued to participate in an expert group on safety features convened by the European Commission. This included completion of the Commission Delegated Regulation which sets out the details around safety features and their implementation. This was finalised in February 2016 with a three year timeframe for implementation. In relation to this, the HPRA has liaised closely with industry, wholesale and retail stakeholders which have come together to implement the so called stakeholder model. This will include the development of a national database (repository) for batches of human medicines bearing safety features that are placed on the Irish market and a system for authentication of packs at various points in the supply chain. While not part of the governance structure of this stakeholder body (the Irish Medicines Verification Organisation), we will continue to liaise closely with it. It is also envisaged that we will have an oversight role in relation to the repository.
- In mid-2016 a number of workshops were held throughout Ireland aimed at providing industry and healthcare sectors with specific opportunities to engage with HPRA in relation to the implementation of safety features.
- The biennial GMP conference for stakeholders was held in February 2017. Updates on GMP and market compliance issues and developments were provided.
- Continued upload of post-inspection good distribution practice (GDP) certificates to the EudraGMDP database. All existing Wholesale Distribution Authorisations (WDAs) had already been uploaded to the database and upload of new or varied WDAs continued.
- Continued upload of Manufacturers' / Importers' Authorisations (MIAs) to the EudraGMDP database.
- Provision of support to the Department of Health on the transposition and implementation of national legislation on quality and safety of human tissues and cells regarding the single European code (Commission Directive (EU) 2015/565 amending Directive 2006/86/EC) and importation requirements (Commission Directive (EU) 2015/566 implementing Directive

2004/23/EC as regards the procedures for verifying the equivalent standards of quality and safety of imported tissues and cells)

- Provision of support to the Department of Health on the implementation of national legislation regarding quality and safety of human organs intended for transplantation – Directive 2010/53/EC. This included monitoring of authorised procurement and transplant centres, via inspections and other follow up measures. The framework for quality and safety of organs for human transplantation, developed in conjunction with Organ Donation and Transplant Ireland, was used in evaluating these centres. A system for reporting and assessment of serious adverse events / reactions remains in place.
- Provision of support to the Department of Health on the development and implementation of national legislation regarding controlled drugs (Misuse of Drugs Regulations 2017), which included the addition of substances to the framework such as zopiclone and zolpidem.
- Continued liaison with wholesalers on the implementation of revised EU Guidelines on Good Distribution Practice of Medicinal Products for Human Use.
- A significant update to the HPRA Guide to Quality Systems for General Sale Wholesale Distributors was published to coincide with additional requirements set out in revised EU Guidelines on Good Distribution Practice of Medicinal Products for Human Use. The HPRA Guide provides stakeholders with template standard operating procedures for different wholesaling activities.
- The wholesale distribution conference for stakeholders was held in February 2017. It was attended by the largest audience, to date, for this biennial HPRA event.
- Monitoring, via inspections, of the implementation of Good Manufacturing Practice requirements, Good Distribution Practice, Good Clinical Practice, and Good Pharmacovigilance Practice standards, and of the required controls relating to Controlled Drugs and Precursors.
- Contributed to the European Commission’s work in producing new guidelines for operators in the area of precursor chemicals.
- Provision of support to the Department of Health in the development of national provisions relating to the implementation of two European Regulations relating to precursor chemicals.
- Monitoring, via inspections, of the activities of Marketing Authorisation Holder companies with respect to their obligations under the Medicinal Products (Control of Placing on the Market) Regulations, 2007, as amended.
- Active participation in harmonisation of standards and inspection practices through EMA working groups, 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 also led on an initiative within the Heads of Medicines Agencies Group on sampling and analysis of mutual recognition and decentralised medicines

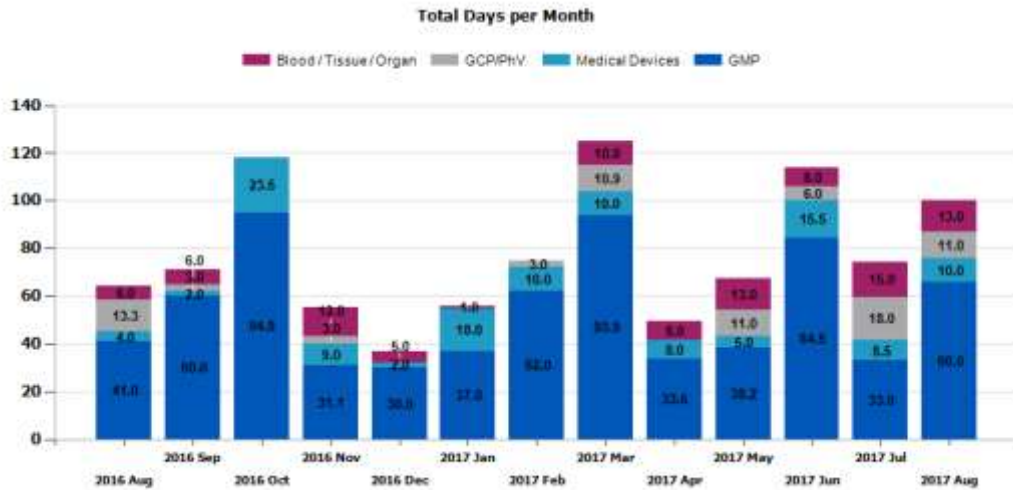
- Continued development of the advertising compliance monitoring programme which includes regular liaison with the industry to outline HPRA requirements and to clarify our interpretation of the legislation.
- Further development of the monitoring of availability of medicines in non-pharmacy retail outlets with appropriate follow up where unauthorised or pharmacy confined / prescription only medicines are identified.
- Continued development of our role as competent authority for cosmetics. This has included maintenance of effective working relationships with the Department of Health, HSE and the Competition and Consumer Protection Commission and the implementation of a coordinated national approach to market surveillance and testing of cosmetics.
- The National Cosmetic Safety Forum was continued by the HPRA and the HSE for the purpose of reviewing the safety of cosmetic products available within the Irish market place. The Forum develops the market surveillance programme in line with risk based principles and to take account of new legislative and technical progress.
- The Cosmetics Regulation, 1223/2009, came into force in July 2013. Accompanying national legislation, the European Union (Cosmetic Products) Regulations, 2013 (S.I. No 440 of 2013) came into force in November 2013. The HPRA continues to work with the HSE and the cosmetics industry on the implementation of these pieces of legislation.
- The development and publication of a Cosmetic Product Information Pack, aimed at companies placing cosmetic products on the market. It contains concise information to guide stakeholders through the regulatory requirements and a checklist to help ensure all tasks are completed before placing cosmetic products on the market.

Other activities included:

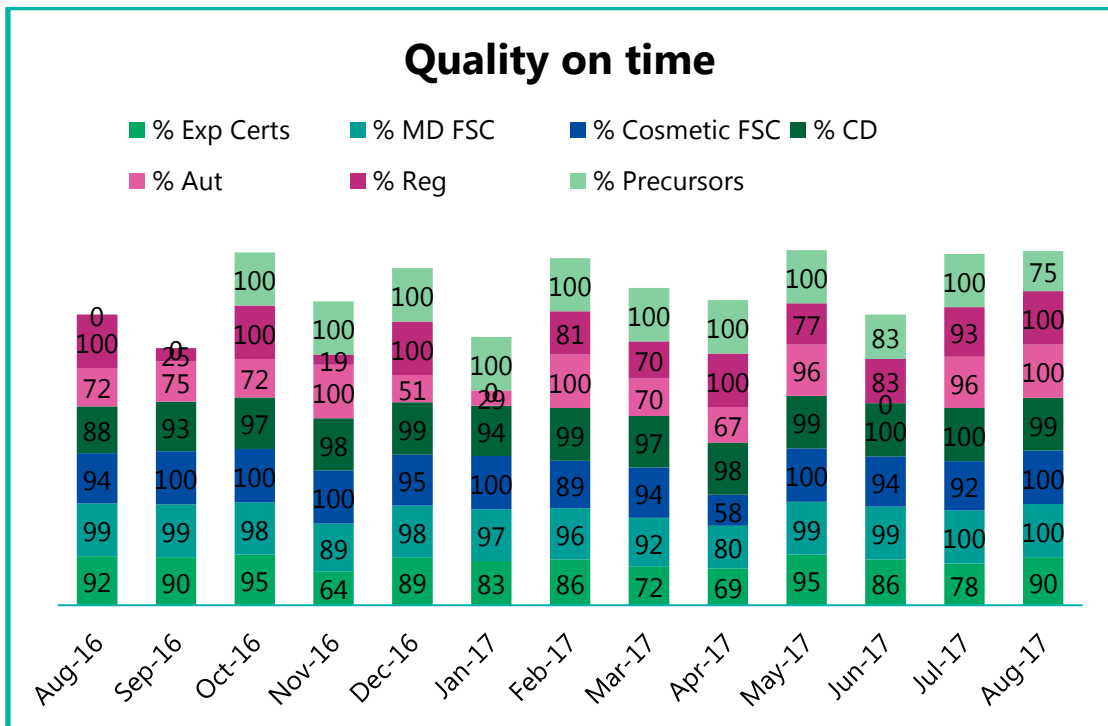
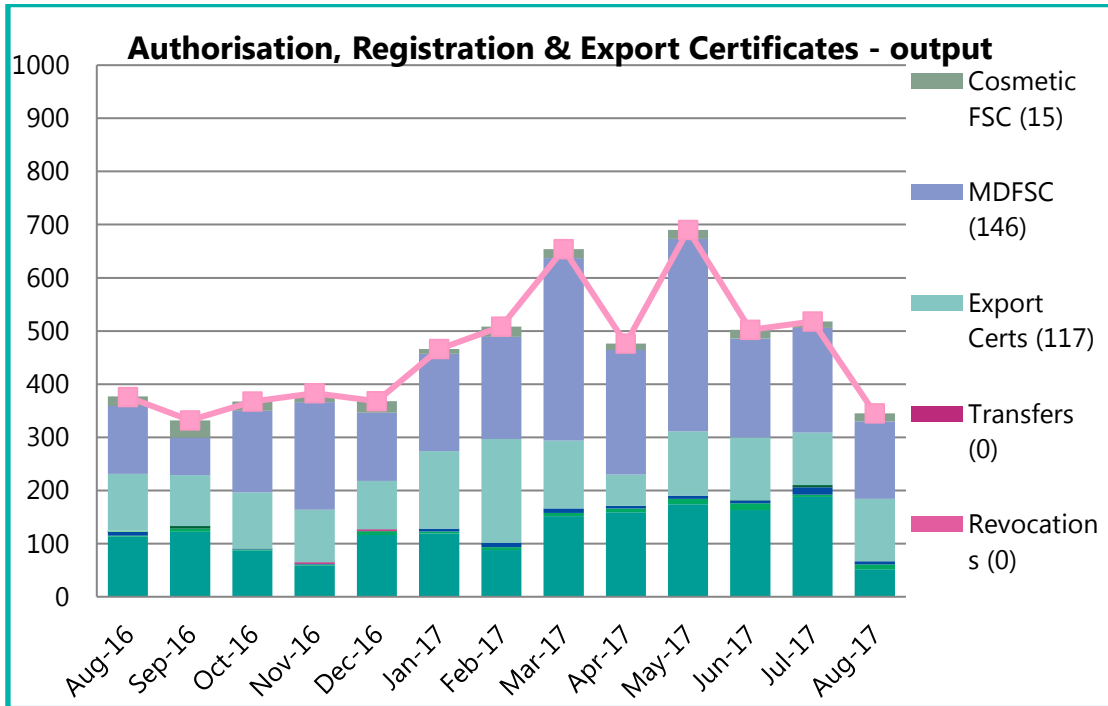
- Continued interaction and communication with stakeholders, including industry and other representative groups. These included meetings with industry representative bodies and individual companies.
- Continued management of the controlled drugs function on behalf of the Department of Health.
- Continued management and use of the Exempt Medicinal Products importation/supply data that are notified to the HPRA. These data may be a source of relevant information for the Quality Defect and Recall programme.
- Rapid turnaround of applications for variations to manufacturers' and wholesalers' authorisations, and for export certificates and controlled drugs licences.
- Further development of good clinical practice 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.

- In co-operation with Revenue's Customs Service, ongoing detection and detention of illegal mail-order importations of prescription-only medicine. Co-operation with Customs, An Garda Síochána and enforcement agencies worldwide on Operation Pangea IX, an Interpol-coordinated international week of action against illegal supplies of unauthorised prescription medicines via the internet.

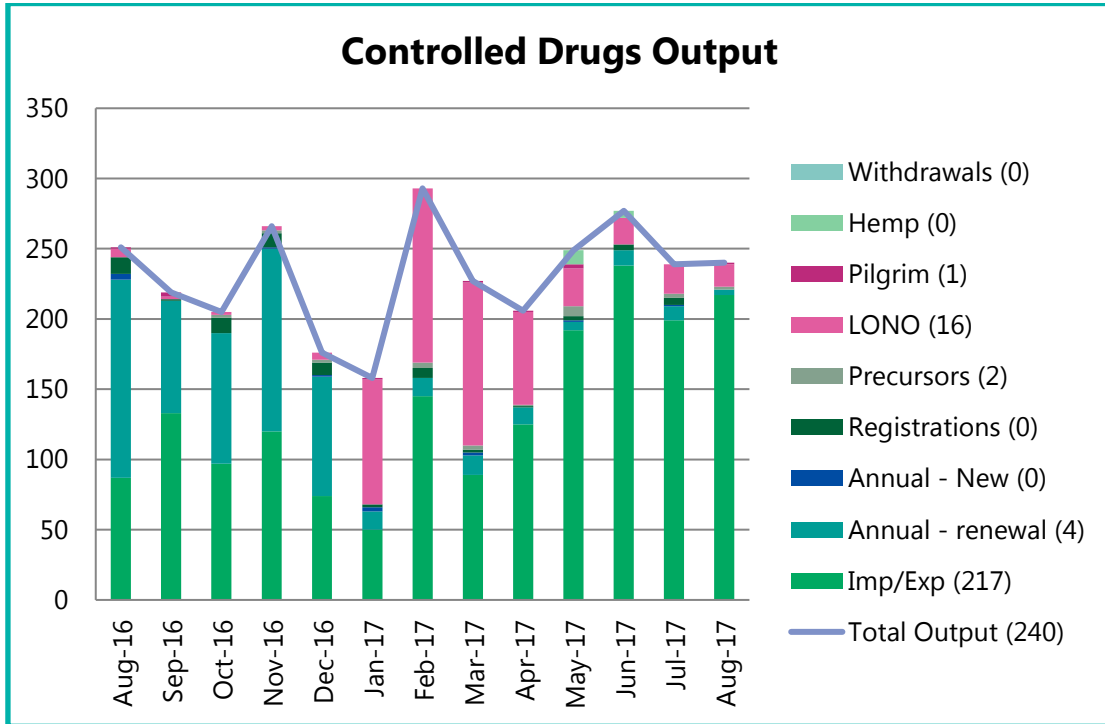
The graph below shows the level of inspection activity over the period August 2016 to month-end August 2017.



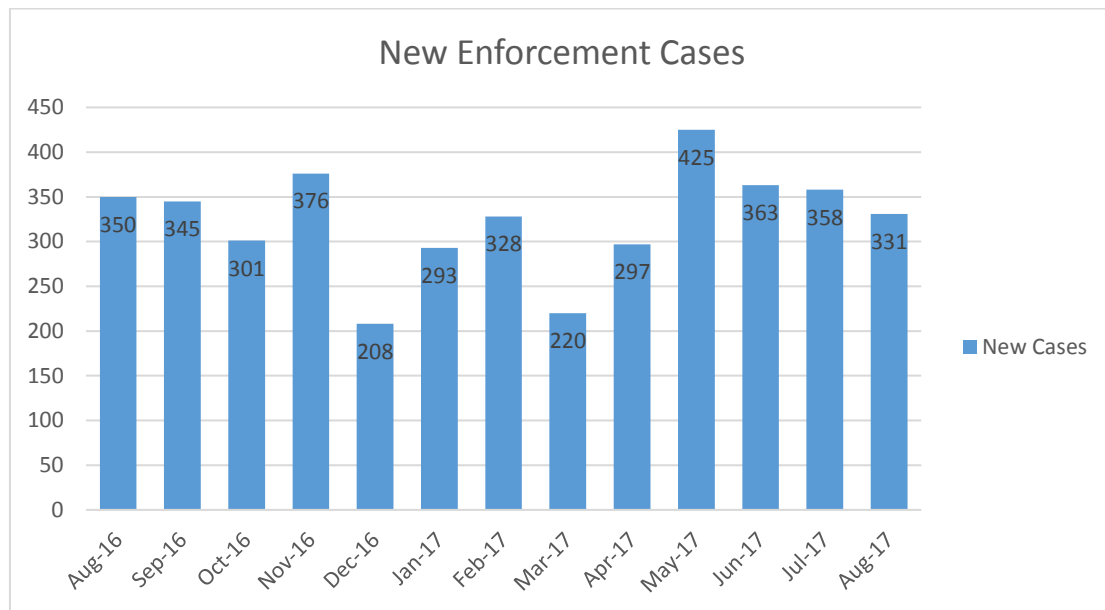
The following graphs show the numbers issued and the percentages issued on time, for export certificates, controlled drugs licences and GDP, GMP and IMP licences, over the period August 2016 to August 2017, inclusive.



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 August 2016 – August 2017 inclusive. The majority of these relate to attempts to illegally import prescription-only medicines, an amount of which are falsified. The remainder involve the supply by wholesale and retail sale of prescription only medicinal products which are authentic, but diverted and falsified medicines.



In 2017 - 2018 the regulated sectors will see further benefits, including:

- Continuing focus on the effective management of resources, activities and relationships with interested parties.
- Continuing application of risk-based planning of inspections in some areas and of risk-based approaches to other activities.
- Greater potential for submission of applications electronically.
- Population of the EudraGMDP database with MIAs.
- Continued focus on clear communication of requirements and expectations.

### **Blood and Tissues & Cells**

During 2016 and 2017, 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 tissues and cells legislation requires all sites involved in the procurement, testing, processing, storage and distribution of tissue and cells to be authorised. To date, a full programme of inspections of tissue establishments has been carried out.



### **Organs for Transplantation**

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

The Organs legislation applies to 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.

### **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. Inspections related to import, export and holding of controlled drugs and drug precursors have been implemented and continue to be developed.

### **Exempt Medicinal Products**

A significant level of notifications of importation of exempt (unauthorised) medicines continued through 2016 and 2017, to date. We have an electronic system for notification and we continued to work closely with the notifying companies to ensure that data have been uploaded correctly. The notifications are an important source of information particularly when checking on whether products, recalled in other countries, have actually been supplied as exempt in Ireland.