



IRISH MEDICINES BOARD

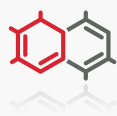


PROTECTING PUBLIC AND ANIMAL HEALTH

ANNUAL REPORT 2009



The Irish Medicines Board's
role is to **protect and enhance**
public and animal health
through the regulation
of medicines, medical devices
and healthcare products.



2
Chairman's
Statement

4
Board Members

5
Organisational
Chart

6
Chief Executive's
Report



14
Human
Products
Monitoring



25
Human Products
Authorisation
and Registration



34
Veterinary
Medicines



37
Compliance

50
Information
Technology
and Change
Management

53
Chief Executive's
Office

57
Finance and
Corporate Affairs

59
Human
Resources

62
Financial
Statements

81
Appendices



Chairman's Statement

Mr. Pat O'Mahony *Chairman*

2009 was a significant year for the Irish Medicine's Board (IMB), marked by a substantial increase in activity across all departments and an extensive involvement in the cross-agency response to the H1N1 virus. This report records the IMB's progress and achievements throughout the year which testify to our dedication to the fundamental principle of the IMB's existence, namely to safeguard public and animal health through the effective regulation of healthcare products. I would like to acknowledge and thank from the outset the management and staff of the IMB for their steadfast commitment to the highest standards of quality in all areas of what proved to be a demanding programme of work.

The H1N1 influenza vaccination programme was a significant focus for the IMB in the latter half of the year. The organisation was actively involved with its national partners, including the HSE, the Department of Health and Children and its working groups and with the relevant marketing authorisation holders, in the implementation of appropriate risk minimisation measures in relation to the programme. Following approval of the vaccines the IMB focussed on the safety monitoring of the vaccines in use. We implemented an upgrade of our website to support access and distribution of information relating to the pandemic medication. The IMB website also facilitated the reporting of adverse reactions particular to the pandemic medication by patients, carers and healthcare professionals. Over 900 reports of adverse reaction to the H1N1 vaccine were received up to the end of 2009. These reports contributed to an overall increase of 19% in the total number of adverse reaction reports received by the IMB during the year, up from 2,742 in 2008 to 3,276. Each was assessed and followed up, as appropriate, by our pharmacovigilance experts.

In 2009, the number of enforcement cases initiated by the IMB grew from 3,037 to 3,729. The vast majority of these breaches related as is to mail order importations of prescription-only products. While this year's figure represents an increase of 19% on 2008, it is significantly less than the twofold increase we saw

in 2008. We continue to co-operate closely and effectively with enforcement agencies throughout the EU and internationally and, at home, with the Garda Síochána and Revenue's Customs Service. During the year, IMB staff identified 1,009 websites seeking to supply medicinal products illegally into Ireland. All were reported to the appropriate authority, LegitScript, the US organisation that facilitates the closing of rogue websites.

We also signed an agreement with the Revenue's Customs Service which improved joint Customs and IMB information exchange practices and procedures in relation to the illicit movement of prohibited and counterfeit products through our borders and specifically at our ports, airports and international postal depots. In addition, the IMB and Revenue's Customs Service agreed to establish and operate a Joint Task Force to deal with intelligence-driven operations and to develop training and liaison exchange programmes for relevant personnel.

Our work in the area of licensing medicines and medical devices involved us in the assessment of around 18,000 applications relating to marketing authorisations for new medicines or changes to existing medicines. A total of 1,925 new human medicine applications were licensed, as well as 113 new veterinary medicines. There were 589 new medical devices also registered during the year, a twofold increase on 2008. We continue to work

Over **900** reports of adverse reaction to the H1N1 vaccine were received. These reports contributed to an overall increase of **19%** in the total number of adverse reaction reports.



closely with the European Medicines Agency (EMA) and its various working groups, and are a full and active participant in their licensing procedures. The IMB also participates in a range of other European and international groups, ensuring that we have access to the latest available information relating to the products we monitor and license in this country.

All of this work has been facilitated by the commitment and support of many. I would like to thank our Board members, our management and staff whose commitment to the IMB's remit is reflected in the significant increase in deliveries across all our areas of operation this year. I would also like to acknowledge the independent experts who gave of their time and expertise throughout the year. Through their active contribution to our many committees, the IMB has access to their considerable expertise and insights across a wide range of disciplines.

We thank the Minister for Health and Children and the Minister for Agriculture, Fisheries and Food and their staff. Their continued co-operation and support has contributed significantly to the IMB's effective operation.

2009 presented new challenges and placed increased demands on the organisation and its staff. We emerged with our position strengthened as a high-quality, efficient, service-based organisation and look forward to the year ahead dedicated to the safeguarding of public and animal health.

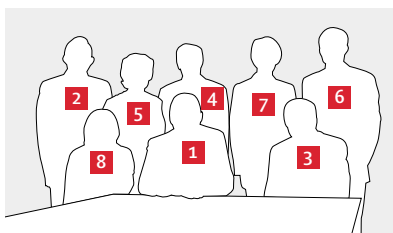
Pat O'Mahony
Chairman



IMB Board Members



The Board of the IMB was appointed on 31 December 2005 by the Minister for Health and Children, Ms. Mary Harney in accordance with the powers conferred on her by subsection 2 of section 7 of the Irish Medicines Board Act, 1995 for the period ending 31st December 2010.



The Board members are:

- 1** Mr. Pat O'Mahony (Chairman)
Business and Banking Consultant
- 2** Prof. Brendan Buckley
Clinical Professor of Pharmacology, University College Cork
- 3** Mr. Pat Brangan
Senior Veterinary Inspector, Department of Agriculture, Fisheries and Food
- 4** Mr. Wilfred Higgins
Principal Engineering Advisor, Health Service Executive
- 5** Ms. Ingrid Hook
Senior Lecturer, School of Pharmacy and Pharmaceutical Sciences, Trinity College
- 6** Mr. Brendan McLaughlin
Farmer and Elected Board Director in the Management Committee of ICOSA
- 7** Ms. Cicely Roche
Senior Lecturer TCD and Consultant Pharmacist
- 8** Ms. Maureen Windle
Practitioner in Public Sector Healthcare Management

Organisational Chart





Chief Executive's Report

Mr. Pat O'Mahony *Chief Executive*

I am pleased to report that 2009 was another successful year for the Irish Medicines Board with sustained achievement in meeting the organisation's mission to protect and enhance public and animal health through the regulation of medicines, medical devices and healthcare products. Any public health issues within our remit which emerged during the year were handled efficiently and successfully with the protection of public health at the core of all our activities.

As we strove to continuously improve efficiencies and standards across the organisation, the implementation and management of change continued to be a key driver within the IMB. In March, we combined all human medicines, medical devices and all regulated human products into a new revised departmental structure. As a result, one department is focused on post-marketing safety issues for all human products, while a second is focused on licensing and registration activities for all human products. This was a major initiative and ensures we can deal with the full range of products, including new innovative and combination products.

In early 2009, we created a stand-alone Human Resources department with the Director a member of the senior management team. This reflects our view of the central role that cutting-edge HR practices play in running an efficient and effective regulatory agency. Indeed, during the year we had to accommodate a moratorium on staffing imposed for a period by government policy and ensure that across-the-board salary reductions did not lead to any reductions in outputs or quality. I am grateful to all staff for their superb performance in these circumstances.

We also continued to develop our quality management system and had all our operations assessed by a team of three experienced assessors from other Member State authorities under the Benchmarking of European Medicines Agencies (BEMA) programme. The outcome was very positive and our systems are seen as mature and

robust. This programme is expected to continue right across the European Union countries and we anticipate the next assessment in 2012. IMB colleagues currently provide logistical and technical support to this BEMA programme and I am the co-chair of the steering committee.

We continued in 2009 to successfully manage the affairs of the IMB in line with our statutory obligation that income at least meets costs.

We are aware of the place Ireland holds as an important global location for the pharmaceutical/biopharmaceutical and medical devices industries, and that products manufactured in Ireland are exported worldwide. The successful delivery of the IMB's regulatory role in these sectors contributes greatly to this ongoing success and to ensuring that appropriate standards are maintained to the benefit of patients and consumers, both at home and abroad.

HUMAN PRODUCTS MONITORING

The Human Products Monitoring department was established in March 2009. This new department has a dedicated focus on post-marketing safety issues. 2009 was a busy and productive year for the new department. The Pharmacovigilance, Medical Device Vigilance and Safety Assessment teams all had high levels of activity in managing public health issues.

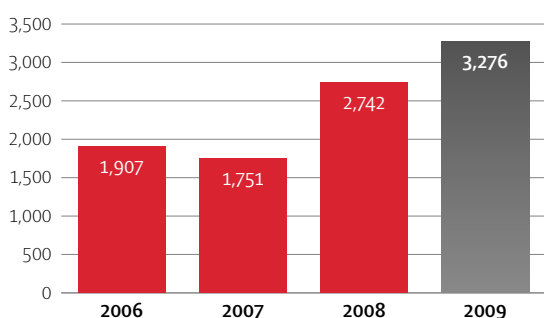
During 2009, the IMB received a total of 3,276 suspected adverse reaction reports to medicines in Ireland.

The online reporting system was increasingly used during 2009, with just over **600** reports submitted via this method.



The online reporting system, available to healthcare professionals and patients/consumers, was increasingly used during 2009, with just over 600 reports submitted by year-end via this method.

Number of adverse reaction reports 2006-2009



The outbreak of the pandemic (H1N1) 2009 influenza virus in April and the implementation of the vaccination programme resulted in the submission of an additional 900 national adverse reaction reports. The data from these reports were particularly helpful in confirming the expected safety profiles of these new vaccines, and the active participation of healthcare professionals and the public in notifying their experience was extremely useful to the monitoring process.

A significant number of variations to product approvals were initiated, assessed and issued by the Pharmacovigilance section during 2009. These followed identification of specific safety issues from adverse reaction reports, review of cumulative safety data, the literature and other sources which were discussed and evaluated at either national or European level. We continued to be actively engaged in the work of the EMA CHMP Pharmacovigilance Working Party (PhVWP) and to increase the transparency of the PhVWP activities

publication of summary PhVWP Monthly Reports after each meeting commenced in September 2009.

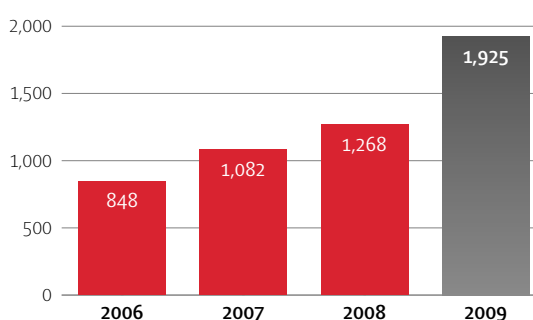
A total of 1,335 vigilance reports for medical devices were received and assessed in 2009, which represented an increase of 15% on the number of reports received in 2008. Class IIa and IIb general medical devices represented the largest number of reports received at 50%.

During 2009, the IMB received 1,033 field safety corrective action notifications relating to medical devices.

HUMAN PRODUCTS AUTHORISATION AND REGISTRATION

The total number of applications received from marketing authorisation holders in 2009 increased by 11.3% and total output increased by 4.8%. Of note were the numbers of variation applications received which were due to the coming into force of a new variations regulation on 1 January 2010.

Total new applications 2006-2009



The total output figure also increased in 2009 primarily due to an increase in the number of determinations of new national applications, new applications submitted

During 2009, **108** applications to conduct clinical trials were approved by the IMB.

Chief Executive's Report

through the centralised and decentralised procedures and new Parallel Import Applications (PPA).

During the year, there was an output of 16,010 variations to marketing authorisations for products authorised through the national or Mutual Recognition (MR) procedures.

During 2009, 108 applications to conduct clinical trials were approved by the IMB. No applications were rejected.

Regulation (EC) 1394/2007 on Advanced Therapy Medicinal Products (ATMPs) came into effect in 2009. This Regulation provides for the authorisation of gene therapy, stem cell therapy and tissue engineered products. The Regulation also resulted in the establishment of a new scientific committee at the EMA, the Committee for Advanced Therapies (CAT).

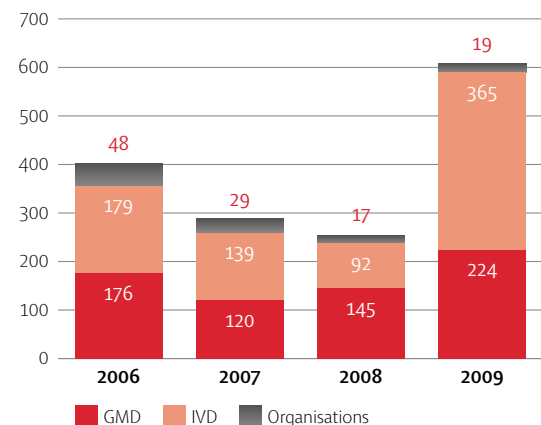
In 2009, the IMB carried out significant preparations in advance of the new 'Variations Regulation' (Commission Regulation 1234/2008) coming into force on 1 January 2010. The new Regulation applies to both the human and veterinary medicinal products authorised through the centralised and MRP/DCP routes. The aim of the regulation is to introduce a simpler, clearer and more flexible framework on variations.

Significant work took place in 2009 in order to facilitate the move from paper to electronic submission of applications. From November, the IMB commenced receiving electronic submissions. It is envisaged that all submissions will be electronic by 2012.

During 2009, four clinical investigation applications for general medical devices were received along with two significant amendments to previously authorised clinical investigations.

There were 589 new notifications to the register for medical devices in 2009. A total of 365 in-vitro diagnostic medical devices and 224 general medical devices were registered. The number of new organisations registered was 19.

Medical Device Registration statistics 2006-2009



During 2009, 464 compliance cases for medical devices were opened, which represented an increase of 22% on the figure for 2008. Class IIa general medical devices represented the largest number of compliance cases with single use medical device representing the most common type of case.

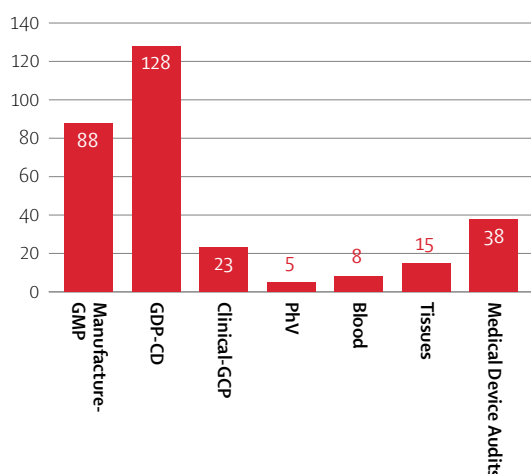
COMPLIANCE

The Compliance department continued to carry out good manufacturing practice (GMP) inspections on the very substantial number of manufacturing sites operating in Ireland. It also contributed significantly to inspections of foreign sites on our own behalf or on behalf of the European Union. Good distribution practice inspections were conducted on the supply chain while tissues and

A total of **3,729** cases involving breaches of medicinal product legislation were initiated, representing an almost 20% increase from 2008.

cells and blood establishment sites were also inspected. Licensing and export certification activities relating to Irish sites were carried out as were good clinical practice (GCP) and pharmacovigilance inspections.

Number of inspections completed in 2009



During 2009, a total of 3,729 cases involving breaches of medicinal product legislation were initiated, representing an almost 20% increase from 2008. A total of 494,502 tablets or capsules were detained, an increase of 39% over 2008. In addition, 1,650 packs of liquids, 449 packs of creams and 3,582 packs of assorted products were detained. Market surveillance programmes, encompassing investigation of quality defects and recalls, and sampling and analysis, were operated. A total of 495 medicinal products were sampled for analytical testing and /or checks on labelling and packaging compliance.

Ninety-nine recalls of medicinal products were requested and overseen by the IMB. This represents a decrease of 30% on 2008 figures. Ninety-one of those related to human medicinal products, while eight related to veterinary products.

VETERINARY MEDICINES

Animal health and welfare is of critical importance to the Irish economy and its reputation for producing quality produce. The food industry is a very important sector in the Irish economy with exports of €7.12 billion recorded in 2009. The regulation of veterinary medicines plays a significant part in assisting the prevention and treatment of disease, in enhancing animal welfare and in ensuring the safety of foods of animal origin.

A record number of 2042 applications for authorisation of veterinary medicinal products were approved by the IMB in 2009. We played a leading role as reference member state/rapporteur in the centralised, mutual recognition and decentralised procedures, acting as reference member state for 24 outgoing applications for decentralised or mutual recognition procedures.

Any pharmacovigilance and public health issues relating to veterinary medicines arising during the year were handled efficiently and effectively. There were 148 reports of suspected adverse reactions associated with the use of veterinary medicinal products received in 2009. Department staff undertook the first inspections of veterinary pharmacovigilance procedures in companies during the year with two marketing authorisation holder facilities being inspected. An IMB representative also participated in a veterinary pharmacovigilance inspection of a marketing authorisation holder facility in the UK as part of the EMA's programme of inspections for centrally-authorised veterinary medicinal products.

CHIEF EXECUTIVE'S OFFICE

The Chief Executive's Office expanded its functions during 2009. Alongside its core work maintaining the quality management system for the organisation,

A new communications function was established within the Chief Executive's Office in November, with the appointment of a Communications and Information Manager.

Chief Executive's Report

it took over management of the website content and updates in March, and the co-ordination of responses to parliamentary questions in April. A new communications function was established within the Office in November, with the appointment of a Communications and Information Manager. The primary role of this new position is the establishment, development and promotion of a new communications, information and education function and a co-ordinated, professional and consistent approach to communications with all stakeholders.

The Office was involved in business continuity planning for the influenza pandemic, ensuring that plans were current and appropriate to the expected impact on operations and that guidance was issued to staff. While the workload of a number of departments increased significantly due to licensing, pharmacovigilance and market compliance issues relating to the supply of vaccines, the overall effect on operations was well-managed and the expected level of outputs was maintained.

During 2009, a substantial increase in the implementation of the quality system was achieved. At the end of the year, 74% of the total expected implementation was in place, up from 49% at the end of 2008.

The IMB provides advice to stakeholders as to whether products should be categorised as medicinal products or medical devices, thereby falling under the remit of IMB, or whether they are outside the scope of our remit. The IMB Classification Committee (human medicines) met 10 times in 2009 and considered a total of 131 new products.

FINANCE AND CORPORATE AFFAIRS

As outlined in the financial statements, the IMB's finances remained stable. The accounts section continued to successfully manage the high volumes of work while maintaining high standards of internal control. The internal financial audit function conducted reviews of systems and reported directly to the Audit Subcommittee of the Board, in compliance with good corporate governance requirements. A detailed review of the IMB's fee structure took place during the year.

2009 was a busy year for corporate services as the increases in operations and staff outlined in all the other departments increased the level of services provided.

Eighteen requests were received under the Freedom of Information Act in 2009, compared to twenty one in 2008. Eleven requests were fully granted, six refused and one withdrawn.

2009 continued to be a busy year in the buildings area in relation to ongoing maintenance of the IMB offices. A number of significant internal buildings projects were undertaken to maximise space utilisation and workflow efficiency.

INFORMATION TECHNOLOGY AND CHANGE MANAGEMENT

The IT and Change Management Department delivers specialist business analysis, information technology and telecommunications services throughout the organisation.

We have a well-established change management programme since 2003, with a strong focus on continuous improvement. In March 2009, following a comprehensive review project, a new organisational structure was implemented to support the management of safety and licensing activities for all human products.

In 2009, the IMB website www.imb.ie received a substantially higher volume of visitors than any other year.



The organisational commitment to continuous improvement was further strengthened by the adoption of 'Lean Six Sigma' methodology, when in the second half of 2009, the organisation initiated its first 'Lean' project in response to the introduction of new legislation relating to medicinal product licensing.

During 2009, the IMB was influential in all aspects of the EU Telematics Programme. In mid-2009 the EMA Management Board Telematics Committee was established and the IMB is represented on this group.

In 2009, the IMB website www.imb.ie received a substantially higher volume of visitors than any other year. A large part of the activity can be attributed to the publication of H1N1 pandemic-related information on the website and the facility to report adverse reactions associated with the vaccination programme. The IMB now routinely publishes all safety notices via the IMB website, with the facility for notification to registered users via e-mail or SMS.

Extranet services continue to play a large part in delivering services to stakeholders. The online tracking and application system (RIO) remains a key system for the pharmaceutical industry.

Technology to assist in compliance-related activities was further developed in 2009. New applications to provide improved planning and management of inspection-related functions were at an advanced stage by the end of the year. Further developments to support market surveillance, controlled drugs and good distribution practice activities are also underway. Support was also provided, in advance of the proposed merger, to the Office of Tobacco Control.

A project to scan legacy documentation was commenced in late 2009. This initiative resulted in the transfer of over two million pages to the IMB systems.

HUMAN RESOURCES

Real effective management of performance is vital to the running of the IMB and we have in place a robust system which we title the Performance Development Programme (PDP). Activities in 2009 led by HR colleagues included a redesign of the PDP framework for roll-out and implementation in early 2010; support to line managers in probation management; and delivery of training and coaching supports to staff as a result of the creation of the new departments of Human Products Authorisation and Registration and Human Products Monitoring.

We made substantial progress in the area of Learning and Development. A comprehensive review was conducted, with the purpose of developing a strategy to ensure staff are effectively trained and developed to meet both current and future needs. This process was further supported by the appointment of a Learning and Development Manager at the end of 2009. The average number of training days per person in 2009 was just over 3, continuing the trend set in 2008. There was strong focus on Dignity and Respect training, with a total of 21 sessions delivered.

2009 continued to reflect a stable industrial relation climate within the IMB. The staff communications group met regularly and each meeting was attended by a HR representative. Health and Safety and wellness initiatives during 2009 included eye tests, provision of seasonal flu vaccine, a walking challenge and a series of lunchtime learning sessions. The uptake on all initiatives was positive.

The IMB continued to enhance its communication with various stakeholder groups with an interest in healthcare products.

Chief Executive's Report

THE EUROPEAN REGULATORY SYSTEM AND INTERNATIONAL AFFAIRS

In 2009, the IMB continued to participate actively in the European Medicines regulatory system through its involvement in EU committees and working parties. We continued to contribute at EMA level and I continued in the role of chairman of the Management Board of EMA. The IMB also continued to contribute very actively at the Heads of Medicines Agencies (HMA) level, providing part of the Permanent Secretariat to the HMA as well as co-chair and technical support to the process of quality improvement of the European network known as BEMA. We were also engaged in the assessment of centralised applications for human and veterinary medicinal products as rapporteur and as reference member state in the mutual recognition and decentralised procedures. The IMB continued to meet all timelines in all these procedures in 2009.

This was another active year in the European medical devices regulatory system with the IMB participating in a large number of meetings at EU level, including the Medical Devices Expert Group and the Classification and Borderline Working Group.

The IMB also continued to represent Ireland at the European Pharmacopoeia, where Dr. Mike Morris, Senior Scientific Advisor, continued to contribute at the highest level. During 2009, Dr. Morris delivered on a range of significant technical projects for the IMB.

Information technology continues to be an important topic on the EU agenda as it works to facilitate better access for patients to information on medicines and swift, accurate and efficient sharing of relevant information between regulatory authorities throughout Europe. During 2009, the IMB's Information Technology department was actively involved in EU IT implementation activities.

The IMB attended the fourth international summit of heads of medicines regulatory bodies which followed on from our successful hosting of this summit in 2007. We will participate in the organising committee for the 2010 meeting which will be hosted in the United Kingdom.

COMMUNICATIONS

In 2009, the IMB continued to enhance its communication with various stakeholder groups with an interest in healthcare products. A number of information meetings were held, these meetings attracted a large number of attendees and positive feedback was received. We also prepared for our participation, for the first time, as an exhibitor at the BT Young Scientist exhibition.

A number of meetings with other organisations and individuals with particular interests in healthcare products were also hosted during the year. These included meetings with:

- The Animal and Plant Health Association (APHA)
- The Association of Pharmaceutical Manufacturers of Ireland (APMI)
- The Irish Association of Health Stores (IAHS)
- The Irish Health Trade Association (IHTA)
- The Irish Medical Devices Association (IMDA)
- The National Standards Authority of Ireland
- The Irish Pharmaceutical Healthcare Association (IPHA)
- Pharmacemical Ireland
- The Pharmaceutical Distributors Federation.

PUBLICATIONS

During 2009, the IMB launched a number of valuable guidance documents as part of its communications efforts, all of which are available from our website (www.imb.ie).

We will continue to offer training and development opportunities so that we can maintain and enhance the skills set required.

A number of editions of the IMB's Medicinal Products Newsletter, Medical Devices Newsletter and Drug Safety Newsletter were published and are available on this website.

THE FUTURE

The IMB faces new challenges and new opportunities for development in 2010 and beyond. The economic downturn is a challenge for all sectors and organisations. Strict controls on public sector recruitment will pose substantial challenges to ensuring we can deliver on our public health remit and services to industry.

The overall workload for the organisation continues to increase and diversify. Meeting this demand in the most efficient and effective manner will require that we carefully scrutinise all aspects of our organisation to ensure we are working in the most optimal way. A risk-based approach will be applied and we will actively participate in various work-sharing initiatives at the European level. Our objective will be to maintain the impetus for change across the organisation and continue to manage change to assist us in delivering ever higher standards of output and outcomes to all stakeholders. In this regard, continuing to develop our performance management, quality management and IT systems will be a priority.

We are aware of the European Commission report from Ernst and Young on the operation of the European medicines regulatory system and also of proposals for revision of the European fees regulations. These matters will be considered as we prepare our next strategic plan, which will coincide with the next EMA and HMA strategy papers. A new IT strategy will also be developed in 2010.

Our staff's expertise and experience are key assets to our organisation. We will continue to offer training and

development opportunities so that we can maintain and enhance the skills set required for the ever-changing and increasingly complex areas under our remit.

We will continue to review our funding provision and to look critically at our own cost base to ensure maximum use of resources.

BOARD AND STAFF MATTERS

In total, over 100 people contribute voluntarily to the work of the IMB through participation on the Board and various Committees. The Board and Committees had a very successful year in office and the access we have to this range of independent expertise and acumen is of immense value to the workings of our organisation. I thank each member for their individual contribution and commitment during 2009.

I acknowledge the support of the Ministers and staff of the Departments of Health and Children, and Agriculture, Fisheries and Food for the work of the IMB.

I welcome all new staff members who joined during 2009 and express my personal appreciation to all the staff of the IMB for their continued generous support in achieving the Board's objectives during the year. I look forward to the support of all staff in dealing effectively with the various challenges ahead as we continue to strive for excellence in all aspects of our daily activities.



Pat O'Mahony
Chief Executive



Human Products Monitoring



Dr. Joan Gilvarry Director of Human Products Monitoring

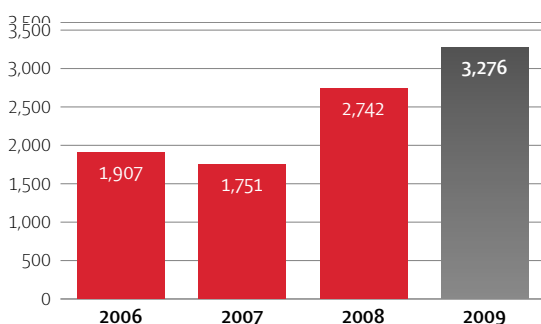


The Human Products Monitoring department was established in March 2009. This new department has a dedicated focus on safety issues relating to medicines and medical devices. Monitoring the safety of these healthcare products in the marketplace is the key day-to-day activity of the staff of the department. 2009 was a busy and productive year, with the pharmacovigilance, medical device vigilance and safety assessment teams all having high levels of activity in managing public health issues.

PHARMACOVIGILANCE

During 2009, the IMB received a total of 3,276 suspected adverse reaction reports occurring in Ireland from healthcare professionals, pharmaceutical companies and patients. The IMB greatly appreciates the contribution of busy healthcare professionals in reporting suspected adverse reactions, facilitating the continued surveillance of the safety of medicines and, in particular, the prompt reporting of experience with use of the pandemic vaccines during 2009. While the time-consuming nature of form-filling and the provision of follow-up information to the IMB is recognised, the collection and evaluation of comprehensive reports are essential to ensure that appropriately detailed case information is available for the continuous surveillance of the safety of medicines on the Irish market. Such reports allow the IMB to make proposals and take regulatory action on the basis of all available data, including information obtained from spontaneous reporting.

Number of adverse reaction reports 2006–2009



The online reporting system available to healthcare professionals and patients/consumers was increasingly used during 2009, with just over 600 reports submitted by year-end via this method. Access to the online reporting system is through the IMB website at www.imb.ie.

A primary objective of the IMB pharmacovigilance system is to provide information on new and emerging safety issues related to medicines in a timely fashion, aided by its website which includes e-mail alerting facilities. Users of the IMB website have the option of registering their contact information with the IMB to enable them to receive direct and immediate notification of safety and regulatory alerts and updates by e-mail or text message. To facilitate prompt access to these updates, users are encouraged to avail of this option by registering at www.imb.ie.

The IMB continued to encourage adverse reaction reporting and provided regular reminders about reporting in the Drug Safety Newsletter and its regular publications in MIMS (Ireland) and the Irish Medicines Formulary (IMF). A number of presentations on pharmacovigilance and adverse reaction reporting were made to healthcare professionals as part of under/post-graduate training, as well as continuing education programmes. While pharmacovigilance uses many sources of data, the need for detailed and comprehensive spontaneous reports remains pivotal for signal detection. The IMB is committed to using these data to promote the safe use

During 2009, the IMB received a total of **3,276** suspected adverse reaction reports occurring in Ireland.

of medicines, manage risk judiciously and communicate safety information in a timely manner.

Breakdown of Reports by Source

Marketing authorisation holders	1,495
General practitioners	452
Community nurses	328
Community care doctors	281
Hospital doctors	155
Hospital nurses	150
Hospital pharmacists	134
Patient/consumers	108
Community pharmacists	81
Clinical trials	52
Healthcare professionals (other)	40
Total	3,276

Individual case reports were followed up by the IMB, with feedback information provided to reporters, as appropriate. Relevant reports (i.e. serious, suspected cases) notified directly to the IMB by healthcare professionals were forwarded to the appropriate marketing authorisation holders (MAHs) and the EMA within the agreed timeframes and formats. The IMB also continued to provide details of reports received to the World Health Organization (WHO) for inclusion on their international database.

PANDEMIC MONITORING EXPERIENCE

The IMB engaged in active and close co-operation with national partners, including the HSE and relevant marketing authorisation holders, to implement

appropriate risk minimisation measures, to promote prompt reporting of suspected adverse reactions and adverse events of special interest, and to ensure active surveillance of medicines effective against pandemic (H1N1) influenza. In addition, the IMB contributed to monitoring and surveillance activities at EU level.

This enhanced surveillance, together with the extent of exposure to the vaccines, resulted in the submission of an unprecedented number of national adverse reaction reports, with over 900 cases received up to the end of 2009. These data were particularly helpful in confirming the expected safety profiles of these new vaccines and the active participation of healthcare professionals and the public in notifying their experience was extremely useful to the monitoring process. The commitment and dedication of the pharmacovigilance team who worked tirelessly to review and process cases and ensure real-time evaluation, with prompt provision to external partners, also contributed greatly to the process. So too did the internal IMB arrangement for the allocation of a staff member from the Human Products Authorisation and Registration department to provide dedicated, additional support. The IMB also actively participated in the relevant EU & WHO initiatives.

DRUGS WITHDRAWN/SUSPENDED FOR SAFETY REASONS

Raptiva (efalizumab)

The IMB suspended the marketing and use of Raptiva in Ireland on 19 February 2009 following a recommendation from the EMA on the same date. This national action was taken following review of the product by the EMA's CHMP. It concluded that the benefits of Raptiva no longer outweighed its risks and that the marketing authorisation

A total of **2,409** periodic safety update reports (PSURs) were processed during 2009.

Human Products Monitoring



should be suspended across the EU. This followed reports of serious adverse reactions, including three confirmed cases of progressive multifocal leukoencephalopathy in patients who had taken Raptiva for more than three years.

Information regarding the suspension and use of Raptiva in Ireland was distributed by letter/fax/e-mail networks to healthcare professionals. The information was also highlighted on the IMB and professional body websites, advising of the action taken and requesting that no further prescriptions be written or dispensed.

SAFETY VARIATIONS

A significant number of variations were initiated, assessed and issued by the pharmacovigilance section during 2009. These followed identification of specific safety issues from adverse reaction reports, review of cumulative safety data, the literature and other sources, which were discussed and evaluated at either national or European level. During 2009, these included variations related to the following products.

- Non-selective alpha-blockers and phosphodiesterase-5-inhibitors: hypotensive effects
- Systemic corticosteroids: risk of early psychiatric side effects
- Antipsychotics: risk of venous thromboembolism (VTE)
- Antipsychotics conventional (typical): small increased risk of mortality in elderly people with dementia
- HMG-CoA reductase inhibitors (statins): addition of warnings related to:
 - Sleep disturbances, including insomnia and nightmares
 - Memory loss

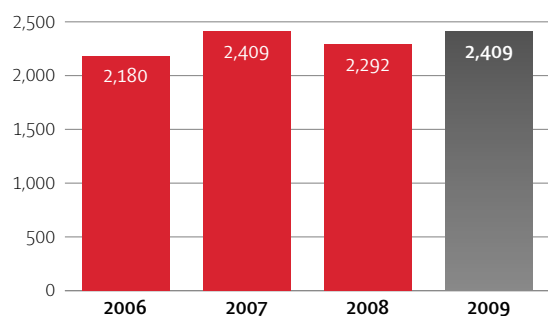
- Sexual dysfunction
- Depression
- Exceptional cases of interstitial lung disease, especially with long term therapy
- Phenytoin-induced Steven-Johnson Syndrome in subjects of Thai/Chinese ethnicity and association with HLA-B*1502
- Short-acting beta agonists: possible risk of myocardial ischaemia.

PERIODIC SAFETY UPDATE REPORTS

A total of 2,409 periodic safety update reports (PSURs) were processed during 2009. This included reports on products authorised through the national, mutual-recognition, decentralised and centralised procedures.

The IMB continued to contribute to the EU PSUR Worksharing project, which aims to support increased performance for PSURs and to ensure a comprehensive and consistent safety evaluation of the active substances under the scheme. The IMB also continued to participate in the Joint PhVWP/CMDh/HMA PSUR Worksharing Working Group.

Number of periodic safety update reports processed 2006–2009



By the end of 2009, **190** companies were in production with electronic reporting to the IMB.

COMPANY LIAISON

Advice on IMB pharmacovigilance reporting requirements was provided to MAHs on request throughout the year. Anonymised cumulative adverse reaction data were provided to them in respect of their products on request and in the case of individual serious suspected adverse reactions associated with use of their products, on an expedited basis.

Company/sponsor compliance with pharmacovigilance obligations was monitored on an ongoing basis.

This was achieved through review and monitoring of the timeliness and quality of individual adverse reaction reports, evaluation of the follow-up information provided for individual reports, assessment of the quality and comprehensiveness of PSURs/ASRs (annual safety reports) and responses to IMB requests for pharmacovigilance data. The pharmacovigilance inspection programme continued in 2009, involving collaboration between IMB pharmacovigilance and compliance colleagues.

ELECTRONIC REPORTING

The IMB continued to report all suspected serious adverse reactions occurring in Ireland electronically via EudraVigilance to the EMA and to those companies with whom satisfactory testing has been completed. By the end of 2009, 190 companies were in production with electronic reporting to the IMB.

Detailed information and guidance on electronic reporting is available from the IMB's 'Guide to Electronic Submission of ICSRs and SUSARs Associated with Use of Human Medicines', which can be located under the heading 'Publications' on the website. Feedback was also provided to participating companies on an ongoing basis, and updates and items of current interest in relation to

electronic reporting were included in the quarterly IMB newsletter for industry.

IMB staff participated at EudraVigilance meetings and training courses organised by the EMA and DIA throughout the year.

A new adverse reactions database is currently being implemented to facilitate enhanced pharmacovigilance activities, with significant additional functionalities to support safety monitoring and data management activities.

INTERNATIONAL COLLABORATION

CHMP Pharmacovigilance Working Party

There were a total of 11 meetings of the CHMP's Pharmacovigilance Working Party (PhVWP) during 2009. During these meetings, the PhVWP evaluated potential signals and ongoing safety concerns. It also provided advice to the CHMP and Member States on confirmation and quantification of risk and on regulatory options, as well as on risk management and monitoring of the impact of regulatory action. In addition, the PhVWP worked on setting standards for procedures and methodologies to promote good vigilance practice, communication and exchange of information and international co-operation.

In order to increase the transparency of the PhVWP activities, publication of summary PhVWP monthly reports after each meeting commenced as of September 2009. This initiative was agreed with the HMA.

The PhVWP continued its regular interaction with the U.S. FDA through tele/videoconferences held during PhVWP meetings.

Information was provided by the IMB pharmacovigilance section in respect of all requests circulated via the rapid

As part of its strategy to strengthen and rationalise EU pharmacovigilance, the European Commission has prepared revised proposals to amend the existing legislation.

Human Products Monitoring



alert/non-urgent information exchange system by other Member States.

The EMA engaged in close co-operation with European and international partners, in ensuring the availability and surveillance of medicines effective against pandemic (H1N1) influenza during 2009 and the PhVWP supported the activities undertaken by the EMA in this respect. In particular, the PhVWP contributed to the EMA's newly established Pandemic Pharmacovigilance Rapid Response Group which provided advice on emerging safety concerns with H1N1 influenza vaccines and antiviral medicines. The IMB actively contributed to these activities and updates on experience with monitoring were made available via the EMA's website www.ema.europa.eu.

European Commission

As part of its strategy to strengthen and rationalise EU pharmacovigilance, the European Commission has prepared revised proposals to amend the existing legislation ('Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency' and 'Directive 2001/83/EC on the Community code relating to medicinal products for human use').

Since April 2009, the IMB has participated at monthly meetings of the Working Party on Pharmaceuticals and Medical Devices in Brussels, together with representatives of the Department of Health and Children. The first reading of the new legislation by the EU Parliament is expected in early 2010 and it is anticipated that the ordinary legislative procedure will take approximately two years.

WHO

IMB staff participated at the annual meeting of national centres participating in the WHO international drug monitoring programme in November 2009. Professor Ralph Edwards retired from his post as director of the Uppsala Monitoring Centre in September 2009 after 19 years in the post. During this time, he initiated and implemented extensive change in the methodology for signalling and evaluation of adverse reaction data. He also contributed to many significant international initiatives in the development of pharmacovigilance guidance and standards, while always striving to enhance global patient safety and promote effective pharmacovigilance communication.

Dr. Marie Lindquist, who has worked for the organisation since 1979, was appointed as the new UMC director in 2009, having previously held the post of deputy director and general manager. Dr. Lindquist has a distinguished career in pharmacovigilance and patient safety, and has played a central role in developing the functionality of the UMC activities and contributing to its reputation. The IMB welcomes this appointment and looks forward to its ongoing co-operation with her in the coming years and the continuing development of the UMC under her leadership in its important global role as the WHO Collaborating Centre for International Drug Monitoring.

PUBLICATIONS

As part of its commitment to ensuring access to information to support safe use of medicines, the IMB also issued a range of publications to communicate important safety information to stakeholders.

Six issues of the IMB's Drug Safety Newsletter were distributed to doctors, dentists and pharmacists during

The IMB published weekly updates on the safety monitoring experience with the H1N1 vaccines nationally on its website.



2009 and published on the IMB website. A wide range of safety issues were communicated in the newsletter, as well as two special editions on antiviral medicines and pandemic vaccines, in the context of the H1N1 pandemic. An overview of the topics covered is provided below:

February 2009 (29th Edition)

- Prograf and Advagraf (tacrolimus): risk of serious medication errors;
- Ezetimibe (Ezetrol/Inegy): update on review of studies on possible increased risk of cancer;
- Inhaled anticholinergics: review of publication concerning risk of death or stroke;
- Ibuprofen and low dose aspirin: interaction potential
- Antiepileptic medicines: risk of suicidal thoughts and behaviour

April 2009 (30th Edition)

- NSAIDs: new data on cardiovascular risk from epidemiological studies;
- Tibolone: update on breast cancer risk (Liberate Trial)
- Bisphosphonates: atrial fibrillation;
- Gadolinium containing contrast agents: update on risk of NSF;
- Antipsychotic medicines: risk of stroke and increased mortality;
- Piperacillin/tazobactam: compatibility issues

July 2009 (31st Edition)

- Clopidogrel and proton pump inhibitors: interaction potential;
- Alli (orlistat): recommendations for safe over-the-counter use;
- ACE inhibitors and Angiotensin II receptor antagonists: use during pregnancy and breastfeeding;
- Aliskiren (Rasilez): recommendations for safe use;
- Erlotinib: update on experience with use and

information on gastrointestinal, ocular and skin disorders

July 2009 (32nd Edition)

- Carbapenems: interaction with sodium valproate
- Bisphosphonates: risk of stress fractures;
- Mycophenolate mofetil: pure red cell aplasia;
- Exenatide (Byetta): risk of pancreatitis and warnings regarding use in renal impairment;
- Amphotericin: recommendations for safe prescription, dispensing and administration;
- Non-selective alpha-blockers and phosphodiesterase-5-inhibitors: additional hypotensive effects following co-administration

Sept 2009 (33rd Edition) (Special Edition)

- Oseltamivir (Tamiflu) and zanamivir (Relenza) for pandemic H1N1 (2009)

Oct 2009 (34th Edition) (Special Edition)

- Pandemic H1N1 Vaccines

The following publications are accessible via the IMB website (www.imb.ie)

- Copies of Drug Safety Newsletters
- Direct healthcare professional communications (DHPC)
- Updates on safety issues/benefit/risk evaluations published in the IMB's regular columns in MIMS (Ireland) and the Irish Medicines Formulary (IMF)
- Warning statements and notices on safety issues or benefit/risk evaluations

The IMB published weekly updates on the safety monitoring experience with the H1N1 vaccines nationally on its website from the start of the national vaccination programme up to the end of 2009.

A total of **1,335** vigilance reports were received and assessed in 2009, which represented an increase of **15%**.

Human Products Monitoring



The IMB also communicates directly with stakeholders, through the provision of information in response to requests. In addition, it participated at various meetings aimed at facilitating continued co-operation and collaboration with healthcare professionals, the pharmaceutical industry and others.

HAEMOVIGILANCE

The IMB continued its regular meetings with the National Haemovigilance Office (NHO) to review haemovigilance events reported, discuss issues of mutual concern and contribute to the development of guidance on haemovigilance reporting. The meetings also considered further developments to facilitate monitoring and revised working practices necessary to meet the provisions of the EU and national legislation.

The EU Commission continued to progress harmonisation initiatives to develop a common approach to the provision of data by Member States through a Working Group on Haemovigilance first convened during 2007. The IMB and NHO continued to actively participate in this group and to the development of current guidance on reporting.

The IMB also presented on 'Rapid Alerts in Tissues and Cells – Learning From Experience' at the annual European Haemovigilance Network conference held in February 2009.

In line with the legislative requirements and following collaboration with the NHO, the IMB submitted an annual report on serious adverse reactions and events to the European Commission during 2009. The report reflected information received from January to December 2008 and included information on 141 serious adverse reactions and 55 serious adverse events. This reflects an increase in reporting from the previous year in which 107

serious adverse reactions and 32 serious adverse events were reported.

TISSUES AND CELLS VIGILANCE

The IMB attended and participated at relevant vigilance and surveillance meetings during 2009 to facilitate monitoring and revised working practices necessary to meet the provisions of the relevant EU and national legislation. The joint WHO/EU project for Standards and Training for the Inspection of Tissue Establishments (EUSTITE) was concluded. As part of this project, the IMB participated in a vigilance and surveillance pilot with partner countries to test the proposed tools and guidance.

Further vigilance developments were planned during 2009, including a three-year project co-funded by the EU Public Health group on Substances of Human Origin Vigilance and Surveillance (SoHOV&S). The IMB will participate as a partner in the various working groups and will act as the lead partner for one work package organising training courses, including e-learning modules, on investigation and management of vigilance and surveillance for tissues and cells.

The European Commission continued to progress harmonisation initiatives to develop a common approach to the provision of data by Member States through a Working Group on Tissues and Cells Vigilance. During 2009 the IMB attended a meeting of this group and has actively participated in the development of guidance for reporting, which incorporated use of the tools proposed by the EUSTITE project. Further updates to this guidance are expected as experience with its use develops.

In line with the legislative requirements, the IMB submitted an annual report on serious adverse reactions and events to the European Commission during 2009.

The IMB received **1,033** field safety corrective action notifications relating to medical devices.

The report reflected information received from January to December 2008 and consisted of 27 reports associated with use of tissues and cells, 25 of which met the legislative reporting requirements, including five serious adverse reactions and 20 serious adverse events. The remaining two donor reaction reports, while not fulfilling the mandatory reporting requirements, were included on a voluntary basis as requested by the Commission. The number of reports received in 2009 has continued to increase over previous years and this data will be reflected in the report submitted to the Commission in 2010.

Information on reporting requirements, including a 'Guide to Reporting Serious Adverse Reactions (SARs) and Serious Adverse Events (SAEs) associated with Human Tissues' and downloadable/online versions of the report forms are available on the IMB's website.

MEDICAL DEVICE VIGILANCE

A total of 1,335 vigilance reports were received and assessed in 2009, which represented an increase of 15% on the number of reports received in 2008. The changes to the MEDDEV 2.12-1 rev 5 'Guideline on a medical devices vigilance system' continued to have an impact on the number of reports received, particularly in the reporting of field safety corrective actions (FSCAs) where an increase of 17% was noted. A significant increase in the number of National Competent Authority reports being circulated by Member States was a result of the improved clarity in the revised guidance on the medical device vigilance system; a total of 470 reports were circulated by European Competent Authorities in 2009 with the IMB issuing 74 reports, an increase of 27% from 2008.

A total of 62% of vigilance reports received were from manufacturers or their legal representatives, 30% were

from other regulatory agencies including web postings, and 7% were received directly from medical device users. Class IIa and IIb general medical devices represented the largest number of reports received, at 50%.

In the class I/IIa group there was an increased trend in reports relating to technical aids for the disabled, reusable instruments and hospital hardware. In the class IIb/III group, a significant number of reports were received relating to defibrillators (internal and external). An increase in the number of reports relating to diagnostic and radiotherapy software/equipment, ventilators and orthopaedic implants was also observed.

Similar to 2008, there continued to be a large number of general medical device recalls relating to device packaging sterility and software issues particularly with diagnostic and treatment planning software. Single use, electro-mechanical medical devices, non-active implantable, diagnostic and therapeutic radiation devices represented the most common reports received per product family.

In the IVD area, the largest number of reports related to clinical biochemistry and microbiology devices. As in 2008, vigilance cases relating to pregnancy tests and blood glucose meters accounted for a large number of IVD clinical biochemistry cases. Software upgrades for clinical chemistry analysers continued to have a high impact on the number of IVD clinical biochemistry vigilance cases.

During 2009, the IMB received 1,033 field safety corrective action notifications relating to medical devices. Of these, 536 actions had a direct impact on the Irish market, 38% related to field safety notices, 41% to product removals, 10% to software upgrades and 11% related to field modifications. The implementation of corrective actions was closely monitored by the Human Products Monitoring department.

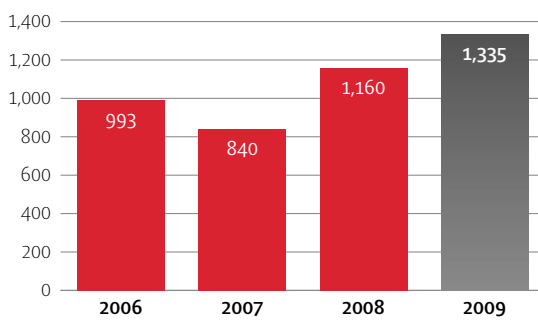
464 compliance cases were opened, which represented an increase of **22%** on the figure for 2008.

Human Products Monitoring

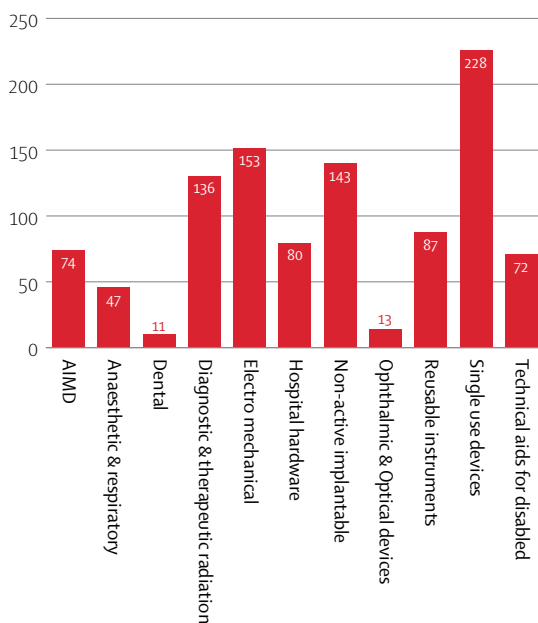


In 2009, the IMB co-operated with other European Competent Authorities, the European Commission and medical device manufacturers on several major issues which needed input from a variety of stakeholders.

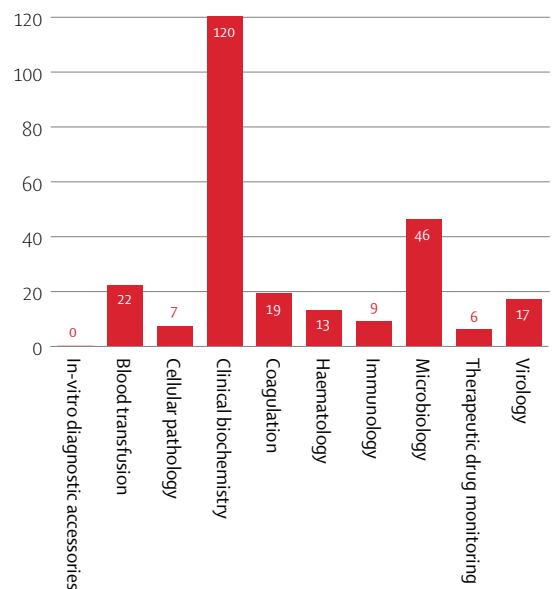
Number of vigilance reports received 2006–2009



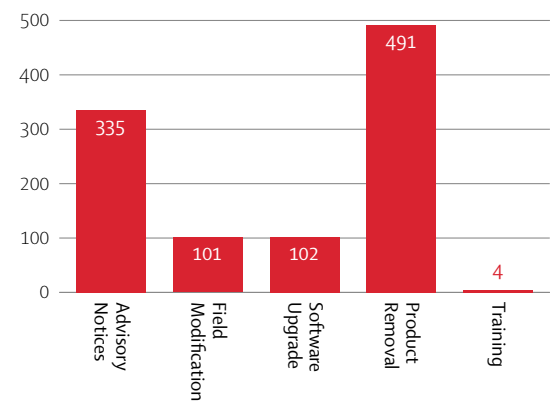
Family groups of general medical devices and active implantable medical devices implicated in vigilance reports in 2009



Family groups of in-vitro diagnostic medical devices implicated in vigilance reports in 2009



Outcome of field safety corrective actions in 2009



Throughout 2009, the IMB continued its regular meeting schedule to communicate on key medical device issues with stakeholders.



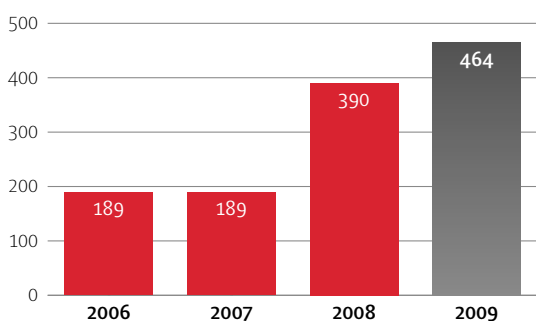
MEDICAL DEVICE COMPLIANCE

During 2009, 464 compliance cases were opened, which represented an increase of 22% on the figure for 2008. Class IIa general medical devices represented the largest number of compliance cases with single-use medical devices representing the most common type of case.

A total of 86% of cases were notified to the IMB by other Competent Authorities and related to notified body certificate withdrawals or issues of concern in another Member State. As in previous years, problems identified and investigated as part of compliance cases included labelling, missing or incorrectly attached CE marking and classification issues.

A number of technical files relating to Irish-based manufacturers were also reviewed in 2009.

Number of medical device compliance cases opened 2006–2009



Contributions and support were also provided to the European working group that is planning co-ordinated market surveillance activity at EU level. A trilateral post-market surveillance operation was undertaken by the UK, Irish and French Competent Authorities in 2009 to review blood glucose meters. This co-ordinated action comprised

a desk review involving an assessment of the 'user manual' for the meters and of the 'instructions for use' for the associated reagents (strips or electrodes), with a focus on issues relating to maltose interference and units of measurement.

PUBLICATIONS

In 2009, guidance documents were published or updated for stakeholders as follows:

- Thirteen safety notices
- 'Guidelines for Safe and Effective Management and Use of Point of Care Testing in Primary and Community Care'
- Six medical device brochures for the general public
- Guidelines for industry and healthcare users on vigilance systems and reporting systems
- Guidelines in relation to legislative requirements
- Manufacturers field safety notices were published on the IMB website.

COMMUNICATION

During 2009, the IMB made presentations at many stakeholder conferences including:

- IEQAS conference
- ETCI Vigilance and Hospital Liaison
- IMDA Regulatory Forum
- BEAI Scientific Meeting
- Informa Post-market Surveillance Conference
- AOTI Conference.

Throughout 2009, the IMB continued its regular meeting schedule to communicate on key medical device issues with stakeholders including the Department of Health

The IMB continued to actively participate in European meetings of the Medical Devices Expert Group and the related working groups.

Human Products Monitoring



and Children, and the Irish Medical Device Association. Assistance was provided to the Department on the transposition of Directive 2007/47/EC into Irish law.

EUROPEAN ACTIVITY

During 2009, the IMB continued to actively participate in European meetings of the Medical Devices Expert Group and the related working groups.

The IMB contributed to the Vigilance Working Group and to the COEN Working Group. A significant focus is being placed on the communication of vigilance issues and improved co-ordination amongst Member States in relation to post-market surveillance. Three meetings of the Medical Device Vigilance Expert Group were held in 2009. Discussion at these meetings included:

- the recast of the medical devices directive
- the implementation of the vigilance enquiry form
- the implementation of MEDDEV 2.12-1 rev 5
- co-ordination between Competent Authorities
- the Eudamed database
- GHTF Study group 2
- the NCAR exchange process.

The IMB participated in an EU Taskforce group set up to investigate the possible improvements of the EU regulatory framework concerning vigilance. Much of the group's agenda focused on the identification of proposals for the recast of the directives.

Two IVD Technical Group meetings took place in March and September 2009. During the year a small ad-hoc group also met to identify the technical points to be addressed in the context of the revision of the IVD Directive (for example, in-house tests, genetic

testing, classification rules, etc). The Common Technical Specifications (CTS) and guidance document for vCJD were also finalised. It is envisaged that the CTS will be updated as scientific knowledge develops in this area. The publication date for the CTS and guidance document has not yet been confirmed.

Three meetings of the COEN working group were held during 2009. Key items discussed included:

- the work programme of COEN for 2009
- the impact of the new approach legislation and the draft guidance on the use of legal tools for market surveillance
- the guidance notes for manufacturers of class I medical devices
- the guidance note for manufacturers of custom-made medical devices in line with the changes agreed in Directive 2007/47/EC.

Updates were also provided on specific market surveillance projects and specific cases of concern for Member States. Member States were asked to comment on a future perspectives document.

An inter-departmental group, co-ordinated by the Department of Trade and Enterprise, was established to consider the impact of the revision to the new approach directive which arose out of the Commission's concern relating to inconsistencies and the level of activity of market surveillance in Member States. Regulation 765/2008 comes into effect on 1 January 2010.

Several meetings of the market surveillance forum were held during 2009, with the focus on each agency preparing their market surveillance plan for 2010 for communication to the European Commission.

Human Products Authorisation and Registration



Ms. Ann O'Connor Director of Human Products Authorisation and Registration

The total number of applications received from marketing authorisation holders in 2009 increased by 11% and total output increased by almost 5%. Of note were the increased numbers of variation applications received which was due to the coming into force of a new variations Regulation on 1 January 2010. Significant preparation was undertaken by the IMB in advance of the change to the variations legislation. Of note in 2009, was a substantial increase in the number of applications received relating to parallel-imported products. Two public consultations were carried out, on the revision to the dual pack registration scheme and the proposal to develop a national rules scheme for homeopathic products.



During 2009, the IMB undertook a reorganisation of the Human Medicines Department and the Medical Devices Department. This resulted in the creation of two new departments, one of which is the new Human Products Authorisation and Registration Department which became effective in March 2009.

Significant work took place in 2009 to facilitate the move from paper to electronic submission of applications to the IMB, which commenced in November. It is envisaged that all submissions will be electronic by 2012.

HUMAN MEDICINES

New Products Authorised

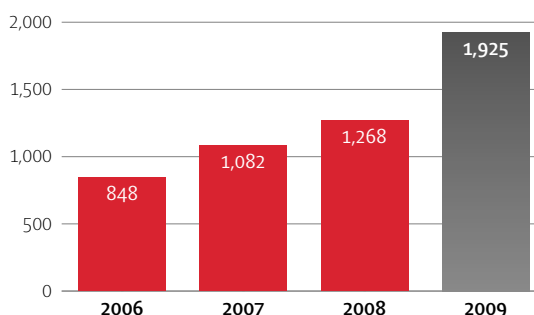
During 2009, the IMB output for new product applications was 1,925. This comprised:

- 785 new national applications, including parallel import (PPA) applications
- 120 new mutual recognition (MR) and 439 new decentralised (DCP) applications
- 345 new centralised* and 216 transfer applications.
- 20 new homeopathic applications.

(*Total number of centralised applications complete in 2009, not all may be authorised by the European Commission at this point).

The following table shows the total output over the last number of years:

Total output for new applications 2006–2009



The total output figure increased in 2009 primarily due to an increase in the number of new national applications, new applications submitted through the centralised and decentralised procedures and new PPA applications.

Variations Authorised

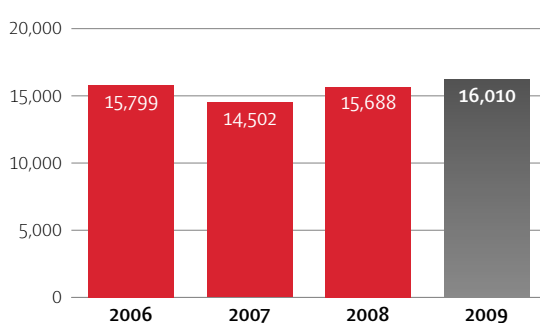
During the year, there was an output of 16,010 variations to marketing authorisations for products authorised through the national or MR procedures. This was a small increase from 2008. There were 18,076 variation applications received, which was an 11% increase over 2008. This was due to the uncertainty around the impact of the new variations regulations and the lack of clear guidelines on implementation.

There was an output of **991** renewals to marketing authorisations for products authorised through the national or MR procedures, a **14%** increase.

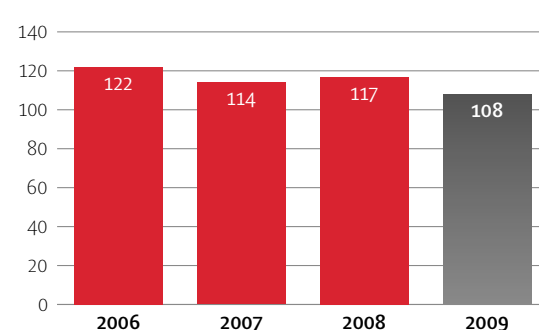
Human Products Authorisation and Registration



Total output for variations 2006–2009



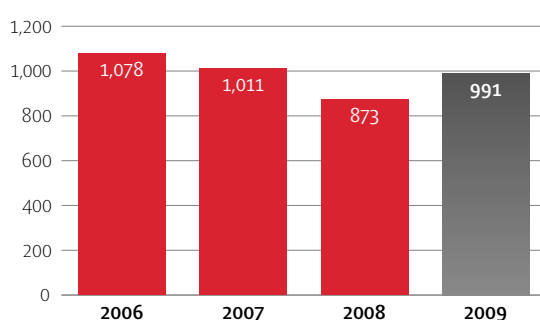
Clinical trials approved 2006–2009



Renewals Authorised

During the year there was an output of 991 renewals to marketing authorisations for products authorised through the national or MR procedures. This was a 14% increase on the previous year.

Total output for renewals 2006–2009



The number of renewal applications received was 1,190.

Clinical Trials Authorised

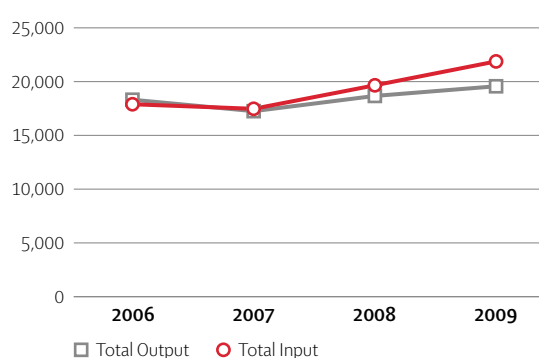
During 2009, 108 applications to conduct clinical trials were assessed by the IMB. No applications were rejected.

A total of 448 clinical trial amendment applications were approved which represents a slight increase from the 2008 figure of 429.

Total Application Input and Output

While there was an increase in applications received during 2009, the total output also exceeded previous years as depicted below.

Total application input and output 2006–2009



	2006	2007	2008	2009
Total input	17,895	17,471	19,657	21,879
Total output	18,314	17,252	18,668	19,566

A total of **448** clinical trial amendment applications were approved which represents a slight increase from 2008.

Advanced Therapies

Regulation (EC) 1394/2007 on advanced therapy medicinal products (ATMPs) came into effect in 2009. This Regulation provides for the authorisation of gene therapy, stem cell therapy and tissue engineered products. The Regulation also resulted in the establishment of a new scientific committee at the EMA, the Committee for Advanced Therapies. The committee's composition includes representatives from clinical and academic settings and patient organisations.

The Regulation describes three procedures to be undertaken by the committee in relation to ATMPs; a classification procedure to determine if a particular product meets the definition of an ATMP; a certification procedure for committee experts to review and feedback on preliminary preclinical and quality data; and applications for marketing authorisation of ATMPs.

The Regulation also describes criteria for assessment of combined ATMP products when an ATMP has been incorporated into a medical device. The assessment undertaken by the committee will include the results of assessment of the device by a medical device notified body.

New Variations Regulation

In 2009, the IMB carried out significant preparations in advance of the new variations regulation (Commission Regulation (EC) 1234/2008) coming into force on 1 January 2010. The new Regulation applies to both the human and veterinary medicinal products authorised through the centralised and MRP/DCP routes. The applicability of this Regulation will be formally extended to 'purely national' marketing authorisations at a later date. However, in line with many other European regulatory

agencies, the IMB has taken the decision to implement the general principles of the new Regulation to all marketing authorisations from 1 January 2010.

The aim of Regulation (EC) 1234/2008 is to introduce a simpler, clearer and more flexible framework for variations. The main changes introduced are the introduction of a 'do and tell' system for Type IA notifications, the change of 'default' category for variations from Type II to Type IB, the introduction of a 'grouping' system for variations by the same MA holder and the introduction of a 'work-sharing' procedure.

The variations page of the IMB website was updated with all relevant information including a 'points to note' document and links to the relevant European legislation and guidance. An information day on the new variations regulation will be held in January 2010.

Parallel Imports/Dual Pack Registration Scheme

Parallel importation is the importation from an EU Member State or a country within the EEA of a medicinal product which is already authorised on the Irish market, by an importer who is someone other than the importer appointed by the marketing authorisation holder of the product on the Irish market. Where a product that is the subject of a national marketing authorisation, and is marketed in another Member State, is identical in all respects (including identical packaging, labels and leaflets) to the product on the Irish market, it is termed a 'dual pack'.

A consultation process on amendments to the current dual pack registration (DPR) scheme was carried out in 2009. The key proposals in the consultation were to introduce an over-label on the product carton which will include the name of the DPR holder and the registration

A significant amount of work was undertaken to ensure that the infrastructure and processes are in place to handle electronic-only submissions of applications.

Human Products Authorisation and Registration



number granted by the IMB. This activity would be conducted by an authorised manufacturer. Feedback was received and subsequent to the review it was agreed to proceed with the implementation of the revised procedure from 1 March 2010. From that date, the outer carton of each DPR product placed on the Irish market will be required to carry an over-label containing the information outlined earlier. In addition, all applications submitted from that date will be required to comply with the updated procedure. A 'catch-up' scheme for currently registered DPR holders will also be implemented.

Traditional Herbal Medicines

The IMB established the Traditional Herbal Medicinal Products Registration Scheme on 31 August 2007. Under this scheme, traditional herbal medicinal products which meet certain criteria regarding traditional-use, safety and quality and are suitable for use without the intervention of a doctor can apply for a certificate of traditional-use registration using the simplified registration procedure. The national legislation states that no medicinal product may be placed on the market without a marketing authorisation or a certificate of traditional-use registration. However it provides an exemption from this requirement until 30 April 2011 for traditional herbal medicinal products that were on the market in the State on the coming into force of the regulations. A transition period for the implementation of the registration scheme is currently in place. In 2009, the IMB received a very small number of applications. Information on the scheme is available on the IMB website.

Homeopathics

Homeopathic medicines can be registered or authorised by the IMB. Registration is under the simplified registration scheme specifically for homeopathic

medicinal products without indications that are administered orally or externally. To date, 32 products have been registered under this scheme (12 in 2008 and 20 in 2009).

Authorisation of homeopathic medicines has been facilitated by the introduction of recent legislation (Medicinal Products (Control of Placing on the Market) Regulations, 2007) (S.I. 540 of 2007) which defines criteria for the licensing of homeopathic medicines under national rules as provided for under Directive 2001/83/EC, as amended.

The IMB launched a public consultation on the proposed new national rules scheme in November 2009. Under this scheme, homeopathic medicines with indications for mild self-limiting conditions can be authorised. It is intended that the IMB will launch this scheme in 2010.

Together with the simplified registration scheme this new national rules scheme will facilitate the licensing of all homeopathic medicines on the Irish market.

Electronic Submissions

In 2009, a significant amount of work was undertaken to ensure that the infrastructure and processes are in place to handle electronic-only submissions of applications. The IMB now accepts and strongly recommends electronic-only submissions, either in eCTD format, non-eCTD (Nees) format without paper copies or through the IMB's online portal RIO. This applies to new applications, responses to validation queries and review of assessment questions, supplementary information, variations, renewals, periodic safety update reports, and active substance master files / drug master files. The transition to electronic submissions brings with it several advantages, not only the obvious reduction in printing, archiving and transportation costs, but also facilitates consistency in

2,293 queries were dealt with by the customer service team, of which **2,065** related to human medicinal products.



information viewed across agencies, the ability to manage the lifecycle of the product, and improved navigation and assessment of documentation.

Customer Service

In 2009, 2,293 queries were dealt with by the customer service team, of which 2,065 related to human medicinal products. A large number of queries related to variations to marketing authorisations, renewals to marketing authorisations and fees for marketing authorisations.

European Commitments

Our commitments to the European medicines and medical devices regulatory systems continued to be substantial during 2009. The IMB's technical staff serviced the following committees and working parties at the EMA and the European Commission.

Committee/ Working Party	Delegate	Duration/ Frequency
Committee for Human Medicinal Products	Dr. David Lyons and Dr. Patrick Salmon	4 days/month
Committee for Orphan Medicinal Products	Dr. David Lyons and Dr. Patrick Salmon	2 days/month
Co-ordination Group for Mutua Recognition and Decentralised Procedures	Dr. Jayne Crowe Mr. Larry O'Dwyer	3 days/month
Committee on Herbal Medicinal Products	Dr. Sinead Harrington/Mr. Cathal Gallagher	4 days/2 months
Paediatric Committee	Dr. Kevin Connolly and Dr. Yvonne Looney Dr. Helene Plein (Pre-clinical subgroup)	3 days/month
Committee for Advanced Therapies	Dr. Maura O'Donovan and/or Dr. Niall MacAleenan	2 days/month
Gene Therapy Working Party	Dr. Vincent Irwin	6 days/year
Pharmacogenetics Working Party	Dr. Helene Plein	4 days/year
Pharmacovigilance Working Party	Dr. Almath Spooner	3 days/month
Safety Working Party	Dr. Lorcan Allen	2 days/3 months
Quality Working Party	Dr. Catherine Mc Hugh	3 days/2 months
Vaccine Working Party	Dr. Tracy Keane	3 days/2 months
Scientific Advisory Working Party (SAWP)	Dr. Sheila Killalea	3 days/month
Efficacy Working Party	Dr. Peter Kiely	2 days/3 months
Biological Working Party	Dr. Vincent Irwin/Dr. Una Moore/ Dr. Maeve Lally	3 days/month

A total of **47** classification queries were received in 2009.

Human Products Authorisation and Registration



European Commitments (continued)

Committee/ Working Party	Delegate	Duration/ Frequency
Blood Products Working Party	Dr. Tracy Keane	2 days/3 months
Clinical Trials Facilitation Group	Dr. Brian Aylward	2 days/3 months
MDEG Classification & Borderline Working Group	Dr. Paul Scannell/Dr. Niall MacAleenan	3 days/year
MDEG Clinical Investigation & Evaluation Working Group	Dr. Niall MacAleenan	3 days/year
EUDAMED	Dr. Paul Scannell	3 days/year

MEDICAL DEVICES

Designation and Monitoring of Irish Notified Bodies

The IMB designates the National Standards Authority of Ireland (NSAI) as a notified body for conformity assessment of medical devices. The IMB conducted three surveillance audits of the NSAI to monitor its performance in this regard and its compliance with the medical device directive, the active implantable medical device directive and the in-vitro diagnostic device directive. Two of these audits were conducted at the NSAI offices in Dublin and one in NSAI's US office in New Hampshire, USA. One observed audit of an NSAI auditor was conducted in 2009 i.e. where the IMB observed a selected NSAI auditor conducting a site audit of a client device manufacturer. Human Products Authorisation and Registration provided support to the Compliance department in relation to these notified body audits. One additional 'for-cause' audit of NSAI was required late in 2009 due to a compliance issue that was identified with one of NSAI's client manufacturers.

See also under 'Compliance – Inspection/Audit' for statistics on audits of medical device manufacturers on page 39.

The IMB continued its participation in the peer review programme established by the European Notified Body Operations Group. The objective of this programme is to ensure consistency and harmonisation in the monitoring of notified bodies throughout the EU. As part of this programme, the IMB conducted a peer review assessment of the Italian designating authority during 2009.

The IMB commenced a project in 2009 to update NSAI's scope of designation as a notified body to align the existing scope with the new guidance on designation scope definitions arising from the Notified Body Operations Group. All Member States participating in the group have agreed to conduct a similar review during 2009-2010.

Clinical Investigations

During 2009, four clinical investigation applications for general medical devices were received as well as two significant amendments to previously authorised clinical investigations.

Three applications were approved to make non-CE marked devices available for use on compassionate grounds.

There were **589** new notifications to the register for medical devices in 2009.

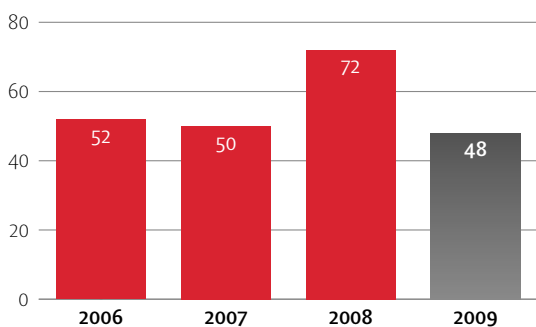
The IMB continues to promote communication with clinical investigators, manufacturers and other investigation sponsors on clinical investigation issues. This approach, including pre-submission queries and meetings, helps to clarify expectations and data requirements and facilitates the review process. During 2009, the IMB undertook a further analysis on the legal aspects of adopting a parallel review approach to clinical investigations such that the IMB reviews applications at the same time as the relevant ethics committee.

Classification Requests

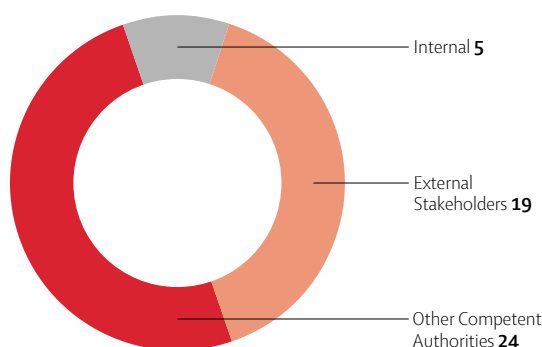
A total of 47 classification queries were received in 2009. 51% originated from other national Competent Authorities, 38% from other external stakeholders (including 9% from NSAI) and 11% were internal queries. Of the 47 classifications, 7 related to drug-device combination or borderline products that required referral to the IMB's Classification Committee.

The IMB contributed to the European system achieving classification consensus through the Classification and Borderline working group. In 2009, the IMB referred one borderline product to the working group for further discussion.

Classification files 2006–2009



Source of classification queries 2009



Registrations

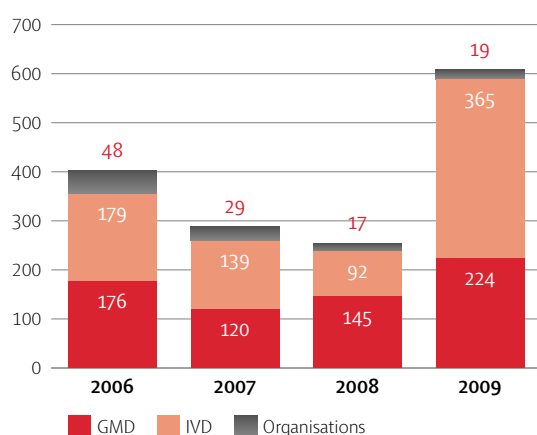
There were 589 new notifications to the register for medical devices in 2009. A total of 365 in-vitro diagnostic medical devices and 224 general medical devices were registered. The number of new organisations registered was 19. The data collected on the registration database were uploaded on a monthly basis throughout 2009 to the European Commission's EUDAMED database. A review of the fees and procedure for registration of medical devices in Ireland was commenced during the year, to be completed during 2010.

During 2009, **487** queries on medical devices were received from external stakeholders.

Human Products Authorisation and Registration



Medical device registration statistics 2006–2009



ACMD

The Advisory Committee for Medical Devices (ACMD) met three times during 2009, with topics discussed including guidance on the safe and effective use of ‘point of care testing’, criticality of IT networks in healthcare settings, and monitoring of notified bodies for medical devices. The ACMD also endorsed a series of brochures for the public to promote the safe and effective use of medical devices. The brochures were distributed to selected healthcare settings and are available from the IMB on request or can be downloaded from the IMB website.

In collaboration with the faculty of pathology, clinical biochemists and medical scientists, the IMB published ‘Guidelines for Safe and Effective Management and Use of Point of Care Testing (POCT) in Primary and Community Care’, settings including primary care centres, pharmacies etc. This document complements guidance on the use of POCT in hospital settings which was published during 2008.

Publications

- In 2009, the guidance document ‘Guide to the classification of a medical device’ was updated for stakeholders.
- Three medical device newsletters were issued during 2009 and these continue to be well received by stakeholders.
- Many contributions were received towards newsletter articles from academia, the healthcare sector and industry, highlighting different medical device issues.

Communication

During the year, the IMB made presentations at several stakeholder conferences including the Irish Cardiovascular Alliance Conference on conducting clinical investigations involving medical devices.

Throughout the year, the IMB continued its regular meeting schedule to discuss key medical device issues with stakeholders including the Department of Health and Children, NSAI and the Irish Medical Devices Association.

In 2009, 487 queries on medical devices were received from external stakeholders, including 370 related to pre-market issues, 98 related to post-market issues, two related to audit issues and 17 miscellaneous queries.

European Activity

During 2009, the IMB made significant contributions to European meetings of the Medical Devices Expert Group and the related working groups. Due to organisational commitments the IMB delegate resigned as the Chair of the Compliance and Enforcement Network.

The IMB provided a medical device delegate to the newly created Committee for Advanced Therapies at the EMA.

The IMB made significant contributions to European meetings of the Medical Devices Expert Group and the related working groups.



The IMB also continued its active participation in the Clinical Investigation and Evaluation Working Group, the Classification and Borderline Working Group and the Notified Body Oversight Group.

Ireland participated in two meetings of the Presidencies of the EU, namely the Czech Republic and Sweden.

As outlined above, during 2009 members of the Human Products Authorisation and Registration department contributed to European meetings including the Medical Device Expert Group, the Clinical Investigation and Evaluation Working Group, the Classification and Borderline Working Group, the EUDAMED working group and the Notified Body Operations Group. The IMB made significant contributions to European regulatory documents published during 2009 including the revision to the MEDDEV guidance on Clinical Evaluation.

In 2009, Directive 2007/47/EC was transposed into Irish law by way of European Communities (Active Implantable Medical Devices) (Amendment) Regulations, 2009 (S.I. 109 of 2009) and European Communities (Medical Devices) (Amendment) Regulations, 2009 (S.I. 110 of 2009). The IMB provided support to the Department of Health and Children on the transposition of this Directive.



Veterinary Medicines



Dr. J.G. Beechinor Director of Veterinary Medicines



The year 2009 marked the second full year of operation under the new management structure in the Veterinary Medicines department. It was another year of record achievement. While the operating environment both internally and externally continued to pose financial and other challenges, the department continued to deliver expected outcomes.

A detailed review of operational performance, customer service, and organisational development is provided together with a report on pharmacovigilance monitoring for the year.

PHARMACOVIGILANCE

Department staff participated in the first inspections of veterinary pharmacovigilance procedures in companies during the year with two marketing authorisation holder facilities being inspected – see also page 38 under ‘Compliance – Inspection/Audit’. An IMB representative also participated in a veterinary pharmacovigilance inspection of a marketing authorisation holder facility in the UK as part of the EMA’s programme of inspections for centrally-authorised veterinary medicinal products in 2009.

REPORT OF SUSPECTED ADVERSE REACTIONS FOR 2009

There were 148 reports of suspected adverse reactions associated with the use of veterinary medicinal products received by the IMB in 2009. Some 126 of the reports originated from marketing authorisation holders, 19 reports were received from veterinarians or other healthcare professionals and 3 reports were submitted by animal owners. In these reports, a total of 75 veterinary pharmaceutical products and 73 immunological products were identified as possibly associated with adverse events.

Suspected adverse events were reported in the following species: human (5 reports), bovine (53 reports), canine

(52 reports), equine (2 reports), ovine (22 reports), feline (8 reports), porcine (5 reports) and rabbit (1 report).

Of the 148 reports associated with the use of veterinary medicinal products, 73 related to suspected adverse reactions in the treated animals, 66 related to suspected lack of expected efficacy, 4 related to maximum residue limit violations and 5 reports involved suspected adverse reactions in individual users following exposure to a veterinary medicinal product. No regulatory action was taken in 2009 relating to issues of target animal or user safety as a result of spontaneous adverse reaction reports.

OPERATIONAL PERFORMANCE

The department reached a record output of 2,042 units. This figure was comfortably ahead of the target of 1,680 set in January 2009.

As in previous years, the department focused on three main areas:

Excellence in our work

37 new or updated standard operating procedures were approved during the year:

- six audits of various procedures operated in the department were undertaken by the IMB’s quality management section
- the introduction of a new key performance indicator on quality of authorisations issued
- exemplary assessments peer-reviewed by the IMB’s expert advisory committee as well as the

The department reached a record output of **2,042** units; this figure was comfortably ahead of the target of 1,680.

benchmarking assessment of the department's assessment, authorisation and pharmacovigilance systems under the BEMA programme.

Efficiency

The department processed all centralised, decentralised and mutual recognition applications in accordance with the agreed timetables. The number of applications held in the work-in-progress queues declined from 690 units in December 2008 to 645 units in December 2009.

Added-value

The department acted as reference member state for 24 outgoing applications for decentralised or mutual recognition procedures. This service to industry supports Irish and European jobs and places the IMB amongst the top two Member States in Europe for such work.

CUSTOMER SERVICE

Customer service remains an important focus for the department, which continued to build on previous achievements and on meeting or exceeding its overall service targets, and appreciates the trust placed in it by stakeholders. During the year the department expanded its focus on the ongoing monitoring of veterinary medicines and strengthened the number of personnel engaged in pharmacovigilance. It also hosted an information day in September which was well-attended by stakeholders.

The IMB initiated a public consultation to seek input into its policy on the appropriate supply categories and criteria for supply for antiparasitic veterinary medicine intended for dogs and cats.

The department contributed articles to all of the IMB newsletters during the year and published one article on antimicrobial resistance in the Irish Veterinary Journal.

As in previous years, personnel from the department held a number of meetings with stakeholders, including the Department of Agriculture, Fisheries and Food.

The Director of Veterinary Medicines continued to be active in initiatives intended to support availability of veterinary medicines.

Concerning national issues on veterinary medicinal matters, departmental personnel also provided input into regulatory seminars on veterinary medicines to the Royal College of Surgeons.

The department continued its work-sharing, harmonisation and joint-labelling initiatives with the UK's Veterinary Medicines Directorate. While delivering a practical benefit to companies and the animal health industry in the delivery of joint labelled veterinary medicines for the UK and Irish markets, such co-operation helps ensure that the IMB retains flexibility to manage varying workloads.

ORGANISATIONAL DEVELOPMENT

The vision of the management team for the department is to develop "an inspired and fulfilled team delivering an innovative, informative and responsive regulatory system for veterinary medicines which enhances the lives of animals and safeguards the health of society."

The department continued to invest in the training and development of staff so that the IMB can continue to meet its performance criteria. During the year, there were a number of changes in personnel. The IMB wishes to acknowledge the contribution of colleagues who left the department during the year. While staff changes can be somewhat disruptive to the smooth running of the business, it is our hope and expectation that our new

There were **148** reports of suspected adverse reactions associated with the use of veterinary medicinal products received by the IMB.

Veterinary Medicines



colleagues quickly learn the business and will bring new knowledge to their roles. During 2009, there was a change in the Irish representation at the Committee for Medicinal Products for Veterinary Use (CVMP). Dr. David Murphy was appointed as CVMP member and Dr. J.G. Beechinor as alternate CVMP member. In 2009, Mr. Paul McNeill was appointed delegate to the Co-ordination Group for Mutual Recognition and Decentralised Procedures (CMDv).

The Director of Veterinary Medicines continues to seek to improve the department's dynamic capabilities through organisational learning and staff development opportunities. The department continues to input to EU strategies which are expected to further these objectives in the years ahead.

Compliance



Mr. John Lynch Director of Compliance

As part of the reorganisation of the Human Medicines and Medical Devices departments, additional functions transferred to the Compliance department in March 2009. These were medical device auditing, issuance of certificates of free sale for medical devices and the project for future integration of the Competent Authority role for cosmetics. The transfer of staff had minimal impact on the work output and medical device audit programme and the integration of new colleagues and processes continued to be one of our main focuses throughout 2009.



The number of licences/authorisations applied for and issued levelled off between 2007 and 2009. This could indicate a steadying of industry activity in terms of the export of pharmaceutical products and few new undertakings that would require inspection and authorisation.

The number of inspections conducted at Irish-based pharmaceutical manufacturers decreased in 2009. This decrease can be attributed, in part, to improved scheduling of inspections of holders of multiple licences so that they occurred within the same site visit. The number of inspections carried out at foreign manufacturing sites was 21 which represented about one quarter of the inspection programme in terms of sites inspected.

HIGHLIGHTS OF THE DEPARTMENT'S ACHIEVEMENTS IN 2009

Initiatives undertaken in 2009 included:

- Full implementation of the new organisational structure with integration of medical device auditing and the cosmetics project within the Compliance Department.
- Thirty-six medical device audits were conducted, exceeding the target of 30.
- Further development of a workflow database for compliance case management to improve efficiency

in processing licences, organisation of inspections, quality defect and recall management.

- Provision of support to the Department of Health and Children in the revision of legislation to prevent the entry of falsified medicines into the legal supply chain.
- Monitoring via inspections of the implementation of updated good manufacturing practice requirements and pharmacovigilance inspection standards.
- Active participation in harmonising standards and inspection practices through EMA working groups and the Pharmaceutical Inspection Co-operation Scheme (PIC/S) Committee and 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.

INSPECTIONS AUDIT

The IMB's Compliance inspections function is structured within four operational groups:

- Good Manufacturing Practice (which incorporated medical device auditing from March 2009)
- Controlled Drugs and Good Distribution Practice
- Good Clinical Practice and Pharmacovigilance
- Blood and Tissues

128 good distribution practice (GDP) inspections were carried out in order to evaluate the level of compliance.

Compliance



Good Manufacturing Practice

A total of 88 good manufacturing practice (GMP) inspections were performed. These included 21 inspections in non-EEA countries, five of which were carried out at the request of the EMA for centrally-authorized products. Thirty-six medical device audits were conducted, 31 of which were of device companies, and five of which were of notified bodies.

Controlled Drugs and Good Distribution Practice

A total of 128 good distribution practice (GDP) inspections were carried out in order to evaluate the level of compliance with the GDP requirements and to assess applications for new authorisations and variations to existing authorisations.

The programme also included a number of inspections that were specifically targeted at wholesalers/distributors involved in the distribution of parallel imported medicinal products to assess the compliance of products supplied to the market.

Twenty controlled drugs inspections were conducted. The inspection programme focussed on licensed distributors and manufacturers of controlled drugs.

Good Clinical Practice and Pharmacovigilance Inspections

The good clinical practice (GCP) inspection programme included inspections at sponsor companies, investigators, contract research organisations and laboratories and applied to clinical trials approved in Ireland and those performed in support of national or EU marketing authorisations.

Inspectors completed 23 GCP inspections. Of these, 15 were carried out at sponsor and investigator sites in Ireland. The other six inspections were conducted at the request of the EMA.

Five pharmacovigilance inspections were performed at Irish-based marketing authorisation holders' facilities. These included inspections of two veterinary marketing authorisation holders to evaluate the systems and staffing in place for dealing with pharmacovigilance.

Blood Bank/Establishment and Tissue Establishment Inspections

Eight blood establishment inspections and one blood bank inspection were conducted.

Fifteen tissue establishments were inspected. The main focus of this inspection programme related to follow-up actions from previous inspections of holders of tissue establishment authorisations.

Performance Targets

Time taken to close-out an inspection

The target for close-out of inspections is 90 days. In order for an inspection to be closed out, the inspector must be satisfied that the company or investigator is compliant and that all deficiencies identified during the inspection have been addressed.

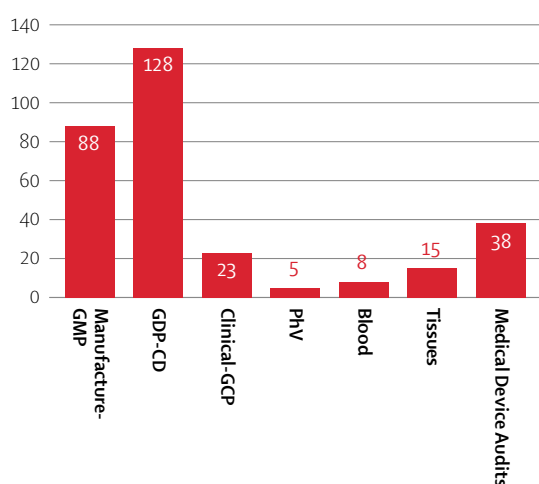
In 2009, the on-time target for close-out was achieved for 58% of inspections performed.

Of the inspections that were closed in 2009, the average time for close-out was 112 days.

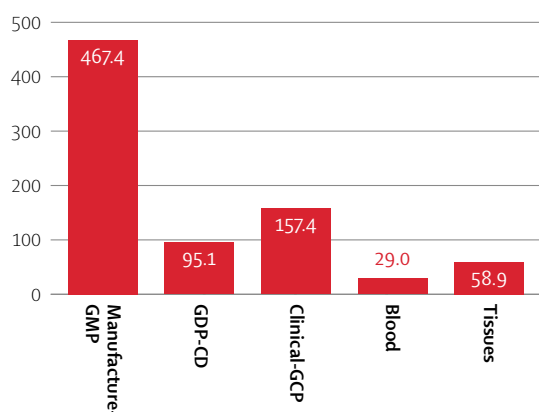
Inspectors completed **23** good clinical practice (GCP) inspections. Of these, **15** were carried out at sponsor and investigator sites in Ireland.

Inspection statistics

Number of inspections completed in 2009



Total number of inspection days per sector 2009



LICENSING

The total number of licences or authorisations in force at year-end, and in the previous two years, is presented below by category.

Total Number of Licences / Authorisations (Sites)	2007	2008	2009
Manufacturers of Medicinal Products for Human Use	85	86	85
Manufacturers of Veterinary Medicinal Products	28	26	25
Manufacturers of Investigational Medicinal Products	43	45	50
Wholesalers of Medicinal Products for Human Use	127	214*	210*
Blood Establishments	4	6	5
Tissue Establishments	0	6	13
Laboratory Certificates	12	11	11

* Includes wholesalers supplying general sale products only

The Licensing section continued to support the Inspection section with regard to the issuing of GMP certificates within 90 days following an inspection.

Controlled Drugs Licensing Activity	2007	2008	2009
Registration	19	23	20
Export and Import	964	1056	998
Annual – New	19	19	31
Annual – Renewal	171	243	224
Letter of No Objection (LONO)	473	489	447
Pilgrims	14	14	11
Hemp	5	46	7

There was an output of **3,109** export certificates during 2009.

Compliance



EXPORT CERTIFICATES

There was an output of 3,109 export certificates as set out below. Note that issuing of medical device certificates transferred to the Compliance department during 2009.

Product Certification Activity	2007	2008	2009
Certification of Documents	316	266	235
Certificates of Free Sale	52	22	22
Certificate of Good Manufacturing Practice for Finished Product Manufacturers	200	212	230
Certificate of Good Manufacturing Practice for Active Substance Manufacturers	62	42	39
Certificate of a Pharmaceutical Product for Human Use	941	1,236	853
Certificate of a Pharmaceutical Product for Veterinary Use	105	37	89
Medical Device Free Sale Certificates	-	-	1,585
Other	82	61	56
Total	1,758	1,876	3,109

Electronic Applications for Authorisations / Licences and Export Certificates

With the objective of reducing paper usage and storage costs, the Compliance department began accepting applications via electronic mail for all licensing and export certificate applications. This is optional and as for any standard electronic mail, the security of transmission is not guaranteed. Electronic documentation may also be provided on CD or DVD.

EudraGMP

The information in the EudraGMP Community database is divided into two parts. The first part comprises all manufacturing and importation authorisations (MIAs) issued by EEA Competent Authorities in their respective territories. The second part includes GMP information, in the form of GMP certificates or GMP non-compliance information, for all authorised sites in the EEA and for inspected sites in third countries.

The EMA launched version 2.0 EudraGMP in July 2009. Among other improvements, EudraGMP v2.0 provides access to the general public for MIAs and GMP certificates, with the exception of any information of a commercial or personal confidential nature. EudraGMP can be accessed via the EMA website eudragmp.emea.europa.eu

In common with a number of other Member States, details of MIAs and GMP certificates issued by the IMB are not yet available via public access on the EudraGMP database. At year-end, the IMB was working on a project to reformat all MIAs into the required EU format and to electronically upload the necessary information to EudraGMP.

In addition, a new procedure on dealing with serious GMP non-compliance was published in the EU Compilation of Community Procedures.

Issuing of Free Sale Certificates for Medical Devices

As part of the change management programme, the issuing of free sale certificates for medical devices transferred to the licensing section of the Compliance department on 2 June 2009. Applicants were able to submit all applications electronically to exportcerts@imb.ie.



286 medicinal and other products were sent for analytical testing, an increase of **27%** over 2008.

MARKET COMPLIANCE

Overview

The Market Compliance section runs a number of risk-based, compliance-related programmes.

These include:

- Proactive market surveillance activities, such as the sampling and analysis programme.
- Reactive market surveillance activities, such as those of the quality defect and recall programme.
- Exempt medicinal products programme, which is a notification system relating to the importation and supply of unauthorised medicinal products in Ireland.
- Regulatory compliance inspections at the premises of marketing authorisation holder companies, designed to assess the level of compliance against various items of national legislation pertaining to the marketing and advertising of medicinal products.
- Advertising compliance programme for medicinal products for human use, which commenced formally in May 2009.

In the following sections, a summary of the activities for 2009 in each of the above areas is presented.

Sampling and Analysis Programme

The sampling and analysis programme is risk-based and includes authorised medicinal products, products manufactured in Ireland for export only, active substances, enforcement-related samples and borderline products.

During 2009, 495 products, spanning the categories referred to above, were sampled and were either subjected to analytical testing and/or packaging and labelling examination work.

Analytical Testing Activities

A total of 286 medicinal and other products were sent for analytical testing, of which 278 were obtained from the Irish marketplace and eight originated from other EU markets. This represented an increase of 27% over 2008.

Information on the product categories selected for analytical testing in 2009	No. of samples sent for analysis (% of total)
---	---

Physico-chemical Analysis:

Active substances	53 (19%)
Medicinal products for human use manufactured for export	5 (2%)
Nationally-authorised biological medicinal products for human use	21 (7%)
Nationally-authorised medicinal products	47 (16%)
MRP/DCP authorised medicinal products for human and veterinary use	28 (10%)
Parallel imported (PPA and DPR) medicinal products	9 (3%)
Centrally-authorised medicinal products for human and veterinary use	10 (4%)
Borderline medicinal / non-medicinal products for human use	14 (5%)
Enforcement-related products for human use	83 (29%)

Microbiological Analysis:

Nationally-authorised medicinal products for human use	9 (3%)
Medical devices for human use (analysed at the request of Medical Device colleagues within the IMB)	7 (2%)

Total	286
--------------	------------

16 non-compliances of packaging and labelling were identified across 15 authorised medicinal products.

Compliance



Principal findings from analytical testing

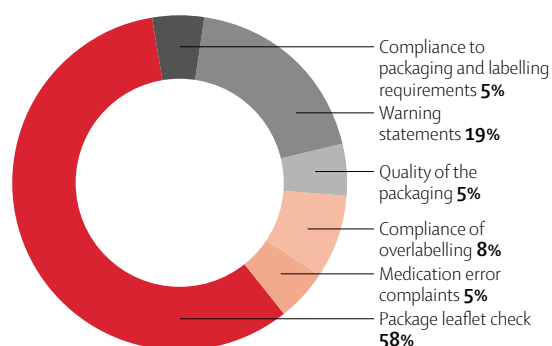
Nineteen out-of-specification results were obtained during testing of 17 authorised medicinal products. One related to supra-potent assay values in three different batches of the same medicinal product; two related to an impurity above the authorised specification in two different medicinal products; and one related to the failure to comply with the registered uniformity of content specification. The remaining 13 related to non-compliance with specifications for appearance. These cases were investigated and appropriate action was taken.

Packaging and Labelling Examinations

A total of 209 medicinal and other products were examined of which approximately 12% were parallel imported medicinal products (PPAs or DPRs). This was an overall increase of 14% (approx) on 2008. The table below shows the general categories:

Description of products examined	No. of samples examined (% of total)
Medicinal products subjected to packaging and labelling monitoring	128 (69%)
Medicinal products subjected to Braille-compliance checks	20 (10%)
Medicinal products associated with quality defects and/or recall issues	13 (8%)
Borderline medicinal/non-medicinal products associated with IMB Classification Committee work	48 (23%)
Total	209

Breakdown of the types of examinations carried out on authorised medicinal products



Packaging and labelling findings

Sixteen non-compliances were identified across 15 authorised medicinal products. Eight of these related to the Braille on packaging, four related to the absence of an approved warning, and four related to non-compliant pack overlabels.

In addition to the above findings, 16 unauthorised medicinal products were identified on the Irish marketplace.

Participation in EU Co-ordinated Market Surveillance Activities

The IMB is an active participant in EU programmes that involve the sampling and analysis of medicinal products. This is achieved via its participation in the Official Medicines Control Laboratory (OMCL) Network.

The IMB participated in the sampling and analysis of centrally-authorised medicinal products. Five were sampled from the Irish marketplace for testing at OMCLs in other countries, and a further five were analysed in Ireland on behalf of the EMA.

614 quality defects in human and veterinary medicinal products were reported to, or identified by, the Market Compliance section.

As part of work-sharing and efforts to make the best use of laboratory resources, the IMB actively participated in the EDQM-co-ordinated surveillance programme for MRP/DCP medicinal products. Seventeen products from the Irish marketplace were analysed by other Member State OMCLs. Twelve borderline medicinal/non-medicinal products were analysed at the IMB's request at the UK's OMCL. Other work-sharing included: 16 medicinal product samples were microbiologically analysed at the OMCL of the Czech Republic for the IMB, 21 biological products (heparins and low-molecular weight heparins) were analysed for the IMB at Sweden's OMCL, four medicinal product samples were analysed at one of the French OMCLs, and nine samples were analysed for the IMB at the Finnish OMCL.

Acknowledgements

The IMB would like to thank the staff of its OMCL, the Public Analyst's Laboratory, Galway, and the staff of the State Laboratory, Young's Cross, Celbridge, Co. Kildare, for their invaluable contributions to the Sampling and Analysis Programme.

QUALITY DEFECT AND RECALL PROGRAMME

The quality defect and recall programme investigates, on a risk-basis, reports of suspected quality defects in both human and veterinary medicinal products, and in their related active substances. A total of 614 quality defects in human and veterinary medicinal products were reported to, or identified by, the Market Compliance section. This represents an 11% increase over 2008 figures. Factors that contributed to this increase included educational work carried out by the section with manufacturers in relation to what should be reported as a quality defect, as well as promotion of the use of the IMB's online reporting system.

Classification of quality defects 2006-2009	2006	2007	2008	2009
Critical quality defects	84	173	127	105
Major quality defects	238	216	299	345
Minor quality defects	40	80	105	147
Number of quality defect reports not justified	9	4	23	17
Total number quality defects reported/identified for the year	371	473	554	614

Of the 614 cases, 469 were determined to be affecting Ireland, meaning that the defective batch or batches were either on the Irish market and/or were manufactured in Ireland.

Major and critical cases accounted for **73%** of all reported quality defects.

Compliance



Major and critical cases accounted for 73% of all reported quality defects. Of the 105 critical cases, 45 directly affected Ireland. This represented a 22% decrease on the 2008 figure and is seen as a positive development. Of these, 44 concerned medicinal products for human use and one related to a veterinary medicinal product.

For eight of the 105 critical cases, it was not possible to conclusively determine whether the concerned medicinal products were on the Irish market. None of these products were authorised and all were distributed via unauthorised supply routes (such as the internet).

The table below shows the areas in which quality defects occurred. A total of 23% concerned packaging and/or labelling issues, down from 38% in 2008.

Stability-related cases almost doubled and accounted for 16% of all quality defect reports in 2009. This increase

may be partially due to the fact that the GMP requirement for batches to be placed in an ongoing stability programme, under ICH conditions, was first introduced in mid-2006, and these first batches are now further along in their shelf life and thus more likely to be the subject of out-of-specification results.

Particulate, microbial, chemical and other product contamination accounted for 13% of all reports. Of the 82 contamination cases, 15 related to the contamination of numerous heparin batches worldwide. These cases were investigated at European level and appropriate action was taken in Ireland.

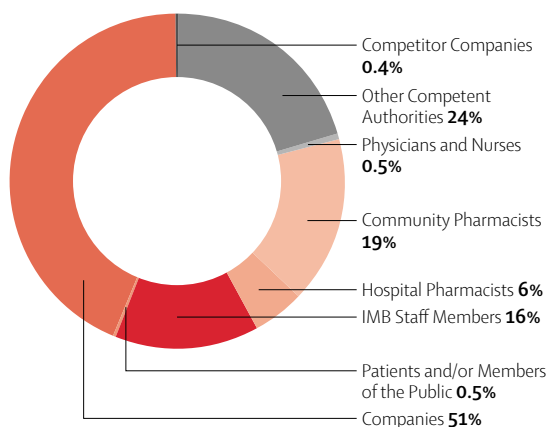
Defects under the category 'Other' (16%) included non-compliances with GMP, erroneous product distribution and other supply issues.

Areas of Quality Defects for 2009

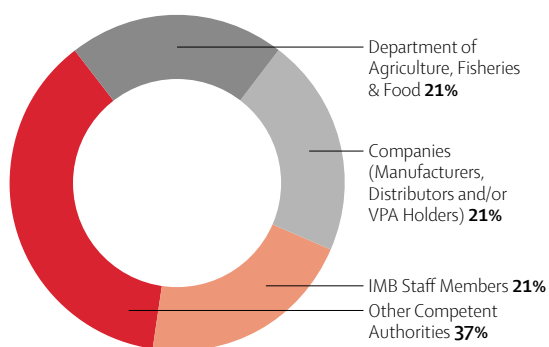
	Human Quality Defects (%)	Veterinary Quality Defects (%)	Human and Vet Quality Defects (%)
Packaging and/or labelling	24	7.9	23
Stability	16	13	16
Non-compliance with PA/VPA	4.3	2.6	4.2
Product safety-related	4.5	0	4.2
Non-compliance with specification	3.6	29	5.2
Non-adherence to cold chain requirements	0.2	0	0.2
Microbial, chemical and particulate product contamination	13	21	13
Product mix-up	4.2	0	3.9
Unauthorised product	7.1	18	7.8
Lack of therapeutic efficacy	0.4	0	0.3
Damaged product	2.1	0	2
Potential counterfeit	1.4	0	1.3
Product usage	3	0	2.8
Other	16	7.9	16

The recall from the Irish marketplace of a batch or a number of batches occurred in approximately **16%** of all quality defect cases.

Sources of human medicinal product quality defect reports



Sources of veterinary medicinal product quality defect reports



In relation to the sources of human and veterinary quality defect reports in 2009, the graphs above present a breakdown of where the reports came from. The following points are some high level observations on the data above.

There was a significant decrease (61%) in the reporting of quality defects by community and hospital pharmacists when compared with 2008 figures. This highlights the need for ongoing promotional work in the area of quality defect reporting, and this area will a focus in 2010.

A total of 150 quality defect and recall notifications were received from Competent Authorities and Official Medicines Control Laboratories (OMCLs) in other countries. Each of those reports was investigated to establish if the report had any potential implications for the Irish market, and where necessary, action was taken.

The recall from the Irish marketplace of a batch or a number of batches of a medicinal product occurred in approximately 16% of all quality defect cases in 2009. This is a reduction from the 2008 figure of 26%, and this is seen as a very positive development – see recalls section below.

Recalls of Human and Veterinary Medicinal Products

A total of 99 recalls of medicinal products were requested and overseen by the IMB. This represents a decrease of 30% on 2008 figures. Ninety-one of those related to human medicinal products, while eight related to veterinary products. The different categories are shown in the tables overleaf.

Unlicensed products on the Irish market accounted for a significant number of recalls. 54% of all reports for this category came directly from IMB staff, particularly from inspections of wholesalers. Distribution of unauthorised products is an ongoing concern for the IMB and three ‘for-cause’ inspections of wholesalers were carried out as a result.

A detailed review of the quality defect and recall programme was performed to identify further risk-based process improvements and efficiency gains.

Compliance



Breakdown of Human Medicinal Product Recalls from the Irish market	2006	2007	2008	2009
Packaging and/or labelling	14	21	72	19
Stability	3	3	6	2
Non-compliance with MA	0	6	3	1
Sterility assurance and various other product safety concerns	8	13	5	9
Non-compliance with specification	4	1	9	7
Non-adherence to cold chain	0	19	1	0
Particulate or other contamination	4	12	5	6
Product mix-up	3	1	3	1
Unauthorised product	11	4	15	35
Lack of therapeutic efficacy	0	3	0	0
Damaged product	3	1	1	0
Other	1	3	7	11
Potential counterfeit	*	1	1	0
Product usage	5	0	0	0
Total	56	88	128	91

Breakdown of Veterinary Medicinal Product Recalls from the Irish market	2006	2007	2008	2009
Packaging and/or labelling	1	2	10	0
Stability	1	0	0	0
Non-compliance with VPA	0	0	0	0
Sterility assurance and various other product safety concerns	0	0	0	0
Non-compliance with specification	0	2	0	0
Particulate or other contamination	0	0	0	1
Product mix-up	0	0	0	0
Unauthorised product	0	4	2	7
Other	0	1	1	0
Total	2	9	13	8

The total number of packs of exempt medicinal products notified to the IMB was **847,238**.



A detailed review of the quality defect and recall programme was performed with a view to identifying further risk-based process improvements and efficiency gains. A restructuring of the Market Compliance section resulted from this review, with the Quality Defect and Recalls Manager overseeing the day-to-day running of the programme and also the exempt medicinal products programme.

Exempt Medicinal Products Programme

Under the medicinal product regulations governing placing on the market and wholesale distribution and manufacture, wholesalers and manufacturers are obliged to provide certain information to the IMB in relation to their sourcing and supply of unauthorised medicinal products. This is done online and 2009 was the first full year of operation for this notification scheme. Since January 2009, the required information must be provided to the IMB within two working days of receipt of exempt products. The main purpose of receiving such information is to facilitate the effective recall of any defective exempt medicinal products from the Irish market.

During 2009, 18,038 product lines were notified, compared with 13,941 product lines notified for 2008 (mid-February to December). (Note: a figure of 16,000 product lines was reported in error in the 2008 Annual Report).

The total number of packs of exempt medicinal products notified to the IMB was 847,238. This compares to 504,647 packs for 2008. While not all wholesalers were registered with the notification scheme during 2008, the IMB is concerned by the increase in volume and the overall extent of supply of exempt medicinal products, and continues to monitor the situation.

Non-compliances and clarifications during the year included:

- Notification by two companies of the incorrect manufacturers' name and address for a large number of products. The concerned companies were required to quarantine all affected products until the details were corrected.
- Several wholesalers failed to register with the notification system during 2008. These were contacted and required to register during 2009 and to submit retrospective data relating to the exempt products they sourced during the intervening period.
- Two companies that had failed to notify the receipt of certain exempt products over a prolonged period were required to notify the data retrospectively.
- One company failed to adhere to an IMB instruction regarding the need to cease supply of an exempt product and was subsequently requested to recall any remaining packs.
- Notifying companies were informed that centrally-authorised medicinal products were not permitted to be supplied as exempt products.

Regulatory Compliance Inspections

Regulatory compliance inspections are carried out at the premises of marketing authorisation holder companies, and are risk-based. These are considered to be key areas of activity pertaining to the marketing and advertising of medicinal products and are distinct from the IMB's inspections of manufacturers and wholesalers. Three such inspections were carried out in 2009. Areas of activity that have a high potential to impact on the quality, safety and the safe use of medicinal products were focussed on during these inspections.

The Enforcement section initiated **3,729** enforcement cases involving breaches of medicinal product legislation, an increase of **19%**.

Compliance



These included:

- Implementation of safety-related changes to product information and product labelling in the marketplace.
- Management and communication of regulatory commitments and regulatory changes.
- Management of registered product information.
- Provision of a medical information service for healthcare professionals.
- Quality management system in place at the companies to facilitate regulatory compliance.
- Medicinal product advertising activities.

The inspections identified a number of non-compliances in the above areas and the IMB oversaw the implementation of the necessary corrective and preventative actions.

Advertising Compliance Programme

While the IMB has dealt for several years with issues relating to the advertising of medicinal products for human use, a formal advertising compliance programme was established in May 2009 within the Market Compliance section.

The programme is based on the Medicinal Products (Control of Advertising) Regulations, 2007 and is closely aligned with the regulatory compliance inspections referred to in the preceding section.

The programme is almost entirely risk-based and formal risk-criteria are used when selecting advertisements and companies for compliance monitoring. It includes proactive and reactive (e.g. complaints) elements. Randomly selected advertisements are included. The programme recognises where self-regulation, consistent with those parts of voluntary codes approved by the Minister for Health and Children, may be effective and is designed to avoid duplication of effort.

Aside from advertisements that were reviewed during regulatory compliance inspections, approximately 260 were reviewed in-house. A particular focus is to ensure that the advertisement is consistent with the summary of product characteristics and promotes the rational use of the product. A number of non-compliances were identified and each was followed up with the marketing authorisation holder/company responsible for marketing.

ENFORCEMENT

Overview

During the reporting year, the Enforcement section initiated 3,729 enforcement cases involving breaches of medicinal product legislation, compared with 3,037 cases initiated in 2008. This represents a year-on-year increase of 19%. The majority were mail order importations of prescription-only medicinal products, continuing the trend from 2008.

A total of 494,502 tablets or capsules were detained, an increase of 39% over 2008. In addition, 1,650 packs of liquids, 449 packs of creams and 3,582 packs of assorted products were detained. Products detained included the following active substances: diazepam, zopiclone, sildenafil citrate, tadalafil (and other actives indicated for treatment of erectile dysfunction) rimonabant, finasteride, testosterone, amoxicillin, other antibiotics, corticosteroids and weight loss products, some of which contained sibutramine.

The majority of unauthorised medicinal products supplied into Ireland originated from India.

Medicinal products destroyed during the year in compliance with the Waste Management Acts 1996–2001 amounted to 2,601 kg compared to 1,902 kg in 2008.

During the year, IMB enforcement officers, customs officers and An Garda Síochána carried out a number of joint operations.

The IMB liaises with other enforcement agencies both nationally and internationally to stem the unauthorised flow of illegal medicinal products and medical devices into and out of Ireland. During the year, IMB enforcement officers, customs officers and An Garda Síochána carried out a number of joint operations. These included joint operations under Operation Pangea II in November 2009, a global initiative to identify and act against illegal websites supplying counterfeit and illegal medicinal products.

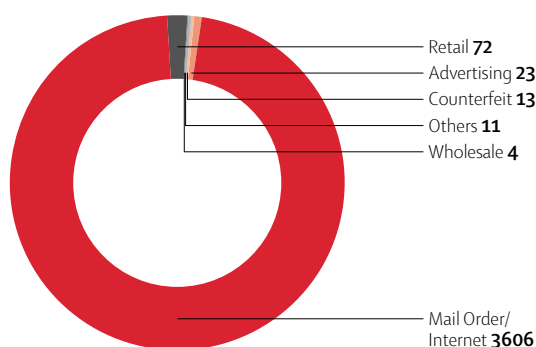
Enforcement carried out additional monitoring on 1,619 mail order cases. These represented some 40% of all such cases. Information gained on the supplying websites enabled the IMB to eliminate duplicating websites and to identify 1,009 websites which had supplied medicinal products to Irish residents. These websites were reported to LegitScript, a US-based organisation which facilitates the closing down of 'rogue internet pharmacies' by working with the ICANN, the international governing body for the internet. Together they compel the registrar, or the internet service provider hosting the website, to display correct details of who owns the site. Many of the websites had concealed their true identities.

Prosecutions relating to breaches of medicinal product legislation were taken in the Circuit Court and District Court. In February, a businessman, Mr. Michael Kehoe, was prosecuted by the Director of Public Prosecutions in the Circuit Criminal Court, Dublin for the sale and supply of prescription-only medicinal products, including ephedrine, and anabolic steroids. Mr. Kehoe pleaded guilty to three charges. The Court imposed fines of €2,000 on each of the three charges and granted an order to the IMB for destruction of the 80,000 tablets seized, which were valued at €80,000. Destruction costs of €3,000 were awarded to the IMB.

At the District Court in Dolphin House in December, Nutrition Connection Ltd., trading as retail outlets in Capel Street Dublin and Tallaght, Dublin, and Future Pack

Ltd., a wholesale company, were found guilty on a total of eleven charges. These include retail and wholesale supply, and mail order supply through an internet website, of prescription-only medicinal products. Mr. Wesley Rea, director of both companies, and his two companies were ordered to pay €5,000 in costs to the IMB, fines of a further €1,000 and a donation of €4,000 to charity. An order for destruction of all products detained, valued at €32,000 (approx), was granted to the IMB.

Analysis of enforcement cases



Planning

The planning section is responsible for planning activities across the department and works closely with the other four sections in this regard. It has a role in collating training and liaises with the IMB's central learning and development section and is also responsible for reporting on all departmental activities.

The main focus of the planning section related to the compilation of the inspection programme for 2009 and the development, in conjunction with the Information Technology and Change Management department, of a workflow system for Compliance.



Information Technology and Change Management



Ms. Suzanne McDonald Director of Information Technology and Change Management

The IT and Change Management department delivers specialist business analysis, information technology and telecommunications services throughout the organisation. Business process improvement skills are also sourced from this area, reflecting the organisation's commitment to the agenda of transformation in the public sector.

The IMB provides internet-based services to a variety of stakeholders. These applications range from online adverse reaction reporting to online application systems. In 2009, support was provided to over 230 staff, with additional support and training provided to over 500 external users of IMB systems. External users requiring IT support services are predominantly based within the medical devices and pharmaceutical sector.

Organisational access to high quality IT services is a key factor in delivering efficient and effective deliverables to stakeholders. In 2009, the organisation continued its investment in solutions in order to deliver on its regulatory commitments.

Support was also provided to a number of external bodies, including the Office of Tobacco Control, and regulatory bodies in Malta and Norway.

The IT and Change Management function has four work streams:



CHANGE MANAGEMENT

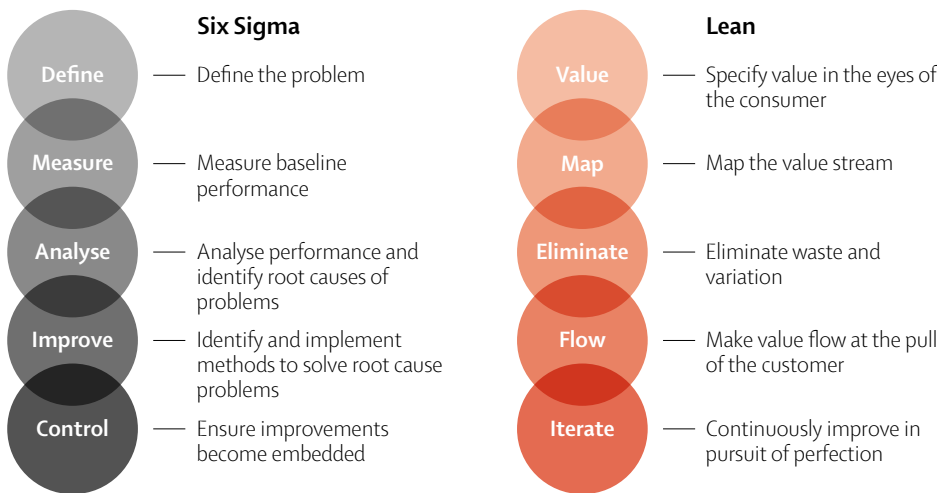
The Irish Medicines Board has a well established change management programme since 2003, with a strong focus on continuous improvement.

In March 2009, following a comprehensive review project, a new organisational structure was implemented to support the management of safety and licensing activities. One department (Human Products Authorisation and Registration) will now focus on licensing and registration activities for all products for human use, while the second department (Human Products Monitoring) will focus essentially on safety matters for human products. 'Human Products' refers to both pharmaceuticals and medical devices.

The organisational commitment to continuous improvement was further strengthened by the adoption of 'Lean Sigma' methodology for a number of projects. In the second half of 2009, the organisation initiated its first 'Lean Sigma' project in response to the introduction of new legislation relating to medicinal product licensing. This project ran for a 12 week period and was approved in November 2009. An ambitious work programme has been designed for 2010 to deliver on the opportunities identified during the project. Eight projects will operate in 2010 with a strong focus on delivering quality and business efficiencies.

A new organisational structure was implemented to support the management of safety and licensing activities.

Lean Sigma Methodology used to streamline variation application management



INFORMATION TECHNOLOGY

EU Telematics Programme

The EU Telematics Programme is a key component in the IMB’s strategy for managing regulatory information. At European level, and managed through the EMA, the EU Telematics Programme covers all aspects of medicinal product licensing and post-marketing activities. Fifty-one national Competent Authorities are linked to the EudraNet system spanning all Member States, and providing a secure communication channel for the regulatory network.

The EU Telematics Master Plan covers a five year period, and seeks to establish standards for communication and exchange of information between industry and regulators. In this context, projects relating to electronic submissions (eCTD) and pharmacovigilance (EudraVigilance) are ongoing both at national Competent Authority level and at a centralised level via the EMA. A range of other projects, including systems to support clinical trial tracking

and good manufacturing practice are ongoing, and will continue to influence the design of technology solutions both at the IMB and across the EU regulatory network.

During 2009 the IMB was influential in all aspects of the EU Telematics Programme. In mid-2009, the EMA Management Board Telematics Committee was established and the IMB is represented on this group.

EU Telematics Programme Architecture consists of the following elements and further information on these can be found at www.eudra.org.

- EudraVigilance (Drug Safety)
- EudraPharm (Medicinal Product Information)
- EudraGMP (Good Manufacturing Practice)
- EudraCT (Clinical Trials)
- EudraNet (Secure network communications)
- CTS (Mutual Recognition/Decentralised Procedure Application Tracking)
- EU Datawarehousing /Reference Data Modelling

Over **77,000** individuals visited the website in 2009 with over **1.5 million** pages viewed.

Information Technology and Change Management

Web-Based Services

In 2009, the Irish Medicines Board website www.imb.ie received a substantially higher volume of visitors than any other year. Over 77,000 individuals visited the website in 2009 with over 1.5 million pages viewed. The target audience was largely EU based – Ireland and the UK – with a significant number of visitors from North America. A substantial part of the activity can be attributed to the publication of Pandemic H1N1-related information on the website and the facility to report adverse reactions associated with the vaccination programme. The listing of licensed human medicines continues to be the most popular section of the site, consistent with prior years.

The IMB now routinely publishes all safety notices via the IMB website, with the facility for notification to registered users via e-mail or SMS. The website also provides online forms to facilitate reports on adverse reactions to medicines, potential quality defects and incidents relating to medical devices, tissues and cells. Users are encouraged to register on the website and to utilise the reporting forms wherever possible. We received very valuable assistance from users in 2009 and we encourage website visitors to send their comments or suggestions for improvement to helpdesk@imb.ie.

Extranet services continue to play a large part in delivering services to stakeholders. The online tracking and application system (RIO) remains a key system for the pharmaceutical industry. RIO provides a mechanism to track the progress of applications and also to make online applications. The introduction of changes in legislation will result in substantial changes to the RIO system in early 2010, and it is planned to extend the services following the successful implementation of these changes. RIO is a free service to the pharmaceutical industry and its agents, and the IMB encourages use of the system, wherever possible.

Compliance and Safety Solutions

Technology to assist in compliance activities was further developed in 2009. New applications to provide improved planning and management of inspection-related functions were at an advanced stage by the end of 2009. Further developments to support market surveillance, controlled drugs, and good distribution practice activities are also underway.

The IT function also worked closely with the Human Products Monitoring department on the development of the new safety monitoring system. This system provides superior case management and signal detection capabilities. It is scheduled to go into operation in 2010.

Document Management

A project to scan legacy documentation was commenced in late 2009. This initiative will result in the transfer of over two million pages to the IMB systems and will enable IMB staff to access data efficiently in the course of their activities. The introduction of European standards for the receipt and evaluation of applications is also contributing to a reduction in the volume of paperwork associated with the licensing of medicines.

Future Developments

The IMB plans to develop a new three-year IT strategy in 2010. This strategy will reflect the business objectives and will focus on delivering benefits to the stakeholders. The requirement for an improved website servicing a broader audience has been identified and this will be addressed as part of the strategy. Other initiatives include the further development of web-based applications across all activities, while working with other EU regulators to identify common solutions and services for stakeholders. Systems to manage the regulation of cosmetics will also form part of the new IT strategy.

Chief Executive's Office



Dr. Mike Morris Senior Scientific Advisor

Dr. Caitriona Fisher Quality Manager

The Office took over management of the content and updates to the IMB website in March 2009. In November, a specific communications function was established within the Office, with the aim of developing the IMB's communications, information and education role and a more co-ordinated, professional and consistent approach to communications with all stakeholders.

During November and December, support was provided to the Human Products Monitoring department in relation to IMB communications on the influenza pandemic, a number of new consumer leaflets on human medicines were developed for publication in 2010, and work was undertaken for market research to be carried out early in 2010.

BUSINESS CONTINUITY

The Chief Executive's Office was responsible for business continuity planning for the influenza pandemic, ensuring that plans were current and appropriate to the expected impact on operations and that guidance was issued to staff. While the workload of a number of departments had significant input in the licensing, pharmacovigilance and market compliance issues relating to the vaccination campaign, the overall effect on routine operations was manageable.

QUALITY MANAGEMENT

During 2009, a substantial increase in the implementation of the quality system was achieved. At the end of the year, 74% of the total expected implementation was in place, up from 49% at the end of 2008.

There was a significant increase in internal audits in 2009. 17 audits were conducted on 21 processes by auditors from the QMS section and from across the IMB. Most audits were of authorisation processes as these constitute a large proportion of processes undertaken by the IMB.

The complaints procedure and the fire drill procedure were also audited. Audit objectives were widened this year to include not only conformance to procedures but also process performance. At the end of the year, most audits were either closed out or had target completion dates for corrective actions in early 2010.

Management review of the system took place in March. Updates were sent to all staff on an ongoing basis, including notifications of new and revised documents, and induction training was carried out for new staff.

BENCHMARKING OF EUROPEAN MEDICINES AGENCIES

The IMB received a visit from benchmarking assessors in May 2009, as part of the BEMA programme under the HMA in the EU. The assessors came from medicines agencies in the UK, France and Greece and spent a week reviewing the IMB's performance in relation to defined standards of best practice. These standards have been developed by the HMA in the areas of management, assessment, pharmacovigilance and inspections. At the end of the week, they presented the report of their findings and their overall conclusions. In particular, they identified the following areas of significant strength:

- Positive leadership provided by the Board and Management Committee, supported by a comprehensive communication programme for individuals and teams which promotes the agency's values.

17 internal audits were conducted on **21** processes by auditors from the QMS section and from across the IMB.

Chief Executive's Office

- Focus on continuous improvement.
- Significant contribution to other Competent Authorities via the HMA meetings and associated working parties.
- Support given by HR to the organisation with a clear and effective performance management system which strives for high performance while at the same time supporting the individual in whatever form is necessary.
- Varied and substantial opportunities for staff to develop their skills and competencies.
- Integration of the quality system into the organisation, its support to the business of the IMB and the value it adds.
- Organisation's change management competence in planning and responding to change.
- Significant investment in IT systems to support business needs.

A small number of opportunities for improvement were also identified for review and implementation.

The IMB co-chairs and participates in the Steering Group for the second cycle of BEMA. During 2009, the BEMA secretariat at the IMB provided support to the assessors and agencies which were visited during the year, and organised a seminar at the EMA for assessors and agency staff to review current issues and opportunities with the programme. Training for a small number of new assessors was also arranged at the EMA. At the end of 2009, 18 visits to EU medicines agencies had taken place, with the remainder scheduled for 2010 and 2011.

SENIOR SCIENTIFIC ADVISOR

Borderline Product Classification

The IMB provides a service to stakeholders to assist in clarifying whether products should be categorised as medicinal products and medical devices and thereby fall under the remit of the IMB from a regulatory perspective or whether they are outside the scope of the IMB's remit. Queries are routinely received in regard to human medicinal products, veterinary medicinal products and medical devices and in each of the three areas, relevant personnel within the organisation have provided an IMB decision on request as to the status of a given product. This service in each of the three areas has been standardised under the quality management system.

A classification service is operated for products which are on the borderline of human medicines and other products such as food supplements, cosmetics and medical devices. Requests for classification, whether external or internal, are ultimately presented to an internal, multi-disciplinary, human medicinal product Classification Committee which meets once a month. The Committee consists of appropriately experienced staff from the Human Products Authorisation and Registration, Compliance and Human Products Monitoring departments and is chaired by Dr. Mike Morris, Senior Scientific Advisor.

The outcome of the decision is conveyed promptly to the enquirers and in turn is accompanied by a recommendation for any action arising depending upon the circumstances. In the event of an appeal to the Classification Committee decision, the matter can be referred to the Advisory Committee on Human Medicines for arbitration. Full details of the procedure can be found in the 'Guide to the Definition of a Medicinal Product' which can be found on the IMB website.

The IMB Classification Committee (human medicines) met 10 times in 2009 and considered a total of **131** new products.

The IMB Classification Committee (human medicines) met 10 times in 2009 and considered a total of 131 new products. In addition, there were 24 products revisited from pre-2009. The majority of the new applications were internal (114) emanating mainly from the Compliance department, with 17 external applications.

The Classification Committee continues to work closely with representatives of the Market Compliance section, which is represented on the Committee, and also the Enforcement section. Externally, there is also a very close working relationship with the Food Safety Authority of Ireland and a number of referrals were made in both directions during the course of 2009. The committee also engaged in regular dialogue with the Department of Health and Children and also with the Advertising Standards Authority of Ireland.

The table below gives the figures for classification queries for 2009 compared with previous years.

EUROPEAN PHARMACOPOEIA

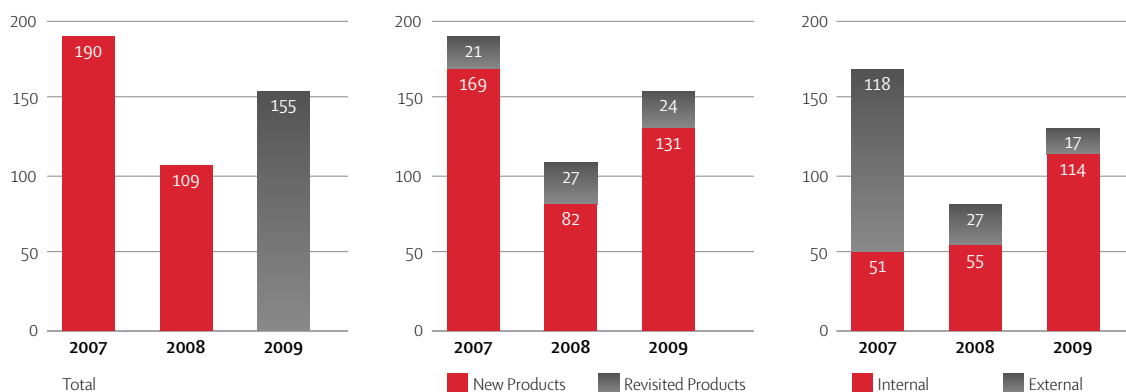
Three meetings of the European Pharmacopoeia (Ph. Eur.) Commission were held in 2009 and were attended by Dr. Mike Morris and Mr. Mirza Catibusic. In addition, delegates from Ireland participated in some of the many groups of experts and working parties which provide expert advice to Ph. Eur. Group 13B on Herbal Medicines met three times in 2009; Ireland is represented by Dr. Des Corrigan.

The Process Analytical Technology (PAT) working party held three meetings in 2009, and made useful progress in developing a new policy on uniformity testing of large sample sizes and in revision of the Ph. Eur method for NIR analysis.

The Homeopathic Manufacturing Methods (HMM) and Homeopathic Products (HOM) Working Parties met twice in 2009 including a visit to manufacturers. These visits were very helpful in moving towards consensus in the monographs on homeopathic substances.

Dr. Mike Morris participates in the work of the above groups and working parties.

Classification queries 2007-2009



An internal multi-disciplinary group was established to prepare for the implementation of the Advanced Therapies Regulation.

Senior Scientific Advisor

VARIATIONS

The new EU guidelines on classification of variations and best practice were published for consultation during summer 2009 and will be finalised in 2010. The internal IMB group continued to meet to provide comments on the consultation, review the likely impact on workload and finances and to look at the EU application form in the context of the likely impact on the IT needs of the organisation. An information day is planned for early 2010.

ADVANCED THERAPIES

The Advanced Therapies Regulation (EC) 1394/2007 became effective on 1 January 2009. This regulation deals with gene therapy, cell therapy and tissue-engineered medicinal products and brings these specialised products under the definition of a medicinal product given in Article 1 of Directive 2001/83/EC as amended. The directive was itself further amended in September 2009 by Commission Directive 2009/120/EC to change the definitions and dossier requirements for marketing authorisation for these highly specialised advanced therapy medicinal products (ATMPs). Applications for marketing authorisations for ATMPs will proceed via the EU centralised procedure as laid down in Regulation (EC) 726/2004 from 1 January 2009. The regulation sets up a specialised Committee on Advanced Therapies (CAT) within the EMA. The committee has one member and one alternate member from each Member State and staff from the IMB have been appointed to this committee.

During 2008, an internal multi-disciplinary group was established in the IMB to prepare for the implementation of the legislation. This group is chaired by the Senior Scientific Advisor and continued to meet during 2009. In February 2009, an information meeting was held at the IMB offices on the subject of the new ATMP legislation. IMB experts and staff and invited experts, mainly from clinical practice, attended this meeting and various presentations were made by IMB staff on the likely impact of the new legislation. In particular, it was emphasised that advanced therapies prepared in hospitals for individual patients will be exempt from the marketing authorisation requirements, but such activities will still be subject to a manufacturer's authorisation. The CAT held its first meeting in 2009 and continues to meet on a monthly basis at the EMA offices in London.

Finance and Corporate Affairs



Ms. Rita Purcell Director of Finance and Corporate Affairs

The Finance and Corporate Affairs department delivers a number of key service areas to the organisation. These include:

- *Management and safeguarding the finances of the IMB*
- *Providing secretarial support to the Board and Committees and ensuring adherence to best practice in the area of corporate governance*
- *Managing the building and accommodation requirements of the IMB*
- *Providing infrastructure requirements for the staff and visitors, reception, canteen, travel service, and library services*
- *Managing the Freedom of Information obligations*
- *Managing legal issues for the IMB*

2009 was another challenging and busy year for the department and some of the highlights are outlined below.

FINANCE

As outlined in the financial statements, the IMB's finances remained stable. The Accounts section continued to successfully manage the high volumes of work while maintaining high standards of internal control. To further increase efficiency and make a contribution towards a greener environment, the section commenced paying staff expenses directly into bank accounts during the year, replacing the previous method of payment by cheque. In addition, customer statements are now being e-mailed out on a monthly basis. A detailed review of the IMB's fee structure also took place during the year. In 2009, internal auditors reviewed the areas of purchasing and procurement. All procedures were carried out using standard operating procedures under the quality management system which has added great value to the operation of the section.

CORPORATE AFFAIRS

2009 was a busy year for corporate services as the increases in operations outlined in all the other departments increased the level of services provided.

The IMB's 'green team' continued to look at all consumables in the organisation and implemented some plans for reducing consumption and costs for the organisation.

The Corporate Affairs section provided support to the Veterinary Information Day on 8 September, which was well attended by industry. During 2009, extensive preparation was conducted for the BT Young Scientist event and four other events scheduled to take place at the beginning of 2010.

The IMB published three Medicinal Products Newsletters in 2009, issue numbers 32, 33 and 34. The newsletters cover a wide range of topics such as:

- electronic reporting for adverse reactions
- direct healthcare professional communications
- guide to electronic submissions of applications for authorisations and registrations of human medicines
- herbal medicinal products
- GMP updates
- new system for controlled licences

The IMB received **18** Freedom of Information Act requests in 2009.

Finance and Corporate Affairs

- Braille and patient-accessible leaflets
- revised format for manufacturer's/importer's authorisation
- veterinary pharmacovigilance
- veterinary regulatory fee consultations

There were a number of Freedom of Information Act requests in 2009. The IMB received 17 non personal requests and one personal request for information. The outcome of these requests is outlined below:

Request outcome

Number of FOI requests received	18
Granted/ part granted	11
Refused	6
Withdrawn/handled outside FOI Act	1
Internal reviews	0
Appeals to the Information Commissioner	0

BUILDINGS

2009 continued to be a busy year in the buildings area in relation to ongoing maintenance of the IMB offices. A number of internal buildings projects were undertaken to maximise space utilisation and workflow efficiency.

Human Resources



Ms. Frances Lynch Director of Human Resources

The HR department was established as a separate department and represented at executive level in 2009.

The HR strategy is to work with the business identifying and implementing innovative solutions to address emerging needs.

The key areas in which services are provided are:

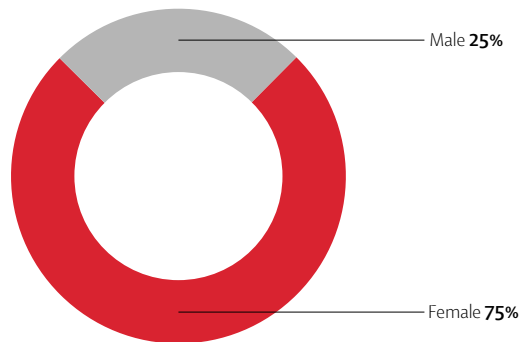
- **Organisation development**
- **Performance management and coaching**
- **Learning and development**
- **Employee relations**
- **Recruitment and selection**

ORGANISATION DEVELOPMENT

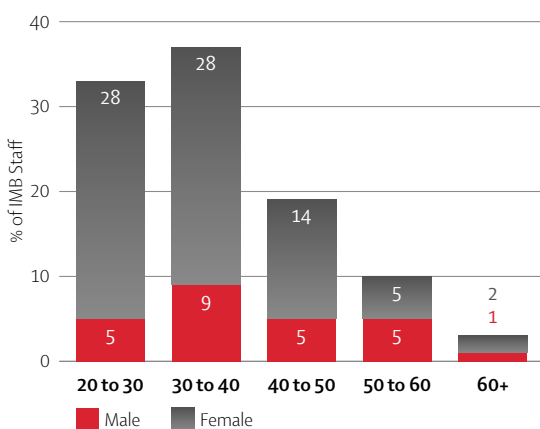
The HR department participated in an organisation-wide BEMA audit which acknowledged the effective people management practices in place within the IMB.

The age and gender profile of staff in the IMB remained unchanged in 2009. The majority of staff are between the ages of 20 and 40 with 75% female and 25% male. The organisation continues to be in compliance with the 3% target set by the Disability Act 2005.

Staff breakdown by gender 2009



Staff breakdown by age 2009



The IMB has a range of family-friendly working arrangements which were supplemented by the introduction of a policy on part-time working in 2009. There are now 11% of staff availing of flexible working arrangements.

Staff retention during 2009 remains strong, evidenced by turnover rates at 11.1% (including entry level administrative posts) and 3.8% (excluding entry level administrative posts). This is significantly below the industry average which ranges from 12.7 to 19.1%.

The HR department was involved during 2009 with other agency partners in the preparation of preliminary planning documents regarding the HR impact of the proposed merger of agencies.

The number of internal training sessions in 2009 increased by **20%** from 2008.

Human Resources

PERFORMANCE MANAGEMENT AND COACHING

This is a priority area for the business and HR and a number of significant activities were undertaken in 2009:

Performance Development Programme (PDP)

In response to the introduction of a new business planning model, the PDP (whose purpose is to cascade such plans through the business to an individual job holder level) was redesigned and support material developed for roll out and implementation in early 2010.

Probation

The management of probation within the IMB is vital to ensure that only those staff members who have the required skills are retained and the HR department plays an active role in supporting line management in this process. In 2009, there were 87 employees (including new joiners and those acting up or promoted) due to complete their probation. Of these 74% completed probation successfully, 5% had probation extended and 14% left during the period of probation. The probation period for the remaining 7% was ongoing.

SUPPORT FOR LINE MANAGEMENT

The HR department has as one of its key objectives the ongoing provision of support to managers in the effective management of their staff. In 2009, this was achieved through access as required to expert advice and assistance and the provision of statistical reports in a range of areas to assist in decision making. These included absence rates, flexitime, annual leave etc. In addition, the department delivered a range of training and coaching supports required as a result of the restructuring of the Human Medicines and Medical Devices departments and the creation of the new departments of Human Products Authorisation and Registration, and Human Products Monitoring.

ABSENCE MANAGEMENT

The overall absence rate for 2009 was 2.8% which was a notable decrease on 2008 (3.4%) particularly in the context of the expectation of increased absence levels due to the presence of the H1N1 flu pandemic. These rates are well below industry average rates of 3% to 4%.

LEARNING AND DEVELOPMENT

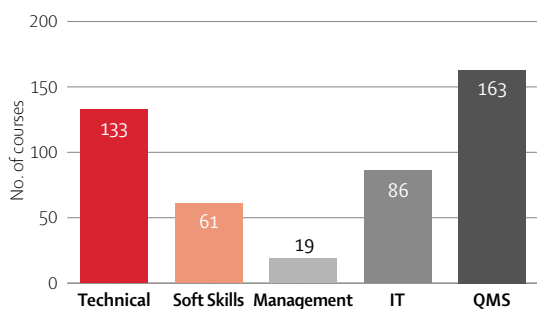
This continued to be a vital element of the effective development of our human resources. Key areas of activity were:

- The HR department undertook a comprehensive review of the approach to the identification of learning and development needs and the delivery of solutions across the organisation. This was with a view to developing a learning and development strategy to put in place the systems and processes to ensure our human resources are effectively trained and developed to meet both current and future needs. This process was further supported by the appointment of a Learning and Development Manager at the end of 2009.
- The average number of training days per person in 2009 was just over three, continuing the trend set in 2008. The nature of courses undertaken was broad as set out on the next page.
- The number of internal training sessions in 2009 increased by 20% from 2008 based on a strong focus by the organisation on dignity and respect training and the implementation of training sessions for all staff and for those managing staff. A total of 21 sessions were delivered, six of which were specifically for those with responsibility for managing staff.

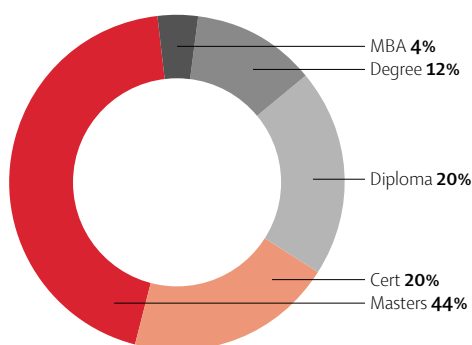
The overall absence rate for 2009 was **2.8%**, well below industry average rates of 3% to 4%.

The IMB continues to support staff in undertaking programmes of further education with 7.6% of staff receiving support for courses.

Training courses broken down by type 2009



Qualification type



A new software module (Empowerment) was purchased to increase the functionality of the HR database and provide a workflow type system to enable an improved process for planning, approving, recording and reporting of training activities.

EMPLOYEE RELATIONS

2009 continued to reflect a stable industrial relations climate within the IMB.

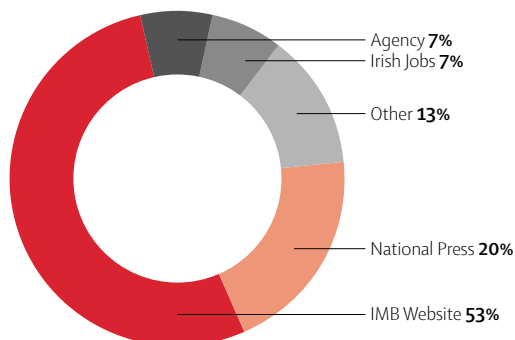
The staff communications group met regularly and each meeting was attended by a HR representative. This forum continues to facilitate communication of policy changes or planned initiatives and allows feedback directly from staff representatives from all departments.

Health and safety and wellness initiatives during the year 2009 included eye tests, provision of seasonal flu vaccine, a walking challenge and a series of lunchtime learning sessions. The uptake on all initiatives was positive.

RECRUITMENT AND SELECTION

In 2009, 27 competitions took place including promotions, filling vacant existing posts and new appointments. The IMB website proved to be one of the most effective means of attracting candidates to technical posts.

Recruitment sources 2009



Financial Statements

For the year ended 31 December 2009

Board Members and Other Information

Board Members :

Mr. Pat O'Mahony (Chairman)
Mr. Pat Brangan
Dr. Brendan Buckley
Mr. Wilfrid Higgins
Ms. Ingrid Hook
Mr. Brendan McLoughlin
Ms. Cicely Roche
Ms. Maureen Windle

The Board was appointed by the Minister for Health and Children for a term of 5 years from 1st January 2006.

Bankers :

Allied Irish Bank
Lower Baggot Street
Dublin 2

Bank of Ireland Corporate
Lower Baggot Street
Dublin 2

Solicitors :

Eugene F. Collins
Temple Chambers
3, Burlington Road
Dublin 4

Head Office :

Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Auditor :

Comptroller and Auditor General
Dublin Castle
Dublin 2

Corporate Governance

The Irish Medicines Board (the IMB) was established under the terms of the Irish Medicines Board Act, 1995, and is governed by a Board which was appointed by the Minister for Health and Children. The Board of the IMB (the Board) consists of a chairman and seven unremunerated non executive members.

The IMB is committed to the highest standards of Corporate Governance and has implemented the Department of Finance "Code of Practice for the Governance of State Bodies". This Code of Practice, which was issued to the Irish Medicines Board in January 2002, incorporates many of the principles under which the IMB operates, taking account of the size and legal nature of the organisation.

An updated Code of Practice was published by the Minister for Finance in June 2009, to take account of administrative and legislative developments in the corporate governance framework since 2001. The IMB have carried out a detailed review of this updated Code, to ensure that its provisions are still reflected in the principles under which the IMB operates.

The IMB has in place an extensive Code of Conduct for all staff, committees and Board members. The IMB applies the highest standards of disclosure and transparency in respect of interests held by staff, committees and Board members.

Audit Committee

The IMB has an audit committee comprising two Board members, which met on 5 occasions during 2009. This committee is responsible for reviewing internal control matters, together with any other issues raised by the external auditors, the Board or management. The external auditor meets annually with the committee to brief them on the outcome of the external audit. In 2005 the IMB appointed Crowleys DFK as internal auditor to the Board under a three-year contract. During 2009 the internal auditors reviewed the areas of purchasing and procurement and reported their findings to the audit committee. The audit committee has also been involved with the review of the quality systems as described below.

Quality Systems

During 2009, the finance section of the IMB continued the process of implementing and reviewing standard operating procedures (SOPs) under the quality management system. This process involved a critical review and analysis of internal controls and processes throughout the section with particular emphasis on risk management. This system now underpins the internal control environment and feeds into the internal audit process and ultimately into the audit committee.

Remuneration Policy - Board Members and Executive Directors

Remuneration and travel expenses paid to Board members are disclosed in note 17 to the financial statements. The Chairman receives remuneration as directed by the Minister for Health and Children in accordance with the Irish Medicines Board Act, 1995. Other Board members receive travel expenses in accordance with circulars issued by the Department of Health and Children. The Chief Executive is remunerated in accordance with guidelines issued from Government and other Executive Directors are paid in accordance with Department of Health and Children pay scales.

Remuneration Committee

The IMB has established a remuneration committee as a sub-committee of the Board to review the remuneration of the Chief Executive in accordance with guidelines issued by the Department of Finance and the Department of Health and Children. The Chief Executive's remuneration is disclosed in note 18 to the Financial Statements.

Internal Control

The Board is responsible for the IMB's systems of internal control. Such systems can only provide reasonable and not absolute assurance against material misstatement or loss. The systems of internal controls in use in the Irish Medicines Board are described more fully in the Chairman's report on page 64.

Report of the Chairman of the Irish Medicines Board

regarding the assessment of internal financial controls of a State body for the year ended 31st December 2009

1. I, as Chairman, acknowledge that the Board is responsible for the body's system of internal financial control.
2. The IMB system of internal control can provide only reasonable and not absolute assurance against material error, misstatement or loss.
3. The Board confirms that there is an ongoing process for identifying, evaluating and managing the significant risks faced by the IMB. This process is regularly reviewed by the Board via the report of the Chief Executive.

Management are responsible for the identification and evaluation of significant risks applicable to their areas of business together with the design and operation of suitable internal controls. These risks are assessed on a continuing basis and may be associated with a variety of internal or external sources including control breakdowns, disruption in information systems, natural catastrophe and regulatory requirements.

Management reports fortnightly on operational issues and risks and how they are managed to the Management Committee. The Management Committee's role in this regard is to review on behalf of the Board the key risks inherent in the affairs of the IMB and the system of actions necessary to manage such risks and to present their findings on significant matters via the Chief Executive to the Board.

The Chief Executive reports to the Board on behalf of the executive management on significant changes in the work of the IMB and on the external environment, which affects significant risks. The Director of Finance and Corporate Affairs provides the Board with monthly financial information, which includes key performance indicators. Where areas for improvement in the system are identified the Board considers the recommendations made by the Management Committee.

An appropriate control framework is in place with clearly defined matters which are reserved for Board approval only or, as delegated by the Board, for appropriate Executive approval. The Board has delegated the day-to-day management of the IMB and established appropriate limits for expenditure authorisation to the Executive. The Chief Executive is responsible for implementation of internal controls, including internal financial control.

The system of internal financial control is monitored in general by the processes outlined above. In addition, the Audit Committee of the Board reviews specific areas of internal control as part of their terms of reference.

4. The Audit Committee of the Board have satisfactorily reviewed the effectiveness of the system of internal control on behalf of the Board. The Audit Committee of the Board carried out a formal review of these systems in respect of 2009 at its meeting on 18th June 2010.



Pat O'Mahony
Chairman

Statement of Board Members' Responsibilities

The Board is required by the Irish Medicines Board Act, 1995 to prepare financial statements for each financial year which give a true and fair view of the state of affairs of the Irish Medicines Board and of its surplus or deficit for that period.

In preparing those statements the Board is required to:


- select suitable accounting policies and apply them consistently
- make judgements and estimates that are reasonable and prudent
- disclose and explain any material departures from applicable accounting standards, and
- prepare the financial statements on a going concern basis unless it is inappropriate to presume that the Irish Medicines Board will continue in existence.

The Board is responsible for keeping proper accounting records which disclose with reasonable accuracy at any time the financial position of the Irish Medicines Board and which enable it to ensure that the financial statements comply with the IMB Act and with accounting standards generally accepted in Ireland. It is also responsible for safeguarding the assets of the Irish Medicines Board and hence for taking reasonable steps for the prevention and detection of fraud and other irregularities.

On behalf of the Board



Pat O'Mahony
Chairman



Maureen Windle
Board Member

Report of the Comptroller and Auditor General

for presentation to the Houses of the Oireachtas

I have audited the financial statements of the Irish Medicines Board for the year ended 31 December 2009 under Section 18 of the Irish Medicines Board Act, 1995.

The financial statements, which have been prepared under the accounting policies set out therein, comprise the Accounting Policies, the Statement of Income and Expenditure, the Statement of Total Recognised Gains and Losses, the Balance Sheet, the Cash Flow Statement and the related notes.

Respective Responsibilities of the Board and the Comptroller and Auditor General

The Irish Medicines Board is responsible for preparing the financial statements in accordance with the Irish Medicines Board Act, 1995, and for ensuring the regularity of transactions. The Board prepares the financial statements in accordance with Generally Accepted Accounting Practice in Ireland as modified by the directions of the Minister for Health and Children in relation to accounting for superannuation costs. The accounting responsibilities of the Board Members are set out in the Statement of Board Members' Responsibilities.

My responsibility is to audit the financial statements in accordance with relevant legal and regulatory requirements and International Standards on Auditing (UK and Ireland).

I report my opinion as to whether the financial statements give a true and fair view, in accordance with Generally Accepted Accounting Practice in Ireland. I also report whether in my opinion proper books of account have been kept. In addition, I state whether the financial statements are in agreement with the books of account.

I report any material instance where moneys have not been applied for the purposes intended or where the transactions do not conform to the authorities governing them.

I also report if I have not obtained all the information and explanations necessary for the purposes of my audit.

I review whether the Statement on Internal Financial Control reflects the Board's compliance with the Code of Practice for the Governance of State Bodies and report any material instance where it does not do so, or if the statement is misleading or inconsistent with other information of which I am aware from my audit of the financial statements. I am not required to consider whether the Statement on Internal Financial Control covers all financial risks and controls, or to form an opinion on the effectiveness of the risk and control procedures.

I read other information contained in the Annual Report, and consider whether it is consistent with the audited financial statements. I consider the implications for my report if I become aware of any apparent misstatements or material inconsistencies with the financial statements.

Basis of Audit Opinion

In the exercise of my function as Comptroller and Auditor General, I conducted my audit of the financial statements in accordance with International Standards on Auditing (UK and Ireland) issued by the Auditing Practices Board and by reference to the special considerations which attach to State bodies in relation to their management and operation. An audit includes examination, on a test basis, of evidence relevant to the amounts and disclosures and regularity of the financial transactions included in the financial statements. It also includes an assessment of the significant estimates and judgments made in the preparation of the financial statements, and of whether the accounting policies are appropriate to the Board's circumstances, consistently applied and adequately disclosed.

I planned and performed my audit so as to obtain all the information and explanations that I considered necessary in order to provide me with sufficient evidence to give reasonable assurance that the financial statements are free from material misstatement, whether caused by fraud or other irregularity or error. In forming my opinion I also evaluated the overall adequacy of the presentation of information in the financial statements.

Opinion

In compliance with the directions of the Minister for Health and Children, the Board recognises the costs of superannuation entitlements only as they become payable. This basis of accounting does not comply with Financial Reporting Standard 17 which requires such costs to be recognised in the year the entitlements are earned.

Except for the non-recognition of the Board's superannuation costs and liabilities in accordance with Financial Reporting Standard 17, the financial statements give a true and fair view, in accordance with Generally Accepted Accounting Principles in Ireland, of the state of the Board's affairs at 31 December 2009 and of its income and expenditure for the year then ended.

In my opinion, proper books of account have been kept by the Board. The financial statements are in agreement with the books of account.



Gerard Smyth

For and on behalf of the Comptroller and Auditor General
10 September 2010

Accounting Policies

Historical Cost Convention

The Financial Statements are prepared in accordance with generally accepted accounting principles under the historical cost convention and comply with the financial reporting standards of the Accounting Standards Board, with the exception of superannuation - see note below.

Income Recognition

Income is recognised in the financial statements on the following basis:

- In the case of applications for product authorisations (new applications, variations to existing authorisations, or transfers) and clinical trial applications, income is recognised in the financial statements when a valid application form is received.
- In the case of wholesale and manufacturing licences and maintenance of product authorisations, fees are payable annually and a full year's income is accrued in each financial year.

Expenditure Recognition

Expenditure is recognised in the financial statements on an accruals basis as it is incurred.

Reporting Currency and Currency Translation

The financial statements are prepared in euros.

Transactions in currencies other than euro are recorded at the rates ruling at the date of the transactions or at a contracted date. Monetary assets and liabilities are translated into euro at the balance sheet date or at a contracted date. Exchange differences are dealt with in the income and expenditure account.

Tangible Assets

Tangible Assets excluding Premises

Tangible assets excluding premises are stated at cost less accumulated depreciation. Depreciation is calculated in order to write off the cost of tangible assets to their estimated residual values over their estimated useful lives by equal annual instalments.

The estimated useful lives of tangible assets by reference to which depreciation has been calculated are as follows:

Leasehold Property : Unexpired portion of the lease

Fixtures and Fittings : 5 years

Computer Equipment : 3 years

Improvements to Premises : 10 years

Premises

The IMB purchased its premises at Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2 on 22 December 2004. The value capitalised was equal to the purchase price plus those costs directly attributable to bringing the asset into use.

No depreciation has been calculated on the value of premises, as the remaining useful economic life is estimated to be greater than 50 years.

Taxation

The Irish Medicines Board is exempt from liability to Corporation Tax under Section 32 of the Finance Act, 1994.

Debtors

Known bad debts are written off and specific provision is made for any amount the collection of which is considered doubtful.

Superannuation

The superannuation scheme operated by the Irish Medicines Board is in accordance with the Local Government (Superannuation Revision) (Consolidation) Scheme, 1986. It is an unfunded statutory scheme and benefits are met from current income as they arise.

The charge to salaries and wages is stated gross of superannuation deductions of €629,478 (2008 – €637,517). The surplus for the year on page 70 is then shown both before and after superannuation transactions for the year. The income and expenditure reserve on the balance sheet is split between retained reserves and superannuation reserves in note 11.

By direction of the Minister for Health and Children, the provisions of FRS 17 are not being complied with.

Provisions

A provision is recognised when the IMB has a present obligation as a result of a past event, it is probable that this will be settled at a cost to the IMB and a reliable estimate can be made of the amount of the obligation.

Library

No value has been placed on the books, audio-visual resources and electronic databases in the library. Expenditure on these items is written off in the year in which it is incurred.

Leases

All leases are treated as operating leases and the rentals thereunder are charged to the Income and Expenditure account on a straight line basis over the lease period.

Statement of Income and Expenditure

For the year ended 31 December 2009

	Note	2009 €	2008 €
Fee Income	2	21,453,656	18,704,256
Other Income	3	4,713,275	5,220,407
		26,166,931	23,924,663
Salaries and Wages	4	15,869,204	15,255,687
Other Operating Costs	5	5,489,743	5,888,006
Depreciation	1	1,502,168	1,606,304
		22,861,115	22,749,997
Surplus for the year before write back of Superannuation contributions		3,305,816	1,174,666
Staff Superannuation Contributions		629,478	637,517
Surplus for the year		3,935,294	1,812,183
Balance brought forward		14,487,130	12,674,947
Balance carried forward		18,422,424	14,487,130

All income and the surplus for the year arises from continuing activities.



Pat O'Mahony

Chairman



Maureen Windle

Board Member

The accounting policies on pages 68 to 69 and the notes on pages 74 to 80 form part of the financial statements.

Statement of Total Recognised Gains and Losses

For the year ended 31 December 2009

	Note	2009 €	2008 €
Retained Surplus for the year		3,935,294	1,812,183
Unrealised Gains for the year		-	-
Total Recognised Gains		3,935,294	1,812,183

The accounting policies on pages 68 to 69 and the notes on pages 74 to 80 form part of the financial statements.

Balance Sheet

As at 31 December 2009

	Note	2009 €	2008 €
Tangible Assets	1	24,194,544	24,684,505
Current Assets			
Debtors and Prepayments	6	2,082,648	1,664,448
Stock of Stationery		2,559	3,451
Cash at Bank and in Hand	12	308,056	5,369
Short Term Deposits		10,127,002	5,857,283
		12,520,265	7,530,551
Creditors - Amounts falling due within one year			
Creditors and Accruals	7	6,392,385	5,487,926
Mortgage	13	793,332	340,000
		7,185,717	5,827,926
Net Current Assets		5,334,548	1,702,625
Long Term Liabilities			
Mortgage	13	11,106,668	11,900,000
TOTAL NET ASSETS		18,422,424	14,487,130
Financed by			
Income and Expenditure Reserve	11	18,422,424	14,487,130
		18,422,424	14,487,130



Pat O'Mahony
Chairman



Maureen Windle
Board Member

The accounting policies on pages 68 to 69 and the notes on pages 74 to 80 form part of the financial statements.

Cash Flow Statement

For the year ended 31 December 2009

	Note	2009 €	2008 €
Reconciliation of surplus to net cash inflow from operating activities			
Surplus for the year		3,935,294	1,812,183
Depreciation Charge		1,502,168	1,606,304
(Increase)/Decrease in Debtors		(418,200)	38,903
(Increase)/Decrease in Stocks		892	1,256
Increase/(Decrease) in Creditors - amounts falling due within one year		904,459	512,091
Deposit Interest		(91,596)	(121,894)
Bank Interest and Charges		512,075	528,025
Loss/(Gain) on Disposal of Fixed Assets		1,694	374
Net Cash Inflow from Operating Activities		6,346,786	4,377,242
Cash Flow Statement			
Net Cash Inflow from Operating Activities		6,346,786	4,377,242
Return on Investments and Servicing of Finance	8	(420,479)	(406,131)
Capital Expenditure	8	(1,013,901)	(1,633,906)
Management of Liquid Resources	8	(4,269,719)	(2,003,618)
Financing	8	(793,332)	(340,000)
Increase/(Decrease) in Cash		(150,645)	(6,413)
Reconciliation of net cash flow to movement in net debt			
Increase/(Decrease) In Cash		(150,645)	(6,413)
Increase/(Decrease) In Short Term Deposits		4,269,719	2,003,618
(Increase)/Decrease In Long Term Finance		793,332	340,000
Change In Net Debt		4,912,406	2,337,205
Net Debt at start of year		(6,377,348)	(8,714,553)
Net Debt at end of year	9	(1,464,942)	(6,377,348)

The accounting policies on pages 68 to 69 and the notes on pages 74 to 80 form part of the financial statements.

Notes to the Financial Statements

For the year ended 31 December 2009

1 TANGIBLE ASSETS

	Fixtures and Fittings €	Computer Equipment €	Leasehold Improvements €	Improvements To Premises €	Premises €	Total €
Cost						
Balance as at 1 January 2009	900,338	6,687,322	502,445	3,271,602	20,383,000	31,744,707
Additions for the year	43,046	940,049	-	30,806	-	1,013,901
Disposals for the year	(25,268)	(47,483)	-	-	-	(72,751)
As at 31 December 2009	918,116	7,579,888	502,445	3,302,408	20,383,000	32,685,857
Depreciation						
Balance as at 1 January 2009	436,002	5,703,686	199,723	720,791	-	7,060,202
Charge for the year	164,482	957,200	50,245	330,241	-	1,502,168
Disposals for the year	(23,574)	(47,483)	-	-	-	(71,057)
As at 31 December 2009	576,910	6,613,403	249,968	1,051,032	-	8,491,313
Net Book value at 31 December 2009	341,206	966,485	252,477	2,251,376	20,383,000	24,194,544
Net Book value at 1 January 2009	464,336	983,636	302,722	2,550,811	20,383,000	24,684,505

2 INCOME

	2009 €	2008 €
Fee Income		
Clinical Trials	140,211	151,762
Human Medicine - National Fees	7,857,555	6,459,620
Human Medicine - European Fees	7,857,155	6,837,485
Veterinary Medicine - National Fees	1,137,328	1,076,667
Veterinary Medicine - European Fees	966,288	915,986
Compliance Department	3,292,018	3,087,380
Medical Devices	203,101	175,356
	21,453,656	18,704,256
Other Income (Note 3)	4,713,275	5,220,407
Total Income	26,166,931	23,924,663

Certain fees, totalling €14,902,621, are required by law to be disposed of in accordance with the directions of the Minister for Finance.

	2009 €	2008 €
3 OTHER INCOME		
Dept Of Health and Children Funding	4,602,032	4,993,212
IT Income	5,000	5,000
Conference Fee Income	15,800	100,675
Deposit Interest	91,596	121,894
(Loss)/Gain on Disposal of Fixed Assets	(1,694)	(374)
Miscellaneous	541	-
	4,713,275	5,220,407
4 SALARIES AND WAGES		
	2009 €	2008 €
Salaries and Wages	14,590,623	13,971,860
Social Welfare Costs	1,278,581	1,283,827
	15,869,204	15,255,687

The average number of staff employed during the year was 270 (2008 – 260).

Staff employed at 31 December 2009 can be analysed across the following departments :

	2009	2008
Medical Technical	22	18
Pharmaceutical Technical	30	32
Veterinary Technical	16	12
Compliance Technical	19	18
Medical Devices Technical	16	17
Enforcement Technical	8	9
Blood Directive Technical	4	4
Controlled Drugs Technical	3	3
Tissues and Cells Technical	2	2
Chief Executive and Corporate	31	34
Operational Staff	105	106
Pensioners	13	11
	269	266

Notes to the Financial Statements
(continued)

	2009 €	2008 €
5 OPERATING COSTS		
Accommodation Costs	1,009,815	1,050,907
Travel, Representation and Training	829,890	1,156,870
Bank Charges and Interest	512,075	528,025
Legal and Professional Fees	979,322	361,706
Stationery, Publications and Postage	389,291	422,104
Other Operating Costs	1,769,350	2,368,394
	5,489,743	5,888,006
6 DEBTORS (ALL DUE WITHIN ONE YEAR)		
	2009 €	2008 €
Trade Debtors	1,386,893	1,160,040
Prepayments	388,605	322,693
Other Debtors	307,150	181,715
	2,082,648	1,664,448
7 CREDITORS (AMOUNTS FALLING DUE WITHIN ONE YEAR)		
	2009 €	2008 €
Trade Creditors	997,509	561,913
Accruals	4,917,858	4,506,106
Revenue	477,018	419,907
	6,392,385	5,487,926

	2009 €	2008 €
8 GROSS CASH FLOWS		
<i>Returns on Investment and Servicing of Finance</i>		
Deposit Interest	91,596	121,894
Bank Interest and Charges	(512,075)	(528,025)
	(420,479)	(406,131)
<i>Capital Expenditure</i>		
Payments to acquire Tangible Fixed Assets	(1,013,901)	(1,634,288)
Receipts from sales of Tangible Fixed Assets	0	382
	(1,013,901)	(1,633,906)
<i>Management of Liquid Resources</i>		
(Increase)/Decrease in Short Term Deposits	(4,269,719)	(2,003,618)
	(4,269,719)	(2,003,618)
<i>Financing</i>		
Increase/(Decrease) in Long Term Finance	(793,332)	(340,000)
	(793,332)	(340,000)

9 ANALYSIS OF CHANGES IN NET DEBT

	As at 01/01/2009	Cashflow	As at 31/12/2009
Cash at Bank and in Hand	5,369	302,687	308,056
Short Term Deposits	5,857,283	4,269,719	10,127,002
Debt Due Within One Year	(340,000)	(453,332)	(793,332)
Debt Due After One Year	(11,900,000)	793,332	(11,106,668)
	(6,377,348)	4,912,406	(1,464,942)

10 ADMINISTRATION EXPENSES

	2009 €	2008 €
Surplus for the year was calculated having charged :		
Auditor's Remuneration	17,390	18,500

Notes to the Financial Statements
(continued)

	2009 €	2008 €
11 INCOME AND EXPENDITURE RESERVES		
The Income and Expenditure Reserve disclosed in the Balance Sheet on page 72 comprises the following :		
Retained Reserves	13,967,287	10,661,471
Staff Superannuation Contributions	4,455,137	3,825,659
	18,422,424	14,487,130

12 CASH AND BANK BALANCES

	2009 €	2008 €
Current Account Balances	306,548	3,217
Cash on Hand	1,508	2,152
	308,056	5,369

13 LONG TERM LIABILITIES

Mortgage

On 22 December 2004 the Board purchased its premises at Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2. The purchase was financed by way of a mortgage, secured on the premises, of €20,400,000 over 20 years from Bank of Ireland Corporate Lending.

The Irish Medicines Board is committed to making the following capital repayments on its mortgage:

	2009 €	2008 €
Within one year	793,332	340,000
Between one and five years	3,173,328	3,626,660
After five years	7,933,340	8,273,340
	11,900,000	12,240,000

14 INTEREST RATE EXPOSURE

The IMB have taken all necessary steps to minimise its interest rate exposure by fixing two-thirds of the borrowings for a period of 10 years. The balance of the borrowings are fully offset by cash reserves. For 2010 it is estimated that the net borrowings for which an interest rate exposure may arise is €0.

2009
€

2008
€

15 FINANCIAL COMMITMENTS

Operating Leases

Amounts payable during the next twelve months in respect of leases which expire:

– within one year	-	-
– between one and five years (in respect of Longphort House)	69,031	-
– after five years (in respect of Alexandra House)	285,984	285,984
	355,015	285,984

On 22 December 2004 the IMB signed a leasehold interest in respect of the 5th floor, Alexandra House, Earlsfort Centre, Dublin 2. At 31 December 2009 this lease had 12 years remaining. On 1 June 2010 the IMB signed a leasehold interest in respect of the 3rd floor, Longphort House, Earlsfort Centre, Dublin 2. At 1 June 2010 this lease had 4 years and 10 months remaining.

16 CAPITAL COMMITMENTS

Contracted For (Contract Signed)

Not Contracted For

2009 €	2008 €
385,000	430,000
250,000	230,000
635,000	660,000

17 BOARD REMUNERATION

Chairman's Salary

Board Members' Travel Expenses

2009 €	2008 €
23,478	25,435
7,798	8,486
31,276	33,921

Notes to the Financial Statements
(continued)

	2009 €	2008 €
18 STAFF REMUNERATION		
Chief Executive's Remuneration		
Basic Salary	159,544	158,965
Performance Related Payment	22,255	22,500
	181,799	181,465

The Chief Executive's pension entitlements do not extend beyond the standard entitlements in the model public sector defined benefit superannuation scheme.

19 RELATED PARTY TRANSACTIONS

There have been no transactions with related parties which require disclosure under Financial Reporting Standard 8.

20 PROMPT PAYMENT OF ACCOUNTS

The Irish Medicines Board (IMB) confirms that it is complying with EU law in relation to prompt payments of account.

21 EXCHANGE RATES

The exchange rates used in preparing these financial statements were as follows :

2009 €1 = STG £0.8881

2008 €1 = STG £0.9525

22 PROVISIONS

The Board has been notified of a number of legal proceedings or potential proceedings. The information usually required by FRS 12 Provisions, contingent liabilities and contingent assets is not disclosed as the Board believes that to do so would be prejudicial to the outcome.

In 2009 the Board was the unsuccessful defendant in a Supreme Court appeal, the issue of costs and damages have been referred back to the High Court. The Board is satisfied that they have made adequate provision against any award.

23 GOING CONCERN

The Board has a reasonable expectation, at the time of approving the financial statements, that the IMB has adequate resources to continue its operations. For this reason, the Board continues to adopt the going concern basis in preparing the financial statements.

24 APPROVAL OF FINANCIAL STATEMENTS

The financial statements were approved by the Board on 24 June 2010.

Appendix I : Committee Members

Management Committee

Mr. Patrick O'Mahony – Chief Executive
Dr. J. Gabriel Beechinor – Director of Veterinary Medicines
Dr. Joan Gilvarry – Director of Human Products Monitoring
Ms. Frances Lynch – Director of Human Resources
Mr. John Lynch – Director of Compliance
Ms. Suzanne McDonald – Director of Information Technology and Change Management
Dr. Mike Morris – Senior Scientific Advisor
Ms. Ann O'Connor – Director of Human Products Authorisation and Registration
Ms. Rita Purcell – Director of Finance and Corporate Affairs

Board

Mr Pat O'Mahony – Chairman
Prof. Brendan Buckley
Mr. Pat Brangan
Mr. Wilfrid J. Higgins
Ms. Ingrid Hook
Mr. Brendan McLaughlin
Ms. Cicely Roche
Ms. Maureen Windle

Audit Committee

Ms. Maureen Windle – Chairman
Mr. Pat Brangan

Advisory Committee for Human Medicines

Prof. Brendan Buckley – Chairman
Dr. Paul Browne
Ms. Eugenie Canavan
Dr. Kevin Connolly
Dr. Des Corrigan
Prof. Mary Horgan
Prof. John Kelly
Dr. David Kerins
Ms. Marita Kinsella
Mr. Tom McGuinn
Dr. Bernard Silke
Dr. Patrick A. Sullivan

Advisory Committee for Veterinary Medicines

Mr. Pat Brangan – Chairman
Mr. Tom Barragry
Dr. Ruaidhri Breathnach
Ms. Eugenie Canavan
Mr. Michael Clancy
Prof. Ann Cullinane
Mr. Tom McGuinn
Mr. Raymond Muldoon
Dr. Hamish Rodger
Dr. Donal Sammin

Advisory Committee for Medical Devices

Mr. Wilfrid J. Higgins – Chairman
Dr. Geoff Chadwick
Ms. Maureen D'Arcy
Ms. Aideen Drury-Byrne
Dr. John Keogh
Prof. Robert McConnell
Dr. Brendan McCormack
Dr. Tim McGloughlin
Dr. John O'Mullane
Ms. Maebh Smith
Prof. Wil van der Putten

**Appendix I : Committee Members
(continued)**

***Experts Sub-Committee of the Advisory Committee
for Human Medicines***

Prof. Mary Horgan – Chairman
Prof. Brendan Buckley
Dr. Colin Buckley
Dr. Owen Carey
Dr. Kevin Connolly
Dr. Noreen Dowd
Dr. Stephen Eustace
Prof. Michael Fitzgerald
Dr. Stephen Flint
Dr. Tim Fulcher
Dr. Joseph Galvin
Dr. Patrick Gavin
Dr. Kevin Kelleher
Dr. Mary Keogan
Prof. David Kerins
Dr. Lorraine Kyne
Dr. Mark Ledwidge
Dr. John McCaffrey
Dr. Patricia McCormack
Prof. Aidan McCormick
Dr. Frank Murray
Dr. Yvonne O’Meara
Mr. Ashley Poynton
Dr. Brion Sweeney
Dr. Jogin Thakore
Dr. Douglas Veale

***Clinical Trial Sub-Committee of Advisory Committee
for Human Medicines***

Dr. Patrick A. Sullivan – Chairman
Prof. David Bouchier-Hayes
Dr. Paul Browne
Dr. Brian Cantwell
Dr. Peter A. Daly
Prof. Ted Dinan
Prof. Sidney Lowry
Dr. Tom Pierce
Dr. John Taaffe

Advisory Sub-Committee for Herbal Medicines

Dr. Des Corrigan – Chairman
Dr. Fiona Barry
Dr. Kevin Connolly
Ms. Nicola Darrell
Ms. Ingrid Hook
Ms. Claudine Hughes
Ms. Helen McCormack
Dr. Hugh McGlynn
Dr. Diarmaid O’Connell
Dr. Donal O’Mathuna
Dr. Camillus Power
Dr. Helen Sheridan

Appendix II : Glossary

ACMD	Advisory Committee for Medical Devices	eCTD	Electronic Common Technical Dossier
AOTI	Association of Occupational Therapists of Ireland	EEA	European Economic Area
ASR	Annual Safety Report	EHN	European Haemovigilance Network
ATMPs	Advanced Therapy Medicinal Products	EMA	European Medicines Agency
BEAI	Biomedical/Clinical Engineering Association of Ireland	ERCI	Electro-Technical Council of Ireland
BPWP	Blood Products Working Party	EU	European Union
BWP	Biological Working Party	EUSTITE	EU Project for Standards and Training for the Inspections of Tissue Establishments
CAT	Committee for Advanced Therapies	EWP	Efficacy Working Party
CD	Controlled drugs	FDA	Food and Drug Administration
CHMP	Committee for Human Medicinal Products	FSCs	Free Sale Certificates
CMD(h)	Co-ordination Group for Mutual Recognition and Decentralised Procedures - Human	GCP	Good clinical practice
CMD(v)	Co-ordination Group for Mutual Recognition and Decentralised Procedure - Veterinary	GDP	Good distribution practice
COEN	Compliance and Enforcement Working Group	GMP	Good Manufacturing Procedure
COMP	Committee for Orphan Medicinal Products	GTWP	Gene Therapy Working Party
CTFG	Clinical Trials Facilitation Group	H1N1	Pandemic A Influenza
CTS	Common Technical Specifications	HMPC	Committee on Herbal Medicinal Products
CVMP	Committee for Veterinary Medicinal Products	HSE	Health Service Executive
DCP	Decentralised Procedure	ICSRs	Individual Case Safety Reports
DHPC	Direct Healthcare Professional Communications	IEQAS	Irish External Quality Assessment Scheme
DIA	Drug Information Association	IMB	Irish Medicines Board
DMF	Drug Master File	IMDA	Irish Medical Devices Association
DOHC	Department of Health and Children	IVD	In-vitro diagnostic
DPR	Dual Pack Registration	LONO	Letter of No Objection
DSN	Drug Safety Newsletter	MAHs	Marketing authorisation holders
		MDEG	Medical Devices Expert Group
		MEDDEV	European Commission DG Enterprise and Industry – Medical Devices Guidance Document
		MIA	Manufacturing and Importation Authorisations
		MIMS	Monthly Index of Medical Specialities
		MR	Mutual recognition

Appendix II : Glossary
(continued)

NBOG	Notified Body Operations Group
NCAR	National Competent Authority reports
NHO	National Haemovigilance Office
NIRS	Near Infrared Spectroscopy
Non eCTD	Non Electronic Common Technical Dossier
NSAI	National Standards Authority of Ireland
OMCL	Official Medicines Control Laboratories
PA	Product Authorisation
PDCO	Paediatrics Committee
PhVWP	Pharmacovigilance Working Party
POCT	Point of Care Testing
PPA	Parallel Import Applications
PREG	Pharmacovigilance Rapid Response Group
PSUR	Periodic Safety Update Report
QMS	Quality Management System
RIO	Regulatory Information Online
SAE	Suspected Adverse Event
SAR	Suspected Adverse Reaction
SAWP	Scientific Advisory Working Party
SoHOV&S	Substances of Human Origin Vigilance and Surveillance
SPCs	Summary of Product Characteristics
UMC	Uppsala Monitoring Centre
vCJD	Variant Creutzfeldt – Jakob Disease
VPA	Veterinary Product Authorisation
WHO	World Health Organisation



IRISH MEDICINES BOARD

Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Tel: +353 1 676 4971

Fax: +353 1 676 7836

Email: imb@imb.ie

www.imb.ie