HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

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

Veterinary Medicinal Products and Veterinary Manufacturing Sites

DATE <3rd October 2017>

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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[1] 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.

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 activities for 2018 include:

[1] 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 further development of the virtual innovation office for both human and veterinary medicines with an emphasis on supporting early innovation.
- 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.
- Managing the impact of Brexit across all our strategic initiatives.

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 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 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 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 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 have frozen fees since 2013.

2.2 Fees for 2017

In 2017 the HPRA froze the fees across all categories and in addition:

- Applied 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.
- Reduced fees for bulk transfer applications.

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 increase responsibilities, the planned increases to staff numbers, increased payroll costs due to the reversal of the Haddington road government pay agreement, 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 of 2% for 2018.

3.1 Risks and uncertainties in relation to the new model

The fee proposal outlined above is based on the volumes and patterns of submissions seen during 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 has been 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

Veterinary income has been performing as expected with an increase in decentralised applications reflecting the early signs of an economic recovery. Variation income has remained stable year on year. 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, due to the application of the government moratorium on recruitment during 2013 to 2016, staff costs have been artificially suppressed. There has been substantive pay cuts across all grades for the last five years but the Haddington Road costs are being reversed over 2017 and 2018 with a consequential impact on costs. Increased salaries are necessary if the regulator can ensure staff with the appropriate level of

experience and qualifications. HPRA draws staff from the same pool as industry and increases to salaries in the industry puts pressure on the HPRA's ability to retain staff. It should also be noted in relation to payroll costs that the HPRA has a significantly unfunded pension liability which is a cost of delivering the service. Although the HPRA expects to break even at the year-end, significant capital expenditure in IT will result in cash outflows in 2017.

5 FINANCIAL CHALLENGES IN 2018

The HPRA Veterinary Sciences department will face further challenges in 2018.

Like all commercial organisations, we are facing challenges from the economic environment and government restraints in staffing and recruitment. One of the impacts of the crisis was a reduction to costs from salaries and we also observed that suppliers were forced to cut prices. While the HPRA will continue to seek the most competitive quotes for all purchases we expect that external costs may increase in 2018.

As outlined in the introduction, the early effects of Brexit, the increased complexity of the European regulatory model and expanded deliverables under the strategic plan mean that the HPRA continues to require additional resources to deliver our goals and objectives. 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 2018 in some categories. The medium and long-term impact of Brexit on the economy is a further unknown which needs to be managed.

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 accordance with the IT strategy we are implementing a new workflow and database system 'Eolas' and the first part of the system to be implemented is 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, some of these reductions have been reversed in 2017, with further reversals due in 2018. 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.

A key challenge for the HPRA's Veterinary Sciences department in 2018 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 increase of 2% in HPRA fees in 2018.

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 31st October 2017. Contributions should be sent by e-mail to 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).

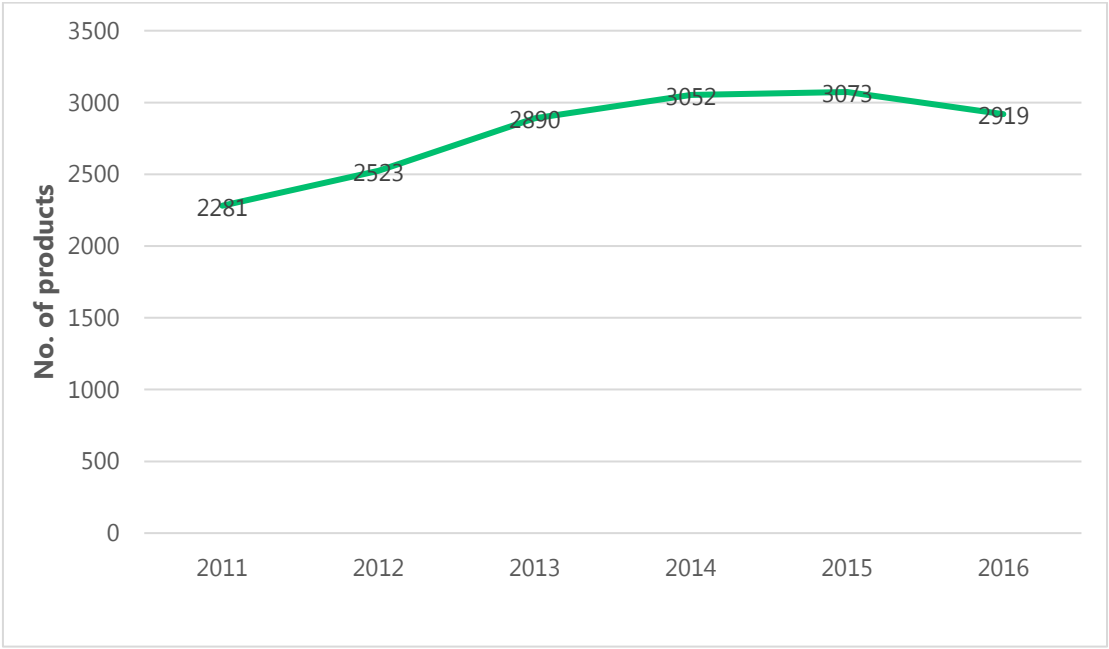

Figure 1: Output of applications in the Veterinary Sciences department 2011–2016

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, 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.

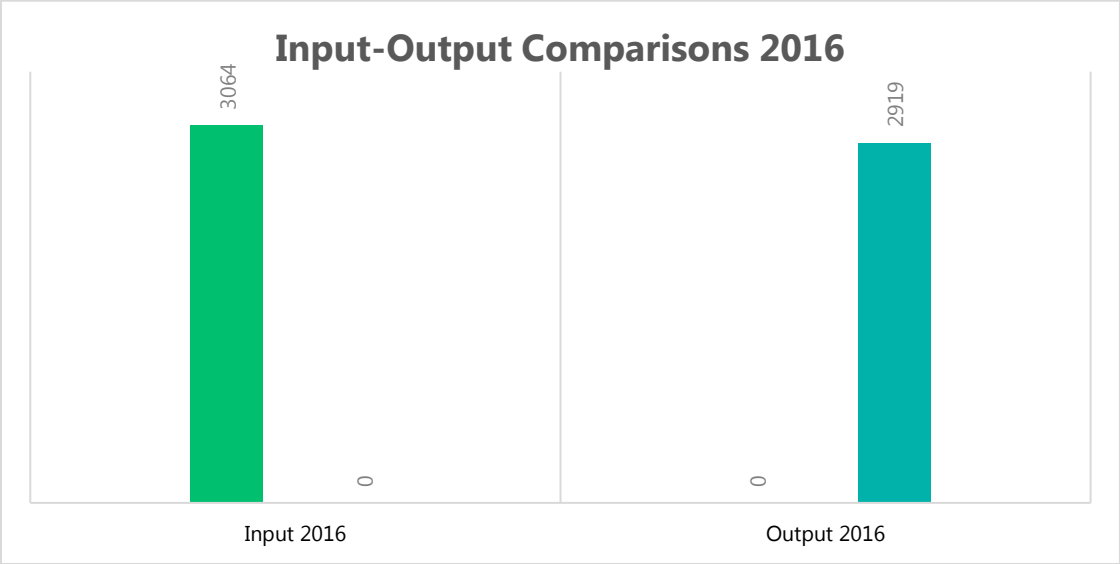

Figure 2: Input and output comparisons for 2016

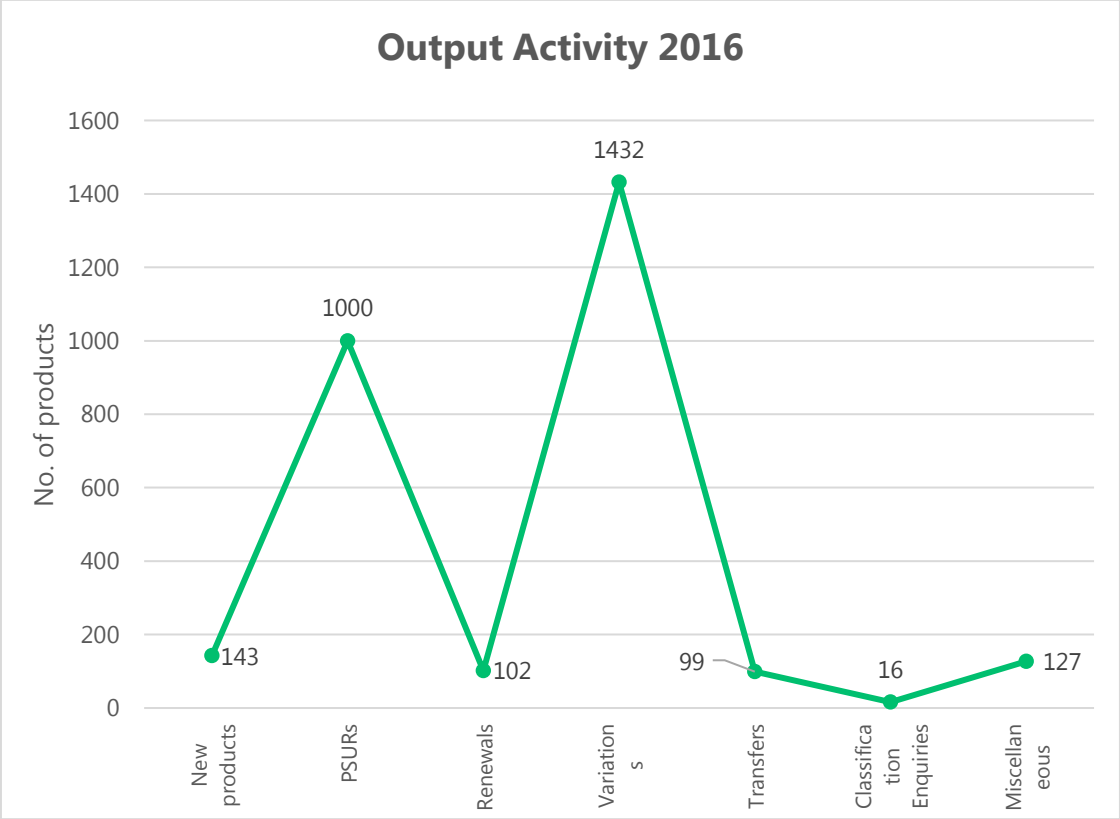

Figure 3: Overall output activity levels 2016

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.