IRISH MEDICINES BOARD

ANNUAL REPORT 2011

Protecting Public and Animal Health

Our Mission

To protect and enhance public and animal health through the regulation of medicines, medical devices and healthcare products.

OUR STRATEGIC GOALS AND BALANCED SCORECARD

STAKEHOLDERS

Enhance healthcare product safety and patient outcomes by effective risk management and market surveillance.

Deliver clear, relevant and timely communications to patients, consumers and healthcare professionals.

PROCESSES

Improve service delivery within a high quality, risk-based regulatory framework.

ORGANISATIONAL DEVELOPMENT

Improve service delivery within a high quality, risk-based regulatory framework.

Influence legislation and policy development at European and international levels for the benefit of public and animal health.

HUMAN RESOURCES DEVELOPMENT

Build future capabilities to meet evolving regulatory requirements, and scientific and technological advances.

FINANCIALS/VALUE FOR MONEY

Build future capabilities to meet evolving regulatory requirements, and scientific and technological advances.

Contents

Statistics at a Glance

1,977
NEW HUMAN MEDICINE APPLICATIONS ASSESSED

25%
INCREASE IN THE NUMBER OF EXEMPT MEDICINAL PRODUCTS PACKS NOTIFIED TO THE IMB

110
NEW VETERINARY MEDICINE APPLICATIONS ASSESSED

112
MANUFACTURING LICENCES IN PLACE AT YEAR END FOR HUMAN AND VETERINARY MEDICINES

489
NEW NOTIFICATIONS TO THE IMB MEDICAL DEVICES REGISTER FOR CLASS I GENERAL, CUSTOM-MADE AND IN-VITRO DIAGNOSTIC DEVICES

2,784
SUSPECTED ADVERSE REACTIONS REPORTS RECEIVED FOR HUMAN MEDICINES

68
APPLICATIONS TO CONDUCT CLINICAL TRIALS APPROVED

228
REPORTS OF SUSPECTED ADVERSE REACTIONS ASSOCIATED WITH USE OF VETERINARY MEDICINES

57
APPLICATIONS RECEIVED UNDER THE TRADITIONAL HERBALS MEDICINAL PRODUCTS REGISTRATION SCHEME

1,775
MEDICAL DEVICES VIGILANCE REPORTS RECEIVED AND ASSESSED

227
MEDICAL DEVICE PRODUCT REMOVALS CONDUCTED IN IRELAND

299
ADVERTS PROACTIVELY REVIEWED AS PART OF THE IMB'S ADVERTISING COMPLIANCE PROGRAMME

253
MEDICINES RECALLED DUE TO QUALITY DEFECTS

271
NATIONAL INSPECTIONS AND AUDITS PERFORMED

4,549
NEW ENFORCEMENT CASES RESULTING FROM THE ILLEGAL MANUFACTURE, SUPPLY AND SALE OF MEDICINES OR MEDICAL DEVICES

15%
INCREASE IN COMPANY TAKE-UP OF IMB EXTRANET SOLUTIONS

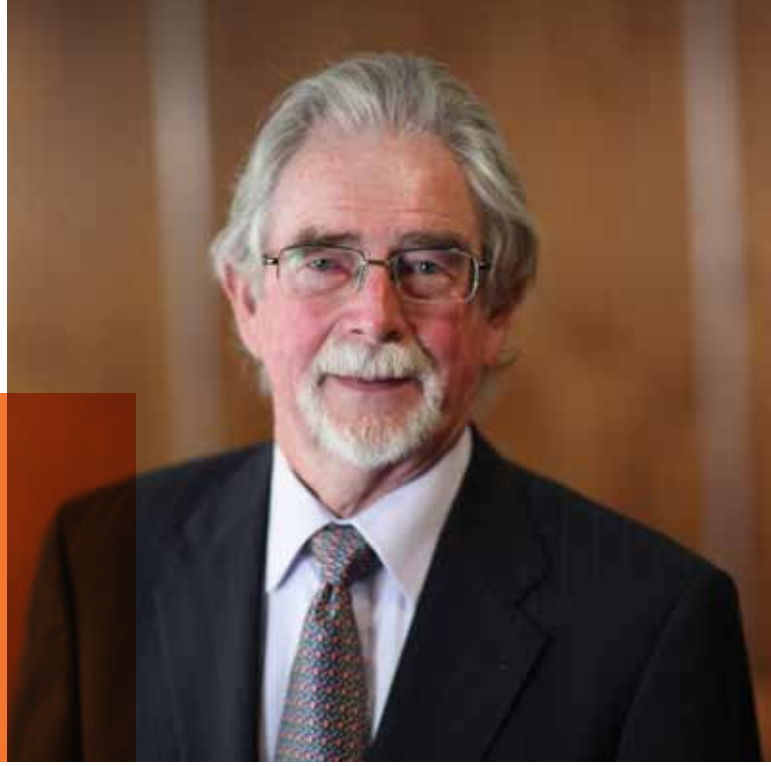
762,641
DOSAGE UNITS OF MEDICINES DETAINED BY ENFORCEMENT STAFF

6
NEW REGULATORY GUIDANCE DOCUMENTS PUBLISHED

126,000
UNIQUE VISITORS ACCESSED WWW.IMB.IE

9
SUCCESSFUL PROSECUTIONS WERE TAKEN IN RELATION TO BREACHES OF MEDICINAL PRODUCT REGULATIONS

77%
OF IRISH ADULTS SUPPORT THE REGULATION TRADITIONAL HERBAL MEDICINES



CHAIRMAN'S STATEMENT

It is a great pleasure to present my first annual report as Chairman of the Irish Medicines Board (IMB).

A number of things have impressed me greatly since taking up office. A positive ethos permeates all levels of the organisation as everyone strives for excellence in their work and decisions they make. There is also the quality of the IMB's staff, people who demonstrate a vigour, passion and enthusiasm in their individual roles.

The IMB has a very crucial function in national healthcare policy. It is charged with protecting public and animal health through regulating and monitoring medicines, medical devices and healthcare products. This demands excellence across all areas of its operations and a total commitment to ensuring the needs and best interests of our citizens and animals underpin everything we do. Together with an expanding remit, the IMB's comprehensive level of activity and responsibility (outlined in some detail in this Annual Report) highlights the need for expertise in strategic management capabilities, robust quality management and technology systems. Good practice standards are also essential to support the organisation's every work output. The fact that the IMB has secured an excellent reputation internationally as a highly effective and strong regulatory agency demonstrates that its structure, policies and work outputs are exemplary.

This report details the IMB's activities over the past year and, as in previous years, it highlights significant developments and progress across all work areas. In the context of the current economic environment, which is bringing new challenges to every element of the public sector, this is a significant achievement.

Our primary objective is to safeguard public and animal health by regulating the healthcare product sectors across the entire product lifecycle from clinical trials, through manufacturing, to marketing, distribution and end use by patients and animal owners. All our regulatory actions are grounded in legislative requirements and the application of scientific and regulatory expertise. Decisions are taken in the interests of public or animal health, based on the best available information at national and EU level, by experienced scientists and healthcare professionals.

A core element of our role in protecting and enhancing public and animal health is achieved through robust monitoring of medicine and medical device safety. It is without doubt that medicines and medical devices bring significant health and

lifestyle benefits to the individuals that need them. These healthcare products, whilst bringing many advantages, also come with side effects and the potential risk of adverse incidents. The IMB and its partners at European level have to apply expert knowledge, ongoing review of adverse reactions and clinical data to ensure that people continue to have access to products where the benefit of using that product outweighs the inherent risks. In 2011 there was, as in previous years, an intense focus on monitoring the safety of these products in use on the Irish market.

Whilst assuming new responsibilities can often prove challenging to any organisation, the IMB has embraced an evolving expansion of its remit and absorbed new important consumer and patient protectorate functions seamlessly. 2011 was the first full year of the IMB's new regulatory role in relation to cosmetics while 2012 and 2013 will see it adopt further additional functions.

The year in review also saw the conclusion of a seven year transition period for herbal medicines. A substantial programme of stakeholder engagement and information communication was undertaken to assist the herbal sector to comply with the new EU regulations. Also, during 2011, a key focus for the organisation was highlighting an increase in the purchasing of medicinal products that were of doubtful origin via the internet and that could pose a threat to people's health. The growth in new media and expanding access to the internet will mean this will now be a constant area of vigilance for the IMB.

The pharmaceutical, medical device and life sciences sector in Ireland is a major contributor to our economy. The IMB's robust regulatory role supports the sector's continued success by ensuring the sector's compliance with good manufacturing practices and adherence to legal requirements. A strong national regulator is a significant asset to Ireland's reputation as a major world player in this specialist sector.

The IMB plays a critical role at EU level where new legislation is developed. It continues to be an active contributor in this area with its objective being to ensure that a strong patient centric regulatory system for human and veterinary products is maintained and enhanced.

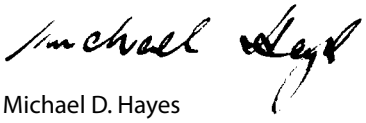
The IMB's five year strategic plan for 2011-2015, which the Board is tasked with overseeing, sets out five high level strategic objectives and a clear roadmap to achieve these goals within the timeframe. To align with our plan's implementation, this annual report now closely mirrors those goals in its layout and structure.

On behalf of the Board, I thank the Minister for Health and the Minister for Agriculture, Food and the Marine as well as their executives and staff for their continued support of the IMB and its activities.

I wish to recognise the effective chairmanship of my predecessor and his contribution to the IMB over a number of years. I have benefited greatly from the Board practices and standards already in place since my appointment in January 2011.

I would like to thank my fellow members of the new Board for the time, effort and expertise they have contributed during the past year. I would also like to express my appreciation to those members who chair IMB advisory committees and sub-committees. The role played by these committees is of immense value to the IMB and I wish to thank all the independent experts who contribute to them for their active participation and commitment.

Finally, I would like to thank the Chief Executive, management and all the staff and acknowledge their achievements during 2011. The IMB comprises expert professionals who are motivated by the fact that their individual contributions can make a difference to the health and quality of life of those who use healthcare products. I am proud to have been asked to chair this important and progressive organisation.



Michael D. Hayes

Chairman

BOARD MEMBERS

The new Board of the IMB was appointed in January 2011 by the then Minister for Health and Children in accordance with the powers conferred on her by subsection 2 of section 7 of the Irish Medicines Board Act, 1995.

Mr. Michael D. Hayes
(Chairman)
Engineering Consultant

Mr. Pat Brangan
Senior Veterinary Inspector, Department of Agriculture, Food and the Marine

Professor Brendan Buckley*
Honorary Clinical Professor in Pharmacology, University College Cork
** Resigned from the Board in September 2011*

Mr. Wilfred Higgins
Principal Engineering Advisor, Health Service Executive

Ms. Anne Horan
Chief Executive, Ryan Academy for Entrepreneurship, Dublin City University

Professor Mary Horgan*
Associate Professor of Medicine, University College Cork
** Appointed to the Board by the Minister for Health in November 2011*

Mr. Brendan McLaughlin
Farmer and Elected Board Director in the Management Committee of ICSA

Mr. Noel O'Donoghue
Veterinary Surgeon

Professor Caitriona O'Driscoll
Professor of Pharmaceutics, University College Cork

Ms. Maureen Windle*
Practitioner in Public Sector Healthcare Management
** Resigned from the Board in November 2011*

MANAGEMENT COMMITTEE

Mr. Pat O'Mahony
Chief Executive

Dr. 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 IT and Change Management

Dr. J.M. Morris
Director of Scientific Affairs

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

Ms. Rita Purcell
Director of Finance and Corporate Affairs

CHIEF EXECUTIVE'S REPORT

I am pleased to report on the activities of the Irish Medicines Board (IMB) during 2011, a year that marked the 15th anniversary of the establishment of our organisation. While our remit has expanded significantly during this time, and will continue to so, our absolute commitment to the protection and enhancement of public and animal health remains constant. The effective and commendable programme of work delivered during this 12 month period is evidence of another successful year in this regard.

STRATEGIC PLAN 2011 – 2015

2011 was particularly significant as it represented the first year of our new five year strategic plan. This plan sets out the IMB's five high-level strategic goals for this time period. These goals were informed by our core remit of protecting public and animal health, the challenges identified in our operating environment and the strategies of our regulatory partners. The plan, which was approved by our Board in November 2010 following a public consultation process, presents a clear roadmap to stakeholders and staff showing how our strategic goals will be achieved.

The five high-level strategic goals are:

1. Enhance healthcare product safety and patient outcomes by effective risk management and market surveillance.
2. Deliver clear, relevant and timely communications to patients, consumers and healthcare professionals.
3. Improve service delivery within a high quality, risk-based regulatory framework.
4. Influence legislation and policy development at European and international levels for the benefit of public and animal health.
5. Build future capabilities to meet evolving regulatory requirements, and scientific and technological advances.

The layout of the annual report for 2011 has been restructured to ensure that the main chapters are closely aligned with the goals set out above.

AUTHORISATION, REGISTRATION AND LICENSING ACTIVITIES

The pre-market authorisation and registration of healthcare products, as well as the licensing of manufacturing, wholesaling and related activities, is one of the IMB's primary public health functions. Essentially, these are the regulatory actions carried out by the IMB before a healthcare product can be marketed and supplied in Ireland.

We are committed to providing an effective and efficient regulatory framework that is focused on timely availability of appropriate healthcare products. 2011 was a busy and demanding year in this respect:

- In 2011, 68 new clinical trial applications were approved to commence in Ireland compared to 98 in the previous year. This decrease is consistent with a decline in clinical trial activity across Europe. An item of note during 2011 was the publication by the IMB of the findings of our investigation into the conduct of a clinical trial using rimcazole hemifumarate. It was concluded that this clinical trial, which took place at the Shandon Clinic in August 2010, was not conducted in full compliance with its approved protocol.
- In respect of human medicines, the number of new product applications approved rose to 1,977, an increase of 10% compared to 2010. There were also 15,458 variations applications approved which was a slight reduction (4%) on the 2010 figures.
- With regard to veterinary medicines, there were 110 new product applications assessed and approved while 1,231 variations to authorisations were granted through the national, mutual recognition or centralised procedures.
- The IMB continued its active role in the European medicines licensing system. For human medicines, we completed 10 mutual recognition (MR) assessments and issued 16 new marketing authorisations via the decentralised (DC) procedure, with Ireland as the reference member state. In addition, the IMB was allocated 27 applications for marketing authorisations to assess by the European Medicines Agency (EMA) and acted as rapporteur for 30 scientific advice procedures. For veterinary medicines, the IMB issued 25 new marketing authorisations through the MR procedure as the reference member state. During 2011, the IMB acted as the rapporteur or co-rapporteur for nine veterinary centralised procedures.
- The IMB maintains a medical devices registration system for Class I general, custom-made and in-vitro diagnostic devices. During 2011, the IMB registered 489 new medical devices within these categories.
- In 2011, the IMB received 9 applications relating to clinical investigation of non-CE marked medical devices comprised of 5 new applications and 4 significant amendments to ongoing investigations.
- The number of site manufacturing licences in place at year end for human and veterinary medicines was 112. This figure has remained broadly stable in recent years. In addition, the IMB operates a register of new medical device organisations including manufacturers. The number of organisations registered during 2011 was 34.

SAFETY AND COMPLIANCE MONITORING

A core public health function of the IMB is to monitor the safety of medicines, medical devices and other healthcare products that have been licensed or registered for use in Ireland. This is known as post-market surveillance. Quality issues related to how a product is manufactured, packaged, labelled, distributed or stored may also arise at the post-market stage. If a healthcare product poses too great a risk to those who use it, we will take appropriate, timely and effective action. Our success in achieving this goal is as a result of the collective efforts of all our staff and our decisions are always based on the best available information regarding benefit and risk.

- A key part of our monitoring efforts is the operation of a national pharmacovigilance scheme for adverse reactions, or side effects, associated with the use of human medicines. During 2011, the IMB received a total of 2,784 suspected adverse reactions associated with the use of human medicines in Ireland. This figure represents a return to expected levels following the enhanced rates of reporting that resulted from the H1N1 national immunisation programme.
- During 2011, the IMB contributed to an ongoing EU review of a potential association between the H1N1 vaccine Pandemrix and narcolepsy, a sleep disorder. Throughout the year, the IMB continued to review a small number of reports of suspected narcolepsy in Irish patients vaccinated with Pandemrix. Comprehensive follow-up with the healthcare professionals involved in each case was conducted. We also interacted with relevant national bodies focused on this issue.
- During 2011, the total output for periodic safety update reports (PSURs) for human medicines was 3,633. The IMB continues to actively participate in the Heads of Medicines Agencies (HMA) PSUR work-sharing project and is currently ranked in the top eight of national competent authorities in Europe in terms of lead member state assessment responsibilities.
- In September 2011, the IMB recommended a number of new measures in relation to the use of over-the-counter cough and cold medicines for children.
- The IMB also monitors the safety and effectiveness of veterinary medicines on an ongoing basis. In 2011, we reviewed 228 reports of suspected adverse reactions associated with use of veterinary medicines, a 9% increase on the previous year. A total of 413 PSURs relating to veterinary medicines were also evaluated.
- Post-market surveillance and vigilance is a critical element in protecting the health and safety of those who use medical devices. During 2011, 1,775 vigilance reports were received and assessed compared to 1,687 reports in 2010. This is the fourth year in succession that the reporting rate has increased.
- In 2011, 882 compliance cases were investigated in connection with medical devices. Similar to previous years, issues identified and investigated as part of these compliance cases included labelling problems, missing or incorrectly attached CE marking and classification issues.

Another key function of the IMB is to monitor and inspect industry compliance with legislation, policies and procedures. We are committed to ensuring that all healthcare products manufactured or distributed in Ireland meet essential quality standards and that they are advertised in an appropriate manner.

- During 2011, there was a total of 271 national inspections and audits performed compared to 263 in 2010 and 238 in 2009. A further 29 foreign inspections and audits were performed in the past 12 months.
- A total of 917 quality defects were reported to, or identified by, the IMB. This is the highest number of quality defect investigations in any one year since the introduction of the programme.
- During 2011, 253 medicine recalls occurred. Of these, 240 related to human medicines and 13 to veterinary medicines. An incident of non-adherence to cold chain requirements resulted in the recall of 65 products while a recall to primary and secondary wholesale level relating to a damaged product resulted in 48 products being recalled.
- The total number of packs of exempt medicinal products notified was 1,474,564, an increase of 25% over 2010. The IMB continues to work with stakeholders in several areas to identify and develop solutions aimed at limiting the use of exempt products in Ireland.
- There were also six recalls of cosmetic products in order to protect the health of consumers. Of these, four were related to high lead content in cosmetic products.
- The nine IMB-initiated prosecutions in the District Courts in relation to breaches of medicinal product regulations resulted in fines and/or suspended sentences. Our enforcement team also participated in Operation PANGEA IV. This was a global initiative to identify and act against illegal websites supplying counterfeit and illegal medicinal products. This operation led to the detention in Ireland of 51,621 tablets, capsules and creams.

LEGISLATIVE AND REGULATORY DEVELOPMENTS

The remit and role of our organisation continues to change and expand due to changes in our operating environment, such as new national and European legislation, and in response to the addition of further competencies.

Legislative Changes

During the past year, representatives from across the IMB were heavily involved in implementing, or preparing for the implementation of, new and updated EU directives which will have a significant impact on the regulation of medicines and medical devices across Europe.

- New EU pharmacovigilance legislation, adopted in December 2010, will begin to come into effect in July 2012. The new measures are intended to further promote and protect public health by strengthening the current European-wide system for monitoring the safety of medicines. Throughout 2011, the IMB worked with a wide range of stakeholders including the European Medicines Agency and other national regulators to prepare for the introduction of this new legislation. This included a very successful stakeholder information day that we held in Dublin in early December.
- The IMB is preparing for the introduction of elements of new legislation on falsified medicines for human use, which are required to be transposed nationally by January 2013. The changes are intended to strengthen the protection of patients and consumers by preventing falsified medicines entering the legal supply chain.
- The three existing European directives defining the requirements for medical devices are subject to an ongoing major revision by the European Commission. It is expected that during 2012, the Commission will adopt draft legislative proposals for discussion by the European Council and Parliament. This Commission initiative was

fully supported during 2011 by the IMB. An IMB proposal, made jointly with the Austrian Ministry for Health, to establish a recast working group of the Competent Authority for Medical Device (CAMD) network was endorsed. This group allows for detailed technical discussions on specific elements of the proposed revision to the medical devices legislation and for close co-operation between European regulators.

Human Organs for Transplantation

It was agreed with the Department of Health during 2011 that the IMB will assume the role of national Competent Authority for the directive on standards of quality and safety of human organs intended for transplantation. As a result, the IMB began a process of reviewing the requirements of the directive and developing an appropriate framework for implementation of the requirements which are due to come into effect in August 2012.

European and International Regulation

The products regulated by the IMB are part of a dynamic and developing global industry. Healthcare products manufactured here are used around the world while products manufactured elsewhere are used in the Irish healthcare system and by Irish patients and consumers. As a result, it is essential that the IMB plays an active role in the global regulatory network to ensure that we represent and protect the interests of Irish patients and consumers.

During 2011, the IMB continued its very active role in the networked European regulatory model and, both formally and informally, worked closely with other relevant international organisations.

- Our participation in the European medicines regulatory system continued to be substantial with IMB scientific and technical staff contributing to a broad range of committees and working parties at the European Medicines Agency, the European Commission, HMA, and other fora. In addition to representing Ireland at relevant meetings and events, IMB delegates were also active in, and in many cases led, a series of European regulatory initiatives. For example, the Irish delegate (human medicines) to the European Medicines Agency's Quality Working Party (QWP) was appointed as rapporteur for the revision of the QWP guideline on process validation while the Irish delegate to the Pharmacovigilance Working Party at the European Medicines Agency represented the EU at the ICH E2C (R2) Expert Working Group.
- During 2011, the IMB Pharmacovigilance Manager was invited to join the Board of the Uppsala Monitoring Centre (UMC) and the World Health Organization Collaborating Centre for International Drug Monitoring. This was international recognition of the prominent role played by the IMB in global pharmacovigilance practice.
- The IMB submitted revised maximum residue limits (MRLs) applications for milk to the European Medicines Agency in August 2011 following the rejection by the European Commission of the proposed MRLs for certain flukicidal veterinary medicines used in cattle. By year-end, positive opinions had been delivered to the European Commission for four separate substances.
- In respect of medical devices, the IMB led discussions on the development of formal co-operation between the existing HMA network and the medical devices networks represented by the Competent Authority for Medical Device (CAMD) and the Central Management Committee (CMC). The goal is to develop a larger, inclusive 'European Health Products Regulatory Network' comprised of regulators from human medicines, veterinary medicines and medical device authorities.

- During 2011, the IMB also participated in regulatory discussions focused on establishing a medical devices competent authority funding mechanism which is fair, transparent and sustainable.
- The IMB announced the signing of three separate international co-operation arrangements with counterpart regulatory bodies in Japan, Mexico and Switzerland. The arrangements are designed to broaden existing contacts and to establish a co-operative framework of mutual support and information exchange. These co-operation arrangements were signed in October at the 6th Global Summit of Heads of Medicines Regulatory Agencies. This annual event provides an opportunity for medicines regulatory agencies from around the world to meet and discuss common challenges and concerns.
- In June of 2011, the IMB and the Medical Council signed a Memorandum of Understanding which will strengthen the co-operation between the two bodies, further promoting the highest standards of practice in medicines.
- The IMB continued its participation in the Benchmarking of European Medicines Agencies (BEMA) steering group of the HMA, which I co-chair. Proposals relating to the third cycle of inspections were developed and by year-end assessor training had been completed. Work also commenced on the visit schedule for 2012–2014.

STAKEHOLDER ENGAGEMENT AND COMMUNICATIONS

As set out in our five year strategic plan, the IMB is committed to expanding and improving our communications activities and to ensuring that all our stakeholders have timely access to relevant safety and regulatory information. As well as our regular meetings and ongoing publication of safety and regulatory updates, newsletters and guidance documents, a number of significant communications initiatives were implemented during 2011.

Consultative Panel on the Legal Classification of Medicines

The establishment at the end of 2011 of the Consultative Panel on the Legal Classification of medicines was a very important development for the IMB. Independently chaired and made up of external representatives drawn from a wide range of interested stakeholders including patients, healthcare professionals, the Department of Health and relevant public bodies, the panel will provide advice on external socioeconomic and policy issues that should be considered when determining the appropriate classification of a medicine. This advice will support the existing scientific assessment carried out by the IMB once we receive applications to reclassify a medicine.

BT Young Scientist and Technology Exhibition 2011

2011 marked the third year of IMB participation at this event and it was again a very positive experience for all involved. We welcomed thousands of students, teachers, parents and members of the general public from all over Ireland to the IMB's exhibition stand. The content of the stand was focused on building awareness of the safe use of medicines and medical devices as well as the role the IMB plays in protecting public and animal health.

Consumer Research – Regulation of Herbal Medicines

The findings of consumer research, from a representative sample of the Irish population, were released in advance of the new regulatory system for traditional herbal medicines which came into effect across all EU member states on 1 May 2011. The results show significant support for this initiative with some 8 out of 10 consumers recognising the importance of regulating traditional herbal medicines.

IMB Leaflet – Automated External Defibrillators

In December 2011, the IMB published an information leaflet providing advice to people on how to correctly maintain an automated external defibrillator (AED). It was produced in light of the increased availability of AEDs in Ireland over the past number of years and a notable increase in the number of AED related issues reported to the IMB.

Website

The IMB website continued to be updated with news, safety information and regulatory documents while further changes and improvements were made in response to stakeholder feedback. The veterinary medicines section of the IMB website was substantially revised early in 2011 to provide more relevant content while a new dedicated webpage was established for content relating to the new pharmacovigilance legislation. Almost 126,000 unique visitors accessed the website during the past twelve months.

DEVELOPING ORGANISATIONAL CAPABILITY

It is essential that we continue to build our organisational capabilities in line with scientific, technological and regulatory advances and requirements. In 2011, as in each of the 15 years since the establishment of the IMB, there were further developments and changes both in the environment in which we operate and in the manner in which we deliver our services. Change is something that we have constantly embraced in this organisation and we are committed to ensuring that we have the requisite structures, systems and supports in place to deliver on our public health mission.

Information Technology and Change Management

A new five year information and communication technology (ICT) strategy aligned to the organisation's five year strategic plan was adopted by the Board in early 2011 and implementation commenced in the second half of the year. Key technologies for the organisation over the coming years will include improved data warehousing solutions, together with upgraded capacity management and case management systems. All information technology initiatives are undertaken in the context of providing new and/or improved services to stakeholders, enhancing decision-making and channelling scientific data to deliver on our public health remit.

The IMB has a long held commitment to continuous improvement. As part of our change management strategy, it was decided to develop a more structured approach to organisational project management. This resulted in the adoption of a project management office model for all relevant activities. Planning for the new office commenced in late 2011, with implementation scheduled for 2012.

Staff Developments

Ireland is recognised as an important global location for the life sciences sectors which are contributing significantly to our economy and playing a key role in driving export-led growth. The IMB supports this growth by indigenous and multinational companies through providing regulatory and technical advice and services, and by ensuring compliance with manufacturing standards. It is vitally important that we have the resources in place to deliver on these functions for the benefit of all our stakeholders.

While recognising the constraints on public sector employment numbers, during 2011 we submitted a proposal as a predominantly self-funded agency on future staffing requirements to the Department of Health. This proposal focused on obligations arising from new responsibilities being assigned to the IMB by the Department as well as the impact of the introduction of a range of legislative changes between now and 2015.

Also during the year, we introduced a leadership development programme. This pilot programme is focused on enhancing the skills of mangers from across the organisation and it is hoped to expand and further develop the programme in the coming years.

Financial Performance

The IMB is largely self-funded by a system of fees which are approved annually by the Minister for Health, following a public consultation. This approach is in line with the typical funding model of healthcare products regulation worldwide. The IMB is committed to the highest standards of independence and governance so as to ensure quality of service combined with value for money. We continued in 2011 to successfully manage the affairs of the IMB in line with our statutory obligation that income at least meets costs.

THE FUTURE

The IMB is focused on both the new challenges and the new opportunities that will no doubt arise during 2012.

The economic situation continues to present challenges across the public sector nationally, and for our regulatory colleagues globally. There is no doubt that resources will continue to be limited and this will pose substantial challenges to us as we continue to deliver on our public health remit and deliver services to stakeholders. Yet, it is clear also that the health products sectors we regulate have shown great resilience during the recent past and indeed have been drivers of growth.

The overall workload for the organisation will continue to increase and diversify as we respond to the developments in respect of new European legislation and the addition of further national competencies. The former includes the implementation of new pharmacovigilance and falsified medicines legislation in addition to further progress in the revision of regulations for medical devices, while the latter involves the IMB assuming the role of national Competent Authority for the directive on standards of quality and safety of human organs intended for transplantation.

Clearly, meeting these new demands will challenge everyone at the IMB to work in the most efficient and effective manner to ensure we meet the high standards we set for ourselves. As in previous years, we will continue to take a risk-based approach to our regulatory activities. We will adopt further necessary and beneficial change across the organisation and enhance further our performance management, quality management and ICT systems. There will be an ongoing review of our funding provision and management of our own cost base to ensure maximum use of resources.

We will also continue our active participation at a European level to ensure the best possible outcomes for Irish citizens. A wide range of legislative reform is foreseen across medical devices, veterinary medicines, clinical trials, cosmetics and precursor chemicals, which will directly affect our future work. There will also be initiatives in cross border healthcare and health technology assessment with which we will also have to engage. Proposals for an agreed Europe-wide fee regimen for funding competent authority activities on medical devices will be developed and we will actively engage in these discussions.

Also in 2012, we intend to develop further our communications and stakeholder engagement

programme. Of particular importance in the year ahead will be direct interaction and co-operation with patient representatives to build understanding of our role and to incorporate patient and public input. In addition, the consultative panel on the legal classification of medicines will examine the various policy positions of panel members and agree terms of reference.

Our staff's expertise and experience are critical to the success of our organisation. We will continue to make learning and development opportunities available so that we can maintain and enhance the skills that are required for our increasingly complex and expanding remit.

ACKNOWLEDGEMENTS

I wish to thank, on behalf of the IMB management team and staff, the Chairman and all members of the Board, as well as all the members of the IMB's various advisory committees, for their valuable contributions during 2011. In total, over 100 people give of their time voluntarily to the work of the IMB through participation on the Board and these committees. Having access to this independent expertise and insight is of immense value to the workings of our organisation.

The commitment and professionalism of the IMB staff members is critical to the successful delivery of our public health remit. I would like to express my personal appreciation to all colleagues for their valuable contribution to an ever-increasing workload during this past year. On the occasion of the 15th anniversary of the establishment of the IMB, I would also like to acknowledge the key role played by former staff to the development and progression of the IMB in the intervening period.

Finally, I wish to thank and acknowledge the Ministers and staff of the Department of Health and of the Department of Agriculture, Food and the Marine for their continued support and co-operation during 2011.

During each of the past 15 years, the IMB has successfully adapted to and indeed embraced new challenges. I have no doubt that we will do so again in 2012 with renewed energy and conviction. Our five-year strategy sets out our high-level goals and, together with our annual business plans, sets out a clear roadmap for the future. As ever, an absolute focus on the protection and enhancement of public health will be our priority.

Go raibh maith agaibh go léir.

Pat O'Mahony

Chief Executive

AUTHORISATION, REGISTRATION AND LICENSING ACTIVITIES

The authorisation and registration of healthcare products is a core public health function of the IMB. Often referred to as 'pre market' activities, these are the regulatory actions carried out by the IMB which happen before a healthcare product can be marketed and supplied in Ireland. Ensuring timely approval of new products applications in particular, following a positive assessment of their safety, quality and effectiveness, gives patients and users access to a range of appropriate treatments.

The IMB is responsible for the authorisation of medicines and clinical trials and for the registration of medical devices and cosmetics. The IMB also licenses the manufacturers and wholesalers of human medicines, the manufacturers of veterinary medicines as well as blood and tissue establishments. In addition, the IMB is responsible for issuing export certificates and we provide a borderline product classification service.

The IMB also provides a service to stakeholders to assist in clarifying which products should be categorised as human medicinal products, veterinary medicinal products and medical devices. Such products fall under the remit of the IMB from a regulatory perspective and are distinct from other products which are outside the IMB's remit.

HUMAN MEDICINES

BORDERLINE PRODUCT CLASSIFICATION

Queries are routinely received in regard to the correct classification of human medicines, veterinary medicines and medical devices.

For products for human use, a classification service is operated for products which are on the borderline between human medicines and other products such as food supplements, cosmetics and medical devices. Requests for classification, whether external or internal, are presented to an internal, multi-disciplinary, human medicinal product Classification Committee.

The Committee, which met 11 times in 2011, consists of appropriately experienced IMB staff from across the organisation and is chaired by the Director of Scientific Affairs. During the past 12 months, a total of 153 new products were considered consisting of 132 internal applications and 21 external applications. In addition, there were eight products revisited from pre-2011.

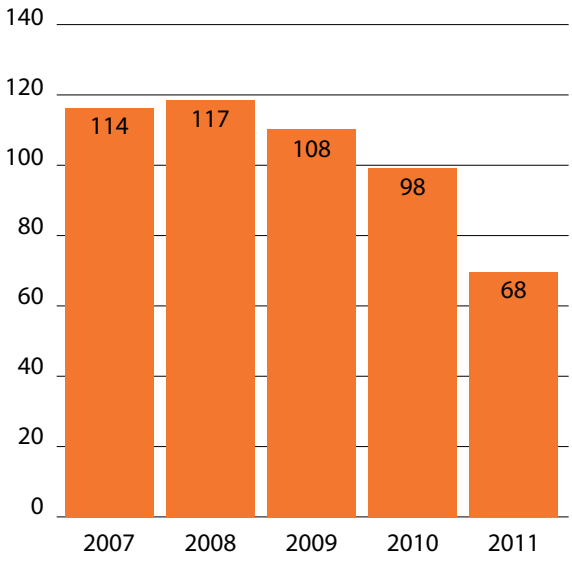
The Committee has a close working relationship with the Food Safety Authority of Ireland while it also engages in regular dialogue with the Department of Health and other national regulatory authorities.

CLINICAL TRIALS

Clinical trials are conducted to determine whether a new medicine is safe and effective when used to treat a disease or condition and whether it provides a real health benefit. Such clinical trials are necessary to establish whether a medicine should be authorised for use in the general population.

The role of the IMB is to assess applications from sponsors permitting them to conduct clinical trials in Ireland. Sponsors typically include pharmaceutical companies and/or research institutions. The IMB approves the clinical trial protocols which describe the details of each trial and outline the steps that will be taken to protect the health of volunteers or patients.

Clinical Trials Approved 2007 - 2011



In 2011, 68 new clinical trial applications were approved to commence in Ireland. This was a decrease compared to previous years and is consistent with a decline in clinical trial activity across the EU.

The IMB also reviewed and strengthened the process for authorisation of clinical trials. As part of this review, the Guide for Clinical Trial Applications has been extensively updated and requirements

for applicants clarified. The IMB met with potential sponsors and investigators seeking to carry out clinical trials in Ireland and responded to a large number of queries from them.

The clinical trials legislation is currently under review by the European Commission. The IMB has contributed to the consultation process and will continue to do so during 2012. The purpose of the review is to assess and improve the functioning of the clinical trials legislation.

Premature Termination of Rimcazole Clinical Trial

In October 2011, the IMB published the findings of its investigation into the conduct of a clinical trial using rimcazole hemifumarate at the Shandon Clinic in August 2010. The IMB concluded that this clinical trial was not conducted in full compliance with its approved protocol.

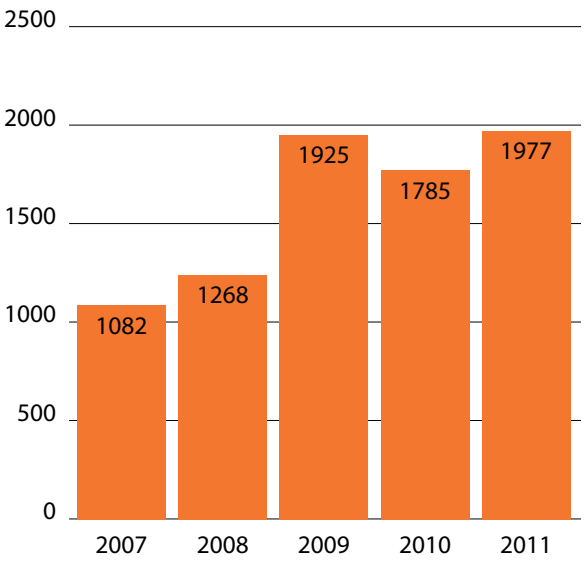
This investigation was initiated after three subjects participating in the trial experienced seizures. All three subjects recovered fully when the administration of the trial medication was discontinued.

NEW MARKETING AUTHORISATION APPLICATIONS

Before a new medicine can be placed on the Irish market, it must be firstly assessed and authorised, or licensed, by the IMB or the European Medicines Agency. When a company seeks approval of a new medicine from the IMB, it submits a dossier including all clinical trial data and analysis of the data, as well as information about how the medicine behaves in the body and how it is manufactured. An IMB assessment team of medical doctors, pharmacists and other scientists will review the company's data and the proposed product information including the package leaflet and label. The IMB team assess the safety of the medicine and the evidence that it is effective for its intended use. If this assessment establishes that the medicine's public health benefits outweigh its known risks, it will be granted a marketing authorisation.

While national applications are assessed solely by the IMB, companies may also choose the mutual recognition procedure (MRP) or the decentralised procedure (DCP). MRP and DCP applications involve a number of national European authorities. (Details of the IMB's contribution to this process are outlined on page 21.)

Total Output for New Applications 2007 - 2011

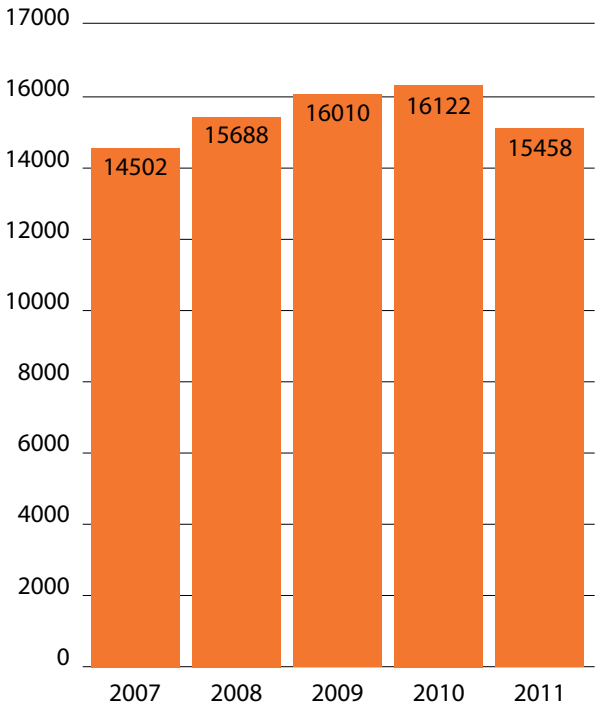


During 2011, the number of new product applications assessed by the IMB was 1,977. This included 493 new national applications and 806 new MRP and DCP applications. There were 233 new centralised applications and 394 transfer applications. The number of assessments completed rose 10% when compared to 2010.

VARIATIONS

After a medicine has been authorised, the terms of the marketing authorisation may subsequently be varied. Examples of variations include the addition of a new indication or potential side effect, or updates to the company's manufacturing or contact details.

Total Output for Variations 2007 - 2011



During 2011, the IMB processed 15,458 variations to marketing authorisations for products authorised through the national or MR procedures. The reduction of 4% from the number in 2010 was due to the impact of the implementation of new variations regulations in that year.

Norlevo – Change of Supply Status

In 2011, the IMB authorised the switch of Norlevo (levonorgesterl) emergency contraception from prescription to non-prescription supply. This followed receipt of an application from the marketing authorisation holder to change the supply status. This application was assessed by the IMB and Norlevo is now available over-the-counter (OTC) in pharmacies.

RENEWALS

Marketing authorisations are valid for five years from the date of first issue. For the authorisation to remain valid, it should be renewed at the end of this five year period.

In 2011, 757 renewals to marketing authorisations for products authorised through the national or MR procedures were processed. This was a 32% decrease compared to 2010. This can be explained by the change in legislation where only one renewal of a marketing authorisation is now required after five years instead of one every five years unless specifically requested by the IMB.

IMB AS REFERENCE MEMBER STATE

In certain circumstances, companies can apply for the simultaneous authorisation of a medicine in more than one EU country. Such applications require one country to be the reference member state (RMS) while the other countries involved are known as the concerned member states (CMS).

The IMB continued to actively contribute to the European licensing system as a reference member state in both the MR and the DC procedures for generic medicines. The IMB completed 10 MRPs and issued 16 new marketing authorisations via DCP with Ireland as the reference member state. The numbers are consistent with our 2010 contribution.

IMB AS RAPPORTEUR/CO-RAPPORTEUR

The IMB was allocated 27 applications for marketing authorisations to assess by the Committee for Medicinal Products for Human Use (CHMP) at the European Medicines Agency. These applications, referred to as centralised procedures, allow a successful applicant to market its product in all member states. The types of medicines included innovative treatments for diabetes, respiratory disease and radiopharmaceuticals. The assessments are complex and involve extensive discussion with EU colleagues. A total of 24 procedures were ongoing during 2011 while four were issued during the year.

The IMB acted as rapporteur (lead assessor) for 30 scientific advice procedures for medicines proposed for the treatment of respiratory, musculoskeletal, allergic and dermatological conditions, diabetes mellitus and infections.

PARTICIPATION IN EUROPEAN MEETINGS

The IMB is an active participant in the European regulatory network. During 2011, representatives of the IMB contributed to and, where appropriate, prepared papers for the following European committees and groups:

- European Medicines Agency:
  - Committee for Medicinal Products for Human Use (CHMP) and its associated Working Parties
  - Committee for Orphan Medicinal Products (COMP)
  - Paediatric Committee (PDCO)
  - Herbal Committee (HMPC)
  - Committee for Advanced Therapies (CAT)
- Heads of Medicines Agencies:
  - Co-ordination Group for the Mutual Recognition and Decentralised Procedures (CMDh)
  - Clinical Trials Facilitation Group (CTFG)

The IMB also participates at Council/Standing Committee meetings, as required.

CMDh

The work of the CMDh is essential for the authorisation of over 90% of the medicines which are available in Europe. A large number of these authorisations are obtained by way of MR and DC procedures. The CMDh is responsible for referral procedures and also promotes harmonisation of product information for medicines. The IMB contributed significantly to the core activities of the CMDh in 2011, which included the implementation of new legislation such as the Variations Regulation and the pharmacovigilance legislation.

TRADITIONAL HERBAL MEDICINAL PRODUCTS

To protect the health of consumers, the EU introduced the Traditional Herbal Medicinal Products Directive in 2004 to allow for the regulation of "traditional herbal medicinal products" (THMPs). This directive was transposed into Irish law on 23 July 2007 and designates the IMB as the Competent Authority for the implementation of the legislation. On this basis, the IMB established the traditional herbal medicinal products registration scheme. Under this scheme, THMPs which meet certain criteria regarding traditional-use and safety 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 transition period for THMPs that were on the market when the 2007 Regulations came into force ended on 30 April 2011. A total of 57 applications had been received under this scheme by year-end and four products were registered in 2011. The number of applications received remains disappointingly low.

In March 2011, the IMB held a second information session for stakeholders (the first was in 2008) to clarify the requirements, and also held meetings with individual applicants to assist them in the application process. A high volume of enquiries about the scheme was received by the IMB during 2011 and much emphasis has been placed on communication to facilitate successful implementation of the regulatory requirements. Guidance documents, questions and answers documents, and other relevant guidance on the scheme have been produced by the IMB and are available on our website. Market surveillance, to monitor adherence to the policy at wholesale and retail level, was carried out during the second half of the year.

The IMB is also advised in this regard by the Herbal Medicines Subcommittee of its Advisory Committee for Human Medicines.

HOMEOPATHIC MEDICINES

Homeopathic medicines must be registered or authorised by the IMB before being placed on the Irish market. Registration is under the simplified registration scheme specifically for homeopathic medicinal products without indications that are administered orally or externally. Between 2008 and 2011, 77 product applications were submitted to the IMB under this scheme. All 77 have been registered, including the 23 new applications received during 2011. This represents another year-on-year increase in the number of products registered. In 2010, there were 22 products registered, 20 in 2009 and eight in 2008.

Authorisation of homeopathic medicines with indications has been facilitated by the introduction of national legislation (Medicinal Products (Control of Placing on the Market) Regulations, 2007 as amended) which establishes criteria for the licensing of homeopathic medicines under national rules as provided for under EU Directive 2001/83/EC, as amended. The national rules scheme, established by the IMB in May 2010, applies to homeopathic medicines with indications for mild self-limiting conditions. A number of applications have been received under this scheme and assessment of these was carried out during 2011. Together with the simplified registration scheme, this new national rules scheme will facilitate the licensing of all homeopathic medicines on the Irish market as well as new products entering the market.

CONTROLLED DRUGS LICENSING

Import, export and holding of controlled drugs (for legitimate purposes) are subject to licensing. The Department of Health is the licensing authority while the IMB handles the administrative aspects of the application and licensing process

During the past 12 months, activity levels increased slightly (5%) compared to the previous year. Details are provided in the following table.

Controlled Drugs Licensing Activity	**2007**	**2008**	**2009**	**2010**	**2011**
Registration	19	23	20	28	26
Export and Import	964	1056	970	1270	1331
Annual – New	19	19	31	19	14
Annual – Renewal	171	243	221	172	170
Letter of no objection (LONO)	473	489	447	448	511
Pilgrims	14	14	11	12	10
Hemp	5	46	7	10	7
Total	**1665**	**1890**	**1707**	**1959**	**2069**

VETERINARY MEDICINES

The IMB is committed to protecting the welfare of treated animals, including fish, poultry, bees and domestic animals, as well as ensuring the safety of foodstuffs obtained from animals treated with veterinary medicines. The assessment of products also includes an evaluation of any possible risks to the user as well as the elaboration of risk-management measures to control any risks. Finally, we also evaluate the safety of the veterinary medicines for the environment.

PRODUCT CLASSIFICATION REQUESTS

The IMB provides a service to stakeholders to assist in clarifying which products should be categorised as veterinary medicinal products. Such products fall under the remit of the IMB from a regulatory perspective and are distinct from other products which are outside the IMB's remit.

During 2011, 72 product classification queries were received in respect of veterinary medicines. There were 81 responses issued which related to queries received both during, and prior to, 2011.

CLINICAL TRIALS

The IMB is regularly consulted by the Department of Agriculture, Food and the Marine prior to the granting of an approval for a clinical trial. The Department is the Competent Authority for licensing of clinical trials in animals. On receipt of a valid application from the Department, the IMB reviews the information based on an assessment of the expected risks to the animal, the user, the consumer and the environment. The IMB also considers the conduct of the proposed study.

During 2011, nine clinical trial applications were received by the IMB and issued to the Department. All were assessed and issued within clinical trial set timelines.

NEW APPLICATIONS

Before a new veterinary medicine can be placed on the Irish market, it must be firstly assessed and authorised by the IMB or the European Medicines Agency. The decision on whether a medicine is authorised centrally in Europe or at a national level by the IMB, is generally dependent on the type of product in question.

When a company seeks approval from the IMB for a new medicine, it submits a dossier that includes critical summary reports, details of the product information, such as the leaflet and label, as well as quality, safety and efficacy data. An IMB assessment team of veterinary surgeons, pharmacists and other scientists will then review the dossier to establish if the medicine's animal and public health benefits outweigh its known risks.

During 2011, the number of new product applications received by the IMB was 115 of which 11 were national applications. We assessed and approved 110 applications, including two new national licences. The number of MRP and DCP licenses issued was 108 while 104 such applications were received. The MRP and DCP figures included both applications where Ireland was the reference member state and where it was a concerned member state. (See also 'IMB as Reference Member State' below).

VARIATIONS

After a medicine has been authorised, the terms of the marketing authorisation may subsequently be varied. Examples of variations include the addition of a new indication or potential side effect, or updates to the company's manufacturing or contact details.

During 2011, the IMB approved 1,231 variations to authorisations granted through the national, MR or centralised procedures while 1,274 variations applications were received.

RENEWALS

Marketing authorisations are valid for five years from the date of first issue. For the authorisation to remain valid, it must be renewed at the end of this five-year period. Following this renewal, the authorisation remains valid for an indefinite period unless a further renewal is deemed necessary by the IMB on animal/public safety grounds.

In 2011, 57 renewals to marketing authorisations for veterinary products authorised through the national or MR procedures were received while 129 were issued.

IMB AS RAPPORTEUR/CO-RAPPORTEUR

In the 'centralised' or 'Community' procedure, the Committee for Medicinal Products for Veterinary Use (CVMP) of the European Medicines Agency is responsible for conducting the initial assessment of veterinary medicines for which an EU-wide marketing authorisation is sought. Under this procedure, the CVMP appoints members from two different EU countries to assess the application and these are known as the rapporteur and co-rapporteur.

During 2011, the IMB acted as the rapporteur or co-rapporteur for nine centralised procedures (including extension applications). These assessments were complex and involved extensive discussion with EU colleagues.

IMB AS REFERENCE MEMBER STATE

The IMB continued to actively contribute to the European veterinary licensing system and issued 25 new marketing authorisations as the reference member state.

WORK-IN-PROGRESS APPLICATIONS

The number of work-in-progress applications continued to decline from 645 units at December 2009 to 596 units at December 2010 and 531 units at December 2011.

MEDICAL DEVICES

CLASSIFICATION REQUESTS

European legislation provides for the categorisation of medical devices into four different classes ranging from low risk to high risk. The class a particular medical device is assigned to depends on classification rules relating to the device's duration of body contact, its degree of invasiveness, its use of an energy source, and the part of the body affected by its use. In addition, in certain cases, it may not be clear if a product falls under the medical device legislation or whether, for example, it should be classified as a medicine or a cosmetic product.

In 2011, the IMB received 64 requests for formal advice on qualification and classification of products as medical devices. Of these requests, 59% came from other regulatory authorities in Europe seeking advice and consensus on the classification of medical devices and borderline products. Other external sources, such as medical devices manufacturers and the National Standards Authority of Ireland, accounted for 27% of the requests.

During 2011, the IMB was asked to act as an external expert on medical device classification for another European regulatory authority. In addition, we circulated two enquiries through the European Commission's Classification and Borderline Working Group to seek consensus opinion on qualification of borderline products.

CLINICAL INVESTIGATION APPLICATIONS

Medical devices intended for clinical investigations are typically required to comply with the requirement for clinical investigation specified in the medical devices directive and must be labelled that they are for clinical investigation.

When clinical investigations are to be carried out in Ireland, it is necessary to make an application to the IMB. Typically, applications are submitted to us by commercial sponsors such as medical device manufacturers. As part of this process, we encourage pre-submission meetings with potential sponsors of clinical investigations.

Applications to conduct clinical investigations are reviewed by an IMB assessment team prior to the investigation starting. We review the regulatory, technical and clinical aspects of the application.

In 2011, the IMB received 9 applications relating to clinical investigation of non-CE marked medical devices comprised of 5 new applications and 4 significant amendments to ongoing investigations. The average time for final opinion was 50 days, with completion of the IMB's initial review at an average of 32 days.

Since the start of 2011, the European Commission medical device database system (EUDAMED) had added functionality to capture details of clinical investigations of medical devices. The database now provides for notification, traceability, monitoring and communication of review decisions between national competent authorities throughout Europe. Notification to this system became mandatory from May. The IMB began uploading details of clinical investigations of medical devices in Ireland at the start of 2011.

DESIGNATION AND MONITORING OF IRISH NOTIFIED BODIES

Manufacturers of certain medical devices require a notified body to carry out a compliance assessment of those products before they can be placed on the market. In Ireland, the notified body is the National Standards Authority of Ireland (NSAI). It is the role of the IMB, as the national Competent Authority for medical devices, to monitor the performance of the NSAI as a notified body. This monitoring includes conformity assessment of medical devices and compliance with the Medical Device Directive, the Active Implantable Medical Device Directive and the In-vitro Diagnostic Device Directive.

(Details of the IMB audit programme at the NSAI are provided on page 53 of this report.)

Various European working groups have been established to promote best practice and harmonise both the performance of medical device notified bodies and their oversight by competent authorities. During 2011, the IMB again participated in the peer review scheme operated by the Notified Bodies Operations Group (NBOG). This scheme seeks to ensure that regulatory authorities apply the same standards of oversight to notified bodies across Europe. The IMB peer reviewed the Medicines and Healthcare Products Regulatory Agency's audit of one of the medical device notified bodies based in the UK.

PRODUCT REGISTRATIONS

The IMB maintains a medical devices registration system for Class I general, custom-made and in-vitro diagnostic devices. In 2011, the IMB registered 489 new medical devices within these categories. Thirty-four new organisations based in Ireland also registered with the IMB as manufacturers of these types of medical devices.

During 2011, the IMB further developed its online registration system for medical devices. Manufacturers utilise the system to register both their company details and details of the devices which they are placing on the market. Such registration is mandatory for Class I, custom-made, system and procedure pack, medical device sterilising services and in-vitro diagnostic manufacturers based in Ireland. The IMB system was upgraded to ensure effective interfacing with the European Commission's new version of the European medical device database (EUDAMED), which became active in May 2011.

The IMB commenced a project during 2011 to validate and verify the information available on the register for medical devices to ensure that manufacturer and device details were up-to-date.

COSMETIC PRODUCTS

PRODUCT NOTIFICATIONS

Manufacturers, importers and persons acting on their behalf who have responsibility for placing cosmetic products onto the market, are required to notify IMB of these activities. During 2011, 4,610 cosmetic product notifications were received from a total of 64 companies. The three most common categories of product notifications were:

1. Make-up products and make-up (23%);
2. Lip products (21%);
3. Creams, emulsions, lotions, gels and oils (17%).

This was the first full year of notification to the IMB after we became the Competent Authority for this area in October 2010.

AUTHORISATION/LICENSING OF SITES AND FACILITIES

The IMB is responsible for the regulation of manufacturers of human and veterinary medicines and wholesalers of human medicines as well as blood and tissue establishments. We are also responsible for the approval of contract laboratories.

Such sites and facilities are required to be authorised by the IMB for the activities which they carry out. The IMB will grant an authorisation based on application for an authorisation/licence and adherence to relevant European legislation and guidelines. Compliance with these requirements is based on satisfactory outcomes of IMB inspections (see also the Safety Monitoring and Surveillance section of this report).

The total number of licences/authorisations in place at year end for the past five years is presented below by category. The figures show that overall the number of manufacturer's authorisations over this period has remained quite stable while the total number of wholesaler's authorisations has increased during the past two years. This latter trend has been influenced by parallel exporting.

Total Number of Licences/Authorisations (Sites)	**2007**	**2008**	**2009**	**2010**	**2011**
Manufacturers of Medicines for Human Use	81	86	85	86	88
Manufacturers of Veterinary Medicines	29	26	25	27	24
Investigational Medicinal Products for Human Use	12	45	50	51	50
Wholesalers of Medicines for Human use	141	214	209	220	243
Blood Establishments	0	6	5	4	4
Tissue Establishments	0	6	13	16	17
Laboratory Approvals	0	11	13	16	16
Total	**263**	**394**	**400**	**420**	**442**

EXPORT CERTIFICATES

Export certificates are required by health authorities in many third country markets as an indication that a product registered/authorised and/or manufactured in the country of origin is of appropriate quality. As Ireland is a large exporter of medicines and medical devices, companies exporting from here request a large number of certificates. Export certificates are also required in many third countries to facilitate the registration of cosmetic products. The inspection and authorisation/registration programmes operated by the IMB form the basis on which certificates are issued. Where possible, certificate formats, as published by the World Health Organization, are used.

There were 4,146 export certificates issued during 2011, a total broadly consistent with the previous year.

Product Certification Activity	2007	2008	2009	2010	2011
Certification of Documents	316	266	235	234	239
Certificates of Free Sale - Medicinal Products	52	22	22	13	34
Certificates of Good Manufacturing Practice for Finished Product Manufacturers	200	212	230	224	233
Certificates of Good Manufacturing Practice for Active Substance Manufacturers	62	42	39	31	39
Certificate of a Pharmaceutical Product	1046	1273	942	1187	1382
Medical Device Free Sale Certificates	432	434	977	2142	1780
Cosmetic Products Free Sale Certificates	N/A	N/A	N/A	174*	388
Other	82	61	56	28	51
Total	**2190**	**2310**	**2501**	**4033**	**4146**

*2011 was the first full year that the IMB was responsible for issuing certificates for cosmetics.

SAFETY AND COMPLIANCE MONITORING

Monitoring the safety of medicines, medical devices and other healthcare products that have been authorised, licensed or registered for use in Ireland is known as post-market surveillance. It is a primary function of the IMB.

Assessing reports of suspected adverse events/ incidents and reactions (also known as side effects), conducting scheduled safety reviews, monitoring field safety corrective actions to medical devices and evaluating new and emerging data from trials and studies are among the tools used to monitor the safety of healthcare products on an ongoing basis. Quality issues concerning how a product is manufactured, packaged, labelled or distributed and stored may also arise at the post-market stage.

In a small number of cases, where it is established that the risks of a particular product outweigh the benefits for those using it, the manufacturer and/ or the IMB may decide that it is necessary to remove or recall that product from the market. In such circumstances, we will work with all stakeholders impacted to ensure such recalls are managed in a timely and effective manner.

HUMAN MEDICINES

PHARMACOVIGILANCE

Pharmacovigilance is defined as the science and activities relating to the detection, assessment, understanding and prevention of adverse reactions, or side effects, associated with the use of medicines. Key to its effectiveness is an active reporting culture. The majority of adverse reaction reports are notified to the IMB by the pharmaceutical companies marketing the medicines, also known as the marketing authorisation holder. Most of these reports will have been initiated by doctors, pharmacists and other healthcare professionals who may also report directly to the IMB. We also receive reports of adverse reactions directly from patients and members of the public.

The IMB monitors adverse reaction reports to look for new types, or increased numbers, of adverse reactions. In co-operation with pharmacovigilance professionals in Europe and further afield, we focus especially on serious and potentially life-threatening risks. If there appears to be a new and serious risk, the issue must be assessed to determine the impact on the overall benefit/risk profile of the medicine concerned and consideration is given as to how any new risks should best be managed and communicated to healthcare professionals and patients.

2011 Reports

During 2011, the IMB received a total of 2,784 suspected adverse reactions associated with the use of human medicines in Ireland. While this represents a decrease of some 14% in reporting rates compared with 2009/2010, it reflects a return to expected levels following the enhanced rates of reporting that resulted from the H1N1 national immunisation programme. The 2011 figures show a small increase in reporting compared to 2008. A percentage breakdown of adverse reaction reports received by source is provided in the accompanying table.

Individual case reports were followed up by the IMB and follow-up information was provided to reporters where appropriate. Serious, suspected cases notified directly to the IMB by healthcare professionals were appropriately forwarded to relevant stakeholders, including the European Medicines Agency (EMA) and marketing authorisation holders within the agreed timeframes and formats.

Source of Suspected Adverse Reaction Reports	%
Marketing Authorisation Holder	63
Community Care Doctor	9
General Practitioner	6
Hospital Doctor	5
Community Nurse	4
Hospital Pharmacist	4
Community Pharmacist	3
Hospital Nurse	3
Member of Public	1
Health Sector - Other	2

In addition, the IMB received and processed some 3,350 follow up reports during 2011.

Online Reporting

The IMB's online reporting system, available to healthcare professionals, patients and other members of the public accounted for 12% (345) of all reports received during 2011. This was a slight increase on the previous year. Access to the online reporting system is available through the homepage of the IMB website www.imb.ie.

In relation to industry, 288 companies were operational with electronic reporting to the IMB by the end of the year. This was an increase of some 25% over the number of companies reporting electronically in 2010.

During 2011, the IMB continued to report all suspected serious adverse reactions occurring in Ireland electronically via EudraVigilance to the EMA.

Monitoring Compliance with Pharmacovigilance Obligations

Company/sponsor compliance with pharmacovigilance obligations is continuously monitored through:

- review 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 cumulative information such as periodic safety update reports (PSURs) and Annual Safety Reports (ASRs); and
- review of responses to IMB requests for pharmacovigilance data.

Throughout 2011, issues identified in relation to the compliance areas above were followed up with the companies concerned through correspondence, meetings and teleconferences. The IMB also reviewed and gave feedback on corrective action plans developed to address the issues raised.

The pharmacovigilance inspection programme continued in 2011, jointly carried out by IMB pharmacovigilance and compliance colleagues. The pharmacovigilance team participated in three inspections during the year.

At a European level, the IMB participated in the Pharmacovigilance Inspectors Working Group workshop which examined the impact of the new pharmacovigilance legislation. In addition, we participated in the development of Good Vigilance Practice (GVP) guidance for pharmacovigilance systems requirements and inspections.

Pharmacovigilance Assessment Activities

A new product application submitted to the IMB for authorisation must include a document known as a 'detailed description of pharmacovigilance systems'. An updated version of this document may also be required for certain variation applications. This part of the product file or dossier is reviewed by our pharmacovigilance assessors. The following table outlines the number of detailed descriptions of pharmacovigilance systems assessed during 2011:

New Product Assessments		Updates Assessed as part of Variations	
New National procedures	41	National Variations	3
New Outgoing MR/DCP	8	Outgoing MR Variations	10
New Outgoing CAP	13	Outgoing CAP Variations	1
		Incoming MRP/DCP/CAP Variations	16

There were also 241 Type 1AIN variations reviewed for updates to the details of the Qualified Person Responsible for Pharmacovigilance. Type 1AIN (immediate notification) variations are those submitted after implementation.

Gardasil

The IMB continued to monitor national experience with Gardasil, the human papillomavirus (HPV) vaccine, used through the HSE school immunisation programme during 2011. As part of this monitoring programme, two updates outlining the number and nature of suspected adverse reactions associated with the use of Gardasil that were reported to the IMB relating to national monitoring were published on our website. The final update was published in July 2011 following completion of the first full year of the school programme. This update outlined the consistency between national reporting experience and the known safety profile of the vaccine, with no new risks identified in association with use of Gardasil in Ireland.

The IMB continued to address numerous queries and requests for information regarding the safety profile of Gardasil throughout 2011. These were received from members of the public, the media, healthcare professionals and interest groups.

Pandemrix – Investigation into Association with Narcolepsy

A potential association between the H1NI vaccine Pandemrix and narcolepsy, a sleep disorder, was first highlighted in August 2010. This followed an increase in the number of narcolepsy cases reported among children and adolescents who received this vaccine in Finland and Sweden. A detailed review of the issue was announced at EU level and this was ongoing at the end of 2011. The IMB is contributing to this review through its participation at the European Medicines Agency and will continue to do so during 2012.

In late 2010, the IMB received preliminary information regarding a small number of reports of suspected narcolepsy in Irish patients vaccinated with Pandemrix. Additional information and confirmation of a diagnosis of narcolepsy was received for some of these cases early in 2011. Throughout the remainder of the year, additional reports of suspected narcolepsy were received by the IMB in addition to many queries from members of the public, healthcare professionals and the media. Comprehensive follow-up with the healthcare professionals involved in each case was conducted. We interacted with relevant national bodies, including the Department of Health and the Health Protection Surveillance Centre (HPSC) in the context of the investigation. The IMB was also represented on the HSE Serious Incident Management Team which was co-ordinating the overall national review.

VIGILANCE ASSESSMENT

For the purposes of lifecycle benefit-risk management, it is necessary to continue to evaluate the risks and benefits of a medicine in everyday medical practice and long term use in the post-market phase. This is to ensure that the benefits of the medicine continue to outweigh the risks and that risk minimisation measures are implemented where needed.

Vigilance assessment activities include evaluation of periodic safety update reports (PSURs), risk management plans and post authorisation safety studies, pharmacovigilance-related referrals, and the assessment and approval of Direct Healthcare Professional Communications issued by companies and risk minimisation plans to be implemented in Ireland.

During 2011, a new signal management system was implemented. This system determines whether, based on an examination of individual case safety reports, aggregated data from active surveillance systems or studies, literature information or other data sources, there are new risks associated with an active substance or medicine or whether risks have

changed. The signal management process covers all steps from detection of signals, through their validation and confirmation, analysis, prioritisation and assessment to recommendations for action.

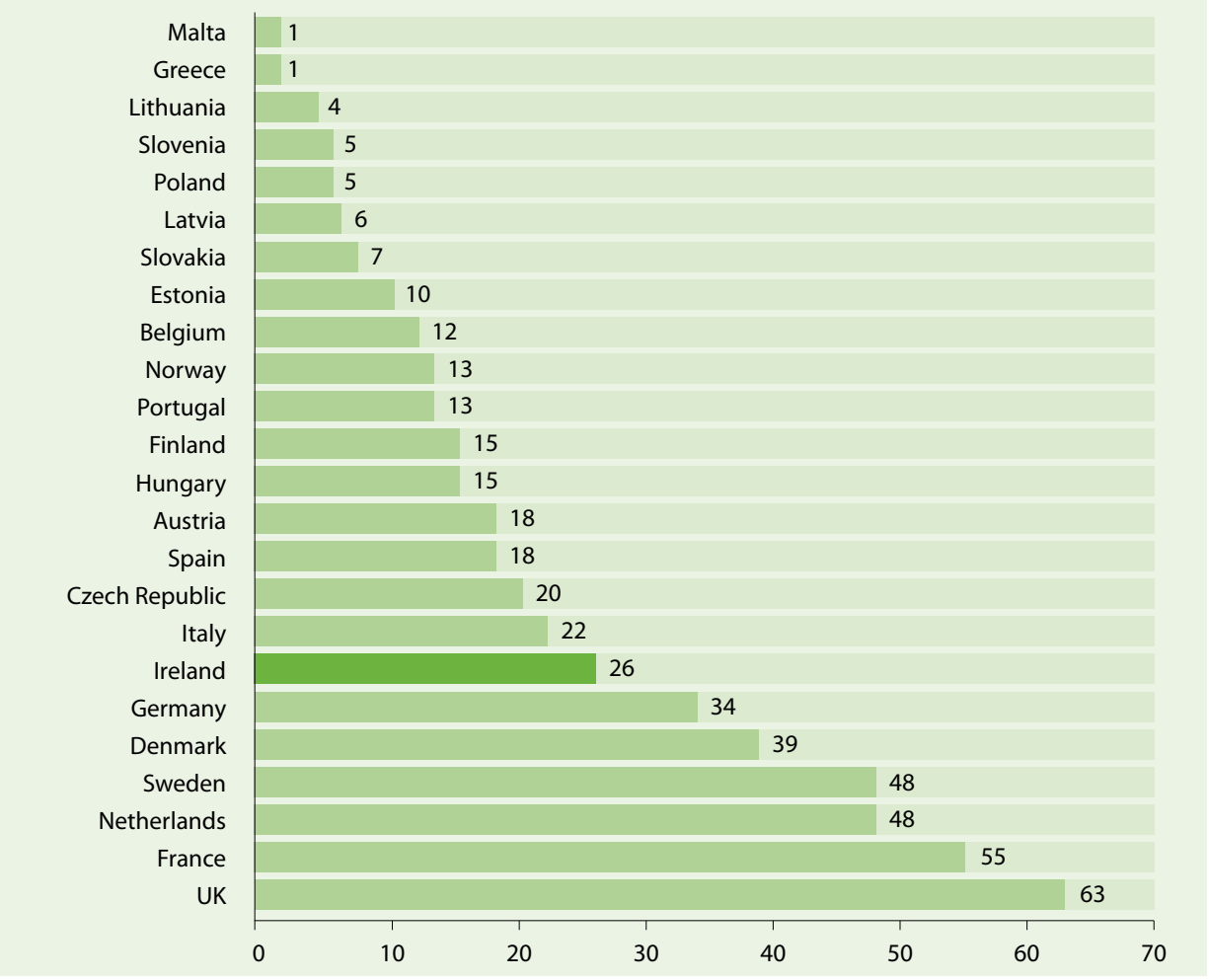
Periodic Safety Update Reports

Periodic safety update reports (PSURs) are a pharmacovigilance tool to monitor the ongoing safety of medicines post marketing. They are submitted by the MAH in respect of each authorised medicine, at defined intervals following the initial authorisation of the product. A PSUR is intended to provide an update of the worldwide safety experience of the medicine. PSURs are evaluated either by the IMB or by other EU medicines agencies operating a work-sharing system.

During 2011, the total output for PSURs was 3633. This includes PSURs for national authorisations, MR, centralised and PSUR work-sharing procedures. The IMB continues to actively participate in the HMA PSUR work-sharing project and is currently ranked in the top eight of national competent authorities in Europe in terms of lead MS assessment responsibilities (see corresponding graph below).

The IMB contributed to the implementation planning for the new pharmacovigilance legislation which introduces substantial changes for PSURs by providing the member state co-lead for the joint member state/EMA project team. In the future, requirements for PSURs will be risk-based and the scope of the evaluation will be extended to integrate cumulative information on both benefits and risks. The link to risk management will be strengthened.

P-RMS allocation



Risk Management Plans

In certain cases, a dedicated risk management plan (RMP) may be required as part of a medicine's approval process and for maintenance of approval. An RMP is a risk mitigation tool for managing a known or potential serious risk associated with a medicine.

The total number of RMPs assessed during 2011 was 629 (76 outgoing and 553 incoming applications). There were also 87 follow-up measures assessed including results of post authorisation safety studies. Some 44 Direct Healthcare Professional Communications providing new safety information or risk minimisation advice were approved. In addition, 39 risk minimisation plans were assessed including risk minimisation tools for healthcare professionals and patients to support the safe and effective use of the medicine.

Pharmacovigilance Working Party Assessments

The IMB provides active representation to the Committee for Medicinal Products for Human Use (CHMP) Pharmacovigilance Working Party and its drafting groups at the European Medicines Agency. During 2011, the working party provided advice to the CHMP and also the CMDh (the HMA's co-ordination group for MRPs and DCPs) for centrally-authorised and nationally-authorised products respectively.

The following assessments for nationally authorised products were concluded in 2011 leading to variations of national marketing authorisations:

- Antipsychotics (conventional and atypical) and use during the third trimester of pregnancy and risk of abnormal muscle movements and/or withdrawal symptoms in newborns;
- Beta-blocking agents for ophthalmic use and systemic adverse drug reactions after ophthalmic administration;
- Citalopram and risk of QT-interval prolongation;
- Domperidone and risk of QTc prolongation, serious ventricular arrhythmias and sudden cardiac death;
- Escitalopram and risk of QT-interval prolongation;
- Fluoroquinolones and risk of QT-interval prolongation;
- Use of Hydrochlorothiazide during lactation, and consolidated wording for the summary of product characteristics and package leaflet of ACE-inhibitors used alone or in combination with hydrochlorothiazide in pregnancy and lactation;
- Insulin products and risk of cardiac failure with concomitant use of pioglitazone;
- Key elements for warnings for summary of product characteristics and package leaflet regarding Stevens-Johnson syndrome) and toxic epidermal necrolysis for 14 'high risk' substances (for systemic use);
- Powder formulations of Plantago ovata seeds and allergic reactions after prolonged occupational exposure;
- Risk of psychiatric adverse drug reactions to inhaled and intranasal corticosteroids and risk of non-psychiatric systemic adverse drugs reactions to intranasal corticosteroids.

New Advice for use of Cough and Cold Medicines in Children

In September 2011, the IMB recommended a number of new measures in relation to the use of over-the-counter cough and cold medicines for children.

Following a review of the safety and effectiveness of cough and cold medicines, we advised that over-the-counter cough and cold medicines should not be used in children under the age of six years. For six to twelve year olds, the advice was that these medicines could continue to be used but care should be taken to ensure that the maximum daily dose is not exceeded and that no other cough or cold medicine is taken at the same time. The product information for these medicines was updated to reflect this advice.

BLOOD, TISSUES AND CELLS

HAEMOVIGILANCE

The IMB is the Competent Authority for legislation concerning blood and blood components.

Haemovigilance refers to a set of organised surveillance procedures relating to serious adverse or unexpected events or reactions in donors or recipients and the epidemiological follow-up of donors.

The IMB continued its interaction with the National Haemovigilance Office (NHO) during 2011 and discussed issues of mutual interest and concern at regular meetings throughout the year. Key items discussed at these meetings included:

- Review and discussion of national experience with haemovigilance reactions and events;
- Updates to guidance on haemovigilance reporting;
- Review of systems to facilitate simultaneous, dual submission of mandatory reports to the NHO and the IMB;
- Further developments to support monitoring activities and ensure compliance with EU and national legislative provisions.

Following collaboration with the NHO, the IMB submitted an annual report on serious adverse reactions and events to the European Commission during 2011. The report reflected information received from January to December 2010 and included information on 151 serious adverse reactions and 122 serious adverse events which met the mandatory legislative reporting requirements. These figures represent substantial increases in reporting over the previous year. There was an increase of almost 50 % in serious adverse reaction reports and of almost 170% in serious adverse event reports. The increase in the number of serious adverse events in this year's report relates to a change in reporting policy as the criteria were expanded to include reports from blood establishments and near miss reporting, in line with the legislative requirements. In addition, information on some 396 non-mandatory donor-related reactions provided on a voluntary basis was included in the report as requested by the Commission.

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 Haemovigilance convened in 2007. During 2011, the IMB attended a meeting of this group and has actively contributed to the development of an updated guidance document, in collaboration with colleagues from the NHO. Further updates to this guidance are expected in 2012.

TISSUE AND CELL VIGILANCE

The IMB is the Competent Authority in Ireland for the purposes of the EU tissues and cells legislation. The legislation focuses on standards of quality and safety for donations, procurement, testing, processing, preservation, storage and distribution of human tissue and cells.

Tissue and cell vigilance activities progressed throughout the year in review and included the three-year project co-funded by the EU Public Health group on Substances of Human Origin Vigilance and Surveillance (SoHOV&S). The project's primary aim is to support the establishment of effective vigilance and surveillance systems for tissues and cells used in transplantation and in assisted reproduction. The IMB continued its participation as a partner in the various working groups of this project and in its role as the lead partner for one of the work packages, with responsibility for organising training courses, including e-learning modules on the investigation and management of vigilance and surveillance for tissues and cells.

In line with the legislative requirements, the IMB submitted an annual report on serious adverse reactions and events associated with tissues and cells to the European Commission during 2011. The report reflected information received from January to December 2010 and consisted of some 32 reports associated with use of tissues and cells, 27 of which met the legislative reporting requirements, including three serious adverse reactions and 24 serious adverse events. The remaining five donor reaction reports, while not fulfilling the mandatory reporting requirements, were included on a voluntary basis as requested by the Commission.

Following submission of the annual report to the European Commission, an overview of the national data was compiled for distribution to stakeholders to provide some feedback on the national reporting experience for the period.

The European Commission also 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 2011, the IMB continued to participate in the development of guidance for reporting.

VETERINARY MEDICINES

PHARMACOVIGILANCE

Effective reporting is central to a successful and robust pharmacovigilance scheme. During 2011, there were 228 reports of suspected adverse reactions associated with the use of veterinary medicinal products received by the IMB. This represents an increase of 9% over the number of reports received in 2010.

The breakdown of the 228 reports is as follow:

- 121 related to suspected adverse reactions in the treated animals
- 94 related to suspected lack of expected efficacy
- 10 involved suspected adverse reactions in individual users following exposure to a veterinary medicinal product

Three reports related to violations of approved residue limits in foodstuffs of animal origin. On investigation, it was determined that residue standards being applied were more stringent than those defined by EU residue legislation.

Periodic Safety Update Reports

PSURs are intended to provide an update of the worldwide safety experience of a medicine. In 2011, a total of 413 PSURs were assessed which compares to 396 for 2010.

Significant Product Suspensions or Variations

The marketing authorisation for Hiprabovis Pneumos Emulsion for injection for cattle was suspended in 2011. This action followed a decision by the European Commission that the benefit/risk profile

had changed due to an increase in the incidence of anaphylactic-type adverse events associated with use of the vaccine, some of which were fatal. The underlying cause of the adverse reactions observed was undetermined and as a result no specific risk-management measures could be devised.

Inspections of Pharmacovigilance Systems

The IMB conducted one inspection of a pharmacovigilance system at a marketing authorisation holder's premises during 2011. In addition, we participated in two inspections in other EU member states in respect of centrally-authorised products for which the IMB was the rapporteur.

USE OF VETERINARY ANTIMICROBIALS IN IRELAND

In accordance with EU policy to help underpin effective strategies to control the spread of antimicrobial resistance in animals and in humans, the IMB gathered information on the usage of veterinary antimicrobials in Ireland. The total consumption in 2011 was 93 tonnes, a slight increase of 2% in usage compared to the previous year.

MARKET COMPLIANCE – HUMAN AND VETERINARY MEDICINES

The IMB is responsible for a number of risk-based market surveillance programmes. These include proactive activities such as the sampling and analysis programme and the advertising compliance programme, and reactive activities such as the quality defect and recall programme.

The IMB also operates an exempt medicinal products notification scheme designed to monitor the importation and supply of unauthorised medicinal products. In addition, we carry out a programme of regulatory compliance inspections at the premises of marketing authorisation holders. The latter is designed to assess the level of compliance against national legislation relating to the placing on the market and advertising of medicines.

SAMPLING AND ANALYSIS PROGRAMME

The IMB's sampling and analysis programme for medicines for human and veterinary use contributes to our monitoring of the quality, safety and efficacy of medicinal products on the Irish marketplace.

This is done through the analytical testing and/or examination of packaging and labelling of active substances, medicinal products, borderline medicinal/non-medicinal products and enforcement-related samples. A risk-based approach is taken when carrying out sampling and analysis work and this determines the degree of analytical work carried out on the sampled products.

A total of 529 product samples were sent for examination and/or analytical testing in 2011.

Examination of Packaging and Labelling

The packaging and labelling of 246 medicinal and other products were examined. Of these, 68% were subjected to general packaging and labelling examinations, with a particular emphasis on the adequacy of the required safety and warning information on package leaflets. A further 27% of products were subjected to Braille compliance checks.

Description of products examined	Number of samples examined
Medicinal products subjected to general compliance monitoring for packaging and labelling attributes	167
Medicinal products subjected to Braille compliance checks	67
Product usability checks	4
Samples arising from monitoring of advertising	4
Work arising from notification of exempt medicinal products	3
Borderline Medicinal/Non-medicinal products associated with IMB Classification Committee work	1
Total	**246**

Analytical Testing

There were 284 medicines and other product samples tested of which 281 were obtained from the Irish marketplace. Three samples originated from other EU marketplaces as part of the IMB's involvement in EU-wide work-sharing surveillance programmes.

Approximately 49% of the analytical work related to enforcement and borderline medicinal/non-medicinal product samples. In addition, 33% related to authorised medicinal products. Of the remainder, 5% concerned active substances while 9% of the programme was taken up by microbiological analysis work.

Product categories selected for Analytical Testing in 2011	Number of samples analysed
Physico-chemical Analysis/Biological Analysis	
Enforcement-related products	138
Nationally authorised medicinal products	30
MRP/DCP authorised medicinal products	30
Centrally authorised medicinal products	25
Active substances	13
Human medicinal products manufactured for export	12
Borderline Medicinal/Non-Medicinal products	5
Exempt medicinal products	2
MRP/DCP authorised biological products	1
PPA and DPR medicinal products	1
Veterinary nationally authorised biological medicinal product	1
Microbiological Analysis	
Nationally authorised medicinal products	20
MRP/DCP authorised medicinal products	6
Total	**284**

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 our participation in the Official Medicines Control Laboratories (OMCL) Network.

We participated in the sampling and/or analysis of 25 centrally-authorised medicinal products. Of these, 21 were sampled from the Irish marketplace for testing at OMCLs in other countries and 4 were analysed in Ireland on behalf of the European Medicines Agency.

The IMB also actively participated in the surveillance programme for MRP/DCP medicinal products co-ordinated by the European Directorate for Quality of Medicines (EDQM). As part of work-sharing and in an effort to make the best use of available laboratory resources, the IMB sampled 21 medicinal products from the Irish marketplace for analysis at other member state OMCLs. There were four borderline medicinal/non-medicinal products analysed by the UK's OMCL and one further such product was analysed at the Public Analyst's Laboratory in Galway. Other work-sharing activities carried out included analysis of 20 Irish market samples by the UK OMCL as part of an anti-counterfeiting project while 26 samples were microbiologically analysed at the Finnish and Czech OMCLs.

Principal Findings

Analysis	Findings
Laboratory analysis	Five out-of-specification results associated with the analytical testing of two authorised human medicinal products were identified. Four of these related to non-compliances with product appearance specifications and one product was out-of-specification for assay.
Packaging and labelling	26 non-compliances were identified in the packaging and labelling of authorised medicinal products. Nine of these related to the Braille that was applied to the product packaging. Other non-compliances related to SPCs and package leaflets containing incorrect information and to the inappropriate overlabelling of parallel imported packs.
Unauthorised medicinal products	Three unauthorised medicinal products were identified on the Irish marketplace via this programme. The products concerned were found to be prescription-only medicines and appropriate follow-up actions were taken.

All non-compliances were followed-up with the relevant companies until the issues could be closed. Follow-up is dependent on the type of non-compliance and can involve:

- initiating company re-testing;
- reviewing stability data;
- reviewing packaging and labelling controls (including Braille); and
- recommending amendments to company methods.

Acknowledgements

The IMB would like to thank the staff of the Public Analyst's Laboratory, Galway, and the staff of the State Laboratory, Young's Cross, Celbridge, Co. Kildare, for their contributions to the IMB's sampling and analysis programme in 2011.

QUALITY DEFECTS AND RECALLS

The quality defects and recalls programme investigates, on the basis of risk to public and animal health, reports of suspected quality defects in both human and veterinary medicines and in their related active substances. It also co-ordinates all recall actions on the Irish market.

Number and Type of Quality Defects

A total of 917 quality defects were reported to, or identified by, the IMB. This is the highest number of quality defect investigations in any one year since the introduction of the programme and represents a 22% increase over 2010.

A number of factors contributed to this increase. These included awareness-raising work carried out by the IMB among manufacturers in relation to what should be reported as a quality defect as well as a significant increase in the number of rapid alerts issued by other national competent authorities. Such alerts enable the immediate sharing of quality defect information across Europe.

Medicines for human use accounted for 847 quality defect reports (92 %) with 70 reports concerning veterinary medicines. The accompanying table illustrates how the various quality defect issues were classified in 2011. For comparison, the corresponding figures for the previous three years are also presented.

Of the total number of defects, 715 (78%) were determined to affect Ireland. In these cases, the defective batch or batches were either on the Irish market and/or were manufactured in Ireland.

Type of Defect	**2008**	**2009**	**2010**	**2011**
Minor Quality Defects	105	147	241	314
Major Quality Defects	299	345	332	364
Critical Quality Defects	127	105	173	231
Number of Quality Defect Reports Not Justified	23	17	5	8
Total Number of Quality Defects	**554**	**614**	**751**	**917**

Critical quality defects, which are those defects defined as potentially life-threatening or a serious risk to health, accounted for 231 of the total reports received. Of these, 100 (11% of the total for the year) were determined to affect Ireland. All related to medicines for human use. One further critical report related to tampering with packs of Nurofen Plus in the UK. While market action were taken in Ireland to check all packs at wholesale and pharmacy level, there was no evidence that the Irish market was affected by the issue.

The 100 critical quality defect reports included eight reports of falsified medicines from other competent authorities where the genuine product was manufactured in Ireland. In none of those cases was the falsified pack identified on the Irish market.

The issues of concern in the remaining 92 critical quality defect cases were:

- Non-adherence to cold chain by wholesalers and manufacturers (57)
- Product contamination (17)
- Product mix-up (11)
- Undeclared active ingredient identified in products (5)
- An unfavourable shift in the benefit/risk profile of a product as a result of newly acquired safety-related information (1)
- Lack of therapeutic efficacy (1)

The type and number of all quality defects received is provided in the accompanying table.

Types of Quality Defects	Human Quality Defects	Veterinary Quality Defects
Contamination Issue	102	1
SPC/Carton/Label/Leaflet	97	2
Other Packaging Component	89	8
Stability	73	14
Cold Chain Issue	69	9
Non-Compliance with MA	62	5
Product Mix-Up	55	0
Damaged Product	55	8
Non-Compliance with Spec	51	3
Product Preparation/Administration	43	0
Unauthorised Product	34	2
Undeclared Active	31	0
Other	18	0
Lack of Sterility Assurance	17	0
Adverse Reaction/Change in Risk/Benefit	16	1
Erroneous Distribution	13	0
Counterfeit Issue	9	0
Non-compliance with GMP	7	17
Lack of Efficacy	6	0

When compared with the quality defect data from 2010:

- Contamination issues increased by 52% during 2011. Part of this increase was attributable to the 40 rapid alerts received from other competent authorities (compared to 11 the previous year);
- Product mix-ups increased by 162% with several products implicated in some cases. In particular, three individual incidents, which occurred at manufacturing facilities outside Ireland, accounted for 35 (64%) of the 55 product mix-ups. However, there were less individual occurrences of product mix-up than in 2010.
- Damaged product cases increased by 75% to 63. However, 38 of those cases related to a single incident at an Irish wholesaler.

(Stability issues decreased by 21 primarily due to re-categorisation of the data.)

Sources of Quality Defects

As in previous years, pharmaceutical companies accounted for the majority of reports of human medicine quality defects received (63%). While the total number increased from 429 in 2010 to 533 in 2011, the percentage of the total remained similar.

There was a 6% increase in the number of human medicine quality defects reported by other competent authorities compared to 2010.

Source – Human Medicine Reports	Number
Companies (Manufacturers, Distributors and/or MA Holders)	533
Other Competent Authorities	196
IMB Staff Members	51
Community Pharmacists	28
Hospital Pharmacists	27
Patients and/or Members of the Public	6
Physicians and Nurses	2
Other	2

In respect of veterinary medicines, other competent authorities again accounted for the majority of quality defect reports (63% in 2011, up from 53% the previous year).

Source – Veterinary Medicine Reports	Number
Other Competent Authorities	44
Companies (Manufacturers, Distributors and/or VPA Holders)	25
Department of Agriculture, Food and the Marine	1

Recalls of Human and Veterinary Medicinal Products

In order to protect the health and safety of patients, it is deemed necessary in certain cases to withdraw, or recall, products from the Irish market. During the year in review, 253 medicine recalls occurred. Of these, 240 (95%) related to human medicines and 13 to veterinary medicines.

The recall from the Irish marketplace of a batch or a number of batches of a medicinal product occurred in approximately 28% of all quality defect cases investigated. This was an increase of 6% on 2010. However, in a number of cases, these recall actions related to multiple products. The most significant example of this was a single instance of non-adherence to cold chain requirements that resulted in the recall of 65 products from the Irish market, accounting for 27% of all recalls in the year. Similarly, a recall to primary and secondary wholesale level relating to a damaged product resulted in 48 human medicinal products being recalled, and this comprised 20% of all recalls.

As shown in the accompanying table, product contamination issues, non-compliance with specifications and errors in printed packaging materials were some of the other issues that resulted in the recall of human medicines from the Irish market.

Type of Quality Defect – Human Medicines	2010	2011
Non-adherence to Cold Chain	9	67
Damaged Product	12	38
Non-compliance with Specifications	5	28
Particulate or other Contamination	4	24
SPC/Carton/Label/Leaflet Issues	*See note 2 below	17
Stability	9	13
Product Preparation/Administration Issue	#See note 1 below	9
Unauthorised Product on the Irish Market	44	8
Lack of Sterility Assurance	3	7
Products Containing Undeclared Active Ingredients	6	5
Other Packaging Component issues	*See note 2 below	5
Adverse Event/Change in Benefit/Risk Ratio	17	4
Erroneous Distribution	1	3
Non-compliance with MA	2	2
Product Mix-Up	4	2
Lack of Therapeutic Efficacy	0	2
Product Usage Issues	0	#See note 1 below
Packaging and/or Labelling	32	*See note 2 below
Other	10	6
Total Number	158	240

#Note 1: 'Product Usage' category is no longer in use and has been replaced by 'Product preparation/administration issue'.

*Note 2: This category has been sub-divided into: 'SPC/Carton/Label/Leaflet issues' and 'Other Packaging Components issue'.

Type of Quality Defect – Veterinary Medicines	2010	2011
Damaged Product	0	8
Non-adherence to Cold Chain	0	3
Stability	3	1
Unauthorised Product on the Irish Market	3	1
Adverse Event/Change in Benefit/Risk Ratio	2	0
SPC/Carton/Label/Leaflet Issues	*See note 1 below	0
Other Packaging Component Issues	*See note 1 below	0
Packaging and/or Labelling	1	*See note 1 below
Other	1	0
Total Number	**10**	**13**

*Note 1: This category has been sub-divided into: 'SPC/Carton/Label/Leaflet issues' and 'Other Packaging Components Issue'.

In respect of veterinary medicines, the above table shows that damaged product accounted for 8 of the 13 product recalls.

Other findings from the recall programme include the following:

- Exempt medicinal products distributed on the Irish market accounted for 23 (9%) of the human product recalls in 2011.
- Compounded products for human use accounted for 24 recalls (10%). This related to one main issue.
- Of the products recalled from the Irish market, 59 (25%) were manufactured at an Irish manufacturing facility.
- There was an increase in the number of recalls to wholesale and patient level. This is in line with an increase in the number of both minor and critical quality defect issues that were reported and investigated.

RETAIL SALES MONITORING

Exempt Medicinal Products Programme

Medicines placed on the Irish market must be authorised by the IMB or, in the case of centrally authorised products, by the European Commission. However, European regulations do provide for an exemption to this rule. In this case, registered doctors and dentists are permitted to prescribe unauthorised medicines for individual patients under their direct responsibility in order to fulfil the special needs of those patients. Such products are defined as 'exempt medicinal products'.

In accordance with the Medicinal Products Regulations 2007-2010, wholesalers and manufacturers of medicinal products are obliged to provide certain information to the IMB in relation to any exempt (unauthorised) products that they source. The main purpose of our receiving such information is to facilitate, when needed, the effective recall of any defective exempt medicines from the Irish market.

The total number of packs of exempt medicinal products notified was 1,474,564, an increase of 25% when compared with 2010. The IMB continues to work with stakeholders in several areas to identify and develop solutions in relation to reducing the use of exempt products in Ireland.

A number of significant non-compliances were identified with the supply of exempt products. As a result, three of the companies involved were required to perform a retrospective review of their notifications to the IMB. Corrections to the IMB database were subsequently required and these contributed to the increase in the notification figures for the year.

General Retail Sale Investigations

There were 13 cases relating to non-compliance with requirements governing general retail sale of medicines investigated. These originated from complaints received by the IMB and from direct surveillance. The majority of cases investigated related to the sale of medicines not authorised on the Irish market. The number of cases investigated was considerably reduced relative to 2009 (43 cases) and 2010 (72 cases). The reduction in the level of non-compliances in this area is considered to be attributable to an increased awareness within this sector of the legislative requirements.

Regulatory Compliance Inspections

These inspections are carried out at the premises of marketing authorisation holders and are fully risk-based. The programme of inspections enables the IMB to inspect compliance with a number of the legal requirements pertaining to the marketing and advertising of medicines in Ireland. Areas of activity that have a high potential to impact the quality and safe use of medicines are the main focus of the inspections carried out. These areas include the following:

- implementation of safety-related changes to product information and product labelling of medicines placed on the market;
- management and communication of regulatory commitments and changes;
- management of approved product information;
- provision of a medical information service for healthcare professionals;
- presence of a quality management system to facilitate regulatory compliance;
- medicinal product advertising.

Five such inspections were carried out, including one that was performed jointly with the UK's Medicines and Healthcare products Regulatory Agency (MHRA). The programme of regulatory compliance inspections has also enabled the IMB to inspect key areas of activity concerning the marketing and advertising of medicines by companies in Ireland. See the following section of this report for related information.

Human Medicines Advertising Compliance Programme

It is important that in the interests of public health, the benefits, uses and effects of medicines are promoted responsibly. It is the role of the IMB to monitor and review advertising and promotion activities by the industry for compliance with the requirements of the Medicinal Products (Control of Advertising) Regulations, 2007.

Overall, 471 individual advertisements were reviewed for compliance during 2011 through the IMB's advertising compliance programme. This programme has four main components:

- Proactive Monitoring
  - There were 299 advertisements across several different media reviewed. Of these, 62% were reviewed as part of risk based pre-planned proactive surveillance projects while 38% were selected on a random basis.

  - The proactive activity identified 40 individual advertisements that were non-compliant while 60 individual advertisements were found to be non-compliant during random surveillance work.
- Inspection of Company Advertising Programmes
  - Five regulatory compliance inspections were carried out at offices of marketing authorisation holders. In three of these cases, advertising programmes and activities were reviewed in detail.
  - A number of deficiencies were identified and the IMB oversaw the implementation of the necessary corrective and/or preventative actions.
- Advertising-related Complaints
  - A total of 17 advertising-related complaints were received from healthcare professionals, pharmaceutical companies, the general public, IMB staff and others. As part of the investigation of those complaints, 90 advertisements were reviewed.
  - Of the complaints received, nine were deemed to be valid. These nine cases concerned 29 non-compliant advertisements.
- Advertising-related Queries
  - Queries were received from a range of interested parties. These resulted in the review of 82 advertisements. Of those, 15 were considered to be non-compliant.

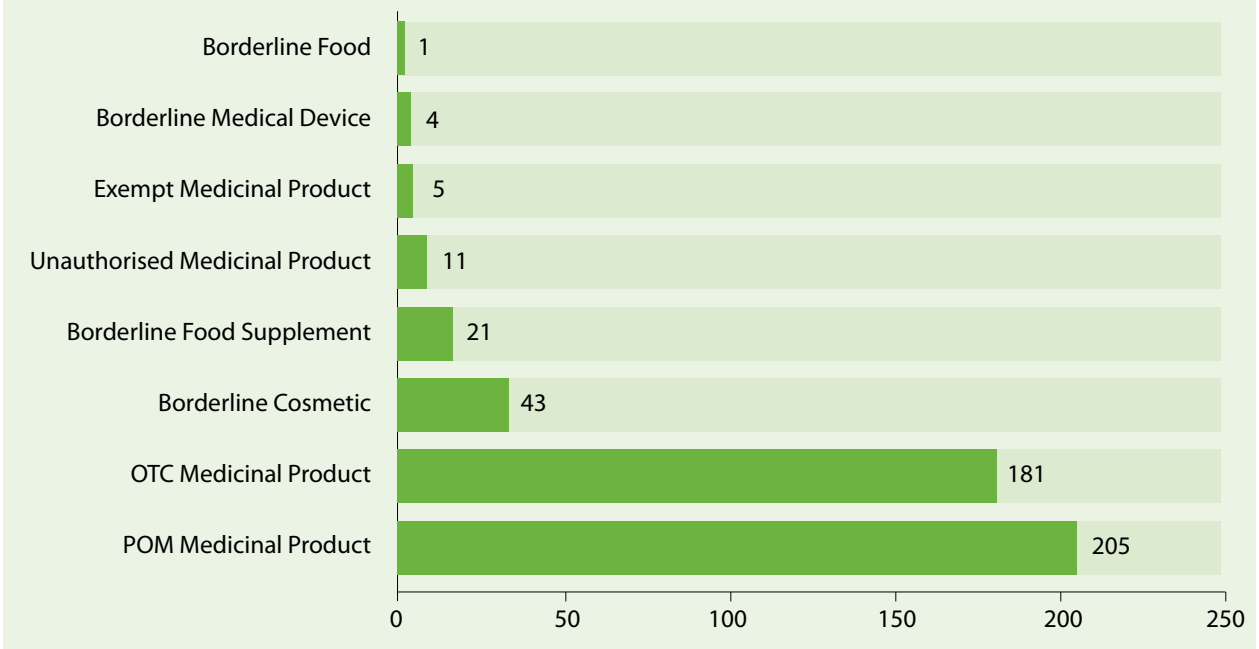
	Total	**Advertisements Reviewed**	**Non-Compliances Identified**
Proactive Monitoring: Pre-planned Projects	10	185*	40 individual advertisements were non-compliant
Proactive Monitoring: Randomly Selected Projects	14	114*	60 individual advertisements were non-compliant
MAH Inspections Performed	5	Not quantified	Several major and other deficiencies identified
Complaints Received	17	90*	29 advertisements were found to be non-compliant
Queries Received	62	82*	15 advertisements were found to be non-compliant

*Note: Some of these figures include website advertisements, and each page of a website is counted as one advertisement, because multiple pages can have multiple advertisements.

A breakdown of the advertisements reviewed based on the type of product promoted is provided in the accompanying graph. Of the 205 advertisements promoting prescription-only products, 44 (21%) were found to be non-compliant. In respect of advertisements promoting over-the-counter medicines, 63 (35%) were deemed non-compliant.

In all cases of non-compliance identified by the different elements of the programme, the IMB supervised the adoption of the necessary corrective and/or preventative actions by the marketing authorisation holder.

Types of Product Advertising Reviewed in 2011



MEDICAL DEVICES

VIGILANCE

Post-market surveillance and vigilance is a key element in protecting the health and safety of those who use medical devices and it is a core function of the IMB.

The European medical devices directives (93/42/EEC, 90/385/EEC and 98/79/EC) include requirements for medical devices manufacturers to report certain types of incidents to the national Competent Authority (IMB). The directives also outline the obligations on competent authorities to share details of certain incidents reported to them, between each other and with the European Commission. The vigilance system is the name given to the process of notification and evaluation of these incidents.

The IMB's reporting system for incidents associated with medical devices is intended to protect the health and safety of patients, users and others by reducing the likelihood of the same type of incident being repeated across Europe and to correct product problems.

2011 Reports

A total of 1,775 medical device vigilance reports were received and assessed, which is an increase on 2010. As can be seen from the accompanying graph, since the IMB assumed the role of Competent Authority for medical devices, there has been a consistent upward trend in the number of vigilance cases received.

Manufacturers accounted for 50% of all vigilance reports received in 2011 while 42% were received from competent authorities. Of the vigilance reports received, 33% were as a result of an incident on the Irish market. During the past year, the IMB issued 108 competent authority vigilance reports.

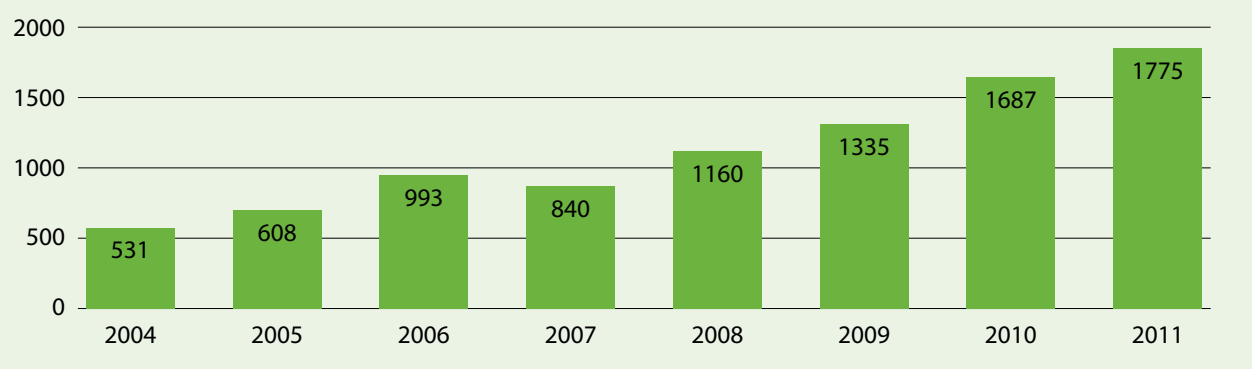
Of the vigilance reports received, 65% resulted in an action being taken. There were 227 product removals conducted in Ireland in 2011 and this was the most common action taken. The publication of a manufacturer's field safety notice, which informs users of safety issues relating to medical devices, was the next most common action. Safety information was also highlighted to the public through IMB safety notices. There were 34 such notices sent to the relevant interest groups and published on the IMB website during 2011.

2011 Report by Product Type

Orthopaedic implants, surgical equipment, infusion and transfusion devices accounted for a large proportion of vigilance reports.

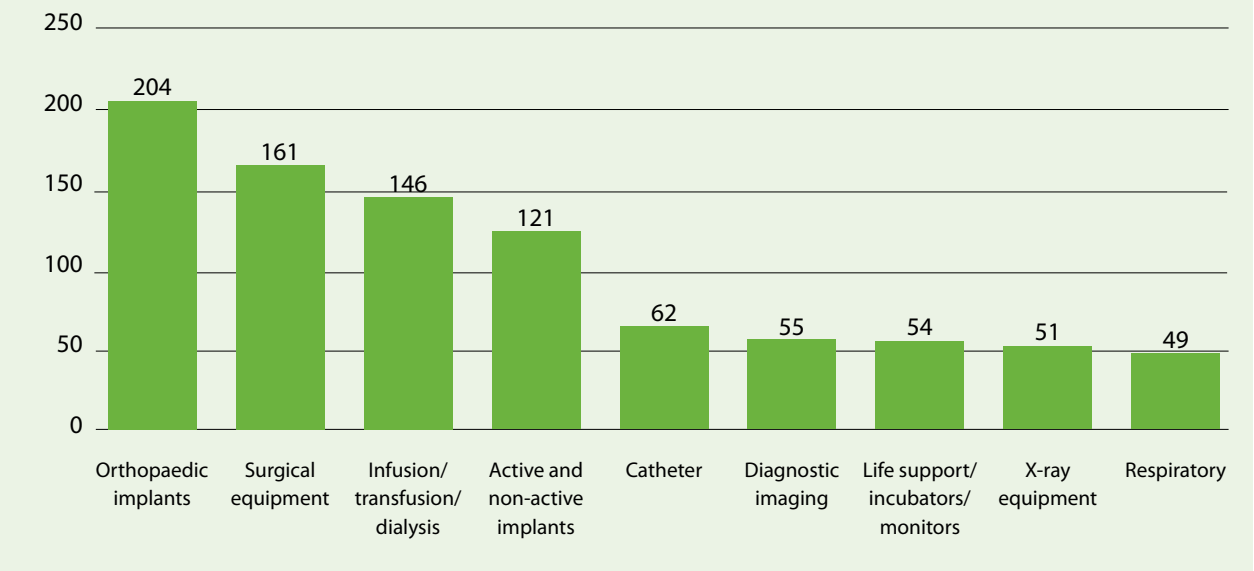
The continued reporting of revision procedures associated with the ASRTM Articular Surface Replacement and ASRTM XL Actabular system manufactured by DePuy contributed to the majority of the orthopaedic implant reports. In addition, vigilance reports following the explantation of breast implants manufactured by Poly Implant Prothese following global recall in 2010 continued to be submitted to the IMB.

Number of vigilance reports received during the period 2004 to 2011



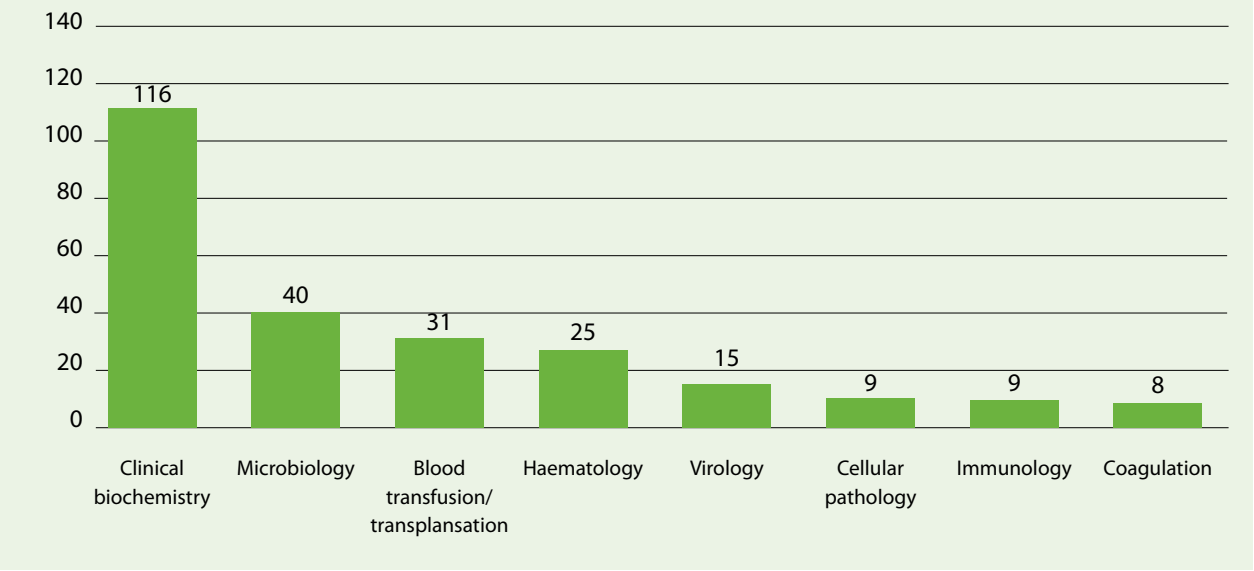
The increasing trend in reports relating to diagnostic and radiotherapy software and equipment noted in 2010 also continued throughout 2011.

Family Group of General Medical Devices and Active Implantable Medical Devices – Number of Vigilance Reports



In the area of in-vitro diagnostic (IVD) devices, the largest number of vigilance reports received related to clinical biochemistry. Field safety corrective actions relating to clinical chemistry analysers continued to have a high impact on the number of IVD vigilance cases.

Family Group of In-Vitro Diagnostic Medical Devices – Number of Vigilance Reports



COMPLIANCE

Medical device compliance activities are focused on protecting the health and safety of those who use medical devices. All potential safety and non-compliance issues identified are subject to investigation and non-compliant devices may be removed from the Irish market.

In 2011, 882 compliance cases were investigated which was a 42% increase on the previous year and continues a broadly upward trend since 2004. Contributing to this increase was the fact that a significant amount of proactive compliance work was focused in the area of Class I and custom made devices, devices for sale in discount stores and pregnancy tests which are sold widely in Ireland.

Similar to previous years, issues identified in 2011 and investigated as part of compliance cases included labelling problems, missing or incorrectly attached CE marking and classification issues.

Of the total cases notified to the IMB, 71% were from other competent authorities and mainly related to notified body certificate withdrawals. A number of these reports related to certification changes resulting from the requirements outlined in European Directive 2007/47/EC.

MARKET COMPLIANCE OF COSMETICS

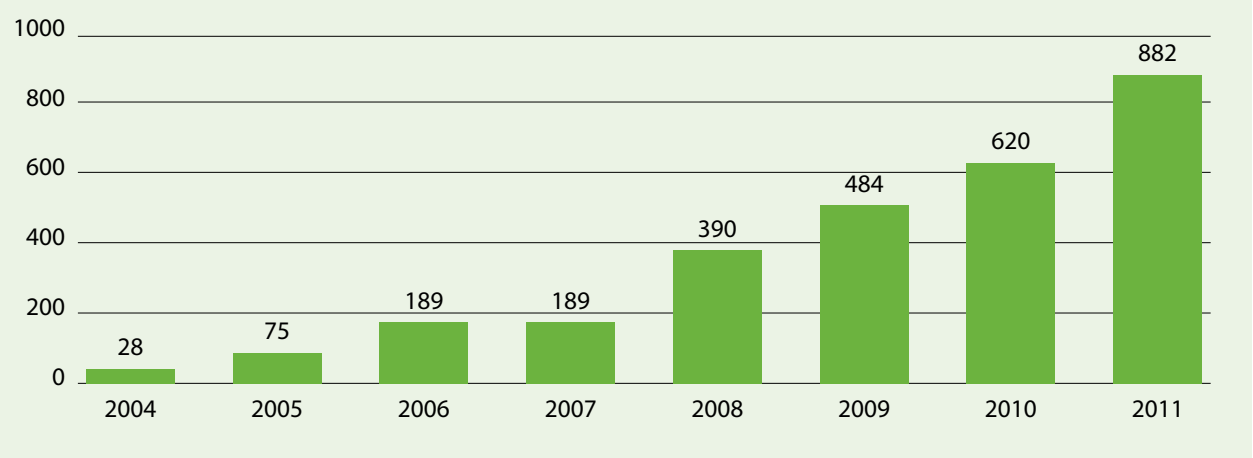
MARKET SURVEILLANCE

Post market surveillance activity relating to cosmetics involves close co-operation between the IMB and the HSE. The HSE Environmental Health Service and the three Public Analysts' Laboratories based in Cork, Dublin and Galway were involved in the preparation of the market surveillance schedule and the subsequent sampling and analysis of cosmetic products on the Irish market.

Reactive surveillance included investigation of quality related complaints (compliance cases) and reports of undesirable effects relating to the use of cosmetics (vigilance cases). There were 106 compliance cases initiated during 2011 and these accounted for the vast majority of investigations. In addition, 22 vigilance cases were investigated.

There were also six recalls of cosmetic products in order to protect the health of consumers. Of these, four were related to high lead content in cosmetic products.

Number of Medical Device Compliance Cases Investigated 2004 to 2011



RAPEX Alerts

Reactive surveillance of cosmetic products also includes investigation of in-coming RAPEX Alerts (EU safety alerts for cosmetic and other consumer products). The National Consumer Agency (NCA) is the national contact point for the receipt and circulation of these alerts. In conjunction with the HSE, the IMB investigated these alerts on the basis of risk and market action was taken as appropriate. Where the product in question was found on the Irish market, a reaction report was submitted to the NCA outlining the market actions taken. The IMB received 114 such alerts. In the case of seven, the products were found to be on the Irish market.

INSPECTIONS AND AUDITS

As part of our regulatory role, the IMB is focused on ensuring industry compliance with relevant standards and legislation. Our inspections and audits work programme includes:

- Regular inspections of manufacturers and wholesalers of medicines to check for compliance to EU guidelines on Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP), respectively.
- Inspection of clinical trial sites for compliance with EU and International Conference on Harmonisation (ICH) guidelines on Good Clinical Practice (GCP). The GCP inspection programme includes inspection of sponsor companies, investigators, contract research organisations and laboratories and applies to clinical trials approved in Ireland and those performed in support of national and EU marketing authorisations.
- Inspection for compliance with Good Pharmacovigilance Practice of the systems put in place by marketing authorisation holders for dealing with reports of adverse reactions to medicines.
- Regular audit of the NSAI, the notified body for medical devices that is designated by the IMB.
- Proactive audit of manufacturers of Class I devices and 'for cause' audits as required, for example, as part of the follow-up to a defect.
- Inspection of blood and tissue establishments for compliance with applicable EU guidelines on the quality and safety of blood, blood products, tissues and cells.
- Inspection, often in conjunction with the National Drugs Unit of An Garda Síochána, of manufacturers and wholesalers of medicines containing controlled drugs (CD) and of precursors (chemicals that can be used in the preparation of illicit drugs) to check for compliance with security and record-keeping requirements for these controlled substances.

OVERVIEW OF THE 2011 INSPECTION PROGRAMME

During 2011, there was a total of 271 national inspections and audits performed compared to 263 in 2010 and 238 in 2009. A further 29 foreign inspections and audits were performed in the past 12 months, a figure broadly similar to the past two years. The average number of days required to close-out the inspections and audits was 79.

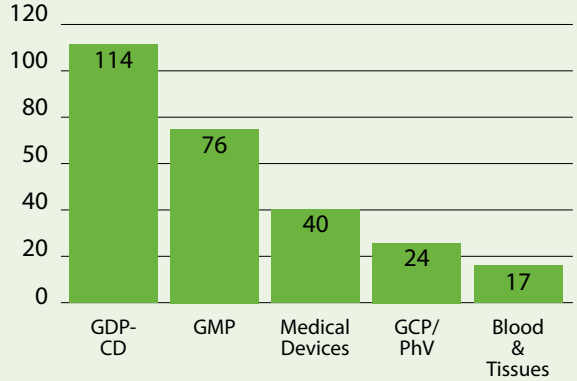
Performance Results and Statistics	2007	2008	2009	2010	2011
No. of national inspections and audits performed	239	228	238	293	271
No. of foreign inspections and audits performed	13	27	28	30	29
% inspections and audits closed on time (≤ 90 days)	79	67	58	62	66
Average time for close-out (days)	139	89	112	194	79
Total	**263**	**394**	**400**	**420**	**442**

In the past year, there were:

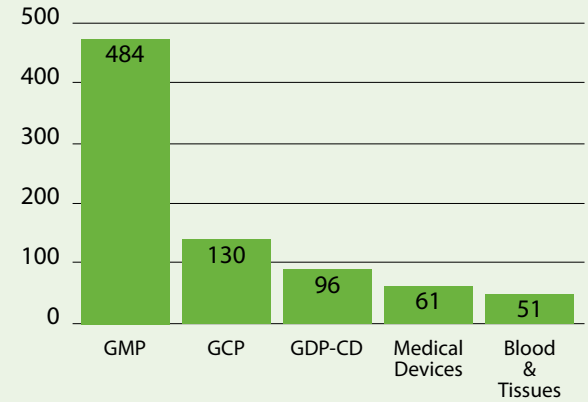
- 76 GMP inspections performed. These included 18 foreign inspections, 6 of which were carried out at the request of the European Medicines Agency for centrally-authorised products.
- 114 inspections performed to assess compliance with GDP and controlled drugs (CD) requirements.
- 18 GCP inspections completed. Of these, 13 were carried out at investigator sites in Ireland with two being GCP system inspections. In addition, three inspections were conducted outside of Ireland at the request of the European Medicines Agency.
- 6 pharmacovigilance inspections. This included three at Irish based marketing authorisation holders' facilities and three inspections for centrally-authorised products that were conducted at the request of the European Medicines Agency.
- 40 audits of Irish medical device manufacturers (5 proactive and 7 reactive audits) conducted while 22 audits were performed of manufacturers of custom made medical devices. Audits of medical device manufacturers included proactive surveillance audits and 'for cause' reactive audits resulting from vigilance/market issues.
- 3 surveillance audits and two observed audits of the National Standards Authority of Ireland (NSAI), the notified body for medical devices in Ireland, were carried out. As the Competent Authority, the IMB is responsible for the continued monitoring of the NSAI. In carrying out this role, we conducted surveillance audits at the NSAI's offices and observed NSAI staff performing audits at device manufacturers' premises. The IMB also performed one peer review audit of another EU Medical Device Competent Authority.
- 4 blood establishment inspections were completed. This included two inspections of facilities maintained by the Irish Blood Transfusion Service (IBTS).
- 13 tissue establishment inspections were carried out. The majority of these inspections were routine compliance inspections at authorised tissue establishments.

In late 2010, the presence of pyrogens (bacterial fragments capable of causing elevated temperatures and other complications in patients) was detected in some products manufactured at an Irish site. This led to the suspension of manufacturing of the products concerned and the eventual recall of unused packs once sufficient replacement stocks were available. Investigation and follow up of these issues required considerable resources across the IMB as these are vital products and the site is a major supplier to the EU and other markets. Following a significant refurbishment programme and intensive inspections, the IMB approved the resumption of manufacture of the products concerned in October 2011. Close monitoring of the manufacturing site and of the usage of the products from there will continue in 2012.

Number of Inspections and Audits Completed in 2011



Number of Inspection and Audit Days in 2011



ENFORCEMENT

Illegal activity involving the manufacture, supply and sale of medicines or medical devices can potentially have consequences for public health. It is the role of the IMB to investigate potential breaches of human medicinal product and medical device legislation. Where necessary, we will take the appropriate corrective action including possible legal proceedings.

ENFORCEMENT CASES

In 2011, a total of 4,549 enforcement cases were initiated internally by the IMB, compared to 3,936 for 2010. This represents a year-on-year increase of 16%. There were 4,475 cases closed during the past year, the majority of which were mail order/internet importations of prescription-only medicines.

DETAINED MEDICINES

A total of 762,641 dosage units of medicinal products were detained. This represents a decrease of 7% compared to 2010. This 2011 figure includes 251,883 dosage units detained which relate to weight-loss products containing the active substance sibutramine. In addition, 63,270 dosage units detained related to erectile dysfunction products. Other products contained diazepam, zopiclone, flurazepam, Tribulus terrestris and anabolic steroids. The majority of these unauthorised medicinal products supplied into Ireland originated from China and India.

Medicinal products destroyed during the year, in compliance with the Waste Management Acts 1996 to 2003, amounted to 4,519 kilograms.

A summary of the IMB enforcement data is provided in the accompanying table.

Year	2007	2008	2009	2010	2011
Product detained	188,784 Dosage Units	393,067 Dosage Units	494,502 Dosage Units	822,484 Dosage Units	762,641 Dosage Units
Cases opened	1,397	3,037	3,729	3,936	4,549
Prosecutions	10	2	2	5	9
Product destroyed	--	1,902kg	2,601kg	1,400kg	4,519kg

INTER-AGENCY CO-OPERATION AND PANGEA IV

The IMB liaises with other enforcement agencies, both nationally and internationally, to stem the unauthorised flow of illegal medicinal products, medical devices and cosmetic products into and out of the State. During the year, officers from the IMB, Revenue's Customs Service and An Garda Síochána carried out a number of joint operations. These included joint activities under Operation Pangea IV in September 2011. This was a global initiative to identify and act against illegal websites supplying counterfeit and illegal medicinal products and it involved 83 countries worldwide. This operation led to the detention in Ireland of 51,621 tablets, capsules and creams with an estimated value in excess of €150,000.

DISTRICT COURT PROSECUTIONS

The IMB initiated nine prosecutions in the District Courts during the course of 2011:

- On 10 January 2011, at Richmond District Court in Dublin, Judge Bridget Reilly convicted Ms. Fang (Susan) Huang, trading as Rong Zing Supermarket, Parnell Street, Dublin 1, on a total of 10 charges. The charges related to the breach of manufacture regulations, prescription and control regulations, and packaging and labelling regulations. Judge Reilly imposed a fine of €500 per charge and awarded costs of €5,550 to the IMB. Mr. Ji Rong Zheng, who owns the business and manages the finances, gave a commitment before the Court that he or his business would not engage in any unlawful activity in contravention of the Irish Medicines Board Acts. This undertaking was summarised in writing and was lodged with the conviction. A forfeiture order was issued by the Court for the 70 products detained during the investigation.

- On 11 January 2011, at Athy District Court, Judge Desmond Zaidan sentenced Ms. Mojisola Olubukola Soleye trading as Bimtom Ventures, Athy. Ms. Soleye had pleaded guilty to 11 charges on 14 December 2010. The charges included importing unauthorised prescription-only medicinal products from Nigeria and retailing prescription-only medicinal products from her shop in Athy. Judge Zaidan imposed a 12-month sentence on each of two charges to run consecutively and suspended the custodial sentence provided that she did not come to the attention of the IMB or commit any offences within the next two years. Judge Zaidan also fined her €500 on each of six charges with the remaining five charges taken into account. Costs of €9,865 were awarded to the IMB and a forfeiture order was issued by the Court for the destruction of the 3,414 medicinal products detained during the investigation.
- On 7 February 2011, at Richmond District Court in Dublin, Judge Bridget Reilly convicted Mr. Mike Ryan and his company Eustace Street Holdings Ltd, trading as Basic Instincts (an adult retail store), on 14 charges. The charges (seven for each party) were in relation to the supply of three prescription-only medicinal products by retail sale without a prescription and by mail order through the company website. In addition, convictions also included charges of having no product authorisation and advertisement offences. Judge Reilly fined both parties a total of €7,000 and awarded costs to the IMB of €3,752. A forfeiture order was also granted for all medicinal product detained during the case.
- Mr. Shaoib Abbasi was convicted on seven charges at Clonmel District Court by Judge Terence Finn on 1 March 2011. Mr Abbasi was supplying medicinal products without a prescription, a manufacturer's authorisation (for importation), a wholesaler's authorisation or a marketing authorisation. He was also engaged in mail order of medicines. Judge Finn handed down a 10-month custodial sentence on each of five charges (concurrent) to be suspended for three years on a bond for good behaviour and fines of €3,000 on the two remaining charges. The Court heard evidence that two products in question were counterfeit and that €65,000 was transacted through Mr. Abbasi's account with €43,000 being sent on to Pakistan and Hong Kong. Costs of €2,000 were awarded to the IMB and a forfeiture order was issued for the destruction of all medicinal products detained throughout the investigation.
- On 17 May 2011, Judge McMahon, at Navan District Court, convicted Mr. Patrick Joseph Delaney and his company The Natter Stores Limited which was trading as Day Brake, The Natter Stores, Clonee, Co. Meath. Mr. Delaney was found guilty on a total of three charges for supplying pharmacy-only medicinal products and for retailing packs of paracetamol tablets containing more than the permitted maximum of twelve tablets. Mr. Delaney was fined a total of €500 and The Natter Stores Limited was fined a total of €1,000 (€500 per charge) with costs of €1,000 awarded to the IMB.
- On 23 May 2011, at Richmond District Court in Dublin, Judge Blake convicted Mr. P. J. Delaney on eight charges. Mr Delaney was charged in connection with retail sale of pharmacy-only medicinal products, for retailing packs of paracetamol tablets containing more than the permitted maximum of twelve tablets and for not possessing a marketing authorisation. Judge Blake fined Mr. Delaney a total of €6,950, and awarded costs totalling €4,550. The Judge also stated that Mr. Delaney showed no remorse for his actions and if Mr. Delaney appeared in his Court again on similar charges he would get a custodial sentence.
- Mr. George Buckley appeared before Judge Patrick McMahon at Navan District Court on 6 July 2011. Mr. Buckley was convicted on nine charges of supply without a wholesaler's authorisation, two charges of supplying pharmacy-only medicinal products and two

charges of supplying medicinal products without a marketing authorisation. Judge McMahon fined Mr. Buckley a total of €2,600 with six months to pay. In addition, costs of €3,750 were awarded to the IMB and a forfeiture order was issued for all products detained during the investigation.

- At Carrickmacross District Court on 20 July 2011, Judge Sean McBride convicted Mr. Michael Quinn and Cloughvalley Stores Limited on ten charges each. The charges concerned the retail sale of pharmacy-only and unauthorised medicinal products, and the retail sale of packs of paracetamol tablets containing more than the permitted maximum of twelve tablets. Judge McBride fined Cloughvalley Stores Limited a total of €8,000 and Mr. Quinn €6,000. The judge also awarded costs of €6,500 to the IMB. A forfeiture order for destruction of all medicinal products detained during the investigation was also issued.
- On 15 December 2011, Judge Gráinne Malone at Balbriggan District Court convicted Mr. Gou Hui Li (aka Tim Li) on thirteen charges. The charges resulted from the supply by retail sale of prescription-only medicinal products, supply by wholesale without a wholesaler's authorisation and for not possessing a marketing authorisation. The products concerned were indicated for erectile dysfunction. Mr. Li made a charitable donation of €7,500 to Ruhama, a Dublin-based non-governmental organisation, and paid costs awarded to the IMB of €7,500. Judge Malone held over sentencing to 6 February 2012 at Swords District Court and fined Mr. Li €100 per charge, totalling of €1,300.

The Director of Scientific Affairs provides scientific advice on an ongoing basis in respect of enforcement activities. This advice includes preparation of statements on various products to support enforcement actions on the products concerned. During 2011, 7 such expert statements were prepared.

LEGISLATIVE AND REGULATORY DEVELOPMENTS

The legislative and regulatory environment in which the IMB operates is changing constantly and this has been the case since the establishment of the IMB as the national regulator in 1996. As a result, the remit and role of our organisation continues to change and expand in line with national and European legislative changes and in response to the addition of further competencies such as cosmetics in October 2010.

This section of our annual report outlines the most significant legislative and regulatory developments during 2011 for each of the healthcare products we regulate, how these changes influenced the work of the IMB and, where relevant, the associated impact on stakeholders.

HUMAN MEDICINES

PREPARING FOR NEW EU PHARMACOVIGILANCE LEGISLATION

New EU pharmacovigilance legislation, adopted in December 2010, will begin to come into effect in July 2012. The new measures are intended to further promote and protect public health by strengthening the current European-wide system for monitoring the safety of medicines. Amending existing provisions, the new legislation is focused on improving the pharmacovigilance system in the EU, making the reporting of adverse reactions (or side effects) easier and the introduction of special provisions for medicines that need additional monitoring. The legislation also aims to ensure that members of the public become better informed about the benefits and risks of taking medicines.

Throughout 2011, the IMB worked with a wide range of stakeholders including the European Medicines Agency and other national regulators to prepare for the introduction of this new legislation. As part of this process, a public stakeholder day was organised in early December (details of which are included in the "Stakeholder Engagement and Communications" section of this report). Additionally, the IMB interacted with Irish and EU citizens impacted by the legislative changes through participation in European Medicines Agency stakeholder days. IMB staff also delivered presentations at these events.

The IMB is committed to continuing our engagement with Irish and EU stakeholders including patient organisations, healthcare professional organisations and the pharmaceutical industry to ensure that the new legislation delivers on its objective of promoting and protecting public health while at the same time making best use of all available resources.

A designated section of the website www.imb.ie has been developed where additional information and guidance will continue to be made available in 2012.

ONGOING IMPLEMENTATION OF THE 2010 VARIATIONS REGULATION

The IMB continued to apply the new Variations Regulation (Commission Regulation 1234/2008) for all variations to marketing authorisations submitted to the IMB in 2011. The new regulation came into force on 1 January 2010. In parallel, the IMB reviewed its internal procedures for the processing of variations in order to streamline and maximise the efficiency of those procedures while maintaining a high quality standard in the review process. One of the main outcomes of this review was a change in the approval process for variations.

ONGOING IMPLEMENTATION OF THE TRADITIONAL HERBAL MEDICINAL PRODUCTS DIRECTIVE

As outlined earlier in this report, the transitional period for traditional herbal medicinal products ended on 30 April 2011. A meeting was held with interested parties at the end of March and guidance on IMB policy was issued in advance of the April deadline. A question and answer document and other guidance were also published on our website including updated policy information at the end of December. Market surveillance, to monitor adherence to the policy, was carried out during the second half of the year.

FALSIFIED MEDICINES DIRECTIVE

In July 2011, the EU adopted new legislation (Directive 2011/62/EU, amending Directive 2001/83/EC) on falsified medicines for human use. The directive aims to strengthen the protection of patients and consumers by preventing falsified medicines entering the legal supply chain. The IMB is preparing for the introduction of elements of this directive which are required to be transposed nationally by January 2013. The remaining measures will be transposed at defined times thereafter.

DECENTRALISED PROCEDURES WINDOW

The IMB actively participates in this European approval system and a 'window' for requests for Ireland to act as RMS for DCP applications was first introduced in 2010. This window was opened once in 2011 for the period January 2012 to December 2012 inclusive. All requests were considered and successful applicants were allocated a dedicated slot for assessment. Detailed information on the process for submitting requests is available on www.imb.ie.

USER TESTING AND BRAILLE

In the interests of patient safety, it is critical that those who use medicines can access and understand the information included on packaging and the accompanying leaflet.

The Medicinal Products (Control of Placing on the Market) Regulations 2007 transposed European legislation requiring user testing of package leaflets into national law. These regulations, which came into force in July 2007, require all marketing authorisation holders (MAH) to submit user test reports carried out on the package leaflet and to introduce Braille to the outer packaging of all marketed products in Ireland by way of variation. The deadline for submission of reports was 30 October 2010. Assessment of these applications continued throughout 2011. By year end, more than 90% of these applications had commenced. Completion of these variations is expected in 2012.

PARALLEL IMPORTS

In July 2011, the IMB published revised guidance in relation to parallel importation of medicines from an EU Member State or a country within the European Economic Area (EEA) which are already authorised on the Irish market. In order to legally distribute such products, a company must apply to the IMB for a parallel import licence.

The IMB guide was updated following consultation with interested parties. In addition, an information meeting was held with parallel importers to present and discuss the revised document and changes to the IMB's procedures for reviewing parallel import applications. The classification of variations for parallel product authorisations was also revised during 2011.

CONTRIBUTING TO THE EUROPEAN AND GLOBAL REGULATORY NETWORK

Europe

Our participation in the European medicines regulatory system continued to be substantial during 2011. IMB scientific and technical staff contributed to a broad range of committees and working parties at the European Medicines Agency, the European Commission, HMA, and other fora. This broad and significant involvement of IMB staff at European meetings is outlined in Appendix 4.

In addition to our regular participation at a European level, highlights from 2011 included the following:

- The Irish delegate (human medicines) to the European Medicines Agency's Quality Working Party (QWP) was appointed as rapporteur for the revision of the QWP guideline on process validation. It is anticipated that the guideline will be adopted by QWP for public consultation in early 2012.
- During 2011 IMB experts were heavily involved in a joint member state/European Medicines Agency project team to support the implementation of the new EU

pharmacovigilance legislation. The IMB was represented in the project teams, in the project co-ordination group and at project oversight level as a member of the HMA European Risk Management Strategy Facilitation Group. Key deliverables were contributions to the drafting of the technical contribution on the European Commission's Implementing Measures and the first wave of Good Vigilance Practice Modules.

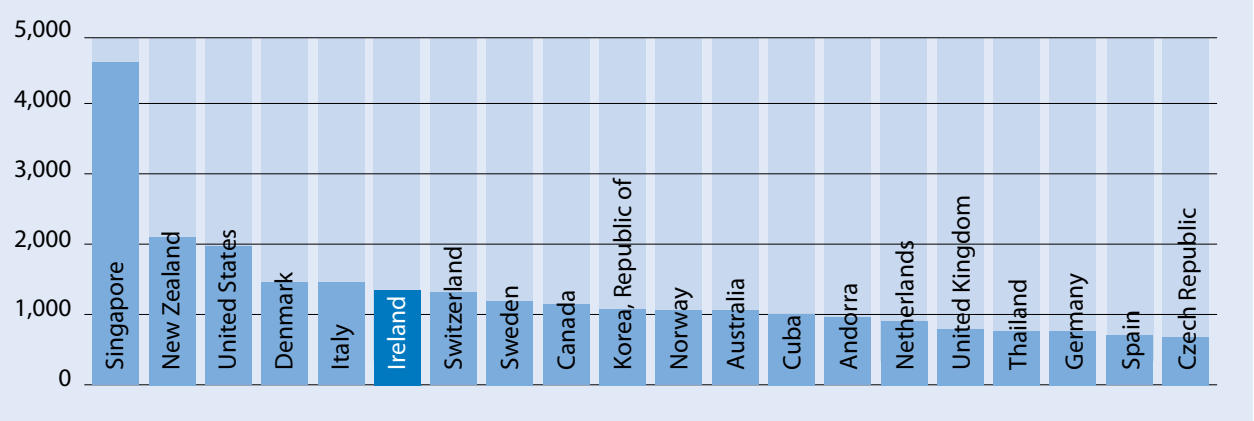
- The Irish delegate to the Pharmacovigilance Working Party at the European Medicines Agency represented the EU at the ICH E2C (R2) Expert Working Group. The ICH concept paper highlights the fact that the technology and science of pharmacovigilance has progressed significantly while the associated documentation has not kept pace. Revision of the E2C guideline will address this and ensure that regulatory and industry resources are more productively linked to public health protection and promotion.
- The public consultation on the updated Commission Guidelines on Good Distribution Practice of Medicinal Products for Human Use closed on 31 December. A representative from the IMB oversaw the production of a section of this document as a member of the GDP drafting group.
- Group 12 (Pharmaceutical Dosage Forms) of the European Pharmacopoeia Commission met twice in 2011 under the chairmanship of the IMB's Director of Scientific Affairs. A monograph on multi-dose veterinary oral pastes was developed by the Group while the monograph on oromucosal preparations and the dissolution test for medicated chewing gums were updated.

World Health Organization

The IMB Pharmacovigilance Manager was invited to join the Board of the Uppsala Monitoring Centre (UMC) and the World Health Organization (WHO) Collaborating Centre for International Drug Monitoring as one of the WHO's representatives to this foundation for a three year period to December 2013. This was a welcome endorsement of the contribution made by the IMB to pharmacovigilance practice at a global level and recognition in particular of the prominent role played by our Pharmacovigilance Manager, Ms. Niamh Arthur.

IMB staff participated at the annual meeting of national centres participating in the WHO international drug monitoring programme and continued to provide details of reports received nationally to the WHO for inclusion on its international database. The volume of adverse reaction reports from Ireland continued to fall within the highest reporting rates among the 104 participating countries in the programme (as of April 2011). As can be seen from the accompanying graph, Ireland ranked as the sixth highest reporter in 2011 (per million inhabitants).

Active ICSRs in the WHO global ICSR database in 2011 per million inhabitants



Pharmaceutical Inspection Co-operation Scheme (PIC/S)

- The Inspection Manager was appointed to the Executive Bureau (management group) of the PIC/S and was due to take up the appointment on 1 January 2012.
- Two week-long training seminars for new inspectors were hosted by the IMB in January and August under the auspices of the Pharmaceutical Inspection Co-Operation Scheme (PIC/S). These were designed to provide a thorough grounding to new inspectors on the conduct of inspections of manufacturers of medicines and were a further contribution to the harmonisation of global inspection standards.

CONTRIBUTING TO NATIONAL HEALTH INITIATIVES

The IMB also contributes at various levels to national cross-agency initiatives. In 2011, these included:

- The Research Ethics Advisory Group established by the Health Information and Quality Authority (HIQA) to draft standards for research ethics committees.
- The National Rare Diseases Strategy Steering Group established by the Department of Health.
- The Ethics Working Group of the Irish Medical Council in relation to updating its guidance for doctors on interactions with pharmaceutical and medical device companies.

ADVISORY COMMITTEE FOR HUMAN MEDICINES

A new Advisory Committee for Human Medicines was appointed by the Minister for Health and Children in early 2011. The committee, which includes both newly appointed and a number of reappointed members, met three times during 2011. Among the topics discussed during those meetings were new applications for medicines, safety issues and updates on new legislation.

VETERINARY MEDICINES

CONTRIBUTING TO THE EUROPEAN REGULATORY NETWORK

Maximum Residue Limits for certain Flukicidal Medicines

Following the rejection by the European Commission of the proposed maximum residue limits (MRLs) for certain flukicidal veterinary medicines used in cattle

on the basis that the legal basis was incorrect, the IMB submitted revised MRL applications for milk to the EMA in August 2011. By year-end, positive opinions had been delivered to the European Commission for the substances clorsulon, closantel, nitroxynil and triclabendazole. The establishment of MRLs is expected to improve consumer confidence in the safety of milk and milk products and to remove uncertainty regarding the conditions of use of such products in dry-cows within the European Community.

WORK-SHARING INITIATIVES WITH THE UK'S VETERINARY MEDICINES DIRECTORATE

In the interests of improving the availability of veterinary medicines in Ireland, the IMB expanded its work-sharing initiatives with the UK's Veterinary Medicines Directorate (VMD) during 2011. A primary objective of these initiatives was to facilitate companies in having common packaging for more than one market, thereby allowing the production of more economical batch sizes. An existing agreement between the IMB and the VMD on work-sharing in respect of the assessment of variations to products marketed in both countries was expanded during the year to include applications in Belgium and the Netherlands. This development is also expected to reduce the overall regulatory costs in all participating countries, thereby helping to reduce the regulatory burden on companies. The IMB and the VMD also published a joint product literature standard to facilitate applicants in the production of common labels for Ireland and the UK.

CONTRIBUTING TO NATIONAL HEALTH INITIATIVES

The IMB participated in an initiative undertaken under the aegis of the Department of Agriculture, Food and the Marine to help minimise the development of anthelmintic resistance in Irish sheep. This initiative will see the introduction of new symbols on certain anthelmintics which will allow for more effective use of the medicines concerned.

ADVISORY COMMITTEE FOR VETERINARY MEDICINES

A new Advisory Committee for Veterinary Medicines, including both existing and new members, was appointed by the Minister for Health and Children in consultation with the Minister for Agriculture, Fisheries and Food in early 2011. The Committee has a general statutory role in providing advice to IMB staff in relation to scientific matters concerning veterinary medicines brought to its attention. It has a specific statutory role in providing advice to the IMB's Board when it proposes to refuse an application for authorisation of a medicine or a manufacturer. The committee met three times during the year.

MEDICAL DEVICES

REVISION OF EUROPEAN MEDICAL DEVICES DIRECTIVES

The three existing European directives defining the regulations for medical devices are subject to an ongoing major revision by the European Commission. It is expected that during 2012, the Commission will adopt draft legislative proposals for discussion by the European Council and Parliament. This initiative was fully supported during 2011 by the IMB. It is expected to be under active discussion during the Irish Presidency of the European Council in the first half of 2013.

CONTRIBUTING TO THE EUROPEAN REGULATORY NETWORK

Medical Devices Directives

A proposal made jointly by the IMB and the Austrian Ministry for Health to establish a recast working group of the Competent Authority for Medical Device (CAMD) network was endorsed at the 27th CAMD meeting in February in Budapest. This group allows for detailed technical discussions on specific elements of the proposed revision to the medical devices legislation and for close co-operation

between European competent authorities, health ministries and the European Commission. During December 2011, we hosted the sixth meeting of the working group at the IMB offices in Dublin.

Resourcing the European Medical Devices Regulatory Network

During 2011, we held a series of meetings in close co-operation with colleagues from the UK's MHRA, with the European Commission, the medical device industry, notified bodies for medical devices and other interested stakeholders. The meetings were held to discuss the proposed development of new structures and mechanisms to optimise resourcing of the medical devices regulatory network and to create a funding mechanism which is fair, transparent and easy to use.

In March 2011, as part of this process, the IMB Chief Executive was invited by the European Commission to make a presentation on optimising resources and co-ordination of the medical devices regulatory framework to the Commission's High-level Conference 'Exploring Innovative Healthcare – the role of Medical Technology Innovation and Regulation'.

European Commission Guidance Documents

During 2011, the IMB also contributed significantly to MEDDEV guidance documents compiled by subgroups of the European Commission's Clinical Investigation and Evaluation Working Group.

Developing a European Health Products Regulatory Network

In 2011, the IMB also led on discussions to seek development of formal co-operation between the existing Heads of Medicines Agency (HMA) network and the medical devices networks represented by the Competent Authority for Medical Device (CAMD) and the Central Management Committee (CMC). Our objective is to develop a larger, inclusive 'European Health Products Regulatory Network' comprised of regulators from human medicines, veterinary medicines and medical device authorities. The aim is to promote mutual co-operation, exchange of experience and best practice, and shared decision making while optimising resources available to the network.

Through the IMB-led initiative to enhance co-operation between the HMA and CAMD/CMC networks, an initiative to examine the regulation of different types of drug-device and combination products throughout Europe was also launched during 2011.

Notified Body Oversight

The IMB is leading work items on notified body oversight for the recently established Central Management Committee (CMC) for medical devices. During 2011, the committee decision to endorse, implement and audit against best practice guidance from the Notified Body Oversight Group (NBOG) was created and proposed by the IMB. In addition, the IMB was appointed to lead on new work items to develop CMC proposals, in close co-operation with experts from NBOG, on:

- New process for designation and ongoing monitoring of notified bodies for medical devices with enhanced co-operation on these activities across Europe;
- New criteria and requirements for notified bodies defining general, organisational, quality, procedural and resource requirements to operate as a notified body for medical devices.

ADVISORY COMMITTEE FOR MEDICAL DEVICES

A new Advisory Committee for Medical Devices, including both existing and new members, was appointed by the Minister for Health and Children in 2011. The committee met three times during the year and considered topics such as key post-market surveillance/safety issues, updates on monitoring of medical device notified bodies and the ongoing revision of the medical devices regulatory framework.

ADVANCED THERAPIES

Applications for marketing authorisations for advanced therapy medicinal products (ATMPs) proceed via the EU centralised procedure as laid down in Regulation 726/2004/EC. The Regulation provided for the establishment of a specialised Committee on Advanced Therapies within the European Medicines Agency. The Committee has one member and one alternate member from each Member State with Ireland represented by the IMB.

The IMB internal group on biological products and ATMPs continued to meet during 2011 as a forum for internal exchange of information on ATMPs, tissue and blood and biological products generally. Also during the past year, the IMB collaborated with the Parenteral Drug Association, Ireland Chapter, to prepare an international conference on gene and cell therapy to be held in Dublin during July 2012 in conjunction with Dublin City of Science.

HUMAN ORGANS FOR TRANSPLANTATION

The Minister for Health appointed the IMB to the role of national Competent Authority for the directive on standards of quality and safety of human organs intended for transplantation (2010/53/EU). An internal multidisciplinary group was established to facilitate review of the requirements of the directive and to develop an appropriate framework for implementation of the requirements which are due to come into effect in August 2012. The IMB was also represented on an implementation steering group convened by the Department of Health.

COSMETICS

TEETH WHITENING PRODUCTS DIRECTIVE

Directive 2011/84/EU concerning the use of hydrogen peroxide in teeth-whitening/oral care products was adopted in September 2011. According to the new directive, products with less than 0.1% hydrogen peroxide may be made available directly to consumers. However, products having between 0.1% to 6% hydrogen peroxide content may only be supplied to and administered by dentists. All other tooth-whitening products with more than 6% hydrogen peroxide will no longer be available in the European Union.

The directive, which is being introduced to ensure the safety of European consumers, will come into force in October 2012. The IMB commenced preparations for its introduction during 2011 in co-operation with other relevant authorities.

STAKEHOLDER ENGAGEMENT AND COMMUNICATIONS

The IMB is committed to expanding and improving our communications activities and to ensuring that all our stakeholders have timely access to relevant safety, licensing and regulatory information. This commitment is one of our core strategic goals and will continue to be an area of focus and development for the IMB over the coming years.

A number of significant communications programmes and initiatives took place during 2011.

STAKEHOLDER ENGAGEMENT

Consultative Panel on the Legal Classification of Medicines

The Consultative Panel on the Legal Classification of medicines held its first meeting in December 2011. The Panel is independently chaired and consists of external representatives drawn from a wide range of interested stakeholders including patients, healthcare professionals, the Department of Health and relevant government agencies. The aim of the Panel is to support the existing scientific assessment within the IMB of applications for reclassification of medicines. The panel will provide advice on external socioeconomic and policy issues that should be considered when determining the appropriate classification of medicines. Quarterly meetings are planned to consider the outcome of the public consultation process on the legal supply classification of medicines which was held during 2011.

Meetings with Stakeholders – Human Medicines

Two joint meetings were held with the Association of Pharmaceutical Manufacturers in Ireland (APMI) and the Irish Pharmaceutical Healthcare Association (IPHA). At these bi-annual meetings, key regulatory issues of mutual concern are discussed. In 2011, these issues included assessment outputs, labelling and electronic submissions.

In March 2011, IMB staff held a meeting with the Irish Association of Health Stores (IAHS), the Irish Health Trade Association (IHTA) and herbal medicines companies and distributors. This meeting focused on the imminent 30 April 2011 deadline for the registration of traditional herbal medicines.

A parallel product authorisation information session was held at the IMB in April 2011. It was attended by most of the applicant companies. The updated Guide to Parallel Imports was presented and issued for consultation. Details on how the IMB will handle new source country variation applications which have been submitted with out-of-date product information was raised with a follow up letter subsequently sent to licence holders.

Three half-day information seminars were held in June for general sale wholesale distributors. The sessions were held in Portlaoise and Sligo and topics included supplier approval, the receipt of medicinal products and the storage of medicinal products including management of temperature excursions.

A meeting of an Advertising Compliance Technical Group including representatives from the IMB, the APMI and the IPHA was held in April. Issues of mutual interest were discussed including clarification of the IMB's interpretation of a number of aspects of the Medicinal Products (Control of Advertising) Regulations 2007 and anonymised feedback on findings from our advertising compliance programme.

Meetings with Stakeholders – Veterinary Medicines

The IMB hosted a number of pre-application meetings during 2011 for interested parties. Such meetings provide applicants intending to use the IMB as reference member state in future European application procedures with an opportunity to outline their proposed applications and to seek clarification on regulatory matters. Two meetings were also held with the Department of Agriculture, Food and the Marine to discuss matters of mutual interest. Additionally, we also met with the Irish Pharmacy Union.

Meetings with Stakeholders - Manufacturers of Medicines

A joint meeting was held with the Animal and Plant Health Association (APHA), the Association of Pharmaceutical Manufacturers in Ireland (APMI) and Pharmachemical Ireland (PCI). At this annual meeting, key manufacturing issues of mutual concern are discussed. In 2011, these issues included revisions to the EU Guide to Good Manufacturing Practice, the Falsified Medicines Directive (2011/62/EU), and obligations of authorised/licensed manufacturers.

Meetings with Stakeholders – Medical Devices

During 2011, four meetings were held with the Department of Health to discuss medical device issues. These useful meetings allowed for discussion, advice and exchange of information in respect of:

- Developments, revision, policy and interpretation of medical devices legislation.
- Updates on specific post-market surveillance issues such as IMB safety notices, field safety corrective actions and recalls of medical devices.
- Oversight and ongoing monitoring of notified bodies at national level and in Europe.
- Clinical investigation and research activities in Ireland.

Meetings were held during 2011 with the Irish Medical Devices Association (IMDA) to discuss regulatory issues affecting the medical device industry in Ireland. These issues included the ongoing revision of the medical devices legislation, clinical investigations and oversight of notified bodies for medical devices.

Regular meetings were also held with the National Standards Authority of Ireland (NSAI), the notified body for medical devices in Ireland. These meetings focused on new legislation, regulatory guidance, requirements and policies. Discussions were also held in respect of audit findings and follow-up and regarding issues identified by NSAI during the course of their certification activities.

Throughout 2011, many additional meetings with medical device stakeholders were held by the IMB to discuss the major revisions to the medical devices legislation expected during 2012. The focus of these meetings was the impact of the possible changes on the many different stakeholder groups involved. In addition, IMB contributions to the development of the European regulatory network were discussed. These included the development of proposals to optimise the utilisation of resources and funding as well as efforts to further develop co-operation between the medicines and medical devices networks.

The IMB also held a range of meetings throughout 2011 with academics, clinicians, innovators and established medical device manufacturers to discuss the further development of different types of medical technologies. Regulatory requirements, clinical investigation of devices in Ireland and post-market requirements were among the topics considered.

Information Days

IMB information days provide regulatory guidance and updates to a range of stakeholders. As well as presentations from IMB staff and, where appropriate, external contributors, the events enable all attendees to submit questions, seek clarifications and network with colleagues. Two information days were held during 2011:

- A veterinary medicines information day was held on 6 October. The event was focused on updating stakeholders on current regulatory topics and ongoing IMB activities and initiatives. Part of the session also examined the expected changes in the EU legislation governing the authorisation and monitoring of veterinary medicines. External subject matter experts, including a representative from the Department of Agriculture, Food and the Marine, joined the IMB in delivering presentations.
- An information day addressing the implementation of the new European Pharmacovigilance legislation was held on 2 December. This event was attended by over 250 participants including patient representatives, healthcare professionals, academic institutions, professional bodies and the pharmaceutical industry. The agenda for the day included a review of the amendments and a discussion on the relevant implications for pharmacovigilance processes, marketing authorisations and public participation. There was a particular focus on the impact the new legislation will have on patients, healthcare professionals, the pharmaceutical sector and the IMB. Representatives from the Department of Health, the European Medicines

Agency, the UK's Medicines and Healthcare products Regulatory Agency and the European Organisation for Rare Diseases joined the IMB in delivering presentations. Feedback from delegates confirmed the success of the meeting in terms of raising awareness of the requirements of the new legislation and promoting exchange of ideas, concerns and opinions.

Presentations to Stakeholders

Throughout 2011, the IMB invested significant time in delivering a programme of presentations and talks at a range of external stakeholder events such as meetings, seminars, conferences and training courses. In addition, a programme of presentations was delivered to undergraduate and post graduate students studying courses related to the role of the IMB.

Such presentations contribute to the IMB goal of providing stakeholders including patients, healthcare professionals and regulatory professionals with access to relevant, up-to-date information. The presentations are delivered by IMB staff from across the organisation and cover all products and functions under our remit. While some are general in nature and primarily focused on explaining the role of the IMB, others were more specific and dealt with specialist areas and/or new regulatory developments.

A full list of all presentations delivered during 2011 is provided in Appendix 2.

PUBLICATIONS

Guidance Documents

IMB guidance documents provide stakeholders, primarily from the industry sectors we regulate, with advice and direction in respect of legislation and regulatory requirements. New and updated IMB guidance documents are published regularly on our website with alerts issued to website subscribers.

During 2011, six new guidance documents were published while a number of existing documents were updated. A full list of these documents is provided in Appendix 3.

Also in 2011, the IMB and the Department of Agriculture, Food and the Marine collaborated on drafting a guidance document addressing cosmetic-biocide borderline products. The guidance was issued for public consultation in October.

In addition, a frequently asked questions (FAQ) document relating to advertising compliance for human medicines was published on the IMB website.

Newsletters

Medicinal Products Newsletter

This newsletter provides regulatory updates for those working in the pharmaceutical and cosmetics sectors on Irish and European legislation, new/revised IMB regulatory publications and stakeholder events such as information days.

Three Medicinal Product Newsletters were published during 2011. Topics covered included:

- Details regarding changes to the submission of product information to the IMB
- Homeopathic medicines update
- Experience to date with the new Variations Regulation

The newsletter is published on the IMB website and issued to those who subscribe to the IMB alerts system via our website.

Drug Safety Newsletter

This newsletter is published on a regular basis and aims to provide healthcare professionals with up-to-date information and clinical advice regarding the safe use of medicines.

Six issues of the IMB's Drug Safety Newsletter (including one edition with a special insert on intravenous paracetamol) were distributed to doctors, dentists and pharmacists during 2011. The publication is circulated by a combination of post and email and is available to download from the IMB website. Topics covered in the past year included a wide range of safety issues a full list of which is provided in Appendix 3.

Medical Devices Newsletter

This newsletter provides regulatory and safety updates for those working in the medical devices sector and professionals working in the health area who regularly use or purchase medical devices. It provides updates on Irish and European legislation, on safety issues as well as details of IMB medical devices publications and stakeholder events. The newsletter includes articles from both IMB and external contributors.

During 2011, the IMB published three Medical Devices Newsletters. Topics included:

- Safety information for users of medical devices. A full list of such articles from the past year is included on in Appendix 3.
- Manufacturer and notified body information such as regulatory updates, regulatory guidance on the legal term 'placing on the market' and new requirements for the European medical device database (EUDAMED).
- Scientific articles on tissue engineering and neural engineering.

External Articles

Pharmacovigilance

There were 15 IMB articles published in MIMS Ireland. One article was published each month while the remaining three were part of special supplements. MIMS (Monthly Index of Medical Specialities) is an independently edited publication designed as a prescribing guide for general practitioners. Two further articles were published in the Irish Medicines Formulary (IMF). The IMB also provided an article for inclusion in the Journal of the Irish Dental Association. The full list of topics covered in these articles in included in Appendix 3. All articles were also published on the IMB website.

Veterinary Medicines

Consistent with our objective to improve stakeholder knowledge on the use of veterinary medicines, we contributed several articles to the veterinary/trade publications (1) Veterinary Ireland Journal and (2) It's Your Field.

The topics covered in these articles are listed in Appendix 3.

Safety Warning and Notices

Throughout 2011, the IMB published various warning statements and notices on safety issues or benefit/risk evaluations of human medicines. There were 44 Direct Healthcare Professional Communications concerning human medicines published on the IMB website and issued to subscribers. Separately, 34 medical devices safety notices were sent to the relevant stakeholder groups and published online.

IMB Advice on Automated External Defibrillators

In December 2011, the IMB published an information leaflet providing advice to people on how to correctly maintain an automated external defibrillator (AED) so that it works effectively in the event it is needed in an emergency.

AEDs can improve a person's survival chances following sudden cardiac arrest when used in an emergency situation. The leaflet highlights the critical importance of maintaining, storing and servicing the AED correctly to ensure it is always in good working order. It was produced in light of the increased availability of AEDs in Ireland over the past number of years and a notable increase in the number of AED related issues reported to the IMB.

The AED leaflet is available for download from the IMB website. Printed copies can also be requested by calling the IMB directly.

MEDIA COMMUNICATIONS

Throughout 2011, we continued our media communications programme to proactively communicate important safety messages and to build awareness of the role of the IMB. We issued 37 press releases concerning safety and regulatory issues to ensure consumers, healthcare professional and other stakeholders received timely and accurate information and advice. In a number of instances, these communications resulted in national and regional media interviews with an IMB spokesperson.

Among the issues highlighted by IMB press releases during the past year were:

- The dangers of mail order and illegal prescription medicines
- Rise of 66% in illegal medicines detained in 2010
- The risk of high levels of lead in certain children's face paints
- New advice for use of cough and cold medicines in children
- Operation Pangea IV targeting the online sale of counterfeit and illegal medicines

In addition, we responded to 438 queries from national, local and specialist media during the year. Providing responses to such queries involves subject matter experts from across the organisation.

PUBLIC CONSULTATIONS

Public consultations enable the IMB to identify the needs and expectations of stakeholders so that we may incorporate their views into the way our services are planned and delivered.

During 2011, the IMB completed public consultations on:

- Fees for 2012
- Legal supply classification of medicinal products
- Herbal substances classification

The IMB also makes submissions to third party consultations where the topic is related to or impacts our regulatory functions and the broader public health agenda. During 2011, we participated in the following consultations:

- Crisis pregnancy strategy (HSE Crisis Pregnancy Programme)
- Accreditation standards (Pharmaceutical Society of Ireland)
- Nurse prescribing (Department of Health)
- Core competency framework (Pharmaceutical Society of Ireland)
- Risk Review Group examination of vaccine under-dosing (Pharmaceutical Society of Ireland)

WEBSITE

The website www.imb.ie is a key component of our communications programme. The site outlines the primary functions and activities of the IMB and facilitates the dissemination of information to a wide variety of audiences including patients and consumers, healthcare professionals and industry personnel. As new content is regularly added to the website, we are focused on its continued development and enhancement to ensure it remains an attractive and user-friendly resource.

2011 Statistics

- Almost 126,000 unique visitors accessed the website during the past twelve months resulting in close to 345,000 visits in total.
- Over 60% of visits to the website originated from Ireland, 11% from the UK and 6% from the US.
- Of the unique visitors, 34% were new or first time users of the site.
- Among the most popular sections of the website were the human and veterinary medicines listings and publications.

Veterinary Medicines

The veterinary medicines section of the IMB website was substantially revised early in 2011 to provide more relevant content. A specific veterinary medicines page was created with a link included on the homepage. In addition, an online reporting form for the notification of suspected adverse events was introduced. Further improvements include a monthly listing of newly authorised products as well as information on licensing procedures and reporting of adverse reactions. New content concerning medicines availability and safety advisory notices relating to veterinary medicines were also incorporated.

Pharmacovigilance

A dedicated webpage on the new pharmacovigilance legislation was developed. Additional information and guidance will continue to be published on this webpage.

BT YOUNG SCIENTIST AND TECHNOLOGY EXHIBITION 2011

Thousands of students as well as teachers, parents and members of the general public from all over Ireland visited the IMB's exhibition stand at the BT Young Scientist Exhibition 2011. The exhibition took place in mid-January in the RDS and it was the second year in succession the IMB was involved.

Our stand focused on building awareness of the significant role the IMB plays in protecting public and animal health. In particular, the important issue of medicines and medical devices safety was highlighted. The stand also focused on the many interesting science related career opportunities that are available in the healthcare products industry.

FREEDOM OF INFORMATION

The IMB is subject to the Freedom of Information Acts 1997 and 2003. The Acts assert the right of members of the public to obtain access to official information to the greatest extent possible consistent with public interest and the right to privacy of individuals. During 2011, the IMB received seven Freedom of Information requests consisting of six non-personal requests and once personal request. While none of these requests were appealed to the Information Commissioner, three appeals to the Information Commissioner from 2010 were finalised and closed.

PARLIAMENTARY QUESTIONS

During 2011, the IMB received and responded to 34 parliamentary questions, and four representations. Over half of the queries related to human medicines and the majority of the remainder related to staff, payroll and expenditure. A number of other queries from our parent department, the Department of Health, were received and responded to.

CUSTOMER SERVICES

In 2011, the customer services team responded to 3,078 queries from industry representatives, healthcare professionals and members of the public. Queries were received primarily via email and by phone. Over 2,000 of these queries concerned human medicines with many relating to product variations as well as product information and packaging.

In addition to the queries managed by customer services staff, a range of stakeholder queries are addressed by specialist staff across the organisation. Many of these queries come from healthcare professionals requesting information about specific medicines.

Also during 2011, 466 queries were received that related specifically to medical devices.

RESEARCH

Attitudes Towards Direct Healthcare Professional Communications

In collaboration with the School of Pharmacy, Trinity College Dublin, an initial pilot research project was undertaken to evaluate healthcare professional awareness and attitudes towards Direct Healthcare Professional Communications. Results will be published during 2012.

Consumer Attitudes towards the Regulation of Herbal Medicines

Research carried out by the IMB during 2011 revealed that some 8 out of 10 consumers think it is important that traditional herbal medicines should be regulated. The same number believe it is necessary to inform their doctor when taking a herbal medicine.

The survey findings were released in advance of the new regulatory system for traditional herbal medicines which came into effect across all EU member states on 1 May 2011.

Industry Experience of National Procedures for Veterinary Medicines

The IMB surveyed applicant companies on their experiences with national procedures in place to improve medicines availability. Results of the survey were used to introduce changes to procedures to facilitate applicant companies and improve the efficiency of the procedures.

ORGANISATIONAL MANAGEMENT AND DEVELOPMENT

It is essential that the IMB has in place the requisite corporate functions, systems and supports to ensure we deliver on our public health mission. We must be flexible and proactive as an organisation to respond to regulatory and other external developments, and to adopt necessary changes in how we deliver our services. We must also ensure that the highest levels of corporate governance are developed and maintained.

HUMAN RESOURCES

The IMB's people management practices and policies are developed to contribute to the achievement of our strategic goals and to attract and retain the relevant skills to maintain organisation capability. While adapting our structures and work practices to enable us to manage our human resources within the constraints of the public sector environment, the following projects were delivered or progressed during 2011:

- Arising from our 2010 Learning and Development strategy was the requirement for further development of leadership skills across the organisation. As a consequence, a programme for managers was launched in September 2011. Ten managers from across the organisation at various levels are participating in this initiative which will run throughout 2012. The objectives of the programme are:
  - To support the development of managers within the IMB, to evaluate the skills they have and how they are applying them now and for the future;
  - To develop skills and behaviours in line with the IMB's Leadership Capability Framework;
  - To foster collaboration across different functions and promote an understanding of cross functional roles and projects.
- While recognising the constraints on public sector employment numbers, in the context of the IMB status as predominantly a self-funded agency, we submitted a proposal on future staffing requirements to the Department of Health. This proposal focused on obligations arising from new responsibilities being assigned to the IMB by the Department as well as the impact of the introduction of a range of legislative changes between now and 2015. It is vitally important that the IMB has the resources in place to fulfil our statutory obligations and to serve the related requirements of all our stakeholders.
- A risk-based approach to the assessment of a range of application types was adopted across the IMB thus targeting resource time to areas of greatest priority. While this approach will continue to be rolled out it will require ongoing monitoring in the context of increasing workloads and application complexity.
- We have maintained our focus on empowering line managers by providing proactive support to assist them with staff management. This contributes to improved performance in an environment which requires flexibility and a timely response to changing structures and processes.
- In line with our commitment to staff continuous learning and development, a number of organisational awareness sessions were held to facilitate cross-departmental engagement.
- Initial planning took place in relation to the consolidation and restructuring of current human resources tools with a view to ensuring improved performance.
- An annual performance management programme has been in place in the IMB since 2004 and was again implemented during 2011. The business plans for each internal department provide the framework for the scheme, which is known as the Performance Development Programme (PDP). The programme incorporates the objectives, tasks and key performance indicators against which individuals are evaluated. In addition, the organisational and personal competencies expected of all our staff are identified as are individual plans identifying training and development needs for the year ahead. This process recognises good performance as well as addressing any under-performance and/or training needs.

2011 Statistics

- The organisation continues to be in compliance with the 3% target set by the Disability Act 2005.
- Absence management practices are in place and attendance statistics are included in monthly management and bi-monthly Board reports. The overall absence rate for 2011 was 2.4%. This rate is well below industry norms of 3.5% - 4%.
- Average spend per employee in relation to training was just under €900 with 9% of employees participating in further education and development programmes.

INFORMATION TECHNOLOGY AND CHANGE MANAGEMENT

The Information Technology and Change Management department delivers specialist business analysis, information technology and telecommunications services throughout the organisation. Change management and business process improvement initiatives are also co-ordinated by the department, reflecting the IMB's commitment to the agenda of transformation in the public sector.

Information Technology

Technology plays a key role both in supporting the efficient operations of the IMB and in providing a range of services to our stakeholders. A broad range of applications are available to the public, healthcare professionals and industry. These services include online reporting systems for potential safety and quality issues relating to medicines, medical devices, tissues and cells as well as a range of extranet solutions. The latter includes registration and licence application systems and close to 1,000 users are registered to avail of these services. During 2011, there was a 15% increase in user take-up of our extranet solutions when compared with the previous 12-month period.

During 2010, we commenced a review of our information technology usage with a view to developing a new five-year strategy aligned to the organisation's new five-year strategic plan. This information technology strategy was adopted by the Board in early 2011 and implementation commenced in the second half of the year. Key technologies for the organisation over the coming years will include improved data warehousing and mining solutions, together with upgraded capacity management and case management systems. Other developments over the life of the strategy include the design of a new IMB website, together with the introduction of relevant knowledge management solutions. All information technology initiatives are undertaken in the context of providing new and improved services to stakeholders, enhancing decision-making and channelling scientific data to deliver on our public health remit.

The IMB is also part of the wider European regulatory network working on a broad and co-ordinated EU Telematics Programme. During 2011, we were active in six significant projects as part of this work programme which is designed to support licensing and safety related activities across the EU. Of note, the IMB had specific responsibility for a project to support electronic submissions from the pharmaceutical industry. This initiative, known as the Common European Submission Portal (CESP), has received a positive response from industry and will move into phase II of its development in 2012.

In 2011, the IMB also provided support to other government agencies in Ireland through the provision of both technology hosting and advisory services. We continued to work with health bodies to enhance communication and data sharing across the regulatory and health network. International interest in our technology solutions, particularly our workflow management systems, remained high with several visits from foreign delegations throughout 2011 and more scheduled for 2012.

Change Management

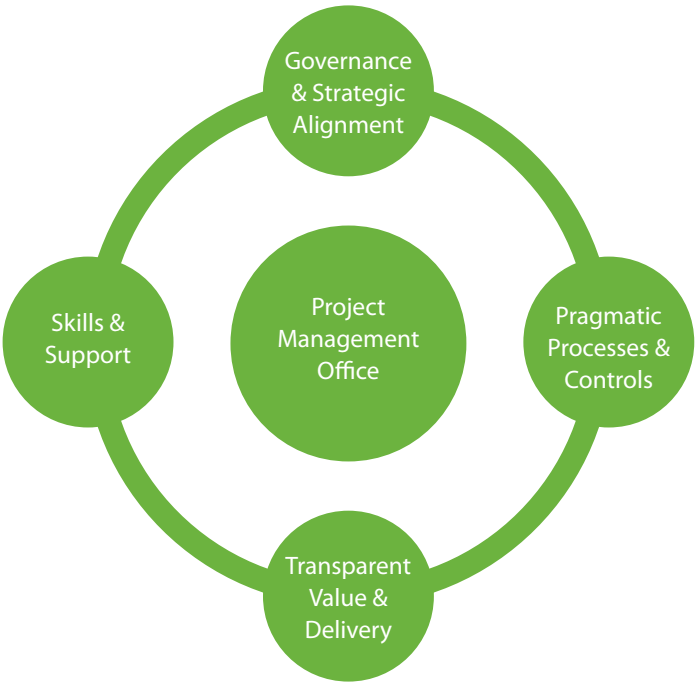
The IMB has a long held commitment to continuous improvement and first implemented change management strategies as far back as 2003. In the interim, the organisation has implemented significant departmental restructuring, taken on a range of new activities and also developed new and innovative approaches to service delivery. While efficiency is a key goal in such initiatives, legislative changes, improved flexibility and the requirement to respond to stakeholder needs are also key drivers for change. All process improvement initiatives take account of the organisation's mission to protect and enhance public health.

In 2011, it was considered timely to develop a more structured approach to organisational project management. This resulted in the adoption of a Project Management Office model for all relevant activities. This office is tasked with supporting the planning process, ensuring alignment with organisational objectives and developing consistent management and control mechanisms. Planning for the new Project Management Office commenced in late 2011, with implementation scheduled for 2012.

Additional change management initiatives in 2011 included the commencement of work on a new IMB enforcement strategy. There has been significant growth in enforcement related activities at both national and international level in respect of medical products over the past five years. Our enforcement strategy must take account of this growth and also the evolution of activities in this area. The new strategy will incorporate mechanisms to focus on the areas of highest vulnerability while taking account of the organisational capacity. The strategy will be available for public consultation in mid 2012.

An impact analysis of the new pharmacovigilance legislation also started in December 2011 with proposals and recommendations due in early 2012. The requirements of the new legislation will necessitate changes to existing work practices. Work also commenced on a review of the IMB's customer service model and the future needs of the organisation in this regard.

The IMB acknowledges the assistance of various partner organisations, both nationally and internationally, in developing new strategies for organisational improvement.



CHIEF EXECUTIVE'S OFFICE

The Chief Executive's Office is responsible for communication, for strategy and planning, for quality management and a number of information functions for external stakeholders. It also provides the secretariat for the benchmarking programme across EU medicines agencies.

BEMA

The Benchmarking of European Medicines Agencies (BEMA) programme provides assurance to the heads of the EU medicines agency network (HMA) with respect to the quality of the systems and practices in place in agencies and a resource for sharing of best practices. The chief executive is co-chair of the BEMA steering group with the head of the Paul Ehrlich institute in Germany. During 2011, the IMB continued its participation in the steering group, as it developed proposals for the third cycle of BEMA assessments and brought them to the heads of the medicines agencies for approval. By year-end, assessors had been trained in the new questionnaire and methodology, and the IMB, which also provides secretariat resources to the steering group, was preparing the visit schedule for 2012 – 2014.

Provision of Information

During 2011, the IMB received and responded to 34 parliamentary questions, and 4 representations (as outlined on page 73).

We provided comments with respect to five consultations (as outlined on page 72).

CORPORATE AFFAIRS

Corporate Affairs is responsible for the delivery of a number of key service areas to the organisation. These include building and accommodation management as well as the provision of reception, canteen, travel, library and event management services. The section also manages legal issues and Freedom of Information requests. In addition, it provides secretarial support to the Board and Committees ensuring adherence to best practice in the area of corporate governance. Across all these functions, 2011 was another busy and productive year.

Event Management

The IMB held six events in 2011 all of which were organised and managed in-house. This approach ensures cost effective delivery of events while also allowing IMB staff to deal directly with stakeholders. This has resulted in very positive feedback from attendees via event questionnaires.

The six events consisted of two information days and four training seminars. The information days, which typically provide regulatory guidance and updates to interested parties, were focused on (1) veterinary medicines and (2) the implementation of the new pharmacovigilance legislation. Close to 500 delegates in total attended both these events.

The training seminars which the IMB provided included three grocery wholesale training half day seminars and two week long Pharmaceutical Inspection Co-Operation Scheme (PIC/S) seminars for new inspectors.

Freedom of Information

During 2011, the IMB received six non-personal and one personal Freedom of Information requests (as outlined on page 73).

Board and Committees

The Corporate Services section provides secretarial support to the Board and Committees of the IMB and ensures adherence to best practice in the area of corporate governance.

- The Board of the Irish Medicines Board met seven times in 2011 and considered a number of strategic matters including corporate policy, planning and finance matters. The latter included monthly management accounts, annual budgets and the financial statements for 2010. The Board also reviewed update reports from the Statutory Advisory Committees and the Audit Committee. In addition, it reviewed the licences for all medicinal healthcare products as approved by the Management Committee.

The number of meetings attended by each Board member during 2011 is as follows:

Board Member	Number of meetings held during the period the member was on the Board	Number of meetings attended during the period the member was on the Board
Mr. Michael Hayes (Chair)	7	7
Mr. Pat Brangan	7	7
Prof. Brendan Buckley	4	3
Mr. Wilf Higgins	7	7
Ms. Ann Horan	7	7
Prof. Mary Horgan	2	2
Mr. Brendan McLaughlin	7	6
Mr. Noel O'Donoghue	7	5
Prof. Caitriona O'Driscoll	7	7
Ms. Maureen Windle	5	5

- The Audit Committee, a subcommittee to the Board, met four times in 2011. Further details are provided in the financial statements.
- The Advisory Committee for Human Medicines assists and advises the Board in relation to any matters pertaining to the safety, quality or efficacy of medicinal products for human use as are referred to it by the Board. It also reviews the licenses for human medicinal products as approved by the Management Committee. The Committee met four times in 2011.
- The Advisory Committee for Veterinary Medicines assists and advises the Board in relation to any matters pertaining to the safety, quality or efficacy of medicinal products for animal use as are referred to it by the Board. It also reviews

the licenses for veterinary medicinal products as approved by the Management Committee. The Committee met three times in 2011.

- The Advisory Committee for Medical Devices met twice in 2011. It assists and advises the Board in relation to any matters pertaining to the safety, quality or efficacy of medical devices for human use as are referred to it by the Board.
- The Herbal Medicines Committee, a subcommittee to the Advisory Committee for Human Medicines, met five times in 2011. The Committee considered a number of matters including the Traditional Herbal Medicinal Products Registration Scheme and updates from the Committee on Herbal Medicinal Products of the European Medicines Agency.
- The Clinical Trials Committee, a subcommittee to the Advisory Committee for Human Medicines, met twelve times in 2011. The Committee considers the suitability of trials submitted for approval under the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004, (S.I. No. 190 of 2004).

FINANCE

It is the role of the finance section to manage and safeguard the finances of the IMB. It must ensure that the IMB fulfils its legislative requirements and applies best practice to the governance of its affairs. All procedures are carried out using standard operating procedures under the quality management system.

The 2011 financial statements presented in conjunction with this report were prepared by the finance section and submitted for audit to the Comptroller and Auditor General. All financial transactions during the period under review are reflected and reported upon in these statements as is our commitment to the highest standards of corporate governance.

OVERVIEW OF ENERGY USAGE IN 2011

With effect from 1 January 2011, the IMB, as a public sector body, has been required to report annually on its energy usage and actions taken to reduce consumption in accordance with S.I. No. 542 of 2009. These regulations transpose the Energy End Use Efficiency and Energy Services Directive (2006/32/EC) into Irish law.

The IMB uses electricity for lighting, air conditioning as required and the provision of hot water. Natural gas is used for central heating.

In 2011, the IMB consumed 759 MWh of energy, consisting of:

- 507 MWh of electricity;
- 0 MWh of fossil fuels;
- 252 MWh of renewable fuels

Actions Undertaken in 2011

In 2011, the IMB further improved energy performance by entering into framework agreements for the supply of both electricity and natural gas. Both of these framework agreements were established by the National Procurement Service for the supply of electricity and natural gas to the Irish public sector. Cost savings were in the region of 12% for electricity and 5% for gas. Energy savings amounted to 10 MWh. Please note that the National Procurement Service contract rates were fixed until the end of 2011.

Total Energy Savings

In total, initiatives undertaken prior to 2010 and the measures outlined above are saving the IMB 117 MWh annually.

Actions Planned for 2012

In 2012, the IMB intends to maintain energy performance by continuing its participation in newly contracted framework agreements for the supply of both electricity and natural gas established by the National Procurement Service. It is not anticipated that there will be energy savings, but the cost savings maintained since 2010 will be in the region of 5% for gas. With regard to electricity, there will be cost savings of 6% over 2011. These contract rates are fixed until the end of 2012 except for an increase to the carbon tax charge from 1 May 2012 as advised in the Budget of the 6 December 2011.

The IMB also intends to replace its single glazed windows on the upper floors to more energy efficient double glazed windows.

FINANCIAL STATEMENTS

BOARD MEMBERS AND OTHER INFORMATION

Board Members:	Mr. Michael Hayes (Chairman)	(until 31/12/2015)
	Prof. Brendan Buckley	(resigned 14/09/2011)
	Ms. Ann Horan	(until 31/12/2015)
	Prof. Mary Horgan	(until 31/12/2015) *
	Mr. Noel O'Donoghue	(until 31/12/2015)
	Prof. Caitriona O'Driscoll	(until 31/12/2015)
	Mr. Pat Brangan	(until 31/12/2013)
	Mr. Brendan McLaughlin	(until 31/12/2013)
	Mr. Wilfred Higgins	(until 31/12/2013)
	Ms. Maureen Windle	(resigned 08/11/2011)

The above Board was appointed by the Minister for Health on 18/01/2011 until the specified dates.
*Professor Mary Horgan was appointed on 08/11/2011.

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

Auditors:

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. The Board of the IMB (the Board) consists of a chairman and eight 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 IMB 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 has 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 and conflicts of interest policy 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 three Board members, which met on 4 occasions during 2011. 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 audit committee to brief them on the outcome of the external audit. In 2010 the IMB re-appointed Crowleys DFK as internal auditor to the Board under a three-year contract. During 2011 the internal auditors reviewed the areas of income, corporate governance and electronic banking 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 2011, 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 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. The Chief Executive is remunerated in accordance with guidelines issued from Government and other Executive Directors are paid in accordance with Department of Health 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. 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 IMB are described more fully in the Chairman's report on the following page.

REPORT OF THE CHAIRMAN OF THE IRISH MEDICINES BOARD

REGARDING THE ASSESSMENT OF INTERNAL FINANCIAL CONTROLS OF A STATE BODY FOR THE YEAR ENDED 31 DECEMBER 2011

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.

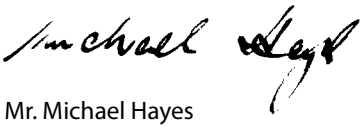
   Management reports fortnightly on operational issues and risks and how they are managed to the Management Committee. The Management Committee's role in this regard is to review on behalf of the Board the key risks inherent in the affairs of the IMB and the system of actions necessary to manage such risks 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 Management Committee approval. The Board has delegated the day-to-day management of the IMB and established appropriate limits for expenditure authorisation to the Management Committee. 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 has 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 2011 at its meeting on 27 March 2012. The internal control work carried out by the Audit Committee was reviewed and approved by the Board at its meeting on 28 March 2012.



Mr. Michael Hayes

Chairman to the Board

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 IMB and of its surplus or deficit for that period.

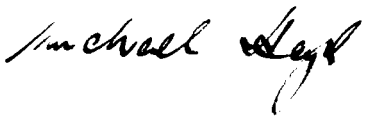
In preparing those statements the Board is required to:

- 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 IMB 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 IMB 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 IMB and hence for taking reasonable steps for the prevention and detection of fraud and other irregularities.

On behalf of the Board

Chairman



Mr. Michael Hayes

Board Member

Ms. Ann Horan

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 2011 under 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 Balance Sheet, the Cash Flow Statement and the related notes.

The financial reporting framework that has been applied in their preparation is applicable law and Generally Accepted Accounting Practice in Ireland as modified by the directions of the Minister for Health in relation to accounting for superannuation costs.

RESPONSIBILITIES OF THE BOARD

The Board is responsible for the preparation of the financial statements, for ensuring that they give a true and fair view of the state of the Board's affairs and of its income and expenditure, and for ensuring the regularity of transactions.

RESPONSIBILITIES OF THE COMPTROLLER AND AUDITOR GENERAL

My responsibility is to audit the financial statements and report on them in accordance with applicable law.

My audit is conducted by reference to the special considerations which attach to State bodies in relation to their management and operation.

My audit is carried out in accordance with the International Standards on Auditing (UK and Ireland) and in compliance with the Auditing Practices Board's Ethical Standards for Auditors.

SCOPE OF AUDIT OF THE FINANCIAL STATEMENTS

An audit involves obtaining evidence about the amounts and disclosures in the financial statements, sufficient to give reasonable assurance that the financial statements are free from material misstatement, whether caused by fraud or error. This includes an assessment of

- whether the accounting policies are appropriate to the Irish Medicines Board's circumstances, and have been consistently applied and adequately disclosed.
- the reasonableness of significant accounting estimates made in the preparation of the financial statements, and
- the overall presentation of the financial statements.

I also seek to obtain evidence about the regularity of financial transactions in the course of audit.

OPINION ON THE FINANCIAL STATEMENTS

In compliance with the directions of the Minister for Health, 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 Practice in Ireland, of the state of the Board's affairs at 31 December 2011 and of its income and expenditure for the year then ended.

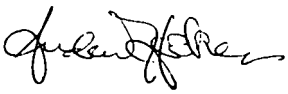
In my opinion, proper books of account have been kept by the Board. The financial statements are in agreement with the books of account.

MATTERS ON WHICH I REPORT BY EXCEPTION

I report by exception if

- I have not received all the information and explanations I required for my audit, or
- my audit noted any material instance where moneys have not been applied for the purposes intended or where the transactions did not conform to the authorities governing them, or
- the Statement on Internal Financial Control does not reflect the Board's compliance with the Code of Practice for the Governance of State Bodies, or
- I find there are other material matters relating to the manner in which public business has been conducted.

I have nothing to report in regard to those matters upon which reporting is by exception.



Andrew Harkness

For and on behalf of the
Comptroller and Auditor General
12 June 2012

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 marketing 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 marketing 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:

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 IMB 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 IMB 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 € 689,860 (2010 - € 641,249). The surplus for the year on page 94 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, 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 ACCOUNT

for the year ended 31 December 2011

	Notes	2011 €	2010 €
Fee Income	2	**21,399,720**	21,901,934
Other Income	3	**3,546,480**	2,043,111
		24,946,200	23,945,045
Salaries and Wages	4	**16,433,330**	15,652,918
Other Operating Costs	5	**6,679,498**	5,532,894
Depreciation	1	**1,272,749**	1,446,488
		24,385,577	22,632,300
Surplus for the year before write back of Superannuation contributions		**560,623**	1,312,745
Staff Superannuation Contributions		**689,860**	641,249
Surplus for the year		**1,250,483**	1,953,994
Balance brought forward		**20,376,418**	18,422,424
Balance carried forward		**21,626,901**	20,376,418

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

The accounting policies on pages 91 to 93 and the notes on pages 97 to 103 form part of the financial statements.

Chairman

Mr. Michael Hayes

Board Member

Ms. Ann Horan

BALANCE SHEET

as at 31 December 2011

	Notes	2011 €	2010 €
Tangible Assets	1	**23,019,503**	23,753,247
Current Assets			
Debtors and Prepayments	6	**1,420,295**	1,530,265
Stock of Stationery		**2,469**	2,366
Cash at Bank and in Hand	12	**36,890**	24,260
Short Term Deposits		**14,669,317**	12,518,096
		16,128,971	14,074,987
Creditors - Amounts falling due within one year			
Creditors and Accruals	7	**7,208,237**	6,345,148
Mortgage	13	**793,332**	793,332
		8,001,569	7,138,480
Net Current Assets		**8,127,402**	6,936,507
Long Term Liabilities			
Mortgage	13	**9,520,004**	10,313,336
TOTAL NET ASSETS		**21,626,901**	20,376,418
Financed by			
Income and Expenditure Reserve	11	**21,626,901**	20,376,418
		21,626,901	20,376,418

The accounting policies on pages 91 to 93 and the notes on pages 97 to 103 form part of the financial statements.

Chairman

Mr. Michael Hayes

Board Member

Ms. Ann Horan

Cash Flow Statement

for the year ended 31 December 2011

	Notes	2011 €	2010 €
Reconciliation of surplus to net cash inflow from operating activities			
Surplus for Year		**1,250,483**	1,953,994
Depreciation Charge		**1,272,749**	1,446,488
(Increase)/Decrease in Debtors		**139,654**	579,624*
(Increase)/Decrease in Stocks		**(103)**	193
Increase/(Decrease) in Creditors - amounts falling due within one year		**862,733**	(46,435)*
Deposit Interest		**(256,205)**	(149,692)
Bank Interest and Charges		**460,323**	492,254
Loss/(Gain) on Disposal of Fixed Assets		**458**	198
Net Cash Inflow from Operating Activities		**3,730,092**	4,276,624
Cash Flow Statement			
Net Cash Inflow from Operating Activities		**3,730,092**	4,276,624
Return on Investments and Servicing of Finance	8	**(233,446)**	(370,605)*
Capital Expenditure	8	**(539,463)**	(1,005,389)
Management of Liquid Resources	8	**(2,151,221)**	(2,391,094)
Financing	8	**(793,332)**	(793,332)
Increase/(Decrease) in Cash		**12,630**	(283,796)
Reconciliation of net cash flow to movement in net debt			
Increase/(Decrease) In Cash		**12,630**	(283,796)
Increase/(Decrease) In Short Term Deposits		**2,151,221**	2,391,094
(Increase)/Decrease In Long Term Finance		**793,332**	793,332
Change In Net Funds/(Debt)		**2,957,183**	2,900,630
Net Debt at start of year		**1,435,688**	(1,464,942)
Net Funds/(Debt) at end of year	9	**4,392,871**	1,435,688

* Certain amounts have been reclassified for presentation purposes

The accounting policies on pages 91 to 93 and the notes on pages 97 to 103 form part of the financial statements.

Notes to the Financial Statements

for the year ended 31 December 2011

1. Tangible Assets

	Fixtures and Fittings €	Computer Equipment €	Leasehold Improvements €	Improvements Premises €	Premises €	Total €
Cost						
Balance as at 1 January 2011	930,309	8,286,297	502,445	3,541,486	20,383,000	33,643,537
Additions for the year	47,926	481,813	-	9,924	-	539,663
Disposals for the year	-	(161,174)	-	-	-	(161,174)
As at 31 December 2011	978,235	8,606,936	502,445	3,551,410	20,383,000	34,022,026
Depreciation						
Balance as at 1 January 2011	694,160	7,490,736	300,213	1,405,181	-	9,890,290
Charge for the year	153,522	713,841	50,245	355,141	-	1,272,749
Disposals for the year	-	(160,516)	-	-	-	(160,516)
As at 31 December 2011	847,682	8,044,061	350,458	1,760,322	-	11,002,523
Net Book value at 31 December 2011	130,553	562,875	151,987	1,791,088	20,383,000	23,019,503
Net Book value at 1 January 2011	236,149	795,561	202,232	2,136,305	20,383,000	23,753,247

2. Income

	2011 €	2010 €
Fee Income		
Clinical Trials	**123,617**	120,743
Human Medicine - National Fees	**7,750,395**	8,839,533
Human Medicine - European Fees	**7,056,707**	6,166,008
Veterinary Medicine - National Fees	**1,104,294**	1,098,288
Veterinary Medicine - European Fees	**1,339,833**	1,391,667
Compliance Department	**3,773,733**	4,068,806
Medical Devices	**251,141**	216,889
	21,399,720	21,901,934
Other Income (Note 3)	**3,546,480**	2,043,111
Total Income	**24,946,200**	23,945,045

Certain fees, totalling €17,740,955, are required by law to be disposed of in accordance with the directions of the Minister for Finance.

Notes to the Financial Statements

for the year ended 31 December 2011

3. Other Income

	2011	2010
	€	€
Dept Of Health Funding	**3,230,479**	1,750,508
IT Income	**-**	5,000
Conference Fee Income	**60,254**	138,109
Deposit Interest	**256,205**	149,692
(Loss)/Gain on Disposal of Fixed Assets	**(458)**	(198)
	3,546,480	2,043,111

4. Salaries and Wages

	2011	2010
	€	€
Salaries and Wages	**15,144,077**	14,425,188
Social Welfare Costs	**1,289,253**	1,227,730
	16,433,330	15,652,918

The average number of staff employed during the year was 289 (2010 - 282).
Staff employed at 31 December 2011 can be analysed across the following departments :

	2011	2010
Chief Executive	**10**	9
Compliance	**58**	57
Finance & Corporate Affairs	**16**	16
Human Products Authorisation & Registration	**108**	109
Human Products Monitoring	**36**	34
Human Resources	**7**	7
IT & Change Management	**13**	12
Scientific Affairs	**2**	2
Veterinary Medicines	**19**	21
Pensioners	**21**	16
	290	283

Pension related deductions for Public Servants of €938,674 were deducted from staff during the year and paid over to the Department of Health.

Notes to the Financial Statements

for the year ended 31 December 2011

5. Operating Costs

	2011	2010
	€	€
Accommodation Costs	**1,347,919**	1,104,086
Travel, Representation and Training	**720,158**	808,855
Bank Charges and Interest	**460,323**	492,254
Legal & Professional Fees	**1,780,330**	514,964
Stationery, Publications and Postage	**438,945**	536,715
Other Operating Costs	**1,931,823**	2,076,020
	6,679,498	5,532,894

Operating costs of €6,679,498 includes an amount of €17,819 in relation to canteen consumables and events which include a lunch to acknowledge each of the unremunerated statutory committees and an event in the canteen to recognise the contribution of the retiring Board and Chair, who with the exception of the Chair are also unremunerated. It also includes an amount of €4,020 related to staff hospitality.

6. Debtors (all due within one year)

	2011	2010
	€	€
Trade Debtors	**788,523**	896,769
Prepayments	**357,405**	375,872
Other Debtors	**274,367**	257,624
	1,420,295	1,530,265

7. Creditors (amounts falling due within one year)

	2011	2010
	€	€
Trade Creditors	**540,975**	629,102
Accruals	**6,146,590**	5,222,976
Revenue Commissioners	**520,672**	493,070
	7,208,237	6,345,148

Notes to the Financial Statements

for the year ended 31 December 2011

8. Gross Cash Flows

	2011	2010
	€	€
Returns on Investment and Servicing of Finance:		
Deposit Interest	**226,521**	122,451 *
Bank Interest and Charges	**(459,967)**	(493,056)*
	(233,446)	(370,605)
Capital Expenditure		
Payments to acquire Tangible Fixed Assets	**(539,663)**	(1,006,314)
Receipts from sales of Tangible Fixed Assets	**200**	925
	(539,463)	(1,005,389)
Management of Liquid Resources		
(Increase)/Decrease in Short Term Deposits	**(2,151,221)**	(2,391,094)
	(2,151,221)	(2,391,094)
Financing		
Increase/(Decrease) in Long Term Finance	**(793,332)**	(793,332)
	(793,332)	(793,332)

* Certain amounts have been reclassified for presentation purposes

9. Analysis of Changes in Net Funds/(Debt)

	As At 01/01/2011	Cashflow	As At 31/12/2011
Cash at Bank and in Hand	24,260	12,630	**36,890**
Short Term Deposits	12,518,096	2,151,221	**14,669,317**
Debt Due Within One Year	(793,332)	0	**(793,332)**
Debt Due After One Year	(10,313,336)	793,332	**(9,520,004)**
	1,435,688	2,957,183	**4,392,871**

10. Administration Expenses

	2011	2010
Surplus for the year was calculated having charged :		
Auditor's Remuneration	**17,390**	17,390

Notes to the Financial Statements

for the year ended 31 December 2011

11. Movement on Income and Expenditure Reserves

	As At 01/01/2011	Movement	As At 31/12/2011
Retained Reserves	15,280,032	560,623	15,840,655
Staff Superannuation Contributions	5,096,386	689,860	5,786,246
	20,376,418	1,250,483	21,626,901

12. Cash and Bank Balances

	2011 €	2010 €
Current Account Balances	35,976	23,279
Cash on Hand	914	981
	36,890	24,260

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 :

	2011 €	2010 €
- within one year	793,332	793,332
- between one and five years	3,173,328	3,173,328
- after five years	6,346,676	7,140,008
	10,313,336	11,106,668

14. Interest Rate Exposure

The IMB has taken all necessary steps to minimise its interest rate exposure by fixing 2/3s of the borrowings for a period of 10 years. The balance of the borrowings are fully offset by cash reserves.
For 2012 it is estimated that the net borrowings for which an interest rate exposure may arise is €0.

Notes to the Financial Statements

for the year ended 31 December 2011

15. Financial Commitments

	2011 €	2010 €
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)	**167,056**	167,056
- after five years (in respect of Alexandra House)	**285,984**	285,984
	453,040	453,040

Included in Accommodation Costs (Note 5) is expenditure of €453,040 under operating leases. 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 2011 this lease had 10 years and four months remaining.
On 1 June 2010 the IMB signed a leasehold interest in respect of the 3rd floor, Longphort House, Earlsfort Centre, Dublin 2. At 31 December 2011 this lease had 3 years and 3 months remaining.

16. Capital Commitments

	2011 €	2010 €
Contracted For (Contract Signed)	**145,000**	212,000
Not Contracted For	**5,212,000**	4,355,000
	5,357,000	4,567,000

17. Board Remuneration

	2011 €	2010 €
Chairman's Salary	**19,596**	22,305
Board Members' Travel Expenses	**4,723**	5,537
	24,319	27,842

18. Staff Remuneration

	2011 €	2010 €
Chief Executive's Total Remuneration		
Basic Salary	**156,386**	174,913
	156,386	174,913

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

Notes to the Financial Statements

for the year ended 31 December 2011

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 :

2011	**€1 = STG £0.838**
2010	€1 = STG £0.8568

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 appoving 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 23 May 2012.

APPENDIX 1
COMMITTEE MEMBERS

MANAGEMENT COMMITTEE

Mr. Pat O'Mahony
Chief Executive

Dr. 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
Director of Scientific Affairs

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

Ms. Rita Purcell
Director of Finance and Corporate Affairs

BOARD

Mr. Michael D Hayes
Chairman

Mr. Pat Brangan

Prof. Brendan Buckley (resigned September 2011)

Mr. Wilfrid J. Higgins

Ms. Ann Horan

Prof. Mary Horgan (nominated November 2011)

Mr. Brendan McLaughlin

Mr. Noel O'Donoghue

Prof. Caitriona O'Driscoll

Ms. Maureen Windle (resigned November 2011)

AUDIT COMMITTEE

Ms. Maureen Windle (resigned November 2011)

Mr. Pat Brangan

Ms. Ann Horan

ADVISORY COMMITTEE FOR HUMAN MEDICINES

Prof. Brendan Buckley
Chairman to September 2011

Prof. Mary Horgan
Chairman from November 2011

Dr. Paul Browne

Dr. Kevin Connolly

Dr. Desmond Corrigan

Prof. David Kerins

Ms. Marita Kinsella

Prof. Patrick Murray

Mr. Ronan Quirke

Dr. Patrick A. Sullivan

Prof. Peter Weedle

ADVISORY COMMITTEE FOR VETERINARY MEDICINES

Mr. Pat Brangan
Chairman

Dr. Ruaidhri Breathnach

Ms. Eugenie Canavan

Mr. Michael F. Clancy

Dr. Martin Danaher

Dr. Rodhri Evans

Dr. Helena Kelly

Mr. Des Leadon

Dr. Nola Leonard

Mr. Ciaran Mellet

Mr. John Moriarty

Mr. John Underhill

ADVISORY COMMITTEE FOR MEDICAL DEVICES

Mr. Wilfrid J. Higgins
Chairman

Dr. Gillian Carlos McDowell

Dr. Geoffrey Chadwick

Mr. Darragh Hynes

Prof. Fergal O'Brien

Dr. John O'Mullane (resigned May 2011)

Prof. Richard Reilly

Ms. Mary Sharp

Ms. Maebh Smith

Dr. Declan Sugrue

Mr. Sean Paul Teeling

Prof. Wil van der Putten

Dr. Vivion Crowley (nominated November 2011)

CLINICAL TRIAL SUB-COMMITTEE OF ADVISORY COMMITTEE FOR HUMAN MEDICINES

Dr. Patrick A. Sullivan
Chairman

Dr. Liam Bannan

Prof. David Bouchier-Hayes

Dr. Geraldine Boylan

Dr. Paul Browne

Dr. Peter Daly

Prof. Timothy Dinan

Dr. Thomas Pierce

Dr. John Taaffe

Dr. Bryan Whelan

Dr. Lee Helman (CT Expert)

Dr. Filip Janku (CT Expert)

ADVISORY SUB-COMMITTEE FOR HERBAL MEDICINES

Dr. Des Corrigan
Chairman

Dr. James Barlow

Dr. Kevin Connolly

Ms. Nicola Darrell

Mrs. Ingrid Hook

Ms. Claudine Hughes

Ms. Anna-Maria Keaveney (nominated May 2011)

Dr. Celine Leonard

Dr. Hugh McGlynn (resigned May 2011)

Dr. Diarmaid O'Connell

Dr. Donal O'Mathuna

Dr. Camillus Power

Dr. Helen Sheridan

Ms. Anne Varley

EXPERTS SUB-COMMITTEE OF THE ADVISORY COMMITTEE FOR HUMAN MEDICINES

Prof. Mary Horgan
Chairman

Prof. Brendan Buckley (resigned September 2011)

Dr. Colin Buckley

Dr. Owen Carey

Dr. Kevin Connolly

Dr. Noreen Dowd

Dr. Stephen Eustace

Prof. Michael Fitzgerald (resigned September 2011)

Dr. Stephen Flint

Dr. Tim Fulcher

Dr. Joseph Galvin

Dr. Patrick Gavin

Dr. Kevin Kelleher

Dr. Catherine Kelly

Dr. Mary Keogan

Prof. David Kerins

Dr. Lorraine Kyne

Dr. Mark Ledwidge

Dr. John McCaffrey (resigned 2011)

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

APPENDIX 2
PRESENTATIONS 2011

THIRD LEVEL PRESENTATIONS

College	Course	Presentation Title
DCU	Chemical and Pharmaceutical Sciences	Irish Pharmaceutical Industry Regulation and the Role of the IMB
Limerick IT	Pharmaceutical and Forensic Analysis	Pharmaceutical Assessment and Related Activities at the IMB
RCSI	Nurse Midwife Prescribing	Role of the IMB (2 presentations)
RCSI	Nurse Midwife Prescribing	Pharmacovigilance (2 presentations)
RCSI	Pharmacy	Regulation of New and Generic Medicines
TCD	Pharmaceutical Medicine	Legal provisions - SPCs, Leaflets and Packaging
TCD	Pharmaceutical Medicine	The Role of the CMDh
TCD	Pharmaceutical Medicine	Regulation: International Quality Standards and Pharmacopoeias
TCD	Pharmaceutical Medicine	Advanced Therapy Medicinal Products
TCD	Pharmaceutical Medicine	Herbal Medicinal Products
TCD	Pharmaceutical Medicine	Role of the Pharmacist in Regulatory Affairs
TCD	Pharmaceutical Medicine	Regulation of Medical Devices
TCD	Pharmaceutical Medicine	Interaction between EU and WHO on Pharmacovigilance
TCD	Pharmaceutical Medicine	Communicating Drug Safety Data
TCD	Hospital Pharmacy	Pharmacovigilance - A Regulatory Perspective
TCD	Biomedical Sciences	Biopharmaceuticals - Introduction to EU Regulation
UCD	Nursing - Prescription of Medications	Role of the IMB (2 presentations)
UCD	Nursing - Prescription of Medications	Pharmacovigilance (2 presentations)
UCD	Veterinary Medicines	Regulation of Veterinary Medicines in Ireland
UCD	Clinical and Translational Research	Medical Device Studies
UCD	Pharmaceutical Management	Regulatory Environment for the Irish Pharmaceutical Industry
UCD	MSc Bioengineering	Regulation of Medical Devices

REGULATORY PRESENTATIONS

Event/Organiser	Presentation Title
Advanced Therapies Medicinal Products Training (EMA)	Regulation of Medical Devices and Combined Advanced Therapies Medicinal Products (ATMPs)
Advanced Therapies Medicinal Products Training (EMA)	Environmental risk Assessments for Genetically Modified Organs
Competent Authorities for Medical Devices	Roadmap for the Revision of the Medical Devices Legislation
Competent Authorities for Medical Devices	Regulation of Drug Device and Combination Products
Competent Authorities for Medical Devices	Funding and Resourcing of Medical Device Authorities
DIA/IFAH Conference	Challenges in Maintaining Availability of Veterinary Medicines
Drug Safety Research Unit	New Pharmacovigilance Legislation - PSURs
Drug Safety Research Unit	New Pharmacovigilance Legislation - Risk Minimisation Plans
EMA ATMP Assessors training	Information on the CTD on the Combined ATMP
EU High-level Conference	Optimising Resources and Co-ordination of Medical Device Regulation
Forum Institute Conference	Variations Regulation
Good Manufacturing Practice Conference	Pharmaceutical Quality Systems
Good Manufacturing Practice Conference	Risk-based Validation and Qualification
HMA - Competent Authorities for Medical Devices	Funding and Resourcing of Medical Device Authorities
IBEC	Ireland's Unique Potential for the Commercialisation of Drug, Device and Biologic Combination Products
Industry Event	Type II Variations According to the Regulation
Industry Events	Advertising Compliance (2 presentations)
Informa	Clinical Investigations of Medical Devices and Revision of the Legislation
Informa	National Perspectives In Regards To Clinical Data Evaluation
Institute of Validation Technology	Qualification and Validation: Regulatory Inspectional Findings - IMB Perspective

REGULATORY PRESENTATIONS

Event/Organiser	Presentation Title
International Society of Pharmacoepidemiology	Risk/Benefit Management: The Importance of Risk Minimisation Activities
Irish Cardiovascular and Stroke Research Network	Medical Device Research
ISPE Conference	Quality Risk Management
ISPE Conference	Issues Driving the European Regulatory Agenda on Drug Risk/ Benefit Management: Importance of Risk Minimisation
IVT Validation Week	Qualification and Validation: regulatory inspectional findings - IMB perspective
PAT and Quality by Design Conference	Quality by Design for Pharma and BioPharma
Pharmacovigilance for the Veterinary Industry Conference	Periodic Safety Update Reports
Pharmacovigilance for the Veterinary Industry Conference	Signal Detection – A Regulator's Perspective
Regulatory Workshop	Risk-Based Validation of Submission Management

APPENDIX 3
PUBLICATIONS AND ARTICLES 2011

CONSUMER INFORMATION LEAFLETS

Topic	Published
IMB Advice on Automated External Defibrillators	December

DRUG SAFETY NEWSLETTERS

Edition	Articles
February 2011 40th Edition	– Multaq (dronedarone) – Association with Severe Liver Injury – Thelin (sitaxentan) – Marketing Authorisation withdrawal – Fluoroquinolones - Risk of QT Prolongation – Viewing the Drug Safety Newsletter online or receiving via email – Safe Use of Insulin Pens
April 2011 41st Edition	– Paracetamol - Available evidence does not support a causal relationship with asthma in children after exposure in pregnancy or use in early infancy – Provigil (Modafinil) – Restriction of use and recommendations to support safer use – Tygacil (tigecycline) – Recommendations for use – Efient (prasugrel) – Reports of hypersensitivity reactions – Revlimid (lenalidomide) – Risk of venous and arterial thromboembolic events
June 2011 42nd Edition	– Cubicin (daptomycin) – Risk of eosinophilic pneumonia – Drospirenone containing combined oral contraceptives (Yasmin, Yasminelle, Yaz and generics) - Risk of venous thromboembolism – Bisphosphonates – Risk of atypical femoral fracture – Revlimid – Investigation of potential risk of second primary malignancies – Intravenous Paracetamol Solutions for Infusion – Risk of medication errors in infants and children (Insert).
August 2011 43rd Edition	– Pioglitazone – New contraindications and warnings following European review of bladder cancer risk – Dexrazoxane (Cardioxane) – Restrictions for use – Dronedarone (Multaq) – Update on benefit-risk review – View the Drug Safety Newsletter online or receive via email – Gardasil – Overview of National Monitoring Experience

DRUG SAFETY NEWSLETTERS

Edition	Articles
October 2011 44th Edition	– Multaq – Restriction of use and new monitoring requirements – MabThera – Association with fatal infusion related reactions in patients with rheumatoid arthritis – Non-prescription cough and cold medicines for young children – New advice – Revlimid – Risk of second primary malignancies in authorised indication – Vimpat 15mg/ml syrup – Discontinuation of supply
December 2011 45th Edition	– Domperidone – Risk of cardiac disorders – Citalopram and Escitalopram – Risk of QT interval prolongation – Strattera (atomoxetine) – Effects on blood pressure and heart rate – Pradaxa (dabigatran etexilate) – Recommendations for assessment of renal function and monitoring in the elderly

IMB HUMAN MEDICINES ARTICLES – EXTERNAL PUBLICATIONS

Topic	Publication	Month
BCG Vaccine SSI and Severe Local Reactions	MIMS	January
Champix – Psychiatric Adverse Reactions	MIMS	February
Antipsychotics – Risk of Venous Thromboembolism	IMF	February
Multaq – Hepatic Adverse Reactions	MIMS	March
Fluoroquinolones – Risk of QT Prolongation	MIMS	April
Paracetamol – Evidence does not support causal association with asthma in children after exposure in pregnancy or use in early infancy	MIMS	May
Revlimid – Venous Thromboembolism risk (Oncology Supplement)	MIMS	May
Bisphosphonates – Risk of atypical femoral fracture	MIMS	June
Drospirenone containing oral contraceptives (Yasmin, Yasminelle, Yaz and generics – risk of venous thromboembolism	MIMS	July
Bisphosphonates and Osteonecrosis of the Jaw: Current Guidance on Risk Minimisation Measures	JIDA	July
Gardasil – Overview of National Monitoring Experience	MIMS	August
Bisphosphonates – Risk of Stress Fractures	IMF	August
Pioglitazone – New contra-indications and warnings following European review of bladder cancer risk	MIMS	September
Non-prescription Cough and Cold Medicines for Young Children – New Advice	MIMS	October

IMB HUMAN MEDICINES ARTICLES – EXTERNAL PUBLICATIONS

Topic	Publication	Month
Multaq – Restriction of use and new monitoring requirements	MIMS	November
Pioglitazone – New contra-indications and warnings following European review of bladder cancer risk (Diabetes Supplement)	MIMS	November
Pradaxa (dabigatran etexilate) – Recommendations for assessment of renal function and monitoring in the elderly	MIMS	December

IMB VETERINARY MEDICINES ARTICLES – EXTERNAL PUBLICATIONS

Topic	Publication	Month
Suspected adverse reactions to veterinary medicinal products 2008-2009	Veterinary Ireland Journal	January
Vigilance in Prescribing and Using Antibacterials in Dry Cows	Veterinary Ireland Journal	August
The Pending EU Review of the Regulatory Framework for Veterinary Medicines	Veterinary Ireland Journal	October
IMB Update on Flukicides Without MRL for Milk	Veterinary Ireland Journal	November
Veterinary Pharmacovigilance in Ireland - A Simple Guide to Reporting Adverse Reactions	It's Your Field	Spring
Understanding Veterinary Product Literature	It's Your Field	Summer
Best Practice for Maintaining the Cold Chain	It's Your Field	Autumn
The Irish Medicines Board Website	It's Your Field	Winter

IMB MEDICAL DEVICES NEWSLETTER – SAFETY ARTICLES

Edition	Topic
April	Increased global activity in relation to the production and supply of counterfeit/illegal medical devices
August	Medicine feeders, including spoons, droppers, syringes, cups and pacifiers/soothers, which are intended for use for administration of medicines – Advice to pharmacists, hospital personnel, retailers and consumers
August	Risk of transmission of blood borne agents associated with the use of blood glucose monitoring systems – Advice to hospital/healthcare professionals and consumers

INDUSTRY GUIDANCE DOCUMENTS

Document title	New/Revision	Date
Guide to Fees for Human Products 2011	Revision	January
Guide to Withdrawal of Authorisations or Certificates for Human Medicines	Revision	February
Guide to the Definition of an Animal Remedy and the Classification Process	Revision	February
Guide to Labels and Leaflets of Human Medicines	Revision	February
Guide to Electronic Submissions - Human Medicines	Revision	March
Guide to Submitting a Request for the IMB to Act as RMS In a Decentralised Procedure for a Human Medicine	Revision	March
Guide to Clinical Trial Applications	Revision	March
Guide to Labels and Leaflets of Human Medicines	Revision	April
Submission of a Variation Application for a Manufacturing Importation Authorisation and a Wholesaler's Authorisation	New	April
Guide to Fees for Veterinary Medicines	Revision	May
Guide to Labels and Leaflets of Human Medicines	Revision	May
Guide to Notification of Marketing Status of Human Medicines	Revision	May
Guide to Applications for Certificates of Free Sale for Cosmetics	Revision	May
Guide to Completion of the Tissue Establishment Annual Report	Revision	May
Guide to Completion of the Tissue Establishment Annual Report for Reproductive Tissues and Cells	Revision	May
Guide to the Quality System for Grocery Wholesale Distributors	New	June
Frequently Asked Questions on Export Certificates	New	June
Submission of Risk Minimisation Plans to the Irish Medicines Board	New	June
Frequently Asked Questions on Advertising Compliance	New	July
Guide to Parallel Imports for Human Medicines	Revision	July
Guide to Labels and Leaflets of Human Medicines	Revision	August
Guide to the Attainment of Qualified Person Status in Ireland: Educational Requirements, Training and Licensing	New	August
Guide to Renewal of Marketing Authorisations - Human Medicines	Revision	September

APPENDIX 4 EUROPEAN AND NATIONAL COMMITTEE / WORKING GROUP PARTICIPATION

EUROPEAN AND NATIONAL COMMITTEE/WORKING GROUP PARTICIPATION

Committee/Working Group	Organisation	Meetings Per Annum
Central Management Committee	CAMD	2
Competent Authority for Medical Devices	CAMD	2
New and Emerging Technologies Working Group	CAMD	2
Notified Body Operations Group	CAMD	3
Recast Working Group	CAMD	5
Compliance and Enforcement Working Party (COEN)	Competent Authorities Working Group	3
In-Vitro Diagnostic Technical Working Group	Competent Authorities Working Group	1
P-SC-COS (Committee of Experts on Cosmetics)	Council of Europe	1
Working Group on Anti-Counterfeiting	Council of Europe	2
National TB Advisory Committee	Department of Health	
Medication Safety Forum and related groups	Department of Health/HSE	10
Notice to Applicants Working Group	EC	1
Advisory Group to Official Medicines Control Network	EDQM	2
Annual meeting of Official Medicines Control Laboratories Network	EDQM	1
Annual planning meeting for sampling and testing of centrally authorised medicinal products	EDQM	1
Ad Hoc Pharmacovigilance Inspectors Working Group (Ph IWG)	EMA	4
Committee for Advanced Therapies	EMA	11
Committee for Medicinal Products for Human Use (CHMP)	EMA	11
Committee for Medicinal Products for Veterinary Use (CVMP)	EMA	11
Committee for Orphan Medicinal Products (COMP)	EMA	7

EUROPEAN AND NATIONAL COMMITTEE/WORKING GROUP PARTICIPATION

Committee/Working Group	Organisation	Meetings Per Annum
Committee on Herbal Medicinal Products (HMPC)	EMA	6
Efficacy Working Party (of CVMP)	EMA	4
EudraCT (Clinical Trials Database)	EMA	3
GCP Inspectors Working Group	EMA	4
GDP Drafting Group	EMA	2
GMDP Inspectors Working Group	EMA	4
Immunologicals Working Party (of CVMP)	EMA	3
Paediatric Committee (PDCO)	EMA	12
Pharmacovigilance Working Party (PhVWP)	EMA	11
Quality Working Party (CHMP/CVMP)	EMA	4
Safety Working Party (of the CHMP)	EMA	4
Scientific Advice Working Party	EMA	11
Technical Implementation Groups (ICT)	EMA	
Telematics Committee - Management Board	EMA	4
Veterinary Joint Implementation Group	EMA	4
Ad hoc group for the development of implementing guidelines for Directive 2001/20/EC	EU Commission	4
Borderline and Classification Medical Device Expert Group (MDEG)	EU Commission	1
Clinical Investigation and Evaluation Working Group	EU Commission	3
Competent Authorities for Blood	EU Commission	2
Competent Authorities for Tissues and Cells	EU Commission	2
Cosmetic Borderline Working Group	EU Commission	2
Cosmetic Standing Committee and Working Group	EU Commission	3
CPNP Working Group (Cosmetics)	EU Commission	3
Drug Precursors Working Group	EU Commission	4
EUDAMED Working Group	EU Commission	3
MDEG Software Working Group	EU Commission	4
MDEG Working Group on Vigilance	EU Commission	2
Medical Device Expert Group	EU Commission	1

EUROPEAN AND NATIONAL COMMITTEE/WORKING GROUP PARTICIPATION

Committee/Working Group	Organisation	Meetings Per Annum
Notified Bodies Operational Group (NBOG)	EU Commission	3
PEMSAC Analytical Methods and Market Surveillance Working Groups	EU Commission	2
Regulatory Committee for Medical Devices	EU Commission	1
Unique Device Identifier Group	EU Commission	2
Working Group on the Common Approach to reporting of SAR/E for Haemovigilance	EU Commission	1
European Directorate for the Quality of Medicines (EDQM)	EU Public Health Organisation	3
SoHO V&S	EU Public Health Project	1
SoHO V&S Steering Committee	EU Public Health Project	1
Vigilance and Surveillance of Substances of Human Origin (SoHO) - WP5 Assisted Reproduction	EU Public Health Project	2
Clinical Trial Facilitation Group (CTFG)	HMA	6
Co-ordination Group for Mutual-recognition and Decentralised Procedures (Human) CMD(h)	HMA	11
Co-ordination Group for Mutual-recognition and Decentralised Procedures (Veterinary) CMD(v)	HMA	11
Heads of Medicines Agencies Working Group of Enforcement Officers (HMA WGEO)	HMA	2
HMA ICT Working Groups	HMA	
Homeopathic Medicinal Products Working Group (HMPWG)	HMA	2
Permanent Forum on International Pharmaceutical Crime	International Enforcement Forum	1
Anti-doping Committee	Irish Sports Council	4
National Haemovigilance Conference	NHO	1
Review of Haemovigilance Monitoring Systems	NHO	2
Haemovigilance Monitoring	NHO/IMB	4
Committee of Officials	PIC/S	2
PIC/S GDP working group	PIC/S	2
Heads of Medicines Agency meetings – Human	EU Presidency	4
Heads of Medicines Agency meetings – Veterinary	EU Presidency	4
National Immunisation Advisory Committee	RCPI	6
Board of the UMC/WHO Collaborating Centre	WHO	3
WHO National PV Centres Meeting	WHO/Croatian Medicines Agency	1

APPENDIX 5
GLOSSARY

AED	Automated External Defibrillator
APHA	Animal and Plant Health Association
APMI	Association of Pharmaceutical Manufacturers in Ireland
ASR	Annual Safety Report
ATMP	Advanced Therapy Medicinal Product
BEMA	Benchmarking of European Medicines Agencies
CAMD	Competent Authority for Medical Devices
CAT	Committee for Advanced Therapies
CD	Controlled Drugs
CESP	Common European Submission Portal
CHMP	Committee for Medicinal Products for Human Use
CMC	Central Management Committee
CMD(h)	Co-ordination Group for Mutual Recognition and Decentralised Procedures - Human
CMD(v)	Co-ordination Group for Mutual Recognition and Decentralised Procedures - Veterinary
CMS	Concerned Member State
COMP	Committee for Orphan Medicinal Products
CTFG	Clinical Trials Facilitation Group
CVMP	Committee for Medicinal Products for Veterinary Use
DCP	Decentralised Procedure
EDQM	European Directorate for Quality of Medicines
EEA	European Economic Area
EMA	European Medicines Agency
EUDAMED	European Database on Medical Devices
FAQ	Frequently Asked Questions
GCP	Good Clinical Practice
GDP	Good Distribution Practice

GMP	Good Manufacturing Practice
GVP	Good Vigilance Practice
H1N1	2009 Flu Pandemic
HIQA	Health Information and Quality Authority
HMA	Heads of Medicines Agency
HMPC	Committee on Herbal Medicinal Products
HPSC	Health Protection Surveillance Centre
HPV	Human Papillomavirus
HSE	Health Service Executive
IAHS	Irish Association of Health Stores
IBTS	Irish Blood Transfusion Service
ICH	International Conference on Harmonisation
IHTA	Irish Health Trade Association
IMDA	Irish Medical Devices Association
IMF	Irish Medicines Formulary
IPHA	Irish Pharmaceutical Healthcare Association
IVD	In-Vitro Diagnostics
JIDA	Journal of the Irish Dental Association
MAH	Marketing Authorisation Holder
MEDDEV	Medical Devices Guidance Document from the European Commission
MIMS	Monthly Index of Medical Specialities
MRLs	Maximum Residue Limits
MRP	Mutual Recognition Procedure
NBOG	Notified Body Operations Group
NCA	National Consumer Agency
NHO	National Haemovigilance Office
NSAI	National Standards Authority of Ireland
OMCL	Official Medicines Control Laboratories
OTC	Over-the-Counter

PCI	Pharmachemical Ireland
PDCO	Paediatric Committee
PDP	Performance Development Programme
PIC/S	Pharmaceutical Inspection Co-operation Scheme
PSUR	Periodic Safety Update Report
QWP	Quality Working Party
RMP	Risk Management Plan
RMS	Reference Member State
SoHOV&S	Substances of Human Origin Vigilance and Surveillance
THMP	Traditional Herbal Medicinal Product
UMC	Uppsala Monitoring Centre
VMD	Veterinary Medicines Directorate
WHO	World Health Organization

IRISH MEDICINES BOARD

Irish Medicines Board
Bord Leigheasra na hÉireann

Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
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