

**Irish Medicines Board**



**Bord Leigheasra na hÉireann**

**Annual Review of and Proposal for Fees – For Financial Year 2012**

**Fees for Veterinary Medicinal Products and Veterinary  
Manufacturing Sites**

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## **1. Introduction**

The 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 they arise. This is both a requirement under the IMB Act, and a stated objective of the Board of the IMB. Since 2004, the IMB has implemented a policy of annual fees reviews following consultation with industry. In the last two years the country has experienced an economic crisis and moved from a period of inflation to deflation. The IMB has also faced considerable uncertainty in relation to fees due to the introduction of the new variations Regulation which substantially changed the way that the IMB handles variations. In addition, the IMB is faced with managing reduced exchequer funding and managing increased workloads with the government staffing moratorium.

The first aim regarding fee income for the IMB must be to match resources from fee income with current work volumes and plan for future activity. The second aim in respect of fee income must be to provide predictability and stability to the timelines and cost of the services that we provide to industry.

To ensure that we manage the business properly we have agreed with our client companies 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 2011 review of fees which encompassed a specific review of the outturn from the new variations Regulation and the general changes to the fees from our annual review. It also sets out the current service levels and activities, as well as the expected changes in service levels and activities for 2012.

## **2. Review of the 2011 Fees**

### **2.1 Introduction**

In 2011 the IMB faced a significant financial challenge with the implementation of revised EU Regulations (EC 1234/2008), which provided for a new system for variations to marketing authorisations. Existing Regulations (EC 1084/2003 and 1085/2003) ceased to have effect from 1 January 2010.

The revised variations Regulation had a number of key impacts on variations and related income. In summary, the key change was that all Type IA variations become 'do and tell' with the majority requiring annual notification and specified variations requiring immediate notification. There was also a significant downgrading in the classification of variations with many variations previously assessed as Type II with a 90 day turnaround now being classified as Type IB variation with a 30 day turnaround. This had a significant impact on both the operations and the income of the IMB.

## 2.2 Fees for 2010

In 2010 we introduced a fee structure to account for the new variation Regulation, the key change to the structure was that the maintenance fee was increased to compensate for the fact that Type I variations would have no fee and the expected reduction to Type II variations. However the outcome for 2010 was not as expected. A key aim of the variation Regulations was to lessen the regulatory burden for variations but this was not achieved. The new Regulation defined variations in such detail that it actually increased the overall number of variations throughout Europe by as much as 20%. Consequently, IMB income was higher than expected.

## 2.3 Fees for 2011

In response to the outturn in 2010, the IMB performed a detailed review of the fee's structure and introduced the following significant reductions to the fees for 2011.

- Type II variations reduced by **20%**.
- Type IB variations reduced by **10%**.
- The maintenance fees are reduced by **5%**
- Type IB incoming fees have been reduced by **20%**.
- Transfer fees have been reduced by **17%**

## 3. Summary of proposed changes for 2012

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 2011 and proposed activities for 2012 the IMB is satisfied that the new fee model is satisfactory overall. However, the IMB has listened to representations from stakeholders who have asked for a reduction to the annual maintenance fees in order to ensure medicines availability. We have therefore reviewed the maintenance fees and propose the following changes for 2012.

- All marketing authorisations (MAs) not marketed at 1<sup>st</sup> January 2012 (excluding temporary cessation) will be eligible for the dormant fee.
- The dormant fee will be reduced by 5%.
- The full maintenance fee will be reduced by 5%.
- The reduced maintenance fee will be reduced by 5%.

### **3.1 Impact on 2012 fees**

As noted above the key changes for industry are a reduction to the rate of annual maintenance fee and a reclassification of the dormant fee. The combined impact of these changes is to reduce the overall maintenance charge by 6%. The nature of the proposal means that all companies benefit but we have also reflected the particular concerns expressed over the cost of maintaining a non-marketed PA.

### **3.2 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 8 months of 2011. 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 IMB therefore commits to review the impact of the new fees during the planning cycle again in 2012 and to amend the fees and fee structure, if required, for 2013.

## **4. Financial position in 2011**

2011 is a challenging year for the IMB.

While income continues to hold up during the year, there is a certain volatility in the number of applications being received month-on-month, although the number of variations continues to remain higher than expected. Overall IMB income has been relatively stable, even if we have seen a reduction across the board in compliance income reflecting the economic pressure that the indigenous Irish industry is experiencing. Costs have stabilised at the 2010 cost base which reflected the fact that IMB had negotiated costs downwards in line with the prevailing economic climate. However, the IMB cost base is approximately 70% staff costs and due to the application of the government moratorium on recruitment during 2010 and 2011, costs have been artificially suppressed. Provision has been made for a recent liability as well as for ongoing legal costs. Although the IMB expects to show an overall surplus at the year-end, significant capital expenditure in IT and office accommodation will result in cash outflows for 2012. These investments have delivered, and will continue to deliver, long-term savings and efficiencies.

## **5. Financial challenges in 2012**

The IMB will face significant financial challenges in 2012.

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.

Despite these challenges, the IMB must continue to invest in and deliver services to stakeholders. In 2012 we will build another two floors on our building which will allow us exit one lease and relocate the Veterinary Medicines Department back into Kevin O'Malley House.

We have completed a strategic plan for the years 2011 to 2015 and have also completed a corresponding IT strategy. The IMB strategic plan, which places human and animal safety at the centre of our work, provides a road map for the organisation and identifies those areas where we must invest time and resources in delivering better service to all our stakeholders.

The IMB has developed its IT capacity and delivers 'best in class' service across the European regulatory environment in which we operate. However an external review to develop the strategy identified that we need considerable investment in our systems and people if we are to continue to deliver and develop this service. The IMB must continue to invest in the business to ensure that we continue to regulate for safe medicines and a regulatory environment which supports industry through efficiency and service deliveries.

A key challenge for the IMB Veterinary Medicines Department in 2012 will be preparing for the European presidency in 2013 and 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 decreases to the maintenance fees with no increase to any fee category.

## 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 medicines

#### 1. Grouping of variations

It was noted that last year rather than introduce group variation fees which were difficult to model we reduced the overall level of variation fees by between 10 and 20 % which delivered savings for all variations rather than those that are grouped. It was agreed that we would continue to charge for grouped variations under the current fee structure. However, we will continue to monitor the variation fees.

#### 2. Batch specific requests

It was proposed that for certain batch specific requests it was more appropriate to charge one fee across the range of VPAs rather than a fee per VPA. It was agreed that there should only be one fee when the change is identical across a number of VPAs and the Guide to Fees will be amended to reflect this.

#### 3. Consequential variations

It was noted that the issue of increased variations arising from the variations Regulation had been raised. The IMB recognises that the loss of the concept of a consequential variation was an unforeseen outcome from the Regulation and that the IMB would support changes in this regard at a European level.

#### 4. Work sharing fees

It was agreed that the current system whereby there are no special fees for work sharing is appropriate as in general the increased workload undertaken by the IMB when acting as Reference Authority is offset by a reduced workload when another Member State acts as Reference Authority.

#### 5. Dormant definition of a maintenance fee

Following submissions from industry that the definition of a dormant MA was too restrictive we reviewed our fee model and agreed that MAs which are not marketed but which may be varied will qualify for the reduced maintenance fee. We also reviewed the overall level of maintenance fees and proposed the following:

Rate	Veterinary Medicines 2011	Proposed 2012	Decrease
Standard	€650	€618	5%
Reduced (For the first 10 authorisations)	€520	€494	5%
Dormant	€442	€420	5% plus additional 1% to overall maintenance from reclassification

#### 6. Variations under C.1.3.a

In 2010 the IMB charged for all changes to the SPC under C.1.3.a as individual variations. This led to some very high fees and we revised the charging structure mid 2011 so that we only charge for the first two changes per VPA range.

**Appendix I**  
**Vet Appendix 2012**  
**Service Levels – Veterinary Medicines Department**

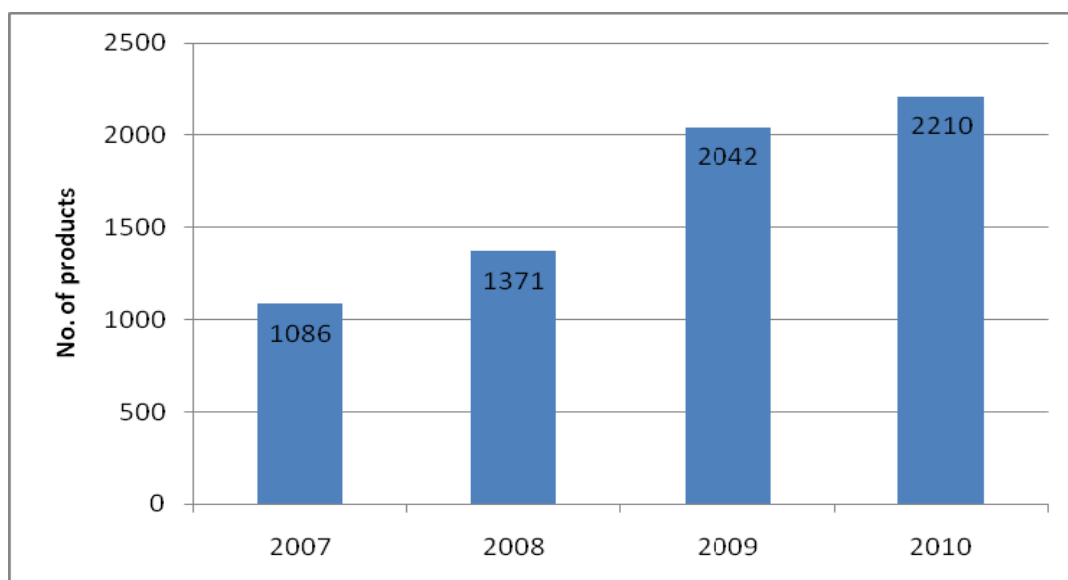
The most significant projects undertaken in the Veterinary Medicines Department, IMB in the last two years have been driven by the requirement to improve service levels to industry.

In summary these projects include:

- Introduction of an automatic e-mailing service which notifies companies of the status of the application at key milestones
- Increased productivity
- Operational work planning designed to meet the needs of the industry
- Further development of the IMB quality management system
- Publishing assessment reports for new veterinary medicines and for significant variations to existing medicines on the IMB’s website
- Improved pharmacovigilance resources and tools
- Improved website content and design

The Veterinary Medicines 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 (Table 1).

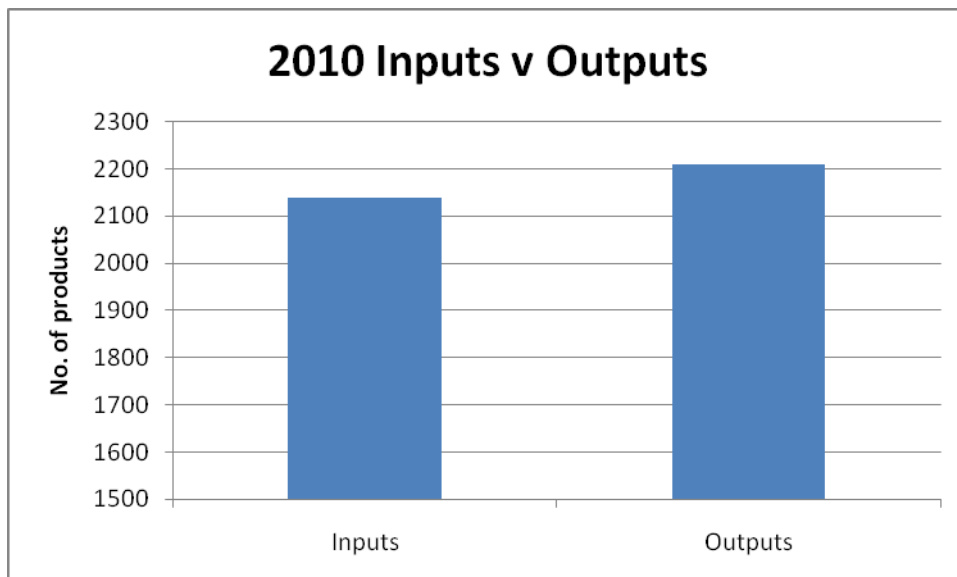
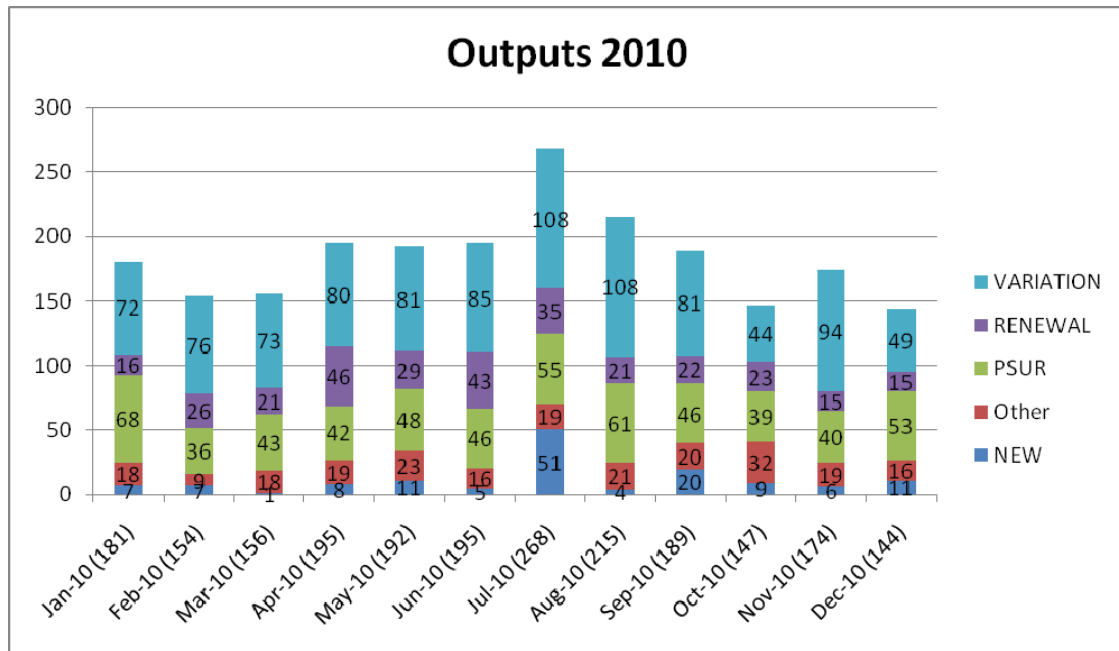
Table 1: Output of applications in the Veterinary Medicines Department 2007–2011



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

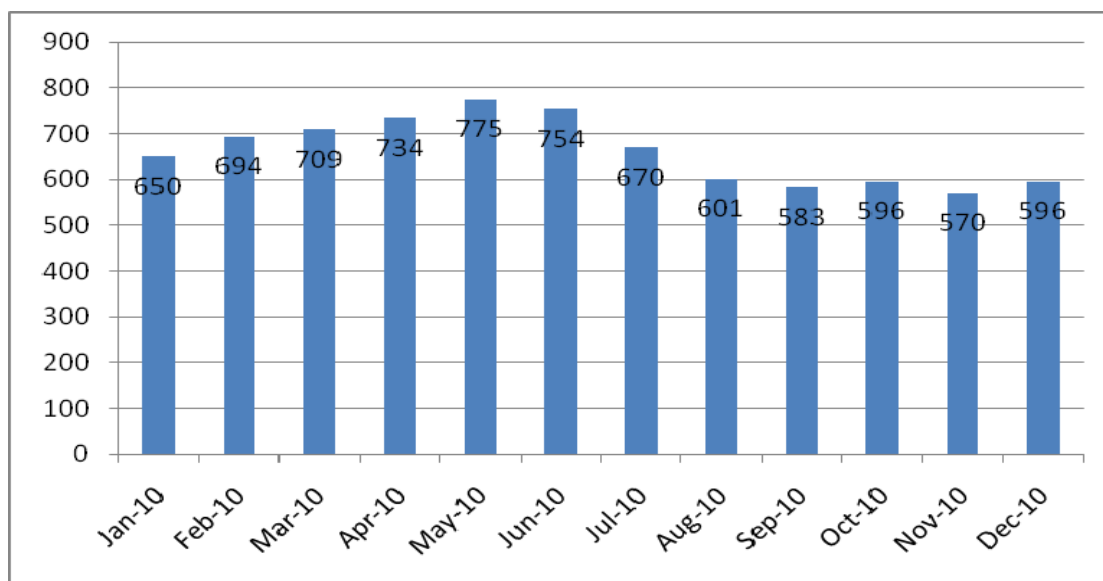
Veterinary Medicines Department continues to ensure that the total output of applications submitted for evaluation matches the input, despite a high level of activity in the centralised procedure and an increased workload in evaluating periodic safety update reports, as can be seen from Table 2.

Table 2: Overall Output activity levels in 2010



Workflows have been relatively stable over recent years with output figures matching incoming applications with a total work-in-progress figure for pre-licensing plus post-licensing activities varying from 775 to 570 as can be seen from Table 3.

Table 3: Activity levels of total applications classified as work-in-progress 2011



While forecasting for future years is difficult, the Veterinary Medicines Department is confident that the business model will continue to deliver and build on the improved service levels achieved over recent years. The IMB 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 IMB 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 we expect that a long-term resolution of the problem will take some time to achieve. The IMB 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 Harmonisation Procedure, Joint Labelling procedure, Partnership Initiative and the leadership role played by IMB personnel in the EU Task Force on Medicines Availability are but some examples of this commitment. Furthermore, the IMB has in place a special low charge and heavily subsidised fee category for such (service item) products, recognising that the IMB must cover the full costs of providing its overall veterinary medicines services from the totality of income from the animal health industry.