

Irish Medicines Board



Bord Leigheasra na hÉireann

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

**Human Medicines, Compliance Activities,
Blood, Tissue Establishments and
Medical Devices**

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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 these 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 2 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 EU 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 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 2011 review of fees and it also sets out the current service levels and activities and expected changes in service levels and activities for 2012.

2. Review of the 2011 fees

2.1 Introduction

In 2010 the IMB faced a significant financial challenge with the implementation of revised EU Regulation (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 only 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 The 2010 fees

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 number of variations throughout Europe by as much as 20%; consequently IMB income was higher than expected.

2.3 The 2011 fees

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%**
- Article 61(3) notification fees reduced by **50%**
- The maintenance fees reduced by **10%**
- No increase to controlled drug fees until 2012
- Type IB incoming fees reduced by **20%**
- Transfer fees reduced by **20%**
- Enforcement fees reduced by **50%**

3. Summary of changes proposed for 2012

The detailed changes and the basis for the changes are outlined in section 7 of this report. Following a review of the income and cost base for 2011 and proposed activities for 2012 the IMB is satisfied that the new fee structure is working well. However, the IMB has listened to representations from stakeholders who have asked for a reduction to the annual maintenance fees. We have therefore reviewed the maintenance fees and propose the following changes for 2012:

- All MAs not marketed as at 1 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%**
- Controlled drugs and precursor chemical fees which have not been increased since 1988¹, will be increased as part of a 4 year plan to align them with the cost of providing the service.

¹ Misuse of Drugs (Licence Fees) (Amendment) Regulations, 1988

3.1 Key change and the basis for the change

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 10%. 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 Controlled drug and precursor chemical fees

Controlled drug fees have not been increased in 23 years which has resulted in an income from fees that is completely inadequate to cover the necessary costs of running the controlled drugs and precursor chemical unit. As a consequence, the Department of Health has provided funding for this function to date. Following the economic crisis the Department is no longer in a position to fund this function. A review by Mazars' in 2010 identified that fees need to be increased by 500% to allow this function to become self-funding. Due to the level of the increases required, it was agreed that the exchequer funding for controlled drugs will be reduced over a four-year period commencing 1 January 2012 and, in conjunction with this, fees will be increased on a phased basis over this time on a scale sufficient to offset the reduction in funding as outlined in appendix IV. The first of these phased fee increases is proposed in 2012. (A separate consultation letter was sent to all users of the controlled drug licensing service in August 2011 to ensure the provision of an early indication of this change).

3.3 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 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 change.

The IMB has been able to reduce fees due to the continued volume of activity in the pharmaceutical sector. Were that to change significantly the IMB would have to increase fees going forward. The IMB therefore commits to review the proposed fees during the planning cycle in 2012 and further 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 perform well, the reduction in government funding has impacted on financial performance. The strengthening of sterling in relation to the Euro has reduced the level of parallel imports received for a second year. Core business remains stable although new applications are slightly less than expected while variations continue to remain high. 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 to reflect 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. Consequently, staff numbers in key areas have been falling and in 2010 for the first time in three years the IMB had increased work-in-progress. While we are tackling that in 2011 it will have costs into the future. Although we expect to show a 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.

In common with all commercial organisations, we are facing challenges from the recession. These challenges are compounded by the proposed reduction in government funding, the reduction in new MA applications for the Irish market and the pressure on Irish manufacturers from the Irish and global recession.

Despite the challenges arising from the recession, the IMB must also 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 that we currently have and relieve crowding in a number of areas. The IMB is also hoping to receive permission to recruit additional staff in 2012 and consequently there is urgency around acquiring extra space. The IMB requires extra resources as it is taking on competency for organs for transplantation in 2012, developing its pharmacovigilance and compliance units in order to implement amendments to the human medicines directive and preparing for the 2013 presidency.

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 continues to place patient 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 regulation to all the 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 to patients and a regulatory environment which supports industry through an effective and predictable regulatory framework.

A key challenge for the IMB in 2012 will be the commencement of the new pharmacovigilance directive (July 2012) and implementation work for the Falsified medicines directive. Both directives increase the regulatory role and will require additional resources. Both also have implications for IT systems which will need further investment.

In the first 6 months of 2013 Ireland will host the European presidency in 2013 and preparatory work has already commenced in 2011 and will entail significant work in 2012.

6. Proposed fees

As outlined above there will be significant decreases to the maintenance fee and an increase to controlled drugs and precursor chemical fees which was postponed from 2010 and which is the first increase in 23 years.

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 human medicines

1. Grouping of variations

It was noted that for 2011 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 PAs rather than a fee per PA. It was agreed that there should only be one fee when the change is identical across a number of PAs 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 works well, as in general, any unfunded work carried out by IMB is offset by work that we receive free assistance on.

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	Human Medicines 2011	Proposed 2012	Decrease
Standard	€855	€812	5%
Reduced (For the first 10 authorisations)	€684	€650	5%
Dormant	€442	€420	5% plus additional 5% to overall maintenance from reclassification

6. Reintroduction of an indication on the expiry of a patent

It was agreed that the introduction of an indication following the expiry of a patent should be charged as a reduced type Ib variation per product range.

7. Variations under c.1.3.a

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

8. Pharmacovigilance – Post authorisation studies and risk minimisation studies under annex 4

It was noted that the new pharmacovigilance directive will bring in two new activities i.e. post authorisation studies and risk minimisation studies for national products for which there is no fee code. It was proposed that the assessment of these would be charged as a complex variation fee and the guide to fees will be amended accordingly. It is not expected that this will impact the fees until 2013 so a further assessment of this fee will take place in 2012 when the Directive is fully implemented.

9. Clinical Trial (CT) amendments

It was agreed that only one clinical trial amendment fee would be charged regardless of the number of changes included in the variation application to one clinical trial. Where an amendment relates to more than one trial the amendment fee will be per trial.

10. Article 61.c changes

It was agreed that no outgoing supplement would be charged for an article 61(3) where Ireland was the RMS. It was also agreed that PPA holders could also use article 61(3) changes where appropriate.

11. Fees for controlled drugs and precursor chemicals

It was noted that the fees for controlled drugs and drug precursors had not been increased in 23 years. Following a review of the level of fees required to fund the administration of the service it was agreed that the increase would be implemented over 4 years. It is therefore proposed that the first of those increases be implemented in 2012. In addition, the intention is to eliminate existing minor differences in the application of fees for controlled drugs and precursors, leading to eventual harmonisation. The proposed fee schedule is as follows:

Process	Current fee€	Proposed fee 2012 Controlled Drug	Proposed Fee 2012 Precursor Chemical
Produce	191-CD 64-Precursor	€340	€340
Produce R & D	127	€226	€226
Produce Preparations	127	€226	€226
Possession	32-CD 64-Precursor	€57	€57
Supply	64	€113	€113
Import	64	€113	€113
Export	0-CD 64-Precursor	€64	€64
LONO	0	€33	N/A
Hemp (Cultivation) licence	0	€33	N/A
Registration	0-CD 64-Precursor	€64	€64

12. Fast track applications for controlled drug (CD) licences

It was noted that companies frequently ask to have their CD import and export licences and LONO fast tracked from the 7 working day standard timeline. It is proposed that companies can request a fast tracked application (4 working days) for a total fee of €226.

13. Pharmacists applying for CD licences

It was noted that pharmacists do not have an exemption from paying fees for CD import licences but traditionally no such fee is charged. Following a review of the circumstances when pharmacists would require this licence it was agreed that we would continue not to charge for these import licences.

14. Use of Controlled Drugs / Precursors in post graduate research

It was agreed that a maximum fee of €127 would be charged to cover possession of all substances used in the course of a research project for post graduate research. This contrasts with the current system where there is a charge per drug or substance. When there is more than one university involved in the project, the fee is payable by each University.

15. Use of Controlled drugs in Pilgrimages

It is proposed that the IMB will continue the practice of not charging for these licences.

16. Cosmetic – inspection fees

It is agreed that for routine inspections fees will only be charged to companies with more than 20 employees. For cause inspections will be charged at the normal inspection rates.

17. Annual Maintenance fee for small Blood and Tissue Establishments

Fee	2011	2012	% reduction
Annual Maintenance Fee	€3,703	€1,000	73%

Following representations from start up Blood and Tissue establishments, it was agreed that where the company had less than 5 employees and turnover less than €300,000 that there would be a reduced fee for the first 4 years of authorisation.

18. Annual reports for Blood banks.

It was agreed that the fee for this activity would be changed from the technical variation fee to the administration variation fee to reflect the maturity in the system.

Appendix I

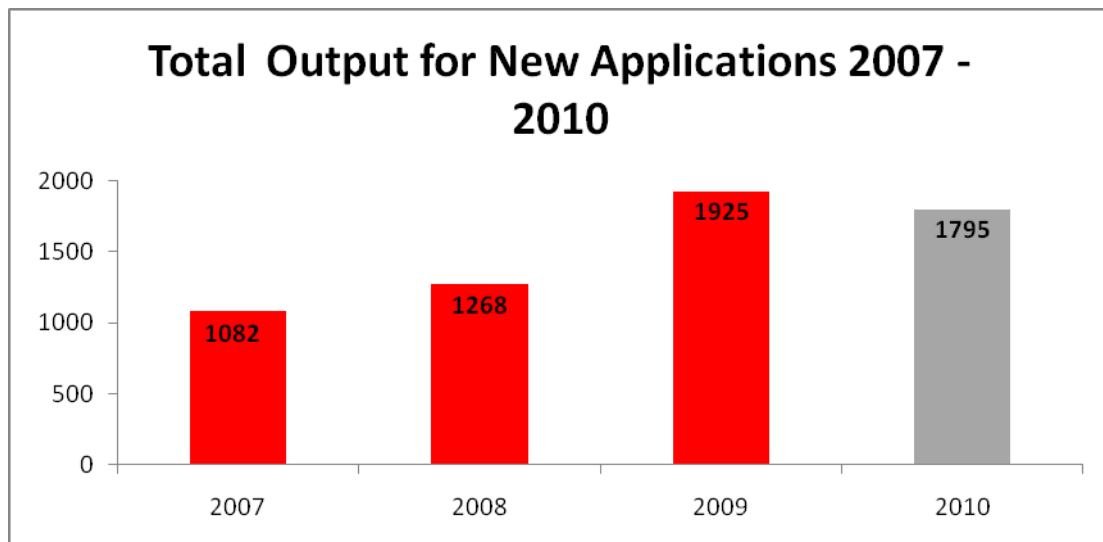
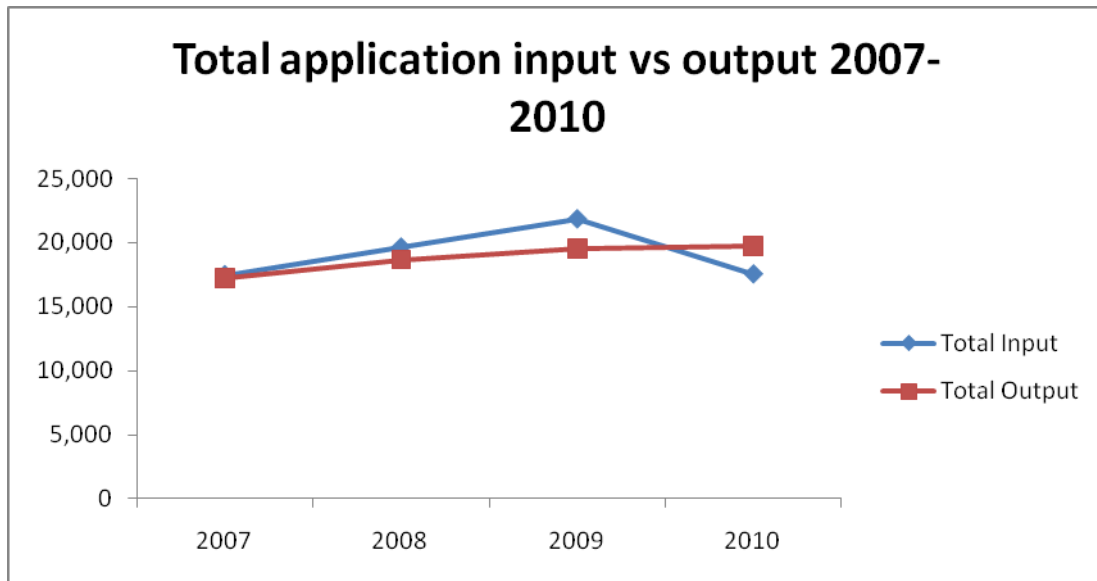
Service levels – Human Products Authorisation and Registration

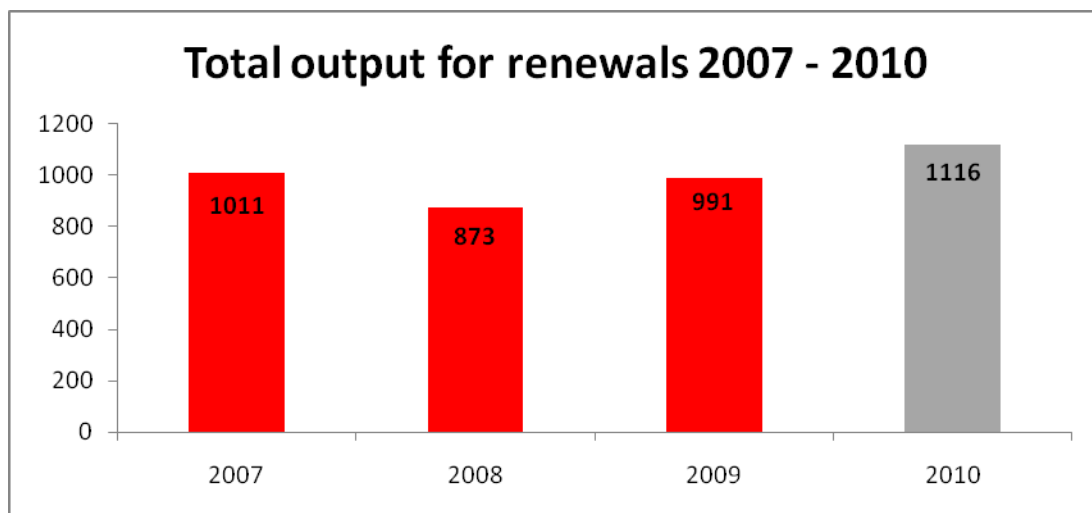
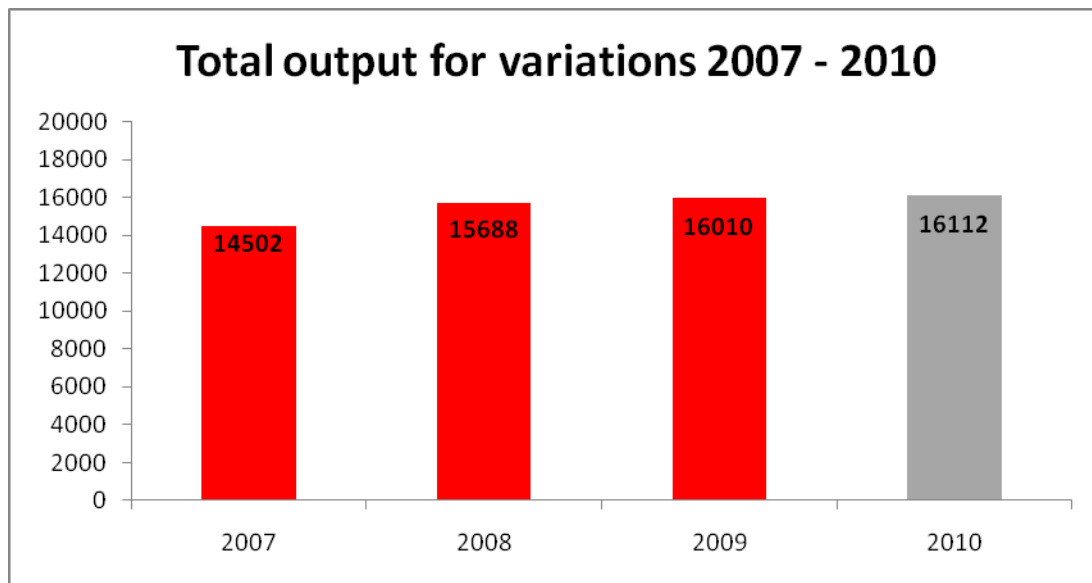
The most significant projects undertaken by the IMB in the last three years are driven by the requirement to maintain and further improve patient safety and service levels to industry.

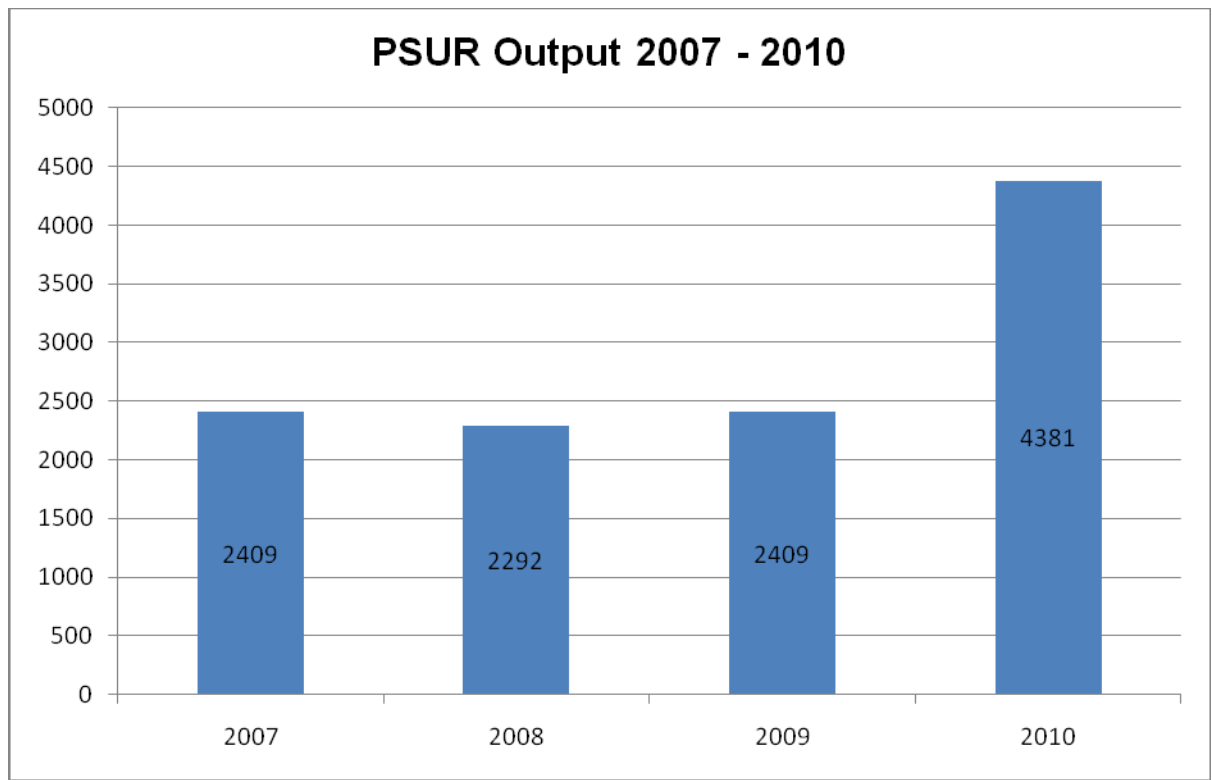
These projects include in summary:

- Refining the IMB's operations more efficiently and effectively to meet the needs of our stakeholders. A large focus has been placed on improving the timelines for approval of applications through analysis of the process for resource allocation and more effective management of the available assessment capacity. Focus has also continued on the use of lean six sigma on IMB processes following the updates to the new 'Variations Regulation' (Commission Regulation 1234/2008). A number of agreed objectives included:
 - improved efficiency with maintenance of quality,
 - streamlined procedures and processes, and
 - improved transparency and standardisation of approach.
- Introduction of online reporting for adverse drug reactions and quality defects, accessible to patients, health care professionals and industry.
- Ongoing increased productivity, and removal of the backlogs.
- Development of a system to record key performance indicators to allow more effective monitoring of timelines.
- Continued customer-focused approach.
- Continuously improving workflow technology within the organisation which has delivered real benefits in the tracking and managing of workloads.
- Clarification in relation to the legislative requirements for applicants for herbal medicinal products. A question and answer guidance document was posted on the IMB website in 2011 to deal with issues of common interest.
- A number of meetings with stakeholders specifically relating to parallel products and herbal medicines.
- As part of ongoing review of IMB processes the process for clinical trials was reviewed and a number of enhancements were made.
- A key public health initiative focused on providing important online information about all medicines licensed by the IMB continues with the summary of product characteristics document as well the legal classification status of all human medicines being available on the IMB website at www.imb.ie.
- The publication of the revised guidance in relation to parallel imports and clinical trials.
- 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 graphs below outline the output across all application types up to the end of 2010.







Appendix II

Service levels – Compliance Department

1. Compliance Department General Activities

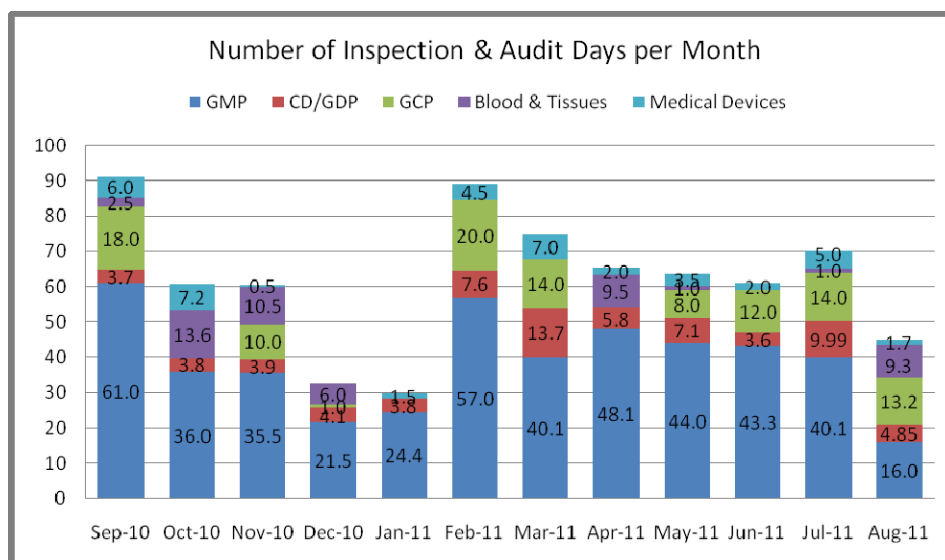
Initiatives undertaken in 2010 / 2011 included:

- Revision of the organisational structure to accommodate the competent authority role for cosmetics, including registration and certification – see also below.
- Continued development of a workflow database for compliance case management to improve efficiency in processing authorisations/licences, organisation and follow-up of inspections, quality defect and recall management.
- Provision of support to the Department of Health on the drafting of European legislation aimed at preventing the entry of falsified medicines into the legal supply chain – since published as Directive 2011/62/EU.
- Monitoring, via inspections, of the implementation of updated Good Manufacturing Practice requirements, Good Distribution Practice, Good Clinical Practice and Good Pharmacovigilance Practice standards.
- Active participation in harmonising 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 European and international enforcement groups aimed at countering the threat from illegal and counterfeit medicinal products and medical devices and in the work of the Official Medicines Control Laboratories (OMCL) network.
- Continued development of the advertising compliance monitoring programme which includes regular liaison with the industry to outline IMB requirements and to clarify the IMB's interpretation of the legislation.
- Taking on, at the request of the Department of Health, the role of competent authority for cosmetics with effect from the 1st October 2010. This has included establishment of effective working relationships with the Health Service Executive and the National Consumer Agency which also have roles in market surveillance and testing of cosmetics. An information day for interested parties was held in the last quarter of 2010. Regular meetings are held with the main industry representative body.
- In conjunction with the Department of Agriculture, Fisheries and Food, which is the competent authority for biocides, a guidance note on the borderline between cosmetics and biocides has been drafted and will be published in late 2011 / early 2012.

- Other activities included:
 - Continued interaction and communication with stakeholders including industry and other representative groups. This included an Information Day on Good Manufacturing Practice and Market Compliance.
 - Continued management of the controlled drugs function on behalf of the Department of Health. The online system for licence applications became fully operational.

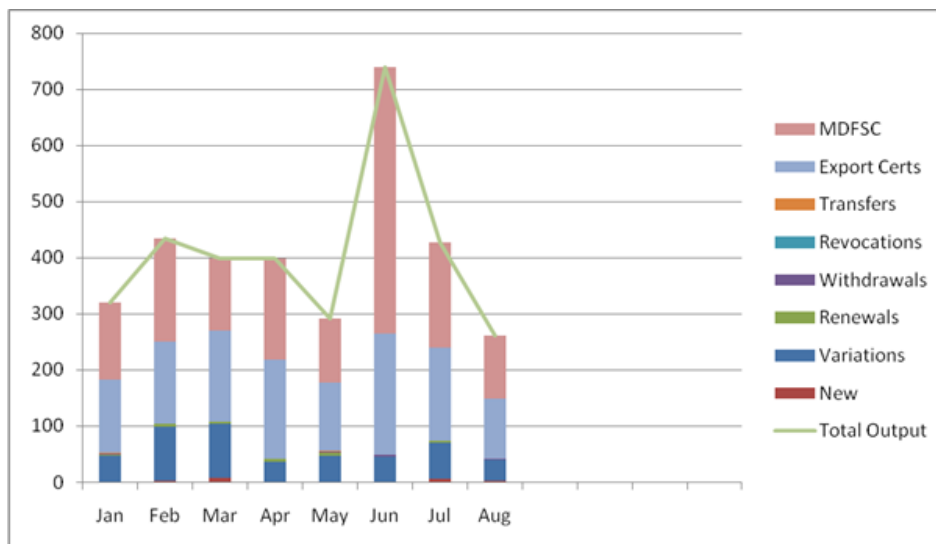
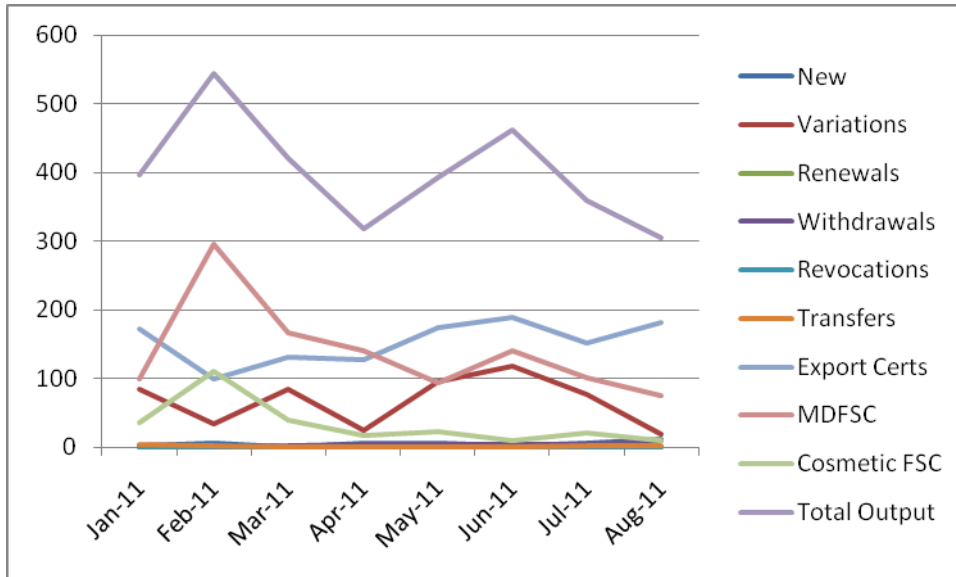
- Rapid turnaround of applications for renewals and variations for manufacturers' and wholesalers' authorisations, and for export certificates and controlled drugs licences.
- Issuing of Deficiency Summary Reports to manufacturers within 15 days of the end of inspection.
- Further development of good clinical practice and pharmacovigilance inspections.
- Full programme of good practice inspections of blood and tissue establishments.
- Continuation of programme for inspections of marketing authorisation holders.
- Continued strong focus, through good distribution practice inspections and enforcement activities, on the legitimate supply chain to prevent infiltration of counterfeit products.
- In co-operation with the Revenue Customs Service, increased level of detection and detention of illegal mail-order importations of prescription-only medicinal products. The IMB co-operated with Customs and An Garda Síochána on Operation Pangea III, an international week of action against illegal supplies of unauthorised prescription medicines via the internet.
- Direct contribution to development and finalisation of an Anti-Counterfeiting Convention by the Council of Europe. This will be open for signature during the last quarter of 2011.

The graph below shows the level of inspection activity over the period September 2010 to month-end August 2011.

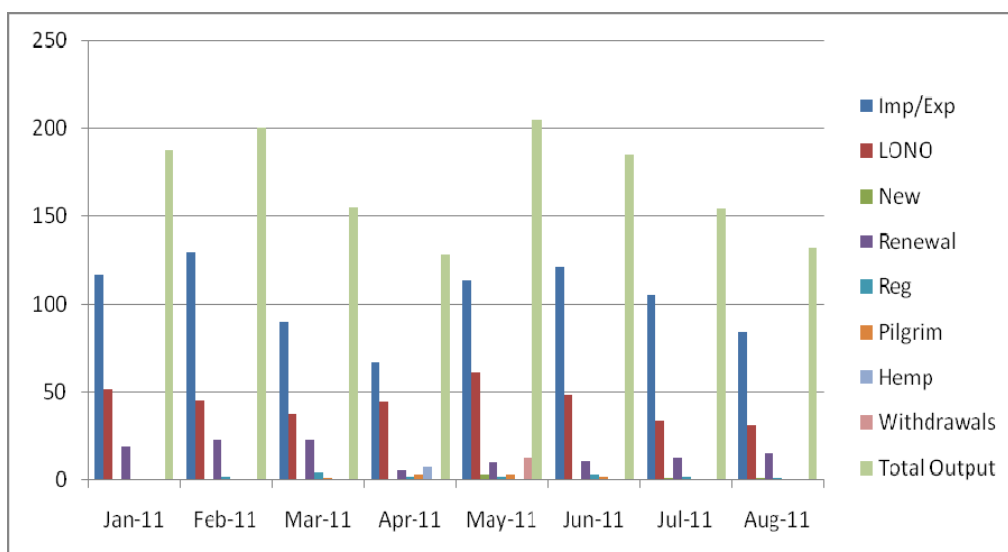


The graphs below shows the numbers issued and the percentages issued on time, for export certificates, controlled drugs licences and GDP, GMP and IMP licences, over the period January 2011 to month end August 2011.

Licences, Export Certificates and Medical Device Free Sale Certificates 2011

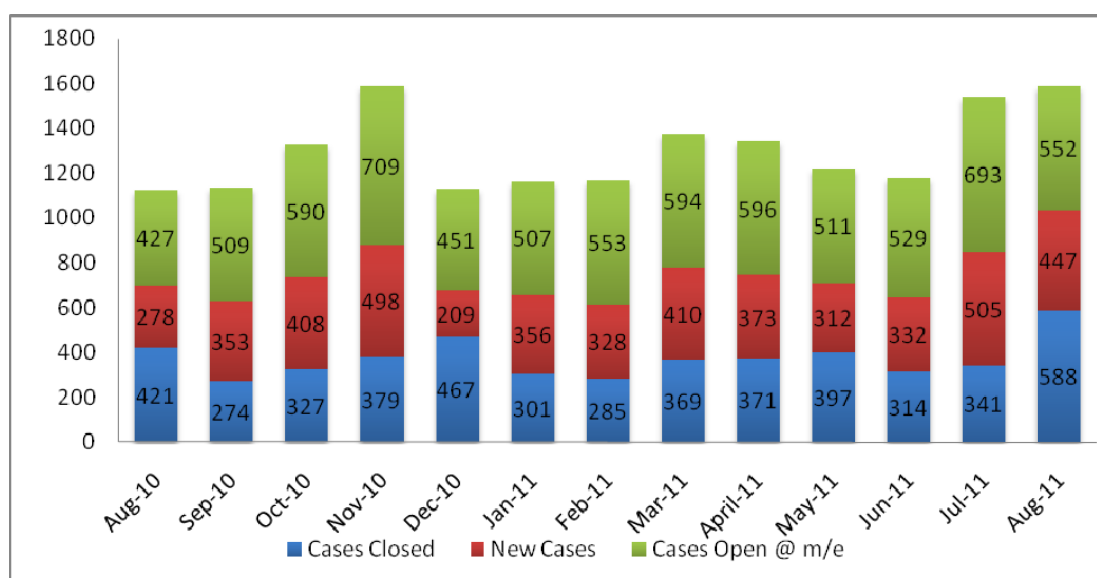


Controlled Drugs 2011



The graph below shows the number of enforcement cases opened, closed and ongoing for January - August 2011. The majority of these relate to attempts to illegally import prescription-only medicinal products, an amount of which are counterfeit.

Analysis of Enforcement Cases 2011



In 2012 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 approach to other activities.
- Greater potential for submission of applications electronically.
- Completion of population of the EudraGMP database.
- Increased focus on clear communication of requirements and expectations.

2. Blood and tissues & cells regulation

During 2010 and 2011, to date, a full inspection programme for blood establishments (i.e. involved in the collection, testing, processing, storage and distribution of blood), and for blood banks selected on a risk basis, 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. During 2010 and 2011, to date, a full programme of inspections of tissue establishments was carried out.

3. Controlled drugs

The controlled drugs licensing functions were successfully integrated into the Compliance Department in September 2005. Since that time the IMB has been responsible for management of the application and issue processes for all such licences, with the Department of Health retaining a signatory role for all official documentation.

4. Exempt medicinal products

A significant level of notifications of importation of exempt (unauthorised) products continued through 2010 and 2011, to date. The IMB's electronic system for notification was further developed during the year and we continued to work closely with the notifying companies to ensure that data were 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.

Appendix III Service levels – Medical Devices

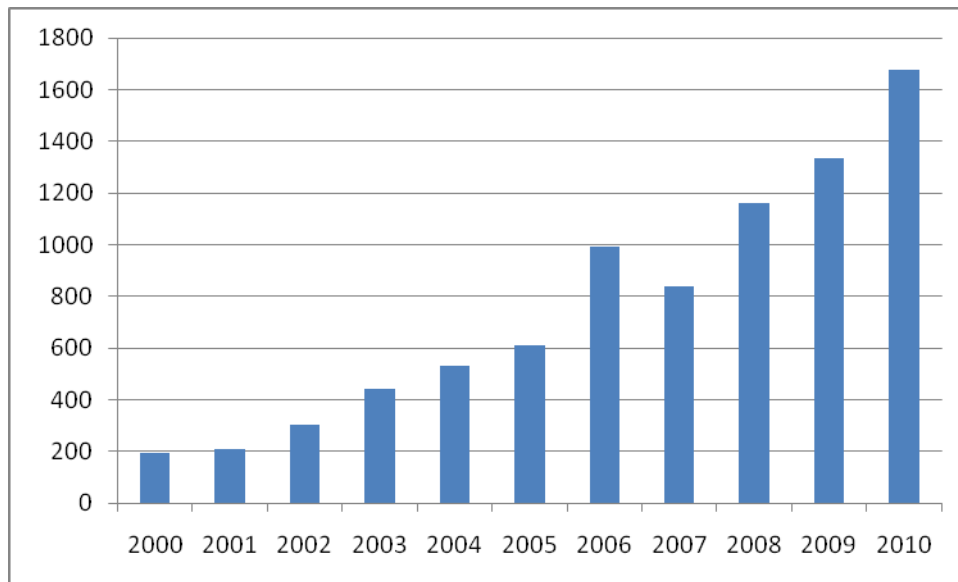
Since the IMB became the Competent Authority in Ireland for medical devices in 2001 there has been a year-on-year increase in overall activity levels. The year 2010 was another busy year for the medical devices teams within the IMB with an ongoing large caseload volume. The revision to the Medical Devices Directive came into force in March 2010 and has placed significant workload on medical device staff to ensure the new requirements are fully implemented in Ireland. In addition, significant work was undertaken during 2010, in relation to changes to the New Approach legislation, including the submission of our detailed plan for post-market surveillance to the European Commission.

Analysis of activity generally indicates a steady increase across all activities. Monitoring of critical safety issues on the Irish marketplace continued to be a key activity.

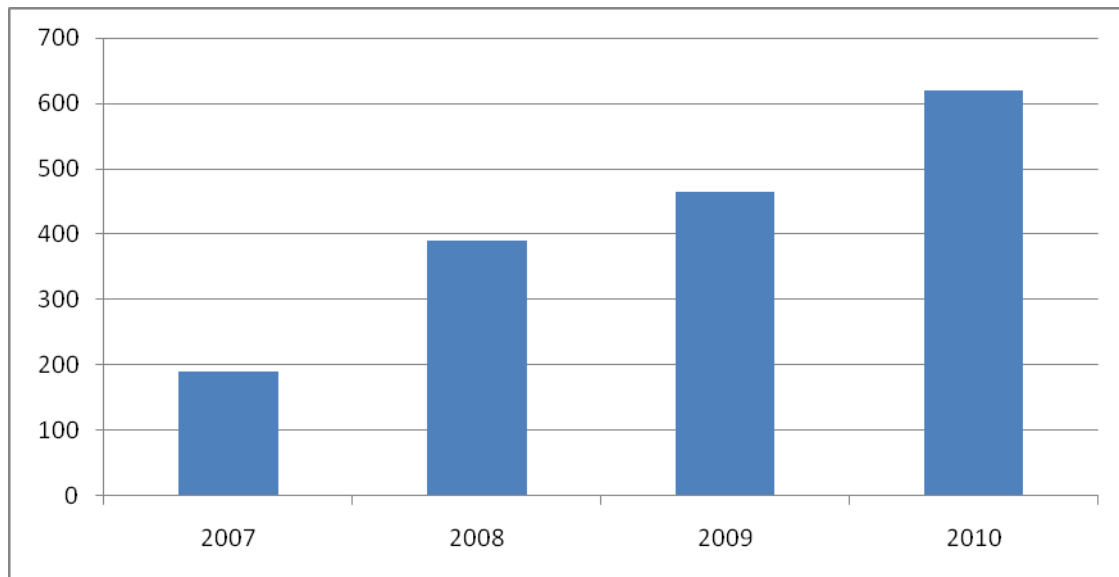
To date 2011 has continued to show an increase in the workload, with an increase in caseload and complexity seen in relation to vigilance and compliance cases. Significant activities also continued in area of audit of manufacturers and notified bodies based in Ireland. In addition, discussions and workload has greatly intensified relating to the future significant revision to the medical devices regulatory framework in Europe. It is expected that these activities will continue to increase and place additional burden on existing resources.

See charts showing increased activity levels below.

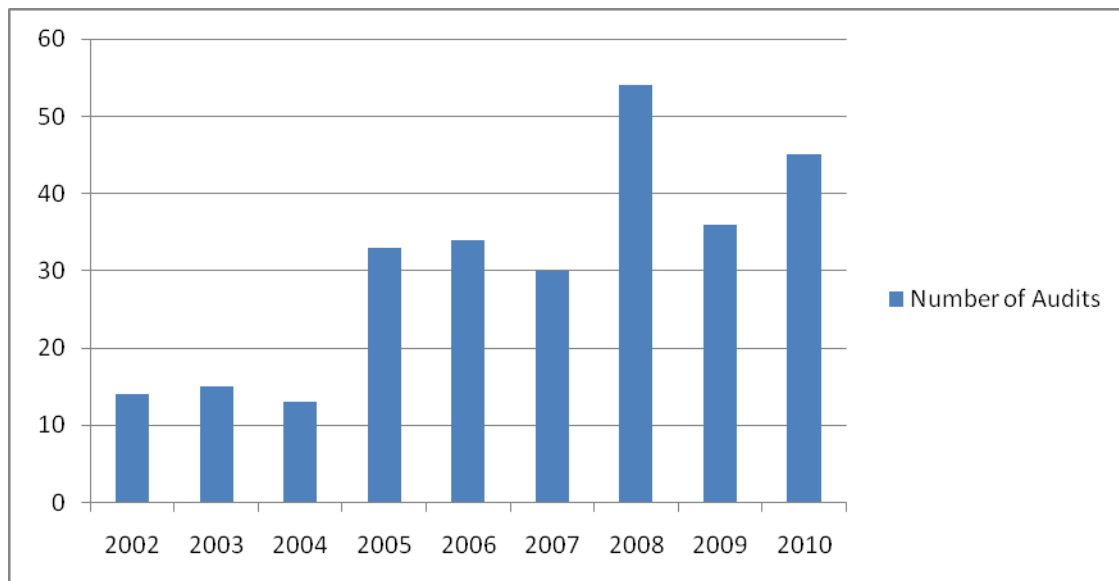
Graph 1: Number of Vigilance Reports Received (2000- 2010)



Graph 2: Number of Compliance Cases Opened (2007 to 2010)



Graph 3: Number of Medical Device Audits Conducted (2002 to 2010)



The service provided by the IMB to provide advice on classification of medical devices has increased significantly in number in 2010 when compared to 2009; the number year to date in 2011 has remained consistent with these activity levels. The IMB placed significant focus on Notified Body management updating designation scopes of Irish notified bodies in line with new European definitions during 2010. In addition, the IMB continued its participation in the European peer review programme for notified body surveillance audit by Competent Authorities in 2010 and 2011. A full plan for surveillance and observed audits on Irish notified bodies is underway and a programme of audits of class I and custom made manufacturers in addition to a series of reactive/for cause audits of medical device manufacturers based in

Ireland. In addition, a significant number of queries for advice on regulatory issues have been processed.

The Medical Devices regulatory function is funded by the Department of Health for the implementation of the medical devices legislation, with a small amount of funding being generated from fees for the following activities:

- (1) Surveillance audits and observed audits of Notified Bodies
- (2) Issuance of certificates of free sale
- (3) Registration of medical device organisations and their devices
- (4) Review of applications to conduct clinical investigations in Ireland
- (5) Review of classification queries from medical device manufacturers
- (6) For cause and reactive audits
- (7) Proactive audits depending on device type and company size

Appendix IV
Controlled drugs – schedule of changes 2012 to 2015

Process	Current fee€	Proposed fee 2012	Proposed fee 2013	Proposed fee 2014	Proposed fee 2015
Produce	191-CD 64- Precursor	€340	€489	€638	€787
Produce R & D	127	€226	€325	€424	€523
Produce Preparations	127	€226	€325	€424	€523
Possession	32- CD 64-Precursor	€57	€82	€107	€132
Supply	64	€113	€162	€211	€260
Import	64	€113	€162	€211	€260
Export	0-CD 64-Precursors	€64	€162	€211	€260
LONO	0	€33	€66	€99	€132
Hemp (Cultivation) licence ²	0	€33	€66	€99	€132
Registration	0-CD 64- Precursors	€64	€162	€211	€260

² Controlled drugs only