

**Public Consultation on  
Annual Review and Proposal for Fees –  
Financial Year 2017**

**Veterinary Medicinal Products and  
Veterinary Manufacturing Sites**

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## 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 particular, the proposed new European veterinary legislation raises challenges for the HPRA and the impact of a Brexit also needs to be considered.

During 2015 the HPRA developed a new strategic plan for the years 2016 – 2020 which also aligns with the EU Medicines Agencies Network Strategy to 2020; the joint strategic plan of the European Medicines Agency (EMA) and the Heads of Medicines Agencies (HMA). 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)
- **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 2017 include:

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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.

- The implementation of a virtual innovation office for both human and veterinary medicines.
- The roll out of a new regulatory work flow and database computer 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 crisis management and GMP.

The first aim regarding fee income for the HPRA must be to match resources from fee income with current work volumes and plan for future activity. The second aim must be to provide predictability, stable timelines and cost of the regulatory system that we operate and ensure that our fee system is fair and fees are proportionate.

To ensure that we manage the business properly we have agreed that we will review our fees on an annual basis to reflect changes to our cost base and service levels. This document summarises the outcome of our 2016 review of fees and it also sets out the current service levels and activities and expected changes in service levels and activities for 2017.

## **2 REVIEW OF THE 2016 FEES**

### **2.1 Introduction**

Since 2011 the HPRA recognised the difficult economic climate that our stakeholders operate in and as a consequence we reviewed and substantially reduced fees in 2011 and 2012 and froze fees for 2013, 2014, 2015 and 2016.

### **2.2 Fees for 2016**

In 2016 the HPRA froze the fees across all categories and in addition:

- discontinued the charging of an additional fee for new MRP/DCP applications which have 15 or more Concerned Member States.
- removed all charges for type IA variations.

## **3 SUMMARY OF PROPOSED CHANGES FOR 2017**

Following a review of the income and cost base for 2016 and proposed activities for 2017 the HPRA is satisfied that the overall fee structure is working well. Given the substantive level of

fee reductions previously delivered the HPRA is not in a position to further reduce the fees. The HPRA is committed to keeping fees at or below the 2016 levels for 2017 and therefore will implement the following changes for 2017:

- application of a reduced fee when the same active substance master file (ASMF) for a number of products from the same applicant is submitted at the same time
- reduction in fees for bulk transfer applications

### **3.1 Risks and uncertainties in relation to the new model**

The fee model outlined is based on the volumes and patterns of submissions seen during the first eight months of 2016. 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 recession experienced by both the Irish and worldwide economies meant that forecasting has been extremely difficult. It seems however that the fall in income experienced over the last number of years has halted and there are some signs of recovery. This is driven mainly by an increase in new applications. The Irish veterinary medicinal product market is very small and therefore small changes in volumes can disproportionately affect income.

The HPRA therefore commits to review the impact of the current volume of transactions on the fee model during the planning cycle in 2017 and to amend the fees and fee structure if required for 2018.

## **4 FINANCIAL POSITION IN 2016**

Veterinary income has been performing well with an increase in decentralised incoming applications reflecting the early signs of an economic recovery. Variation income has remained stable year on year. General costs are showing some signs of increasing and while inflation remains low, it is apparent that certain costs were artificially suppressed during the crisis. As buying power returns to the market it is expected that costs may start to increase, as firms no longer need to sell at cost or below cost as occurred previously. However, our cost base is approximately 70% staff costs and, due to the application of the government moratorium on recruitment during 2013 to 2016, staff costs have been artificially suppressed. It is expected that some of the reductions under the Haddington Road Agreement will start to reverse in 2017. Although the HPRA expects to show an overall surplus at the year-end, significant capital expenditure in IT will result in cash outflows in 2016.

## **5 FINANCIAL CHALLENGES IN 2017**

The HPRA Veterinary Sciences department will face further challenges in 2017.

Like all commercial organisations, we are facing challenges from the economic environment and government restraints in staffing and recruitment. While there are signs of an economic recovery, these challenges are compounded by the proposed reduction in government funding to the overall organisation. It is also clear that among the impacts of the crisis were a reduction to costs from salaries and suppliers being forced to cut prices. While the HPRA will continue to seek the most competitive quotes for all purchases we expect that costs may increase in 2017.

In addition the HPRA is making substantial investments in its IT systems. The HPRA has developed its IT capacity and delivers a top class service across the European regulatory environment in which we operate. However, an external review to develop the IT strategy identified that we need considerable investment in our systems and people if we are to continue to deliver and develop this service. In particular, the core workflow and medicinal product database system is more than 10 years old and can no longer be supported nor support the needs of the organisation into the future. In accordance with the IT strategy we are implementing a new workflow and database system 'Eolas' across the organisation in 2016/2017 and the first part of the system to be implemented will be the veterinary module. This will establish the HPRA as 'best in class' across Europe, with systems that are compatible with all the European systems and databases in development. Given the size and complexity of the system this represents a very significant investment in IT.

As noted above the HPRA saw significant reductions to its payroll from the Haddington Road agreement but, as stated, we expect some of these reductions to unwind in 2017. We also believe that, with the wider recovery and the performance in parts of the pharmaceutical sector, the current levels of salaries have the capacity to impact negatively on the ability of the HPRA to retain staff. It should also be noted in relation to payroll costs that the HPRA has a significantly unfunded pension liability which will have to be addressed in the future.

A key achievement and opportunity for the HPRA's Veterinary Sciences department is the election of one of our veterinary managers to the position of Chair of the Committee for Medicinal Products for Veterinary Use (CVMP). This key European role will place the HPRA at the forefront of the development of veterinary medicines regulation in Europe and will benefit all our stakeholders. This will represent a significant investment in resources over the next three years but will cement the HPRA's position as one of the leading veterinary regulators.

A key challenge for the HPRA's Veterinary Sciences department in 2017 will be the proposed recast of the veterinary legislation and the development of better systems to aid and improve performance.

## 6 PROPOSED FEES

As outlined above there will be a general freeze on HPRA fees in 2017. Other proposals are outlined below:

### 6.1 Detailed amendment to fees

- 1 It is proposed to apply the reduced fee to the third and subsequent products when assessing the same Active Substance Master file for a number of products with the same company number, and where the applications have been submitted at the same time.
- 2 It is proposed to reduce fees for bulk transfer applications. It is proposed that where bulk transfers are notified in advance the first 10 veterinary product authorisations are charged at the normal rates and thereafter at €308 per transfer.

## 7 CONSULTATION

The HPRA welcomes comments on this proposal and invites respondents to comment.

**Contributions to the consultation** on this proposal may be provided to the HPRA by 30 October 2016. Contributions should be sent by e-mail to [feesconsultation@hpra.ie](mailto:feesconsultation@hpra.ie).

## APPENDIX I SERVICE LEVELS VETERINARY SCIENCES DEPARTMENT

The Veterinary Sciences department has been highly efficient in its operations over recent years and continues to meet all deadlines for EU centralised, decentralised and mutual recognition applications, despite an increase in the numbers of applications (Figure 1).

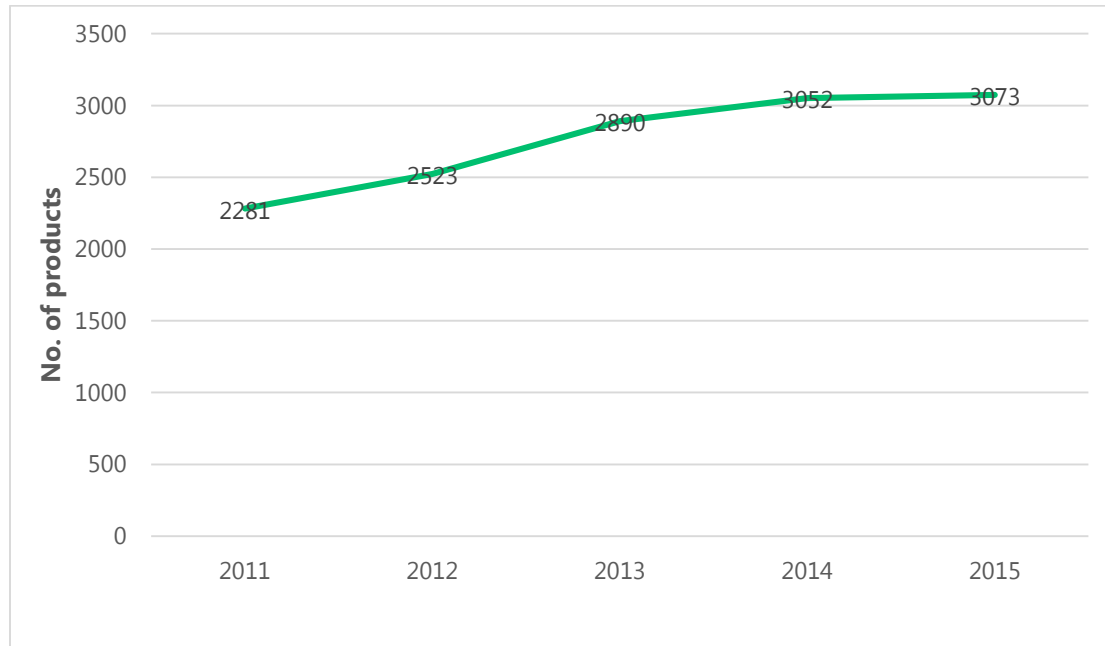


Figure 1: Output of applications in the Veterinary Sciences department 2011–2015

While public health and animal welfare needs continue to be the main drivers in the allocation of resources, the Veterinary Sciences department is business-focused and also gives priority attention to variation applications and to new applications for authorisation.

Indeed, the Veterinary Sciences department continues to ensure that the total output of applications submitted for evaluation matches the input, as can be seen in Figure 2 below, despite a consistently high level of activity in the centralised and decentralised procedures and an increasing workload in evaluating periodic safety update reports, as can be seen from Figure 3.



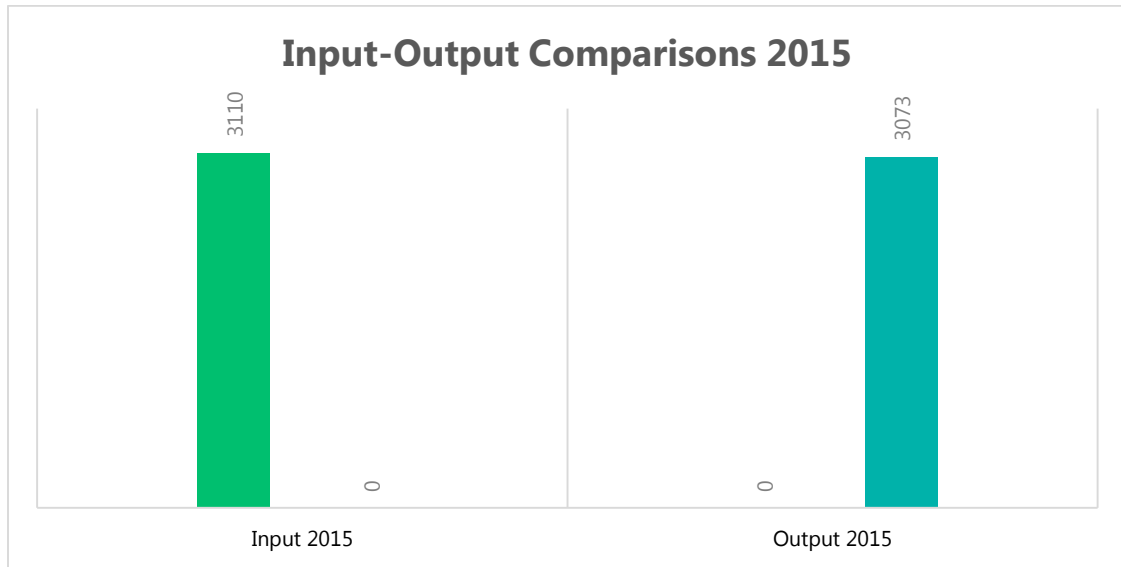


Figure 2: Input and output comparisons for 2015

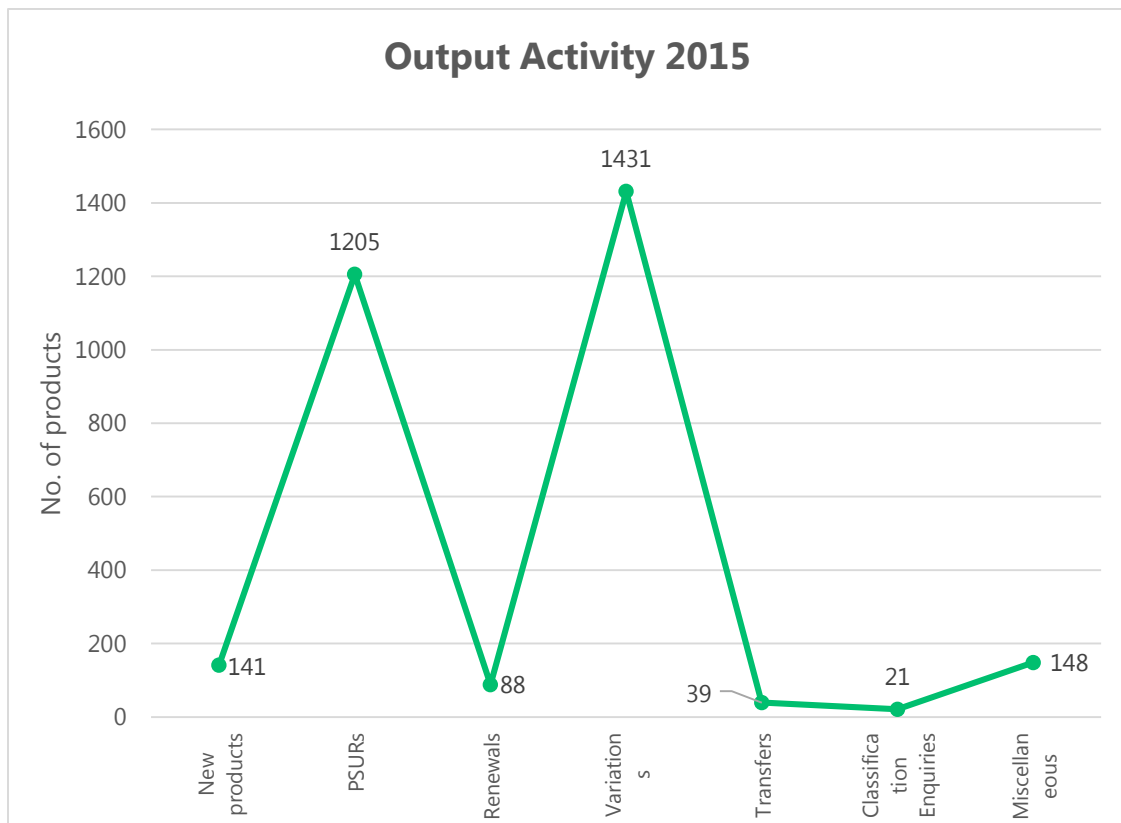


Figure 3: Overall output activity levels 2013 to 2015

Workflows have been relatively stable over recent years with output figures matching incoming applications and the total work-in-progress figure for pre- and post-licensing activities has decreased to approximately 400 from varying around 790 to 650.

While forecasting for future years is difficult, we are confident that the business model will continue to deliver and build on the improved service levels achieved over recent years. The HPRA is continuing to adapt its business and operational processes to deal with the requirements for enhanced pharmacovigilance monitoring, improved access to information on authorised veterinary medicinal products and compliance monitoring.

As in previous years, the HPRA wishes to acknowledge the particular challenge posed to the animal health industry by the relatively small size of the market for veterinary medicinal products in Ireland. We note that discussions on a suitable regulatory environment to maintain and bring to the market niche medicines for minor indications and for minor species are still ongoing both nationally and internationally, and expect that a long-term resolution of the problem will take some time to achieve. The HPRA is committed to helping to find solutions to this long-standing problem and is continuing to work with stakeholders to this end. Indeed, the Ireland-UK joint labelling procedure and the leadership role played by HPRA personnel in the EU Task Force on Availability of Medicines are but some examples of this commitment. Furthermore, we have a special low charge and heavily subsidised fee category for such (service item) products, recognising that we must cover the full costs of providing our overall veterinary medicines services from the totality of income from the animal health industry.