HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Annual Review and Proposal for Fees – Financial Year 2015 (Veterinary Medicinal Products and Veterinary Manufacturing Sites)

08 OCTOBER 2014

CONTENTS

1 INTRODUCTION

Since its establishment in 1996, the HPRA (formally the Irish Medicines Board [IMB]), has successfully run its core operations without recourse to exchequer funding, established sufficient reserves to allow it to fund capital and IT expenditure and deal with unexpected costs as they 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. In the last 5 years, the country has experienced an economic crisis, which has created a difficult operating environment for both the HPRA and stakeholders. The HPRA has also experienced a period of considerable increase in its workload arising from both European and new national legislation. In addition, the HPRA is faced with managing reduced exchequer funding and increased workloads within the context of staffing constraints imposed by the government recruitment moratorium.

The first aim, in respect of fee income for the HPRA, must be to match resources from fees with current work volumes and plan for future activity. The second aim must be to provide predictable, stable timelines and cost of the regulatory system that we operate.

To ensure that we manage the business properly we have agreed that we would review our fees on an annual basis to reflect changes to our cost base and service levels. This document summarises the outcome of our 2014 review of fees and it also sets out the current service levels and activities and expected changes in service levels and activities for 2015.

2 REVIEW OF THE 2014 FEES

2.1 Introduction

In 2010 the HPRA remodelled the fees to take account of the implementation of revised EU Regulation (EC 1234/2008).

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

2.2 Fees for 2014

In 2014 HPRA froze fees across all categories and in addition, decreased the caps on multiple variations to the same Veterinary Product Authorisation (VPA) or VPA family and to cap the

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

fee on variations that go through the EU work-sharing model, delivering further savings to industry.

3 SUMMARY OF PROPOSED CHANGES FOR 2015

The detailed changes and the basis for the changes are outlined in section 7 of the report. The high level summary of those changes is as follows:

Following a review of the income and cost base for 2014 and proposed activities for 2015 the HPRA is satisfied that the overall fee structure is working well. Given the substantive level of fee reductions previously delivered HPRA is not in a position to further reduce the fees. However we are aware of the government aim to freeze fees in respect of government agencies in 2015 and the HPRA therefore is committed to keeping fees to a large extent, at 2014 levels. This is despite the increase in our responsibilities arising from new legislation which is outlined below in Section 5. The details and basis for the changes are outlined in section 7 of this report.

3.1 Risks and uncertainties in relation to the new model

The fee model outlined above is based on the volumes and patterns of submissions seen during the first eight months of 2014. 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 severe recession being experienced by both the Irish and worldwide economies means that forecasting is extremely difficult and subject to significant change.

The HPRA therefore commits to review the impact of the new fees during the planning cycle again in 2015 and to amend the fees and fee structure if required, for 2015.

4 FINANCIAL POSITION IN 2014

2014 is a challenging year for the Veterinary Sciences Department (VS) of HPRA.

Income from new applications is lower than expected for the first 7 months of the year and there is volatility in the number of applications being received month-on-month. Variation income has remained stable year on year. Overall HPRA Veterinary Sciences Department income is below the forecast for 2014, reflecting the economic pressure that the indigenous Irish industry is experiencing. Costs have stabilised at the 2014 cost base, which reflected the fact that HPRA had negotiated costs downwards to reflect the prevailing economic climate as well as the impact of government pay constraints. However, our cost base is approximately 70% staff costs and due to the application of the government moratorium on recruitment during 2013 and 2014, costs have been artificially suppressed. Although the HPRA expects to

show an overall surplus at the year-end, significant capital expenditure in office accommodation resulted in cash outflows in 2014. This investment in the building allowed the Veterinary Sciences Department to return from off-site rented accommodation and will deliver long-term savings and efficiencies.

5 FINANCIAL CHALLENGES IN 2015

The HPRA Veterinary Sciences Department will face significant financial challenges in 2015.

Like all commercial organisations, we are facing challenges from the recession. These challenges are compounded by the proposed reduction in government funding to the overall organisation, as well as the continuing economic pressure on Irish manufacturers from the Irish and global recession.

Since 1st January 2013, the HPRA became the competent authority under the Protection of Animals Directive[2]. While this function is initially being funded by the Department of Health, there is significant pressure on this funding and the long term aim is that this will be funded through a fee regime. These fees will be charged to those breeding, supplying or keeping animals that fall under the scope of the Directive. Responsibility for the services involved has been given to the HPRA's Veterinary Sciences Department.

In July 2014, the HPRA was appointed as competent authority for veterinary clinical field trials. While this is a complementary fit with the other tasks performed by the Veterinary Sciences Department, this presents an increased workload.

Despite these challenges, the HPRA must continue to invest in and deliver services to stakeholders. In 2013, the HPRA offices were extended to add an additional two floors to the existing building, which allowed an exit from a lease and relocate the Veterinary Sciences Department back into Kevin O'Malley House.

In addition, the HPRA must make substantive investments in its IT systems. The HPRA has developed its IT capacity and delivers a top class service across the European regulatory environment. However, an external review of the IT strategy identified that considerable investment is required in IT systems and people, if the HPRA are to continue to deliver and develop this service. In particular, the core workflow and medicinal product data base system is more than 10 years old and can no longer be supported, nor support the needs of the organisation into the future. In line with the IT strategy, modernisation of this system in will commence in 2014/2015, but given the size and complexity of the system this will represent a

[2] Directive 2010/63/EU

very significant investment in IT. In addition, the new activities and responsibilities deriving from the legislation will result in further investment in IT systems.

A strategic plan has been completed for the years 2011 to 2015, which continues to place human and animal safety at the centre of our work, provides a road map for the organisation and identifies those areas where the HPRA must invest resources, in delivering better regulation to all the stakeholders. The HPRA must continue to invest in the business to ensure that it continues to regulate for safe medicines to patients and a regulatory environment, which supports industry through an effective and predictable regulatory framework.

A key challenge for the HPRA's Veterinary Science Department in 2015 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 in HPRA fees with changes to certain categories as outlined below.

7 DETAILED CHANGES TO FEES

7.1 General change to fees

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

7.2 Other proposed adjustments to fees Veterinary Sciences Department (VS)

7.2.1 Decentralised Procedure (DCP) outgoing applications

To distinguish the incoming and outgoing fees for DCP applications it was considered, whether the fee for "each additional strength (at the same time)" for DCP outgoing applications should be increased to €1,260.

Following a discussion on the matter, it was agreed to retain the current fee of €630 as the larger DCP outgoing fee would cover any additional work required.

7.2.2 Subsequent extensions

It was proposed and agreed to amend the Vet fee form to transfer all subsequent extension fees from the various new applications sections into Section 1.2.

7.2.3 Work-sharing cap fee

Following a discussion on the work-sharing fees it was agreed that the current cap of €4,500 was appropriate and would cover all work-sharing applications.

7.2.4 Pharmacovigilance fees – bulk variations

It was noted that these types of variations are not received in bulk and when they are received they are processed as IA's and IB's.

It was proposed and agreed that these fees would be removed from the fee form.

7.2.5 Transfer of ownership fees

It was proposed and agreed to amend transfer of ownership fees proportionately in line with the human fee structure for transfer of ownership fees.

Description	Fee
Change of Ownership – related 1st authorisation	€864
Change of Ownership – related, additional authorisations	€308
Change of Ownership – Non related, 1st authorisation	€1,263
Change of Ownership – non related, additional authorisations.	€308

7.2.6 Parallel imports

It was proposed and agreed that a new fee (proportionate to the same fee for human medicines) would be introduced for a parallel import where the originator is not on the Irish Market.

Description	Fee
Parallel import where the originator is not on the Irish market	€4,800

7.2.7 Outgoing homeopathic fee

It was proposed and agreed to remove the fees for outgoing homeopathic fees as we do not receive outgoing homeopathic applications.

7.2.8 Additional target species/multiple target species

It was proposed and agreed that a cap of €7,350 be put in place for applications relating to multiple target species.

It was also discussed and agreed that only one fee of €2,450 would be charged for generic products.

7.2.9 Clinical trials

When the function was taken over by HPRA during 2014, the Department of Agriculture fees applied. It was agreed that the existing fees will be applied in 2015. These fees will be reviewed in 2015 to consider whether the fees are sufficient to cover the cost of this function:

Description	Fee
Research trial for a veterinary medicine containing a novel substance	€630
Research trial for a veterinary medicine containing an established ingredient	€315
Variation of a current research trial licence	€60

APPENDIX - 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).

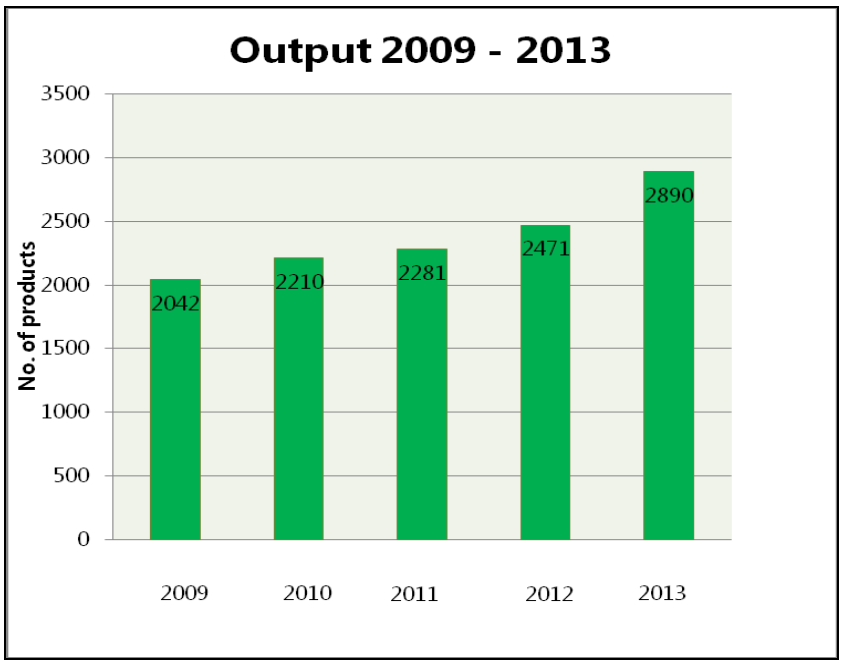

Figure 1: Output of applications in the Veterinary Sciences Department 2009–2013

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. 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 high level of activity in the centralised and decentralised procedures and an increased workload in evaluating periodic safety update reports (PSUR), as can be seen from Figure 3.

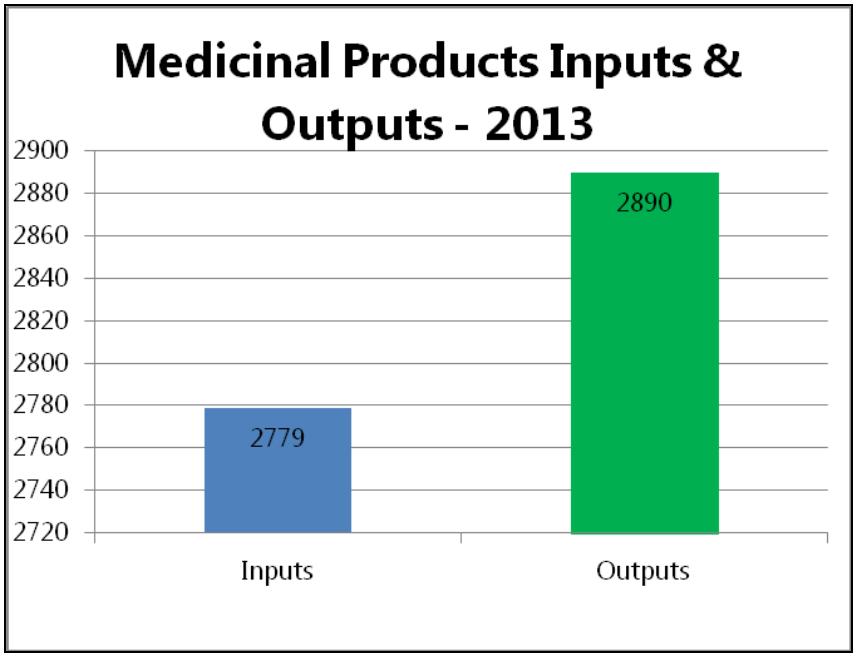

Figure 2: Input and Output comparisons for 2013

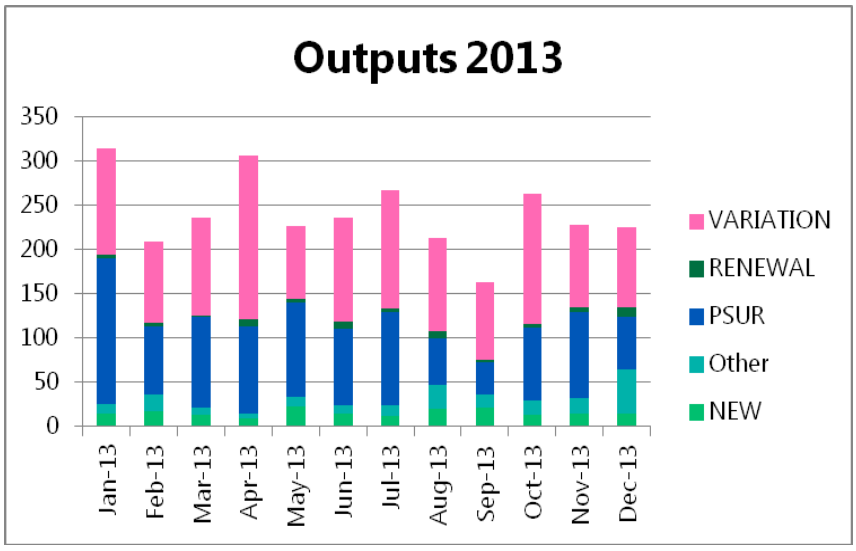

Figure 3: Overall Output activity levels in 2013

Workflows have been relatively stable over recent years with output figures matching incoming applications and a total work-in-progress figure for pre- and post-licensing activities varying from around 790 to 650 as can be seen from Figure 4.

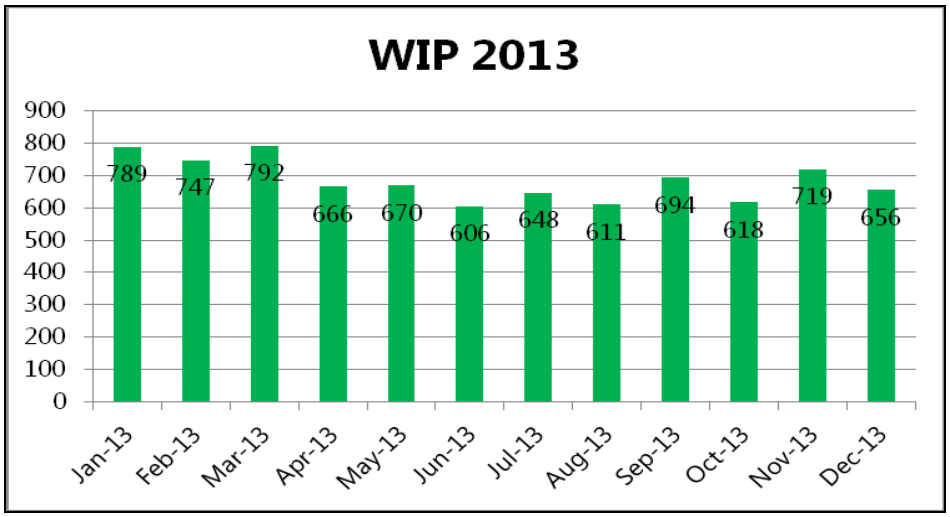

Figure 4: Activity levels of total applications classified as work-in-progress 2013.

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. The HPRA are conscious 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 Medicines Availability is just one example of this commitment. Furthermore, with a special low charge and heavily subsidised fee category in place for such (service item) products, it is recognised that the full costs of providing an overall veterinary medicines service from the totality of income from the animal health industry, must be covered.