IRISH MEDICINES BOARD

ANNUAL REPORT 2012

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.

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36%

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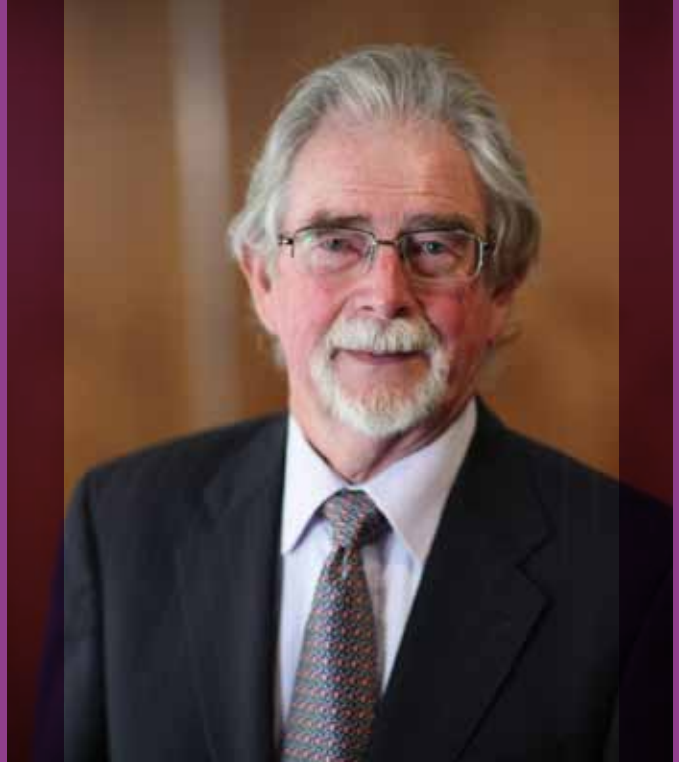
CHAIRMAN'S STATEMENT



It gives me great pleasure to present the 2012 Annual Report of the Irish Medicines Board (IMB). This report details the IMB's activities over the past year and it is evident that this was a very busy period for the organisation. While fulfilling the core remit of protecting public and animal health, management and staff also made significant progress on the strategic objectives contained in the IMB's Strategic Plan for 2011-2015.

In last year's report, which was my first as Chairman of the IMB, I noted how impressed I was with the positive ethos permeating the organisation and the dedication to excellence that underpinned every task and decision that was made at all levels of the organisation. I continue to be impressed by the commitment of everyone at the IMB notwithstanding the challenges presented by a busy year and an expanding remit.

The IMB's core objective of safeguarding public and animal health involves regulating healthcare products and sectors. In the case of medicines, this involves regulating across the entire product lifecycle from clinical trials, through manufacturing, to marketing and distribution, and end use by patients and animal owners. For other products, such as medical devices and cosmetics, the IMB has responsibility for key stages in the regulatory process with a particular focus on monitoring the safe use of these products. In 2012, executing this remit led to significant work outputs in all divisions across the organisation. Additionally, the IMB's remit grew this past year to include responsibility for key aspects of the EU Directive on the standards of quality and safety of human organs intended for transplant. Throughout the year detailed preparations were also made towards becoming the competent authority on the protection of animals used for scientific purposes (in 2013.

Decisions taken by the IMB are done so in the interest of public and animal health. They are taken by experienced scientists and healthcare professionals based on the best available information at national and EU level. From time to time, this information can lead to the IMB issuing national recommendations to ensure safe use of medicine and in 2012 the organisation made two such recommendations both in respect of children's medicines.

The IMB's has a strong reputation as a robust and effective regulator. The respect and regard with which it is held in Europe and wider afield is testimony to this. Staff, led by the Chief Executive, are heavily involved in planning for and implementing new legislation and policy at both national and EU level, playing an active and highly influential role. The

senior positions they hold on many committees and the valuable contributions they make ensure that the health interests of Irish people are well represented. These committee positions are taken in addition to their day to day responsibilities and I commend the staff involved for their uncompromising commitment to their work despite the many demands that are made of them.

The pharmaceutical, medical device and broader life sciences sector in Ireland exports products globally and is a major contributor to our economy. The IMB as a robust regulator plays an important role in supporting the sector's continued success. Compliance and monitoring of good manufacturing practices underpin the sector and a strong and effective regulator is a significant asset to Ireland's reputation as major world player in this specialist sector.

It is important that the regulatory decisions taken by the IMB, and the policy and legislation behind these, are clearly understood. Communicating with key stakeholders is important in aiding a better understanding of IMB actions as well as how and why particular decisions are taken. During the last year, there was considerable progress in the achievement of a primary strategic goal which is to ensure that all stakeholders have access to relevant and timely safety, licensing and regulatory information. An example of this is the important strides made in increasing engagement with key stakeholders. The Consultative Panel on the Legal Classification of Medicines, for example, is a valuable forum for the sharing of views and perspectives on the reclassification of medicines while the IMB's information days and seminars which were held across a range of issues provided regulatory guidance and updates as well as valuable opportunities for two way dialogue with the IMB.

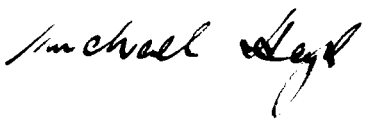
Looking to the future, 2013 marks the mid-way point of the organisation's five year strategic plan and as such is an important milestone as efforts continue to build and enhance organisational capabilities in response to ongoing scientific, technological and regulatory changes. It will also see the organisation begin preparations for a significant brand transformation as the current Irish Medicines Board will give way to the Health Products Regulatory Authority (HPRA) early the following year. The hard work and effort put in during 2012 has meant we are well placed for the work ahead in 2013 as we continue this transformational progress.

The IMB plays and will continue to play a critical role at EU level where new legislation is developed that protects our citizens in relation to healthcare products. The organisation will 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. This will be particularly evident in the first half of 2013 as Ireland holds the EU Presidency.

I would like to thank again the Chief Executive, management and staff of the IMB for their unwavering dedication to best practice across all aspects of the organisation and their contribution to the significant progress that was made across the year in pursuit of core strategic goals.

I would also like to thank my fellow Board members for their commitment, time and support across the year. My thanks also to the chairs and members of the IMB advisory committees and sub-committees who make such a significant contribution to the regulatory process.

Finally, 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. Their continued support of the IMB and its activities is greatly valued and of significant importance to us as we strive to fulfill our remit and safeguard public and animal health now and into the future.



Michael D. Hayes

Chairman

BOARD MEMBERS

The Board of the IMB is appointed by the Minister for Health in accordance with the powers conferred by subsection 2 of section 7 of the Irish Medicines Board Act, 1995. There were nine Board members as of 31 December 2012.

Mr. Michael D. Hayes
(Chairman)
Engineering Consultant

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

Mr. Wilfred Higgins
Former 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

Dr. Elizabeth Keane
Adjunct Professor of Epidemiology and Public Health, University College Cork

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

MANAGEMENT COMMITTEE

Mr. Pat O'Mahony
Chief Executive

Dr. Gabriel Beechinor
Director of Veterinary Sciences

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. 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 very pleased to submit our 2012 annual report in accordance with Section 19 of the Irish Medicines Board Act, 1995. The report outlines the significant efforts made across the organisation during the year in review and the progress made towards achieving our strategic objectives as set out in the five-year Strategic Plan for 2011 to 2015.

The report also details the addition of further functions which were effectively and efficiently merged with the existing activities under our remit. Despite the ongoing challenges faced by the public sector, my colleagues across the Irish Medicines Board (IMB) again responded with diligence and professionalism in delivering on our absolute commitment to the protection of public and animal health.

STRATEGIC GOALS

The IMB's 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 2012 is structured 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 a core regulatory function of the IMB. By operating an efficient regulatory framework we play an important role in ensuring patients have timely access to appropriate treatments. The following activities were of particular note during 2012:

- In respect of human medicines, there was an 11% increase in variations applications to 17,153 for products authorised through the national or mutual recognition (MR) procedures. The number of new product applications assessed by the IMB in 2012 was 1,372 down from 1,977 the previous year. This decrease was mainly due to a 40% fall in the number of new parallel product authorisations applications.
- In 2012, we assessed and approved 144 new product applications for veterinary products, a total that has remained broadly constant over the last number of years. There were 1,242 variations to authorisations granted through the national, MR or centralised procedures.
- The IMB continued to actively contribute to the European licensing system throughout 2012. For human medicines, we were allocated as lead assessor (rapporteur) or joint lead assessor (co-rapporteur) for 10 new marketing authorisations at the European Medicines Agency. The IMB also completed 12 new marketing authorisations via the MR procedure with Ireland as the reference member state. As regards veterinary medicines, the IMB acted as the rapporteur or co-rapporteur for 16 centralised procedures (including extension applications) and issued 42 new marketing authorisations as the reference member state.
- During 2012, the IMB processed 388 notifications to the medical device register. These related to class I, in-vitro diagnostic and custom made medical devices and to system and procedure packs.
- There were 110 site manufacturing licences in place at year end for human and veterinary medicines. 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 2012 was 48, up from 32 the previous year.

SAFETY AND COMPLIANCE MONITORING

Post-market surveillance, which involves monitoring the safety and quality of medicines, medical devices and other healthcare products that have been authorised, licensed or registered for use in Ireland, is a primary function of the IMB. Our decisions in this area are always evidence based and are decided ultimately by the benefit / risk balance.

- Under our national pharmacovigilance programme, the IMB monitors adverse reaction reports to look for new types, or increased numbers, of adverse reactions. During the past year, the IMB received a total of 2,757 suspected adverse reaction reports in association with the use of human medicines, consistent with the reporting rates seen in 2011.
- Periodic safety update reports (PSURs) are a tool to monitor the ongoing safety of medicines. In 2012, the total output for PSURs was 3,372. This includes PSURs for national authorisations, mutual recognition, centralised and PSUR work-sharing procedures. The IMB continues to actively participate in the Heads of Medicines Agencies (HMA) PSUR work-sharing project and is ranked in the top eight of national competent authorities in Europe.
- The IMB also monitors the safety of veterinary medicines on an ongoing basis. There were 244 reports of suspected adverse events associated with the use of veterinary products received in 2012, an increase of 7% from 2011. PSURs for a total of 805 products were assessed.

- The IMB's reporting system for medical devices is intended to protect the health and safety of patients and other users of medical devices by monitoring adverse incident and correcting product problems. A total of 2,225 medical device vigilance reports were received and assessed in 2012. This figure represents a 25% increase on the previous 12 months. A total of 725 compliance cases were investigated in 2012.

Where necessary, the IMB will also implement or issue national recommendations to ensure the continued safe use of medicines. During 2012, two such recommendations were announced in respect of children's medicines.

- New dosage instructions for liquid paracetamol medicines for paediatric use were announced by the IMB in March 2012. The updated instructions provide more precise age and dosage bands so that children receive the most effective amount of medicine for their needs.
- In August, the IMB advised that children's herbal products containing Echinacea should not be used for children under 12 years of age due to a lack of scientific data to support their use.

The IMB is committed to ensuring industry compliance with relevant standards and legislation. Healthcare products manufactured or distributed in Ireland must meet essential quality standards and they must be advertised appropriately.

- A total of 289 national inspections and audits were carried out in comparison with 271 in 2011. A further 26 foreign inspections and audits were performed.
- During the past 12 months, 741 quality defects were reported to, or identified by, the IMB. This 19% annual decrease was the first year-on-year reduction in the number of quality defects recorded.
- In certain cases, so as to protect the health and safety of patients, it may be necessary to withdraw, or recall, products from the Irish market. During 2012, there were 141 medicine recalls of which 136 related to human medicines and five related to veterinary products.
- Where necessary, the IMB will take legal proceedings against those who breach medicinal product and medical device legislation. We initiated, or were party to, 11 prosecutions and court proceedings during the 12 months under review.

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

Colleagues from across the IMB were heavily involved in implementing, or preparing for the implementation of, new and updated European and national legislation. Such developments can have a significant impact on the functions and workload of our organisation.

- Throughout 2012, the IMB continued to work with a wide range of stakeholders in planning for and implementing provisions contained in the new European Union (EU) pharmacovigilance legislation. The aim of the new legislation is to enhance public health by strengthening the current European safety monitoring system for medicines.
- The European falsified medicines directive aims to strengthen the protection of patients and consumers by preventing falsified (counterfeit) medicines entering the legal supply chain. Preparations continued during 2012 for the introduction of parts of this directive which must be transposed nationally by January 2013. The remaining measures will be transposed at defined times thereafter.
- The Health (Pricing and Supply of Medical Goods) Bill 2012, which is due to be enacted and commenced in the first half of 2013, outlines the circumstances under which medicines are considered interchangeable (also often referred to as generic substitution) and where they are not considered interchangeable. Under the legislation, the IMB will be charged with responsibility for the establishment, consultation, publication and subsequent maintenance of a List of Interchangeable Medicinal Products. During 2012, the IMB actively supported the Department of Health in preparation for the implementation of this legislation. An internal project group was also established to plan for this additional IMB responsibility.
- The European Commission adopted proposals in 2012 to introduce two Regulations to strengthen the EU medical devices regulatory system and to standardise the application of rules throughout the EU. During 2012, the IMB continued to contribute to working groups and subgroups in the development of technical aspects of the regulatory system which may be reflected in the new legislative proposals.
- The European Directive on standards of quality and safety of human organs intended for transplantation (Directive 2010/53/EC) was transposed into Irish legislation in August 2012 and resulted in the appointment of the IMB and the HSE as the responsible Competent Authorities for the implementation of different aspects of the Directive. At the IMB, we are responsible for the inspection and authorisation of organ procurement and transplant centres and for the development of a system for reporting of serious adverse reactions and events. During the year, an internal multidisciplinary group continued to review the requirements of the directive from an IMB perspective and developed appropriate internal systems and procedures for implementation of these requirements.
- The IMB implemented a range of activities during 2012 in advance of becoming the competent authority responsible for the implementation of Directive 2010/63/EU on the protection of animals used for scientific purposes from 1 January 2013. This is significant and complex legislation intended to improve the welfare of animals used for scientific purposes and to promote the principles of the 3Rs (replacement, refinement and reduction). Among the primary functions of the IMB in respect of this legislation is the authorisation of establishments and the monitoring of animal welfare at establishments where animals used for scientific purposes are kept. Authorisations will also be required at project level and at individual level.

Participation in the European and International Regulatory Systems

The products regulated by the IMB are part of an ever-changing and developing international industry. Healthcare products manufactured here are used around the world while products manufactured elsewhere are used by Irish patients and consumers. As a result, the IMB is committed to playing its part in the global regulatory network to ensure that we represent and protect the interests of Irish patients and consumers.

Throughout 2012, our participation across the European medicines regulatory system continued to be significant. IMB scientific and technical staff again contributed to a broad range of committees and working parties at the European Medicines Agency, the European Commission, the Heads of Medicines Agencies (HMA) and via other platforms. The IMB also worked closely with relevant international organisations as necessary. Among the significant contributions and achievements from an IMB perspective during the past year include the following:

- In respect of human medicines, the Irish delegate to the European Medicines Agency's Pharmacovigilance Risk Assessment Committee (PRAC) was elected to the position of Vice-Chair of the committee for a 3-year period. The establishment of the PRAC was one of the main provisions of the new EU pharmacovigilance legislation which was transposed into Irish law in July 2012. IMB experts were also significantly involved in a joint project team, involving representatives from Member States and the European Medicines Agency, to support the implementation of the this new legislation.
- The IMB is a significant contributor to the Benchmarking of European Medicines Agencies (BEMA) steering group of the HMA of which I am co-chair. During 2012, we continued to lead the steering group as preparations for the third cycle were finalised and the first visits began.
- The IMB Pharmacovigilance Manager (human medicines) continued to represent the World Health Organization (WHO) as a member of the Board of the Uppsala Monitoring Centre (UMC) and WHO Collaborating Centre for International Drug Monitoring.
- At the start of the year, the IMB Inspection Manager took up her appointment to the Executive Bureau (management group) of the Pharmaceutical Inspection Co-operation Scheme (PIC/S).
- With regard to the proposed new legislation for veterinary medicinal products, the IMB was an active contributor to the preparatory workshops which were held by the European Commission during the summer of 2012.
- The IMB welcomed the establishment in 2012 by the European Commission of maximum residue limits (MRLs) for certain flukicidal veterinary medicines used in milk producing animals. This action followed a specific request from the IMB to the European Medicines Agency to provide a more suitable reference level for residue monitoring purposes.
- In early 2012, the European Commissioner for Health and Consumers wrote to all European Ministers for Health outlining a 'joint plan of immediate actions' focused on reinforcing the existing regulatory system for medical devices. The plan outlined actions for Member States and the Commission in respect of the functioning of notified bodies, market surveillance, coordination, communication and transparency. The most significant work items arising from the joint plan during 2012 for the IMB included a review of class III notified bodies for medical devices, and analysis and communication of resource and activities relevant to market surveillance of medical devices. In addition, significant input was provided to the preparation of an implementing Regulation and a Commission recommendation on notified bodies for medical devices in advance of the plan's deadline.

- The IMB continued to engage actively during 2012 in discussions with other European competent authorities, the European Commission and relevant stakeholders on how to optimise resourcing of the network for medical device regulation in Europe. The IMB also continued to promote discussions during the year on enhancing cooperation and partnership between the HMA and the Competent Authorities for Medical Devices (CAMD).

STAKEHOLDER ENGAGEMENT AND COMMUNICATIONS

A core strategic goal of the IMB is to ensure that all our stakeholders have access to relevant and timely safety, licensing and regulatory information. As well as our regular meetings and ongoing publication of safety and regulatory updates, newsletters and guidance documents, a number of additional engagement and communications initiatives were progressed during 2012.

Consultative Panel on the Legal Classification of Human Medicines

Established in 2011, the Consultative Panel on the Legal Classification of medicines held quarterly meetings during the past year. The aim of the independently chaired panel is to assist in developing the debate on policies in the area of legal classification of human medicines. It consists of external representatives drawn from a wide range of interested stakeholders including patients, healthcare professionals, the Department of Health and relevant government agencies. During 2012, each representative was invited to present their views and perspectives to the panel. The final meeting of the panel was planned for early 2013 and it is anticipated that a report on its deliberations will be finalised later in the year.

Events

- IMB information days and seminars provide regulatory guidance and updates to a range of stakeholders. These events also afford attendees the opportunity to submit questions, seek clarifications and network with colleagues. In late September 2012, a GMP / market compliance information day and a wholesale distribution information day were both held. A clinical trials information seminar for academic sponsors and investigators was also held in June 2012. Additionally, a training seminar for distributors of cosmetic products was held in March.
- In October 2012, the IMB co-hosted The Organisation for Professionals in Regulatory Affairs (TOPRA) annual symposium which was held in University College Dublin. The event brought together over 600 representatives of regulatory agencies, industry and the European Commission to review and discuss current regulatory issues and to debate future planned developments.
- The IMB and the Parenteral Drug Association (PDA) Ireland Chapter hosted a major two day scientific gathering entitled Making Gene and Cell Therapy Medicines a Reality in July 2012. The two day event was organised as a satellite event to the EuroScience Open Forum (ESOF2012).
- For the third year in succession, 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 in mid-January in the RDS.

Drug Safety Newsletter: 50th Edition

The IMB's Drug Safety Newsletter provides safety updates to doctors, dentists and pharmacists. A special 50th edition, which highlighted the changes arising from the revised pharmacovigilance legislation, was published in November. Additionally, an information leaflet for patients and consumers on the safety monitoring of medicines in the context of the revised legislative framework was also distributed to patient organisations and published on the IMB website.

Website

The IMB website 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. More 171,000 unique visitors accessed the website during the past twelve months representing an annual increase of 36%.

Media Relations

We continued to progress our proactive media communications programme to highlight important safety messages and to build awareness of the role of the IMB. In total, we issued 38 press releases concerning safety and regulatory issues and responded to 532 queries from different media sources during the year.

DEVELOPING ORGANISATIONAL CAPABILITY

It is essential that the IMB continues to build our organisational capabilities in response to scientific, technological and regulatory changes. In particular, we are committed to ensuring that we have the necessary structures, systems and supports in place to deliver on our public health remit.

Staff Developments

It is vitally important that the IMB has the human resources in place to fulfil all our functions for the benefit of our many 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. Following consideration of the report by the Department, I am pleased to report that in 2012 we were able to successfully recruit new specialist staff for those areas of additional competencies.

Also during the year, we continued with the operation of the IMB's first leadership development programme. The eight participants in the programme engaged in a range of activities throughout the year and this initial course will conclude early in 2013. The feedback from the participants, their managers and all others involved in the programme has been hugely positive. I am delighted to report that the quality of the programme has also been recognised externally with accreditation from the Institute of Leadership and Management (ILM) achieved in late 2012.

Information Technology and Change Management

Work progressed during the past year on the delivery of the IMB's IT Strategy (2011 to 2015) which focuses on the delivery of a range of technologies to support the management of core IMB activities. The range of new and enhanced requirements identified in the strategy highlight the growing dependence on information technology in delivering services to stakeholders.

Also during 2012, as part of the IMB's contribution to the wider European regulatory network, we continued our development of the Common European Submission Portal (CESP). Our lead role in this project now means that multiple Member States are utilising the services of the IMB to manage the secure delivery of medicines data. During the Irish EU Presidency, over 20 Member States are scheduled to formally agree a three year contract with the IMB in respect of CESP usage.

The IMB has a long held commitment to change management and continuous improvement. This was further evidenced by the establishment of an organisational project management office (PMO) in 2012 to support project prioritisation, ensure consistency with organisational objectives and to develop consistent control mechanisms. The PMO is already supporting a range of key IMB regulatory, organisational and technology programmes.

Financial Performance

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 2012 to successfully manage the affairs of the IMB in line with our statutory obligation that income at least meets costs. The IMB is largely self-funded by a system of fees which are approved annually by the Minister for Health following an annual public consultation process. This approach to funding is similar to the model employed by other healthcare products regulators globally.

THE FUTURE

It is clear that 2013 will be another busy year for the IMB and will present both challenges and opportunities. Our focus will remain the promotion and protection of public and animal health. We will continue to enhance both our pre and post market activities for all products under our remit. We will respond to regulatory developments, communicate openly with stakeholders, and further progress our vision of a modern and efficient organisation.

A significant event in 2013 for the IMB will be Ireland's Presidency of the Council of European Union. We will have the honour of hosting over 20 informal meetings of our regulatory peers from across the member states, European Medicines Agency and European Commission in the various areas we regulate. We intend making substantial progress in the organisation of the medical devices competent authorities, indeed the regulation of medical devices will receive enhanced input as we respond to the joint plan of immediate actions and to the real need to improve this system for the benefit of patients and consumers. We also plan to host the first joint meeting of the CHMP, CMDh and PRAC with a view to enhancing understanding of their respective roles and how they must collaborate to the benefit of patients.

ACKNOWLEDGEMENTS

On my own behalf and on behalf of the IMB management team and staff, I would like to thank our Chairman, the Board members and all members of the IMB's advisory committees. Their contributions are of immense value and critical to the effective performance of our organisation.

The ability of the IMB to deliver on our broad and expanding role is of course dependent on the huge contribution of all staff. While we are operating in times of some uncertainty and increasing demands, my colleagues have demonstrated great versatility, adaptability, resilience and professionalism for which I thank them all.

Finally, I would like to thank and acknowledge the continued support during 2012 of the Ministers and staff of the Department of Health and the Department of Agriculture, Food and the Marine.

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 functions 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 licenses the manufacturers and wholesalers of human medicines and the manufacturers of veterinary medicines. The IMB also licenses blood and tissue establishments and, since August 2012, is a competent authority in respect of the quality and safety of human organs intended for transplantation. In addition, the IMB is responsible for issuing export certificates and we provide a borderline product classification service.

HUMAN MEDICINES

BORDERLINE PRODUCT CLASSIFICATION

The IMB 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.

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 2012, 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 144 new products were considered consisting of 127 internal applications and 17 external applications. In addition, there were 22 products revisited from pre-2012.

The accompanying table outlines the numbers of classification queries for 2012 compared with previous years. Queries are generally evaluated within the normal 28 day timeframe and written explanations of the outcome are provided.

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.

Number of Applications Received		**2009**	**2010**	**2011**	**2012**
Source	Internal	114	72	132	127
	External	17	33	21	17
Classification Outcome	Medicinal Product	88	63	88	91
	Medical Device	4	4	9	6
	Food Product	13	24	36	26
	Cosmetic Product	3	6	4	10
	Biocide			2	1
	Pending	21	7	12	6
	Other	2	1	2	4
	Total	**131**	**105**	**153**	**144**

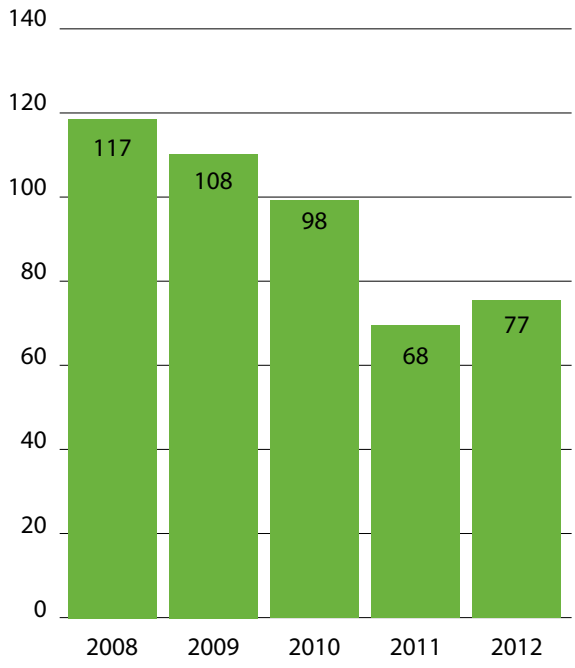
CLINICAL TRIALS

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

In 2012, 77 new clinical trials were approved to commence in Ireland representing a 13% increase compared to 2011. While this increase is encouraging, overall there continues to be a general decline in clinical trial activity across the European Union. As in previous years, the majority of clinical trials were authorised for the treatment of cancer (38%) and haematology indications (21%).

The European Commission is proposing new legislation in an effort to increase the number of clinical trials being carried out in Europe. The IMB contributed to the consultation process surrounding these new proposals during 2012.

Clinical Trials Approved 2008 - 2012



Voluntary Harmonisation Procedures

The IMB participated in five voluntary harmonisation procedures (VHP) during 2012 and acted as Rapporteur, or the lead Member State, for the assessment of the clinical trial application in one of these procedures. A VHP is a co-ordinated work sharing assessment procedure for multinational clinical trials. This procedure was established by the Clinical Trials Facilitation Group of the HMA.

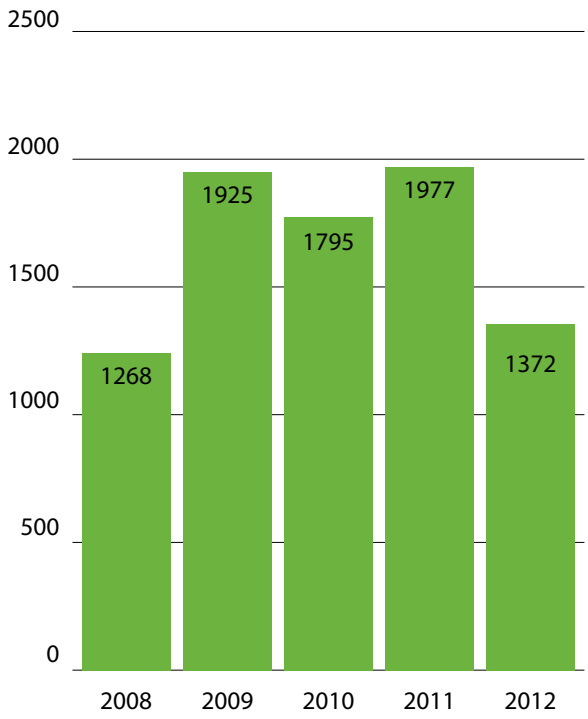
NEW MARKETING AUTHORISATION APPLICATIONS

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. Licences granted by the IMB result from companies submitting either new national applications or applications via the mutual recognition procedure (MRP) and the decentralised procedure (DCP). Both MRP and DCP applications involve the input of a number of national European competent authorities with one country acting as the reference member state while the other countries involved are known as the concerned member states. Details of the IMB's contribution to this process as a RMS are outlined on page 19.

During 2012, the IMB continued to assess all new product applications received with regard to safety and efficacy. Where the IMB assessment team establish that a medicines public health benefits outweigh its known risks, it is granted a marketing authorisation.

The number of new product applications assessed by the IMB in 2012 was 1,372. This included 279 new national applications, including both parallel product authorisations and dual pack import registrations, as well as 92 new MRP and 532 new DCP applications. There were 184 new centralised applications and 285 transfer applications.

Total Output for New Applications 2008 - 2012



The number of submissions of new parallel product authorisations applications has been declining since its peak in 2009. There was almost a 40% drop in these applications in 2012 compared to the previous 12 month period. In addition, there was a 21% decrease in new decentralised procedures reflecting the known trend in Europe.

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. In the past year, the IMB issued 17,153 variations to marketing authorisations for products authorised through the national or MR procedures. The 11% annual increase in variations applications was mostly in the Type IA notifications (those not requiring immediate notification).

RENEWALS

In 2012, 650 renewals to marketing authorisations for products authorised through the national or MR procedures were processed. This reduction of 15% compared to 2011 reflects the lifecycle of the products in question as marketing authorisations are valid for five years from the date of first issue. For the authorisation to remain valid, it must then be renewed at the end of this five year period.

IMB AS RAPPORTEUR/CO-RAPPORTEUR

The IMB was allocated as lead assessor (Rapporteur) or joint lead assessor (Co-Rapporteur) for 10 new marketing authorisations 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 application types included respiratory, radiocontrast agent (ECHO), treatment of inborn errors of bile acid metabolism, alcohol dependence, IVF media and lysosomal storage disease.

Companies may also seek scientific advice from the CHMP. During 2012, the IMB acted as Rapporteur for 26 scientific advice procedures for medicines proposed for the treatment of a broad range of conditions. Areas of focus included respiratory medicine, diabetes mellitus and musculo-skeletal conditions.

IMB AS REFERENCE MEMBER STATE

In certain circumstances, companies can apply for the simultaneous authorisation of a medicine in more than one EU country. As outlined, 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 throughout 2012 and completed 12 new marketing authorisations via the MR procedure with Ireland as the RMS.

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 with the IMB designated as the national Competent Authority for the implementation of the legislation. On this basis, the IMB established the traditional herbal medicinal products registration scheme. The registration is a simplified procedure which takes into account the "traditional use" of these products.

At national level, registration requirements have applied to new products coming onto the market since 2007. With the ending of a transitional protection period in April 2011, registration requirements now apply to all products on the marketplace. Since then, the number of applications received by IMB has remained disappointingly low. In total, 61 applications had been received under the scheme by the end of 2012 and 10 products had been registered by the IMB. During the past year, the IMB focus was on progressing assessment of the applications received thus far. As a result, a significant number were progressed to an advanced stage of assessment with completed registration expect during 2013.

HOMEOPATHIC MEDICINES

There are two registration schemes which apply to homeopathic medicines. The Simplified Rules Scheme (SRS) applies to products marketed without indications. The National Rules Scheme (NRS) applies to products marketed with indications.

In 2012, the three new applications received under the Simplified Rules Scheme were completed and registrations issued. During this period, two homeopathic variations, the first under scheme, were received and processed. In total, 80 homeopathic medicinal products have been registered under the Simplified Rules Scheme to date.

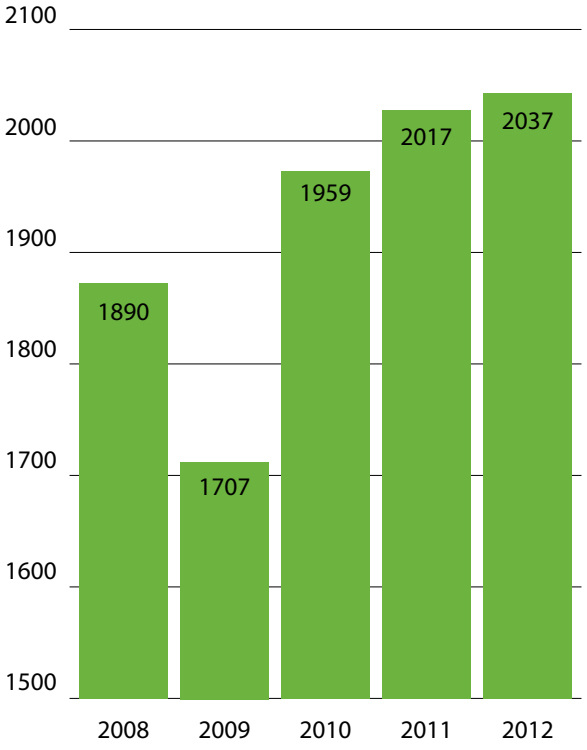
A legislative deadline of 31 May was put in place for receipt of applications under the National Rules Scheme enabling products to remain on the Irish market as long as an application under the NRS was submitted to the IMB. In total, nine applications were received and assessment is on-going.

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, licensing activity increased marginally as outlined in the following table.

Controlled Drugs Licensing Activity 2008 - 2012



VETERINARY MEDICINES

In the conduct of its veterinary medicines licensing activities, 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 veterinary 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 potential impact of new veterinary medicines on the environment.

PRODUCT CLASSIFICATION REQUESTS

The IMB provides a service to stakeholders to assist in clarifying whether a product falls within the scope of medicines legislation and thus should be categorised as a veterinary medicinal product. Such products fall under the remit of the IMB and are distinct from other products which may be regulated by the Department of Agriculture, Food and the Marine such as biocides and feeding stuffs.

During 2012, 74 product classification queries were received in respect of veterinary medicines. There were 70 responses issued which related to queries received both during, and prior to, 2012.

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 in animals. The Department is the Competent Authority for licensing of these trials. 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 design and conduct of the proposed study.

During 2012, three clinical trial applications were received by the IMB and issued to the Department. All were assessed and issued within clinical trial set timelines.

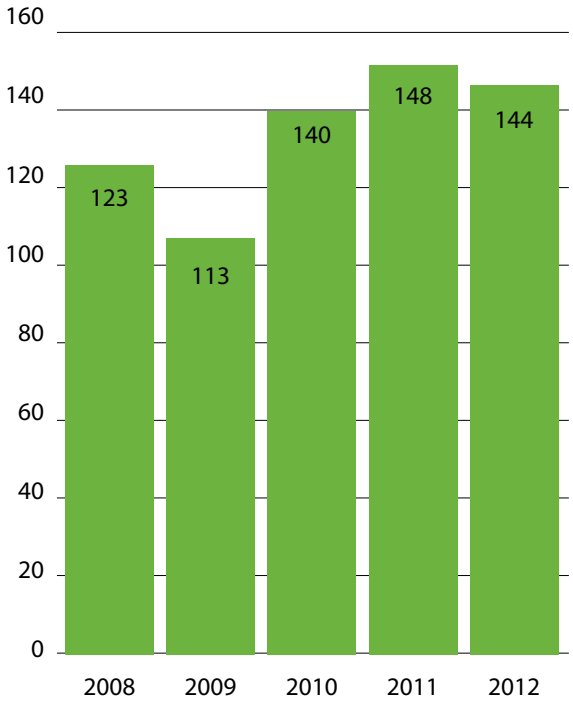
NEW APPLICATIONS

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, is generally dependent on the type of product in question and/or the choice of the marketing authorisation holder.

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 practitioners, pharmacists and other scientists will then review the dossier to establish if the medicine's benefits, including animal and public health where relevant, outweigh its known risks.

During 2012, the number of new product applications received by the IMB was 185 of which 18 were purely national applications. This equates to a 20% increase in new products received for assessment compared to 2011. We assessed and approved 144 applications, including 11 new national licences. This figure has remained constant over the last number of years. The number of MRP and DCP licenses issued was 107 while 127 such applications were received. The MRP and DCP figures included both applications where Ireland was the reference member state as well as those where it was a concerned member state. (See also 'IMB as Reference Member State' below).

Total Output for New Applicants 2008-2012



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 the year in review, the IMB approved 1,242 variations to authorisations granted through the national, MR or centralised procedures while 1,251 variations applications were received. These figures were broadly similar to the previous 12 month period.

RENEWALS

New 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 2012, 58 renewals to marketing authorisations for veterinary medicinal products authorised through the national or MR procedures were received while 66 were issued. This issued figure is a 47% decrease compared to 2011. The continuous decrease can be explained by the change in legislation where normally only one renewal of a marketing authorisation is now required after five years instead of one every five years.

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 2012, the IMB acted as the rapporteur or co-rapporteur for 16 centralised procedures (including extension applications) up from nine in 2011. 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 42 new marketing authorisations as the reference member state, 41 of these through the decentralised procedure.

WORK-IN-PROGRESS APPLICATIONS

The overall work-in-progress at the end of the year was 831 units (made up of various application types).

MEDICAL DEVICES

CLASSIFICATION REQUESTS

European legislation provides for the categorisation of medical devices into four different classes ranging from low risk to high risk. 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.

The IMB received 56 applications for the classification of medical devices or products queried as medical devices. Of these queries, 55% were received from other medical device competent authorities in Europe and related to complex classification questions or where a consensus was sought on the classification of a particular product. Of the remaining queries, 2% were received from notified bodies, 18% were received from other external stakeholders, such as medical device manufacturers or distributors, and 25% were received by other departments within IMB.

CLINICAL INVESTIGATION APPLICATIONS

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.

The IMB received one application for a clinical investigation of a novel medical device to be conducted in Ireland in 2012. In addition, one amendment to an ongoing clinical investigation was received.

The number of clinical investigations of medical devices ongoing in Ireland remains at a very low level. The last revision of the European medical devices legislation, Directive 2007/47/EC, put greater emphasis on the conduct of clinical investigations. However, the anticipated increase in clinical investigation activity has not been seen in Ireland. Several European authorities, including the IMB, have suggested that further analysis be conducted at European level to review recent legislative revisions.

The IMB continues to raise awareness of clinical investigation processes and requirements at relevant national and international conferences, meetings and directly with interested stakeholders. It is worth noting that the medical device legislation in Europe only requires application/notification to the IMB of pre-market clinical investigations from medical device manufacturers. Other types of clinical research involving medical devices are not required to be notified under national or European legislation, so the number of research applications received by IMB may not necessarily be indicative of the clinical research of medical devices in Ireland.

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.

There was significant attention at European level on medical device notified bodies during 2012. The European Commission's joint action plan for immediate actions compiled in February required all European competent authorities to review notified bodies for class III medical devices based in their territory.

Therefore, in addition to our normal designation and monitoring activities, the IMB completed a review in September 2012 of the NSAI as a notified body for class III medical devices.

Normal scheduled designation and monitoring activities were realigned during the year as a result of the additional requirements of the joint action plan. As part of its normal surveillance activities, the IMB conducted a surveillance audit of the NSAI's Dublin headquarters in October 2012.

The IMB received 148 certification notifications, including certificate issuance, modification and withdrawal, during 2012 which were then uploaded to the European database (EUDAMED) as required.

PRODUCT REGISTRATIONS

The IMB received 388 notifications of medical devices to the medical device register during the past year. These relate to class I, in-vitro diagnostic and custom made medical devices and to system and procedure packs. Registration of these devices in the Member State in which the manufacturer or their authorised representative is based is required by legislation and there is a self-declaration of conformity made by the manufacturer. During the 12 months under review, 48 organisations registered with the IMB as Irish based manufacturers or authorised representatives of these types of medical devices.

The IMB completed a review of registered organisations in 2012 to ensure that registered details were correct and up-to-date. Of the organisations registered with the IMB, 32% required amendment or update to their registration details while 22% of organisations withdrew or were removed from the register. A further 14% require further follow up surveillance.

A new IMB extranet registration system became operational in August 2012. The update to this system was in response to the European Commission's further development of EUDAMED which captures registration information from national competent authorities.

COSMETIC PRODUCTS

PRODUCT NOTIFICATIONS

Manufacturers, importers and persons acting on their behalf who have responsibility for placing cosmetic products onto the EU market are required to notify such placement. This can be done either nationally, to the IMB and counterparts in other member states or, since January 2012, via the European Commission's Cosmetic Product Notification Portal (CPNP). This centralised portal will replace national notification requirements from July 2013.

In 2012, the IMB received 1,050 cosmetic product notifications. The three most common notification categories were:

- Make-up products and make-up (21%);
- Lip products (21%);
- Creams, emulsions, lotions, gels and oils (18%).

AUTHORISATION/LICENSING OF SITES AND FACILITIES

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

Such sites and facilities are required to be authorised or licensed by the IMB for the activities which they carry out. The authorisation is based on satisfactory outcomes to IMB inspections (see also the Safety Monitoring and Surveillance section of this report) during which adherence to relevant European guidance is evaluated.

The total number of authorisations/licences in force at year end is presented below by category. The figures for 2012 remained broadly stable.

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 was an output of 3,646 export certificates in 2012 as set out in the accompanying table:

Total Number of Licences/Authorisations (Sites)	**2008**	**2009**	**2010**	**2011**	**2012**
Manufacturers of Medicines for Human Use	86	85	86	88	87
Manufacturers of Veterinary Medicines	26	25	27	24	23
Investigational Medicinal Products for Human Use	45	50	51	50	47
Wholesalers of Medicines for Human use	214	209	220	243	258
Blood Establishments	6	5	4	4	3
Tissue Establishments	6	13	16	22	21
Laboratory Approvals	11	13	16	16	17
Total	**394**	**400**	**420**	**447**	**456**

Product Certification Activity	**2008**	**2009**	**2010**	**2011**	**2012**
Certification of Documents	266	235	234	239	272
Certificates of Good Manufacturing Practice for Active Substance & Finished Product Manufacturers	254	269	255	272	276
Certificates for Medicinal Products	1295	964	1200	1416	1350
Medical Device Free Sale Certificates	434	977	2142	1780	1522
Cosmetic Products Free Sale Certificates	N/A	N/A	174*	388	210
Other	61	56	28	51	16
Total	**2310**	**2501**	**4033**	**4146**	**3646**

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

SAFETY AND COMPLIANCE MONITORING

Post-market surveillance, which refers to the safety monitoring of medicines, medical devices and other healthcare products that have been authorised, licensed or registered for use in Ireland, 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, distributed or 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 (MAH). 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. We assess such reports and trends in co-operation with pharmacovigilance professionals across Europe and further afield. Where the overall benefit/risk profile of a medicine appears to be impacted, consideration is given as to how any new risks should best be managed and communicated to healthcare professionals and patients.

During 2012, the IMB received a total of 2,757 suspected adverse reaction reports in association with the use of human medicines, consistent with the reporting rates seen in 2011.

Individual case reports were followed up by the IMB, with feedback information provided to reporters as appropriate. Serious, suspected cases notified directly to the IMB by healthcare professionals were appropriately forwarded to relevant stakeholders, including the European Medicines Agency and marketing authorisation holders within the agreed timeframes and formats.

Source of Suspected Adverse Reaction Reports	**%**
Marketing Pharmaceutical Company	69
Community Care Doctor	8
Hospital Doctor	5
General Practitioner	5
Hospital Pharmacist	4
Community Pharmacist	4
Hospital Nurse	2
Patient/Consumer	2
Community Nurse	1
Haemovigilance Officer	<1
Health Sector - Other	<1

In addition to the initial reports outlined earlier, the IMB also received and processed some 2,744 follow up reports during the year.

Online Reporting

The online reporting system, available to healthcare professionals, patients and other members of the public, accounted for 12% (335) of all reports received during 2012. Access to the online reporting system is available through the IMB website at www.imb.ie.

By the end of the year, some 324 companies were operational with electronic reporting to the IMB, an increase on the 288 companies reporting electronically in 2011.

During 2012, the IMB continued to report all suspected serious adverse reactions occurring in Ireland electronically via EudraVigilance to the European Medicines Agency.

Monitoring Compliance with Pharmacovigilance Obligations

Company/sponsor compliance with pharmacovigilance obligations is monitored on an ongoing basis through:

- Review of the timeliness and quality of individual adverse reaction reports;
- Evaluation of follow-up information provided for individual reports; and
- Assessment of responses to IMB requests for pharmacovigilance data.

Issues identified in relation to compliance 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 2012, jointly carried out by IMB pharmacovigilance and compliance colleagues. The pharmacovigilance team participated in two inspections during the year.

At a European level, the IMB continued to contribute to the Pharmacovigilance Inspectors Working Group in relation to the revised pharmacovigilance legislation and to the development of Good Vigilance Practice (GVP) guidance for pharmacovigilance systems requirements and inspections.

VIGILANCE ASSESSMENT

Vigilance assessment activities encompass particular aspects of benefit-risk management of medicines throughout the product lifecycle and include the evaluation of periodic safety update reports (PSURs), risk management plans (RMPs) and protocols and results relating to post-authorisation safety studies. Post market evaluations undertaken also include referrals on issues of safety or benefit-risk balance to the European Medicines Agency, assessment and approval of Direct Healthcare Professional Communications issued by MAHs, and signal management.

During 2012, the IMB worked with a wide range of stakeholders including the European Medicines Agency and other national competent authorities to ensure the successful and timely implementation of new and updated assessment procedures introduced under the legal framework of the new pharmacovigilance legislation which came into effect throughout the EU in July 2012 (see page 51 for further information).

Pharmacovigilance Working Party Assessments

During the first half of 2012, the IMB provided active representation to the CHMP Pharmacovigilance Working Party and its drafting groups at the European Medicines Agency. During this period, 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 working party held its final meeting in July 2012 following

the establishment of the Pharmacovigilance Risk Assessment Committee (PRAC). Dr. Almath Spooner, the IMB delegate to the PRAC, was elected vice-chairperson of the committee for a three year period at its first meeting.

During 2012, 468 safety variations were assessed and concluded by the IMB and these included variations to implement the following CHMP Pharmacovigilance Working Party recommendations for nationally authorised products:

- Risedronate and the risk of oesophageal cancer;
- Levodopa, dopamine agonist and COMT inhibitor products and risk of impulse control disorders (ICDs);
- Risk of allopurinol-induced serious cutaneous adverse reactions – association in patients who are carriers of the HLA-B*5801 allele;
- Tramadol and the risk of convulsion, serotonin syndrome, suicide and posology in the elderly and in patients with renal or hepatic impairment;
- Inconsistency in product information of prazepam-containing medicinal products regarding contra-indication in glaucoma;
- Association of oxcarbazepine with risk of hypersensitivity adverse drug reactions potentially associated with HLA-A*3101 allele;
- Risk of carbamazepine-induced cutaneous reactions – association with HLA-A*3101 allele in European and Japanese patients and update of recommendation on testing for HLA-B*1502 allele in some Asian populations;
- Paracetamol, solution for infusion (MRP Perfalgan (FR) and generic products) and risk of accidental overdosing of neonates and infants, due to medication errors following confusion between mg and ml, and underweight adults;
- Fluoroquinolones and risk of QT-interval prolongation;
- Selective serotonin reuptake inhibitors (SSRIs) (fluvoxamine, citalopram, escitalopram, fluoxetine and sertraline, paroxetine) and possible risk of male infertility due to sperm impairment.

Periodic Safety Update Reports

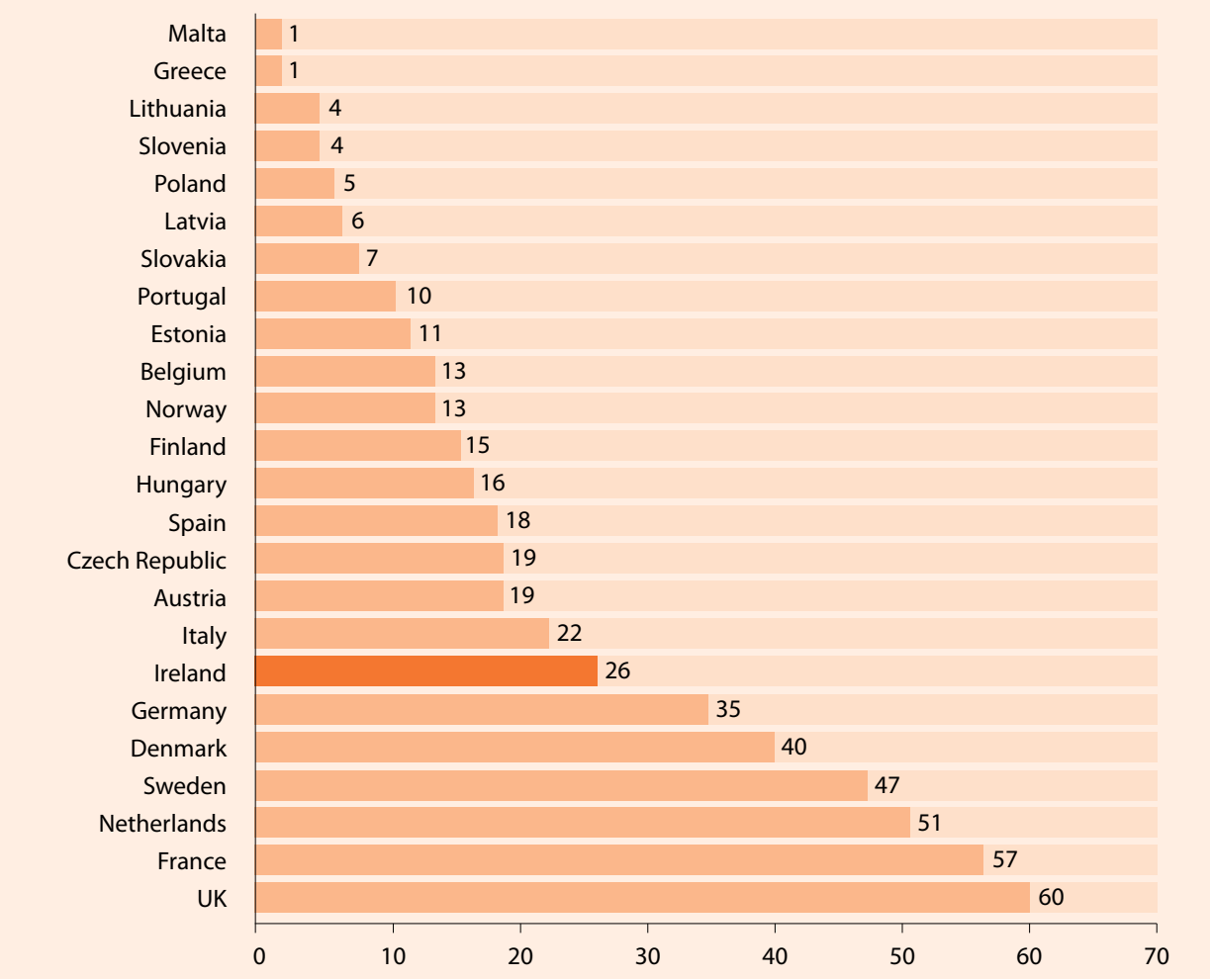
Periodic safety update reports (PSURs) are intended to provide an update of the worldwide safety experience of a medicine to competent authorities at defined time points following the authorisation of the medicine and are a tool to monitor the ongoing safety of medicines. PSURs are evaluated either by the IMB or by other EU medicines agencies operating a work-sharing system.

As a result of the new EU pharmacovigilance legislation, the format and content of PSURs are changing and the extent of the evaluation will integrate cumulative information on both the benefits and risks. The link to risk management is also strengthened. The assessment procedure involving the Pharmacovigilance Risk Assessment Committee (PRAC) at the European Medicines Agency commenced for PSURs for centrally authorised products during 2012 and may result in automatic regulatory action such as variation, suspension or revocation.

During 2012, the total output for PSURs was 3,372. This includes PSURs for national authorisations, mutual recognition, centralised and PSUR work-sharing procedures. Since July, a PSUR submission has been based on a risk based approach and submission is no longer routinely required for certain types of medicinal products such as the majority of products authorised as generics.

The IMB continues to actively participate in the HMA PSUR work-sharing project and is ranked in the top seven of national competent authorities in Europe in terms of lead MS assessment responsibilities.

P-RMS allocation



Risk Management Plans

The Risk Management Plan (RMP) describes what is known and not known about the side effects of a medicine and states how these risks may be prevented or minimised in patients. It also includes plans for studies and other activities to gain more knowledge about the safety of the medicine and the risk factors for developing side effects. RMPs are continually modified and updated throughout the lifetime of the medicine as new information becomes available.

Since July 2012, all new marketing authorisation applications require an RMP as part of the initial submission for approval. New guidance documents regarding the format and content of RMPs were published during the year.

The total number of RMPs assessed during 2012 was 331 which consisted of both incoming and outgoing centralised applications. There were also 32 follow-up measures which included assessment of the results of post authorisation safety studies. Some 34 Direct Healthcare Professional Communications, which provided new safety information or risk minimisation advice, were approved. In addition, 50 risk minimisation plans were assessed including risk minimisation tools for healthcare professionals and patients to support the safe and effective use of particular medicines.

Signal Management

A safety signal is information on a new or incompletely documented adverse event that is potentially caused by a medicine and that warrants further investigation. Signals are generated from several sources such as spontaneous reports, clinical studies and the scientific literature. Signal management is the process whereby new risks associated with a medicine or significant changes to known risks can be detected, confirmed, analysed and prioritised for review. This process may ultimately lead to a recommendation for regulatory action at a European level.

During 2012, the IMB implemented new procedures and processes for signal detection and management including work-sharing for signal detection within the EU. The IMB provides the lead in management of signals for 59 active substances which are nationally authorised within the EU and also assesses signals for 21 centrally authorised products for which Ireland is rapporteur.

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 2012 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;
- Options to facilitate simultaneous, dual submission of mandatory reports to 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 EU Commission during 2012. The report reflected information received from January to December 2011 and included information on 129 serious adverse reactions and 157 serious adverse events which met the mandatory legislative reporting requirements. These figures represent a decrease of approximately 15% for serious adverse reaction reports and an increase of approximately 30% for serious adverse event reports when compared with the previous year. These trends were not unexpected and are consistent with the impact of changes to agreed EU reporting criteria.

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 first convened in 2007. During 2012, the IMB attended a meeting of this group and, in collaboration with colleagues from the NHO, actively contributed to the development of updated guidance.

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 during 2012 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 primary aim of the project 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 was the lead partner for one of the work packages, with responsibility for organising training courses on the investigation and management of vigilance and surveillance for tissues and cells. In 2012, this training was provided in the form of two training courses with each comprising a four week e-learning module followed by a two-day interactive residential module.

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 EU Commission during 2012. The report reflected information received from January to December 2011 and consisted of some 47 reports associated with use of tissues and cells, 43 of which met the legislative reporting requirements. These 43 reports included six serious adverse reactions (three in 2011) and 37 serious adverse events (24 in 2011). The remaining four donor reaction reports, while not fulfilling the mandatory reporting requirements, were included on a voluntary basis as requested by the Commission.

The EU Commission continued to progress harmonisation initiatives to develop a common approach to the provision of data by member states through a working group on tissues and cells vigilance. During 2012, the IMB continued to participate in the development of guidance for reporting which was further updated during the year.

VETERINARY MEDICINES

PHARMACOVIGILANCE

Effective reporting is central to a successful and robust pharmacovigilance scheme. During 2012, there were 244 reports of suspected adverse events associated with the use of veterinary medicinal products received by the IMB. This represents an increase of 7% compared to the number of reports received in 2011.

The breakdown of the 244 reports is as follows:

- 117 related to suspected adverse reactions in treated animals;
- 116 related to suspected lack of expected efficacy;
- 10 involved suspected adverse reactions in individual users following exposure to a veterinary medicinal product;
- 1 related to a violation of an approved residue limit in foodstuffs of animal origin.

Periodic Safety Update Reports

PSURs are intended to provide an update of the worldwide safety experience of a medicine. In 2012, PSURs for a total of 805 products were assessed. This represents a 44% increase on the number of PSURs assessed in 2011.

Inspections of Pharmacovigilance Systems

The IMB conducted one inspection of a pharmacovigilance system at a marketing authorisation holder's premises during 2012. In addition, we participated in one inspection in another EU member state 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 88.4 tonnes. This figure compares favourably with 93.2 tonnes in 2010 and 91.1 tonnes in 2009.

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.

QUALITY DEFECTS AND RECALLS

The quality defect and recall 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. Recalls from the Irish market are also co-ordinated under this programme.

Number and Type of Quality Defects

During the past 12 months, 741 quality defects were reported to, or identified by, the IMB. This represents a 19% decrease on the 2011 figure. This first annual reduction in the number of quality defects was likely due to the fact that there were fewer multiple product defect investigations.

Human medicines accounted for 703 quality defects with 38 relating to veterinary medicines. Of the total number of defects, 74% 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.

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

Types of Quality Defects	Human Quality Defects	Veterinary Quality Defects
Stability	88	14
Non-Compliance with MA	80	3
Contamination Issue	74	2
SPC/Carton/Label/Leaflet	73	3
Non-Compliance with Spec	62	8
Other	49	1
Other Packaging Component	48	0
Undeclared Active	39	0
Non-compliance with GMP	36	1
Product Prep / Admin Issue	34	0
Product Mix-Up	28	0
Unlicensed Product	20	0
Damaged Product	16	0
Falsified Medicine Issue	16	0
Lack of Sterility Assurance	14	3
Erroneous Distribution	8	1
Adverse Reaction / Change in Risk - Benefit	8	1
Lack of Efficacy	6	1
Cold Chain Issue	4	0

Comparisons with the quality defect data from 2011 show that:

- Good Manufacturing Practice (GMP) non-compliances increased by 54%. This was in part due to individual non-compliance issues identified at manufacturing facilities in Italy and India;
- Of the 83 cases pertaining to marketing authorisation non-compliances, 47 (57%) related to the non-implementation of variations within the agreed timeframe. Other MA non-compliances included assignment of erroneous expiry dates, sourcing of active substances from non-registered suppliers and non-compliances with Braille requirements;
- Cold chain issues decreased significantly by 95%. A single significant issue had affected 65 products in 2011;
- Damaged product issues decreased by 75%. A single significant issue had affected 38 products in 2011;
- There was a decrease of 51% in reports related to non-printed packaging components.

The below table illustrates the breakdown of quality defects by classification over the past five years.

Type of Defect	2008	2009	2010	2011	2012
Minor Quality Defects	105	147	241	314	236
Major Quality Defects	299	345	332	364	303
Critical Quality Defects	127	105	173	231	189
Number of Quality Defect Reports Not Justified	23	17	5	8	13
Total Number of Quality Defects	**554**	**614**	**751**	**917**	**741**

Critical quality defects, which are those defects defined as potentially life-threatening or a serious risk to health, accounted for 189 of the total defects recorded. Of these, 59 were determined to affect Ireland.

A breakdown of the Irish market data shows that 23 defects related to an unlabelled unit which was unaccounted for during a compounding campaign at an Irish facility. A further nine defects were associated with falsified medicines. While the genuine products were manufactured in Ireland in eight of these cases, none of the related falsified products were identified on the Irish market. The remaining case related to the presence of a possible falsified product within the Irish distribution chain. However, IMB investigations concluded that the product was genuine. Other critical quality defect cases included product mix-up, breaches of cold chain, non-compliance with specifications and damaged products.

Sources of Quality Defect Reports

While as in previous years, companies accounted for the majority of reports of quality defects received (54%), there was a year-on-year reduction of 22% in the number of reports from this source. The reduction in this reporting category can be partly attributed to a revision of the IMB Guide to Reporting Quality Defects which provided further guidance for industry stakeholders on which types of quality defects are reportable / non-reportable.

Source	Human Medicines Reports	Veterinary Medicines Reports
Companies (Manufacturers, Distributors and/or MA Holders)	398	16
Other Competent Authorities	199	17
Hospital Pharmacists	35	
IMB Staff Members	35	3
Community Pharmacists	28	
Community Pharmacists	28	
Patients and/or Members of the Public	7	
Physicians and Nurses	1	
Department of Agriculture, Food and the Marine		1
Veterinary Practitioners		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 2012, there were 141 medicine recalls of which 136 related to human medicines and five related to veterinary products. The recall of a batch (or batches) of medicines occurred in approximately 19% of all quality defect cases investigated during the year, compared to 28% in 2011. This reduction was mainly due to the number of multiple product recalls which occurred during 2011.

Cause of Recalls - Human Medicines	**2011**	**2012**
Contamination Issue	24	21
Stability	13	15
Unauthorised Product on the Irish Market	8	14
Non-compliance with Marketing Authorisation	2	11
Printed Packaging Component Issue	17	11
Non-compliance with Specifications	28	6
Product Mix-Up	2	6
Erroneous Distribution	3	5
Lack of Sterility Assurance	7	5
Adverse Event / Change in Benefit/Risk Ratio	4	4
Non-printed Packaging Component Issue	5	4
Lack of Therapeutic Efficacy	2	3
Undeclared Active Substance	5	2
Damaged product	38	1
Product Preparation / Administration Issue	9	1
Non-adherence to Cold Chain	67	0
Falsified Medicine Issue	0	0
Non-compliance with GMP	0	0
Other	6	27
Total	**240**	**136**

Cause of Recalls - Veterinary Medicines	**2011**	**2012**
Non-compliance with Specifications	0	2
Stability	1	1
Contamination Issue	0	1
Printed Packaging Component Issue	0	1
Non-adherence to Cold Chain	3	0
Damaged Product	8	0
Unauthorised Product on the Irish Market	1	0
Total	**13**	**5**

Of the 141 recalls, 8% involved products which were recalled to patient / user level, 55% to pharmacy / retail level and 37% to wholesale level. While there was a 41% annual decrease in patient / user level recalls, this corresponded with a 41% decrease in critical quality defects impacting Ireland.

Other findings from the recall programme include the following:

- Exempt medicinal products accounted for 18 (13%) of human medicinal product recalls.
- Compounded products for human use, accounted for 29 (21%) of all recalls. As already outlined, 23 of the recalls related to one issue at an Irish compounding facility.
- Of the products recalled from the Irish market, 45 (32%) were manufactured at an Irish facility.

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 and safety of medicines on the Irish marketplace as well as to the identification of borderline medicinal/non-medicinal products that may be present.

This is achieved 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 total of 435 product samples were sent for analytical testing and/or examination in 2012.

Analytical Testing

There were 287 medicines and other product samples tested during the year in review. Of these, 273 were obtained from the Irish marketplace and 14 originated from other EU marketplaces as part of IMB's involvement in EU-wide work-sharing programmes.

Approximately 39% of the analytical work carried out related to enforcement and borderline medicinal/non-medicinal product samples while the remainder related to medicinal products within the legal supply chain.

Product categories selected for Analytical Testing in 2012	Number of Samples Analysed
Enforcement-related and borderline products	121
Human medicinal products (nationally and centrally authorised, parallel imports, biological, export only)	158
Veterinary medicinal products (nationally authorised including biologicals	8
Total	**287**

Description of products examined	Number of samples examined
Medicinal products subjected to general compliance monitoring for packaging and labelling attributes	155
Medicinal products subjected to Braille-compliance checks	28
Product usability checks	3
Borderline Medicinal / Non-medicinal products associated with IMB Classification Committee work	4
Total	**190**

Examination of Packaging and Labelling

During 2012, 190 medicinal and other products on the Irish marketplace were examined.

A significant element of this programme was directed towards examining the adequacy of safety-related information on package leaflets. This work resulted in the identification of significant non-compliance issues, each of which required further follow-up activity.

Participation in EU Co-ordinated Market Surveillance Activities

The IMB is an active participant in EU programmes, co-ordinated through the Official Medicines Control Laboratories (OMCL) Network, that involve the sampling and analysis of medicinal products on behalf of the European Medicines Agency.

We participated in the sampling of 13 and the analysis of 17 centrally authorised medicinal products, while 13 MRP/DCP products from the Irish market were analysed at OMCLs in other countries.

Additional work sharing activity included:

- The analysis of nine borderline products by the UK's OMCL at the request of the IMB;
- The analysis of 12 Irish market medicinal products at the UK's OMCL as part of an ongoing falsified medicine detection project running in conjunction with the UK regulator, the MHRA;
- The microbiological analysis of 26 samples for the IMB at the Finnish and Czech OMCLs.

Principal Findings

The laboratory analysis findings included five out-of-specification results and 24 deficiencies in the analytical methods for a total of nine products. Each non-compliance was followed-up with the relevant companies until the issues could be closed.

The packaging and labelling findings consisted of 26 non-compliances which included issues relating to product information details, the application of Braille on product packaging, incorrect/out-of-date package leaflets and SPCs, and the over-labelling of parallel imported products.

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, County Kildare, for their contributions to the IMB's sampling and analysis programme during 2012.

RETAIL SALES MONITORING

Exempt Medicinal Products Programme

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 of 2007-2012, wholesalers and manufacturers of medicinal products are obliged to provide certain information to the IMB in relation to any exempt products that they source. This is done by submitting electronic notification to an IMB database. The main purpose of receiving such information is to facilitate, when required, the effective recall of any defective exempt medicinal products from the Irish market.

The total number of packs of exempt medicinal products notified was 1,661,483, an increase of 13% on 2011. 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.

A number of non-compliances were identified with the supply of exempt products and the IMB monitored the implementation of corrective actions at the companies concerned.

General Retail Sale Investigations

We operate both a proactive and reactive risk based monitoring programme that encompasses retail outlets such as grocery shops, health food shops and, where necessary, pharmacies.

This retail monitoring programme checks for:

- Medicines that have not authorised for placement on the Irish market;
- Pharmacy confined medicines that are being sold in non-pharmacy outlets;
- Traditional herbal medicinal products (THMPs) and products containing herbal substances that require a THMP registration or marketing authorisation, respectively, before being placed on the Irish market.

The main findings and subsequent actions from the 2012 programme included:

- The recall of nine unregistered THMPs (without transitional protection);
- The recall of two unauthorised products containing herbal substances that require a marketing authorisation before being placed on the Irish market;
- A number of actions arising from the completion of 12 proactive inspections of retail outlets encompassing both health food shops and pharmacies during the fourth quarter of 2012. Certain issues arising from these inspections were ongoing at year end;
- The identification and recall of a total of 59 different unauthorised medicinal products from the Irish market. These included two products that were subject to prescription control and eight pharmacy-only products all of which were identified in non-pharmacy retailers.

Regulatory Compliance Inspections

These inspections are carried out at the premises of marketing authorisation holders and are risk-based. The programme of inspections enables the IMB to inspect key areas of activity relating to the marketing and advertising of medicinal products in Ireland so as to determine the level of compliance with the relevant legal requirements. Areas of activity that have a high potential to impact upon the quality, safety and the safe use of medicinal products are the main focus of these inspections.

Two such inspections were carried out and a number of significant non-compliances were identified. Monitoring and follow-up of these compliance issues were continuing at year end.

Human Medicines Advertising Compliance Programme

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, 464 individual advertisements were reviewed for compliance during 2012 through the IMB's advertising compliance programme. The main findings, categorised under the four main components of the programme, were as follows:

- Proactive Monitoring
  - There were 352 advertisements across several different media reviewed. Of these, 77% were reviewed as part of risk based pre-planned proactive surveillance projects with the remainder selected on a random basis.
  - Arising from the pre-planned activity, 22 advertisements were found to be non-compliant while 23 were found to be non-compliant during random surveillance work.
- Inspection of Company Advertising Programmes and Related Activities
  - As previously outlined, two regulatory compliance inspections were carried out at the offices of marketing authorisation holders.
  - During one of these inspections, the advertising programmes and activities were reviewed in detail and one major deficiency was identified.
- Advertising-related Complaints
  - A total of 18 advertising-related complaints were received primarily from healthcare professionals, companies, the general public and IMB staff. As part of the investigation of these complaints, 76 advertisements were reviewed.
  - Of the complaints received, 7 complaints were upheld concerning approximately 59 non-complaint advertisements. Three complaints were carried into 2013.
- Advertising-related Queries
  - There were 89 advertising-related queries received from a range of interested parties resulting in the review of 36 advertisements. Of those, eight were considered to be non-compliant.

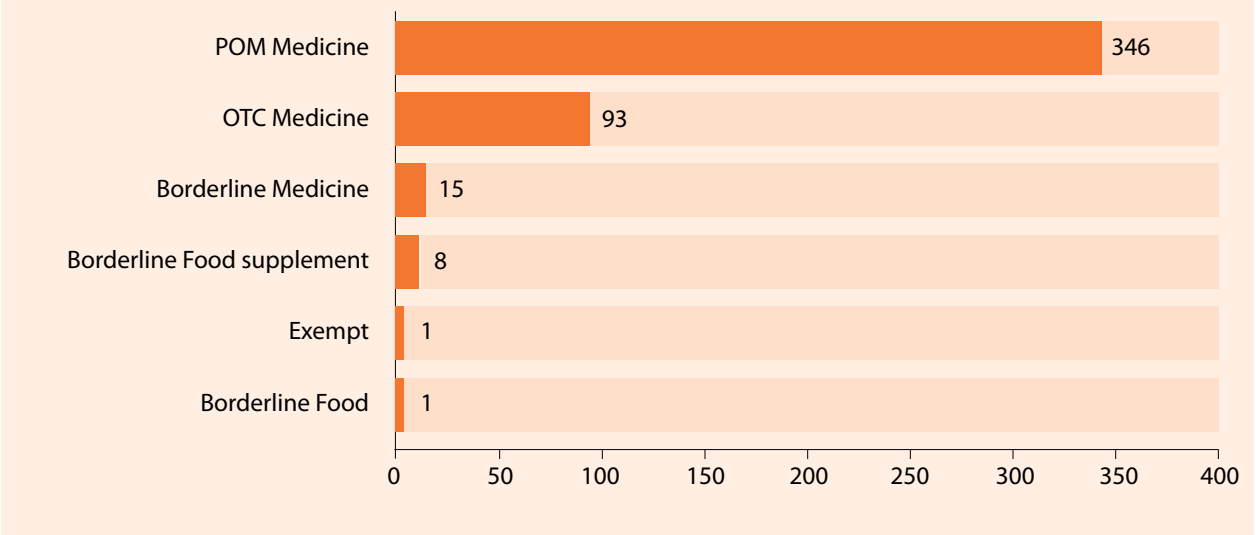
	Total	Advertisements Reviewed	Non-Compliances Identified
Proactive Monitoring: Pre-planned Projects	9	271*	22 individual advertisements were non-compliant
Proactive Monitoring: Randomly Selected Projects	13	82*	24 individual advertisements were non-compliant
MAH Inspections Performed	2	Multiple	1 major deficiency identified
Complaints Received	18	76*	59 advertisements were found to be non-compliant
Queries Received	89	36*	8 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 advertisements reviewed by product type is provided in the accompanying table. Of the 346 advertisements promoting prescription-only products, 54 (16%) were found to be non-compliant. In respect of advertisements promoting over-the-counter medicines, 23 (25%) 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. In a small number of cases, this follow-up was ongoing at year end.

Advertisements Reviewed in 2012 by Product Type



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 is a core function of the IMB.

The medical devices vigilance system was established under the European medical device directives (93/42/EEC, 90/385/EEC and 98/79/EC). Together with the Guidelines on a Medical Devices Vigilance System (MedDev 2.12-1), the directives detail the reporting requirements for medical devices manufacturers to national competent authorities such as the IMB. The MedDev guidelines also outline the obligations on competent authorities to share information reported to them with each other and with the European Commission. The vigilance system refers to the process of notification and evaluation of vigilance reports.

The IMB's reporting system for 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 occurring elsewhere and to correct product problems.

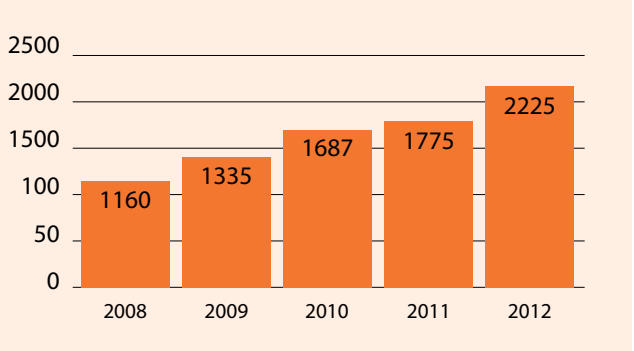
2012 Reports

A total of 2,225 medical device vigilance reports were received and assessed representing a 25% increase on 2011. As can be seen from the accompanying graph, there has been a consistent upward trend in the number of vigilance cases received annually. This is a result of greater clarity on reporting criteria, communication of issues among Member States and the IMB encouraging reporting on an ongoing basis.

Manufacturers accounted for 53% of all vigilance reports received in 2012 while 34% were received from competent authorities. Users accounted for 12% of reports, up from 7% in 2011. In total, 45% of the reports received were as a result of an incident on the Irish market.

Concerning the regulatory response to the reports received, 51% resulted in an action being taken in Europe. In Ireland, the IMB published online 441 manufacturer's field safety notices directly affecting the local market. These notices are intended to inform users of safety issues relating to medical devices. In addition, there were 204 product removals conducted in Ireland in 2012. Safety information was also highlighted to the public through IMB safety notices. There were 19 such notices sent to the relevant interest groups and published on the IMB website. During the year in review, the IMB issued 81 national competent authority reports.

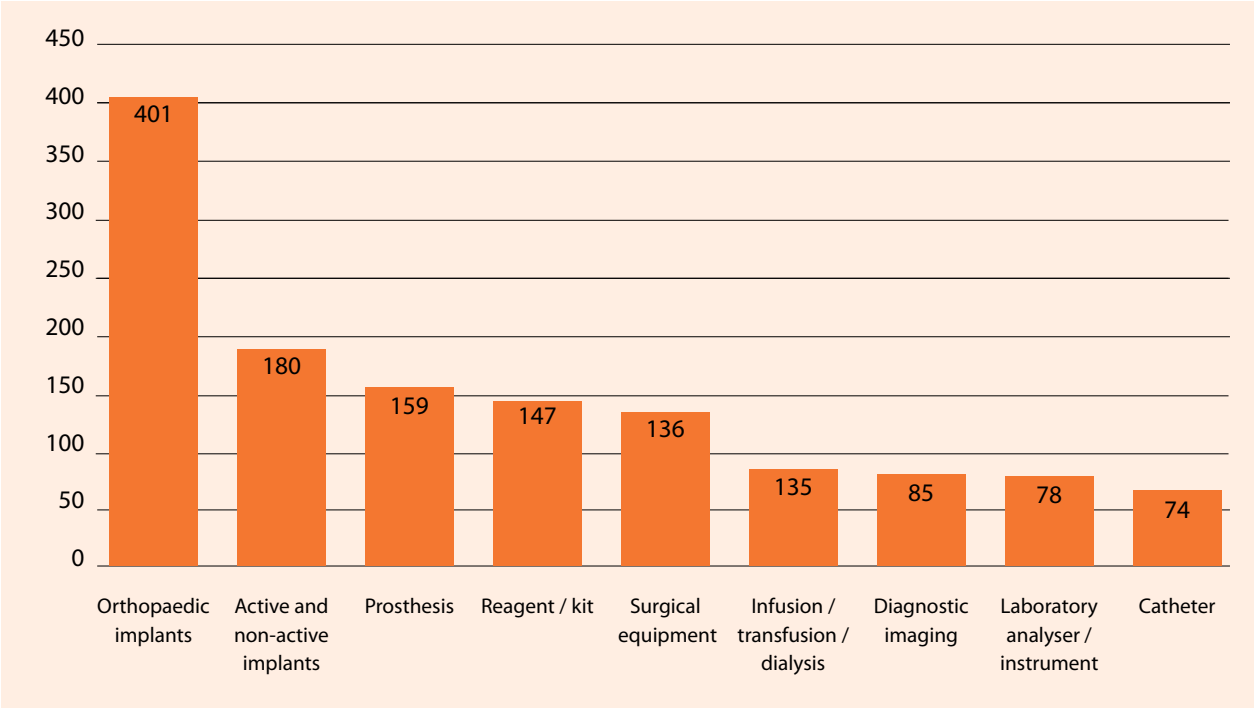
Number of Vigilance Reports - 2008 to 2012



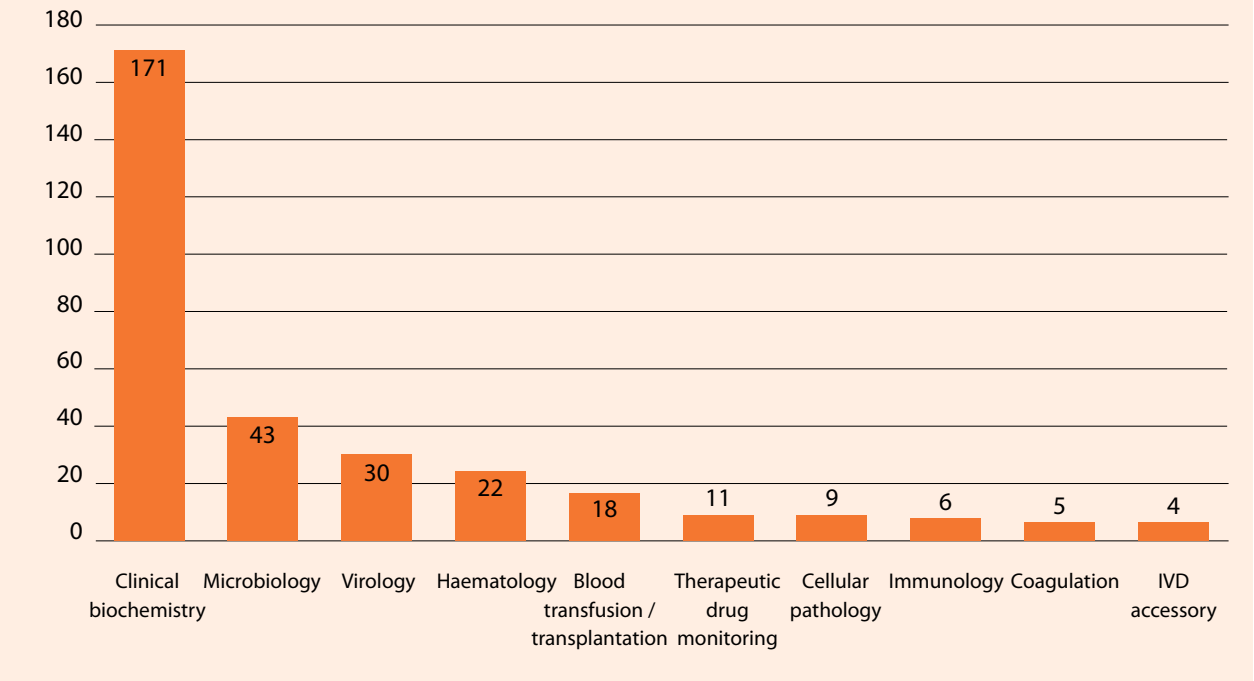
2012 Reports by Product Type

Orthopaedic implants, surgical equipment, and infusion and transfusion devices accounted for a large proportion of vigilance reports received. A number of field actions relating to automated external defibrillators were also received. The continued reporting of revision procedures associated with the ASR Articular Surface Replacement and ASR XL Acetabular system manufactured by DePuy contributed to the majority of orthopaedic implant reports received. In addition, vigilance reports following the explanation of breast implants manufactured by Poly Implant Prothese following a global recall in 2010 continued to be submitted to the IMB. There have been a number of reported revision surgeries in relation to implanted defibrillation leads.

Vigilance Reports Received - General Devices



Vigilance Reports Received - IVD Medical Devices



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 biochemistry reagents and analysers continued to have a high impact on the number of IVD vigilance cases.

COMPLIANCE

Medical device compliance activities ensure that medical devices on the Irish market comply with the relevant European directives. All potential safety and non-compliance issues identified are subject to investigation and follow up. In 2012, a total of 725 compliance cases were investigated. A significant amount of proactive compliance work was focused in the area of self-test IVDs. Similar to previous years, issues identified in 2012 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, 86% were from other competent authorities and mainly related to notified body certificate withdrawals.

MARKET COMPLIANCE OF COSMETICS

MARKET SURVEILLANCE

Post market surveillance activity relating to cosmetics involves close co-operation between the IMB and the HSE. In this context, 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). Compliance cases were initiated and these accounted for the vast majority of investigations. A total of 16 vigilance cases were investigated.

There were also six recalls of cosmetic products in response to public health concerns.

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 receipt and circulation of these alerts. In conjunction with the HSE, the IMB investigated 105 RAPEX Alerts during 2012. In respect of the subsequent five products found on the Irish market, a reaction report was submitted to the NCA outlining the market actions taken.

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).
- 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).

OVERVIEW OF THE 2012 INSPECTION PROGRAMME

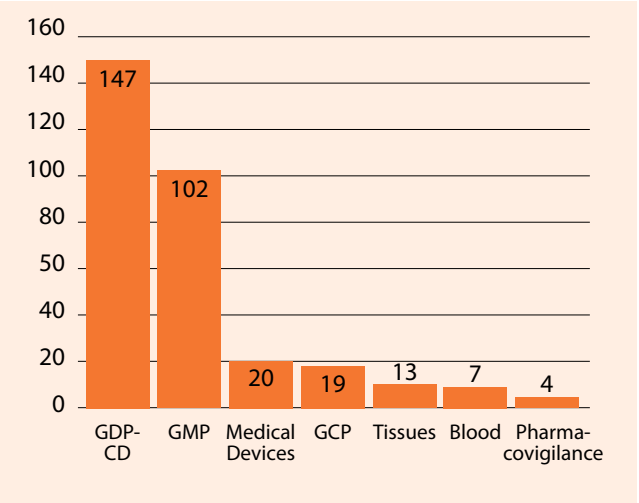
During 2012, there was a total of 289 national inspections and audits performed compared to 271 in 2011. A further 26 foreign inspections and audits were performed in the past 12 months. The average number of days required to close-out the inspections and audits was 76.

Performance Results and Statistics	2008	2009	2010	2011	2012
No. of national inspections and audits	228	238	293	271	289
No. of foreign inspections and audits	27	28	30	29	26
% inspections and audits closed on time (≤ 90 days)	67	58	62	66	61
Average time for close-out (days)	89	112	194	79	76

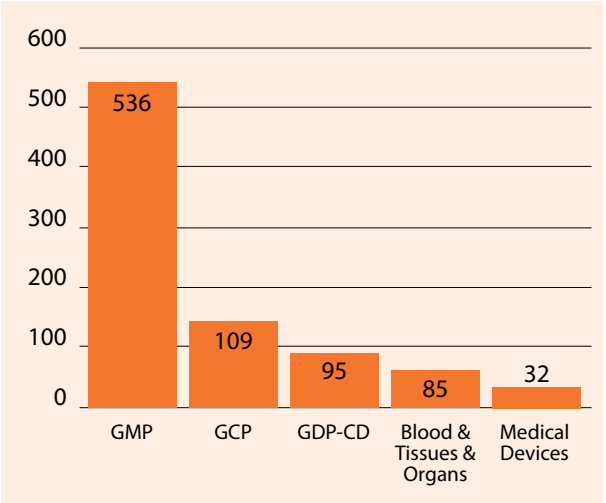
During the 12 months under review:

- 102 GMP inspections were performed. These included 25 inspections in non-EEA countries, five of which were carried out at the request of the European Medicines Agency and related to centrally-authorised products.
- 147 inspections were conducted to assess compliance with GDP and CD requirements. Of these inspections, five specifically related to the assessment of compliance with THMP legislation.
- 19 GCP inspections were completed all of which were carried out at investigator sites in Ireland.
- 4 pharmacovigilance inspections were completed. Three of these inspections were at the facilities of Irish based marketing authorisation holders while one foreign inspection for centrally-authorised veterinary medicinal products was conducted at the request of the European Medicines Agency.
- 6 audits were conducted of authorised representatives of medical device manufacturers while 13 audits were conducted of manufacturers of custom made medical devices. Audits of medical device manufacturers included proactive surveillance audits.
- 1 surveillance audit of the NSAI, the notified body for medical devices in Ireland, was conducted. This took place at the NSAI's offices and also via observation of NSAI staff performing audits at device manufacturers' premises.
- 7 blood establishment inspections were completed, including inspection of facilities maintained by the Irish Blood Transfusion Service (IBTS).
- 13 tissue establishment inspections were carried out including an inspection related to an application for a new tissue establishment authorisation.

Number of Inspections and Audits Completed in 2012



Number of Inspection and Audit Days in 2012



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

During 2012, 3,911 enforcement cases were initiated, down 14% on 2011 (4,549). The reduction represents a decrease in the number of importations by mail order of prescription only medicinal products that were detected. There were 3,925 cases closed.

DETAINED MEDICINES

The quantity of medicinal products detained reduced marginally in 2012 to a total of 758,276 dosage units. This represents a slight decrease when compared to 2011. These detained products included 153,042 dosage units indicated for weight-loss products and containing the active substance sibutramine. Sibutramine is not permitted in any authorised medicinal product in the EU. In addition, 52,089 dosage units detained related to Erectile Dysfunction products. Other products contained diazepam, zopiclone, melatonin, Tribulus terrestris, Corticosteroids and anabolic steroids. The majority of these unauthorised medicinal products supplied into Ireland originated from India and China.

Medicinal products destroyed during the year, in compliance with the Waste Management Acts 1996 and 2003, amounted to 1,065 kilograms.

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

INTER-AGENCY CO-OPERATION AND PANGEA V

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 2012, 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 V in September and October. This global initiative, co-ordinated by INTERPOL to identify and act against illegal websites supplying counterfeit and illegal medicinal products, involved 180 agencies from 100 countries worldwide. This operation led to the detention in Ireland of 121,026 tablets, capsules and creams with an estimated value in excess of €375,000.

Year	2008	2009	2010	2011	2012
Product detained	393,067 Dosage Units	494,502 Dosage Units	822,484 Dosage Units	762,641 Dosage Units	758,276 Dosage Units
Cases opened	3,037	3,729	3,936	4,549	3,911
Prosecutions	2	2	5	9	9
Product destroyed	1,902kg	2,601kg	1,400kg	4,519kg	1,065kg

PROSECUTIONS / JUDICIAL REVIEWS 2012

The IMB initiated, or were party to, 11 prosecutions and court proceedings during the course of 2012.

Date	Court	Defendant	Outcome	Fines / Costs
20/02/2012	Dublin District Court	IMB v John Nolan	Guilty on 13 charges pertaining to supply without a prescription / no marketing authorisation. Nine month custodial sentence suspended for 2 years.	IMB awarded €3,000 costs and destruction order for products detained.
20/02/2012	Dublin District Court	IMB v Yu (Eric) Gou	Mr. Gou pleaded guilty to 15 charges pertaining to no manufacturer's authorisation, wholesaler's authorisation or marketing authorisation. Nine month custodial sentence suspended for 2 years.	IMB awarded €2,500 costs and destruction order for products detained.
27/02/2012 and 20/04/2012	Circuit Criminal Court	DPP v James Bellamy DPP v Harmony Products Ltd	Mr. Bellamy pleaded guilty to one charge of importation and two charges of wholesale. Harmony Products Limited pleaded guilty to three charges. Mr. Bellamy sentenced to three years imprisonment with last year suspended and also fined.	Mr. Bellamy fined €100,000. Harmony Products Limited fined €150,000.
03/04/2012	Dublin District Court	IMB v Cosmic Closet Limited; IMB v Gary Murphy	Mr. Murphy pleaded guilty to two charges supplying unauthorised medicinal products & received the Probation Act. Cosmic Closet Limited pleaded guilty to four charges.	Cosmic Closet Limited fined €1,000 and costs of €2,550 awarded to IMB.
06/07/2012	Supreme Court	Applicant: Paschal Carmody. Judicial Review Appeal	Mr. Carmody commenced Judicial Review proceedings in 2006 to quash convictions imposed in 2005. The relief sought was refused by the High Court on 28 January 2010. Mr. Carmody appealed to the Supreme Court (3 March 2010). The appeal was struck out on 6 July 2012.	

Date	Court	Defendant	Outcome	Fines / Costs
19/07/2012	Balbriggan District Court	IMB v David Power IMB v Green EcoTech Limited	Mr. Power and Green EcoTech Limited both pleaded guilty to 11 counts of the supply of medicinal products without a prescription and without having a Marketing Authorisation.	Mr. Power was fined €1,250 and Green EcoTech Limited was fined €1,750. The Court awarded costs to the IMB of €3,550.
23/07/2012	High Court	District Justice Kilrane respondent in the Judicial Review	The President of the High Court granted the Judicial Review to the IMB in relation to a ruling regarding Section 33, Irish Medicines Board Acts 1995-2006	
11/10/2012	Midleton District Court	IMB v Brian Buckley	Mr. Buckley pleaded guilty to six charges of supply of prescription only medicinal products without a prescription and by mail order	Mr. Buckley was fined fined €6,000 and the Court awarded €3,000 costs to the IMB.
24/10/2012	Bray District Court	IMB v Li Tao	Li Tao pleaded guilty to the retrial supply of unauthorised prescription only medicinal products.	Probation Act applied and donation to charity of €2,000 (and costs of €2,000 awarded to the IMB).
24/10/2012	Bray District Court	IMB v Fei Tan	The Judge dismissed this case. He ordered that the prescription only medicinal products detained not be released to Fei Tan.	Detained products ordered into possession of IMB for destruction.
06/12/2012	Dun Laoghaire District Court	IMB v John Furlong IMB v Tanning Warehouse Limited	This case related to the importation of 14,400 slimming capsules containing sibutramine. Both parties pleaded guilty.	Tanning Warehouse Limited fined €750. The Probation Act applied to Mr. Furlong and costs of €2,250 awarded to the IMB.

LEGISLATIVE AND REGULATORY DEVELOPMENTS

The legislative and regulatory environment in which the IMB operates is constantly evolving. 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.

This section of our annual report outlines the most significant legislative and regulatory developments during 2012 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

NEW EU PHARMACOVIGILANCE LEGISLATION

New European Union (EU) pharmacovigilance legislation came into effect and was transposed into Irish law in July 2012. The aim of the new legislation is to further protect public health by strengthening the current European-wide system for monitoring the safety of medicines. In particular, the new legislation aims to improve the pharmacovigilance system in the EU, enhancing the scope of adverse drug reaction reporting and introducing 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.

Many of the new provisions contained in the legislation have been effective since July 2012. These include:

- The publication of guidance documents for stakeholders;
- The establishment of the Pharmacovigilance Risk Assessment Committee (PRAC);
- Increased transparency such as the publication of PRAC agendas and minutes.

The implementation of additional provisions, such as the collection of key information on medicines and enhanced analysis and understanding of data and information, will continue beyond 2012.

Throughout the year in review, the IMB continued to work with a wide range of stakeholders including the European Medicines Agency and other national regulators in planning for and implementing provisions contained in the new legislation. Patients, the pharmaceutical industry and healthcare professionals were also consulted by the regulatory authorities to ensure effective implementation. The IMB actively contributed to the drafting of the first wave of Good Vigilance Practice modules. Additionally, further information and guidance was made available to stakeholders via a dedicated section of the IMB website. The PRAC agenda, the meeting highlights and minutes are also now published on the website following each PRAC meeting. Within the IMB, new business processes were established and a number of existing business processes were revised.

ONGOING IMPLEMENTATION OF THE TRADITIONAL HERBAL MEDICINAL PRODUCTS DIRECTIVE

As outlined earlier in this report, the number of applications received by IMB has remained disappointingly low. Given that the registration process is a new regulatory requirement, progress in assessing applications has been in line with expectation. The IMB has been working closely with applicants, in providing the necessary guidance and support to ensure that appropriate standards of quality, safety and efficacy for registration of products are reached, and also to encourage applications through the registration scheme. Meetings were held with a number of industry and company representatives and a total of 123 queries specifically relating to traditional herbal medicines were received and processed by IMB during 2012. Other initiatives included the provision of up-to-date guidance materials to relevant stakeholders.

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 (counterfeit) medicines entering the legal supply chain. Preparations continued during 2012 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.

One of the important changes in the Directive, to apply from 2 July 2013, concerns the new rules on importing active substances into the Europe. The IMB led an information gathering initiative by conducting a survey of medicinal product manufacturers in Ireland that use active substances produced outside of the European Economic Area (EEA). The methods used by the IMB were adopted by a HMA falsified medicines task force to determine the number of non-EEA active substance sites (and their locations) supplying finished product manufacturers into Europe.

Concerns have been raised that the new rules under this Directive could lead to shortages of medicines. However, this area was evolving rapidly at year end and the IMB continues to monitor developments closely.

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. In 2012, this window closed on 18 July. All 18 requests received were considered and the five successful applicants were allocated a dedicated slot for assessment.

CLINICAL TRIALS REGULATION

In July 2012, the European Commission published a proposal on a Regulation to revise the EU clinical trial legislation. IMB staff actively participated in the consultation and development stages of the draft Regulation.

CONTRIBUTING TO THE EUROPEAN AND GLOBAL REGULATORY NETWORK

Europe

Throughout 2012, we continued to actively participate in the European medicines regulatory system. IMB scientific and technical staff contributed to a broad range of committees and working parties, preparing papers as appropriate, at the European Medicines Agency, the European Commission, the HMA, and at 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 the past year included the following:

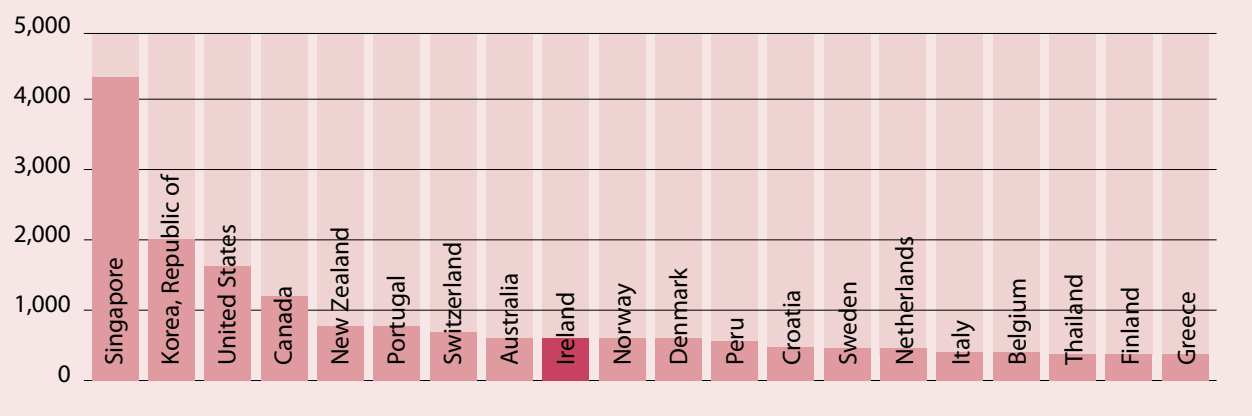
- The Irish delegate to the PRAC was elected as Vice-Chair of the committee for a 3-year period.
- The Irish Delegate to the PRAC represented the EU at the ICH E2C (R2) Expert Working Group tasked with evaluating the ICH pharmacovigilance documentation, conducting a gap and potential improvement analysis and drafting a new ICH Guideline covering periodic benefit risk evaluation reporting. This process reached Stage 4 in November 2012. The concept paper highlights the fact that the technology and science of pharmacovigilance has progressed significantly and the associated documentation has not kept pace. In order to address this and to ensure that regulatory and industry resources are more productively linked to public health protection and promotion, the E2C guideline has been revised.
- IMB experts were significantly involved in a joint project team, involving representatives from Member States and the European Medicines Agency, to support the implementation of the new EU pharmacovigilance legislation. In addition, the IMB was represented in the project coordination group and at project oversight level as a member of the HMA European Risk Management Strategy Facilitation Group. Key deliverables included input to the drafting of the technical contribution on the European Commission's Implementing Measures and the first wave of Good Vigilance Practice Modules.

World Health Organization

The IMB Pharmacovigilance Manager continued to represent the World Health Organization (WHO) as a member of the Board of the Uppsala Monitoring Centre (UMC) and WHO Collaborating Centre for International Drug Monitoring during 2012. In addition, 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 participating countries (111 full country members as of February 2012). As can be seen from the accompanying graph, Ireland ranked as the ninth highest reporter for the year during 2012.

Active ICSRs in the WHO global ICRS database in 2012 per million inhabitants



Pharmaceutical Inspection Co-operation Scheme (PIC/S)

At the beginning of the year the Inspection Manager took up her appointment to the Executive Bureau (management group) of the PIC/S.

In January, the IMB hosted a training seminar for new inspectors under the auspices of the PIC/S. The seminar was developed to provide a thorough grounding to new GMP inspectors on the conduct of inspections of manufacturers and was a further contribution to the harmonisation of global inspection standards. Subsequently in October, we also conducted a training seminar for new GMP inspectors from the Commonwealth of Independent States region organised by the State Administration of Ukraine on Medicinal Products (SAUMP).

Also in 2012:

- Two IMB trainers presented talks and hosted workshops at the PIC/S annual seminar in Kiev on the subject of 'Qualification and Validation – Today and Tomorrow'.
- Active substance inspectors from IMB participated in the steering group tasked with developing the PIC/S International API Inspector Training Programme and two inspectors contributed to advanced training for inspectors from a number of countries in Washington DC, USA.
- An IMB inspector presented at the PIC/S Expert Circle on Quality Risk Management.

International Pharmaceutical Federation (FIP)

FIP is the global federation representing pharmacists and pharmaceutical scientists worldwide. The IMB's Director of Scientific Affairs is a member of the FIP special interest group on dissolution testing. Dissolution testing is considered an important tool in both drug development and quality control.

During 2012, the Director of Scientific Affairs contributed actively to the activities and deliberations of the group. This included a presentation to the FIP annual (centennial) conference held in Amsterdam in October and a contribution to a workshop on dissolution testing held in June in Romania.

CONTRIBUTING TO NATIONAL HEALTH INITIATIVES

Memorandum of Understanding with the Irish Sports Council

In May, the IMB and the Irish Sports Council signed a Memorandum of Understanding to formalise the sharing of information and intelligence in an effort to protect Irish athletes and to combat the illegal use of medicinal products. In recent years, the two state agencies have co-operated and shared intelligence in the area of anti-doping. This Memorandum of Understanding places this relationship on a formal basis and signals that it will have a more prominent role in the general battle against doping in sport.

Consumer Warning on Health Dangers of Illegal Stimulant (DMAA)

In July, the IMB and the Food Safety Authority of Ireland issued a joint precautionary message for consumers on the health dangers of taking food supplements or products containing the substance DMAA (1,3-dimethylamylamine). The warning came after a number of adverse reactions internationally related to products containing DMAA.

HEALTH (PRICING AND SUPPLY OF MEDICAL GOODS) BILL 2012

The Health (Pricing and Supply of Medical Goods) Bill 2012, which is due to be enacted and commenced in the first half of 2013, outlines the circumstances under which medicines are considered interchangeable (also often referred to as generic substitution) and where they are not considered interchangeable. The purpose of the legislation is to provide for generic substitution of medicines that are considered interchangeable so that a pharmacist can dispense a less expensive medicine than the one prescribed. Once enacted, the IMB will be charged with responsibility for the establishment, consultation, publication and subsequent maintenance of a List of Interchangeable Medicinal Products, which will be grouped together under their respective active substance, strength and pharmaceutical form(s).

During 2012, the IMB has actively supported the Department of Health in preparation for the implementation of this legislation. This included IMB contributions to a series of stakeholder meetings held in November. An internal project group was also established for purposes of developing internal procedures to enable the generation and publication of the lists of interchangeable medicinal products.

NEW DOSAGE INSTRUCTIONS FOR CHILDREN'S LIQUID PARACETAMOL MEDICINES

New dosage instructions for liquid paracetamol medicines for paediatric use were announced by the IMB in March 2012. The updated instructions include more precise age and dosage bands to ensure that children get the most effective amount of medicine for their needs whilst making it easier for parents and carers to know how much paracetamol they should give their children. The changes were highlighted by broadcast and print media while the product information (package leaflets and labels) for these products was subsequently updated to reflect these new recommendations.

RECOMMENDATION THAT ECHINACEA-CONTAINING HERBAL PRODUCTS SHOULD NOT BE USED IN CHILDREN

In August, the IMB advised that children's herbal products containing Echinacea should not be used for children under 12 years of age due to a lack of scientific data to support their use. The IMB communicated with retailers and others within the supply chain to inform them of this recommendation and to request that children's echinacea-containing products were removed from sale. The action was further highlighted via the media.

ADVERTISING COMPLIANCE PROGRAMME

The IMB participated in the first meeting of a new regulatory network known as the Forum on Advertising of Medicines (FOAM), hosted by the UK's Medicines and Healthcare Products Regulatory Agency (MHRA) in London in November. This forum is under the auspices of the HMA and comprises advertising regulators from 30 countries (all 27 EU Member States as well as Norway, Iceland and Croatia). The forum aims to provide a platform for the exchange of information about regulatory practice / challenges and advertising cases with cross-border relevance.

There was one meeting of the Advertising Technical Working Group in 2012. This group is comprised of IMB staff members as well as representatives from the pharmaceutical industry in Ireland. It is a forum for the communication of advertising-related issues between the IMB and the industry representatives with a view to the promotion of good practice and compliance in this area.

ADVISORY COMMITTEE FOR HUMAN MEDICINES

The Advisory Committee for Human Medicines, which is appointed by the Minister for Health, met four times during 2012. The committee assists and advises the IMB 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.

There are also a number of sub-committees appointed by the Advisory Committee for Human Medicines.

- The Clinical Trials Committee met 12 times during the year. The Committee considered 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).

- The Herbal Medicines Committee met two times in 2012. 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.

VETERINARY MEDICINES

CONTRIBUTING TO THE EUROPEAN REGULATORY NETWORK

The IMB continued to be an active participate in the European medicines regulatory system for veterinary medicines during 2012. The extensive involvement of IMB staff members as part of European committees and working parties is outlined in Appendix 4. In addition to this regular participation at a European level, highlights from the past year included the following:

- In respect of the proposed new legislation for veterinary medicinal products, preparatory workshops were held by the European Commission during the summer of 2012. The IMB was an active contributor throughout this initiative which is expected to assist the Commission in developing the new legislative framework;
- The IMB is a participant to the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC). This initiative is part of the European response to antibiotic resistance through the surveillance of the use of veterinary antibiotics in the region. The IMB is committed to this annual exercise and publishes the a report of the national consumption of veterinary antibiotics on an annual basis;
- The IMB continued to participate in both the European Surveillance Strategy group and the Antimicrobial Resistance group at the HMA. The IMB is a regular contributor to both groups which are increasingly making use of teleconferencing rather than physical meetings.

Maximum Residue Limits for certain Flukicidal Medicines

The IMB welcomed the establishment in 2012 by the European Commission of maximum residue limits (MRLs) for the substances clorsulon, closantel, nitroxynil and triclabendazole. This followed a request from the IMB to the European Medicines Agency to determine MRLs for certain flukicidal veterinary medicines used in milk producing animals. The establishment of MRLs provides a more suitable reference level for residue monitoring purposes and is expected to encourage marketing authorisation holders to develop appropriate residue studies in pregnant or lactating livestock. This is in turn will establish appropriate withdrawal periods for milk for such animals. A referral procedure to harmonise the warnings/withdrawal periods on the labelling of products containing flukicidal substances was initiated by the Commission during the year. This is expected to lead to a harmonised approach to the labelling of affected veterinary medicines in 2013.

As a result of this IMB initiated process, consumers can have greater confidence in the safety of milk and milk products and it removes any uncertainty regarding the conditions of use of the affected products in pregnant cattle that are intended for milk production for human use.

CONTRIBUTING TO NATIONAL HEALTH INITIATIVES

The IMB continued to participate to an initiative of the Department of Agriculture, Food and the Marine to help minimise the development of anthelmintic resistance in Irish sheep. New symbols have been introduced on certain anthelmintics which will allow for more effective use of the medicines concerned. The success of the initiative will depend on efforts of stakeholders in educating users to the meaning of the symbols and in changing existing practices in the use of the products concerned.

ADVISORY COMMITTEE FOR VETERINARY MEDICINES

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 2012.

MEDICAL DEVICES

REVISION OF EUROPEAN MEDICAL DEVICES DIRECTIVES

In September 2012, the European Commission adopted proposals to introduce two Regulations to strengthen the EU medical devices regulatory system and to standardise the application of rules throughout the EU. The proposed medical device Regulation will replace the current directives on medical devices and active implantable medical devices (Directives 93/42/EEC and 90/385/EEC, respectively) and the proposed IVD Regulation will replace the in vitro diagnostic medical device directive (Directive 98/79/EC).

The IMB has contributed extensively over the past number of years to working groups and subgroups in the development of technical aspects of the regulatory system which may be reflected in the new legislative proposals. The IMB will act as an advisor to the Department of Health on the medical device proposals during relevant discussions at the European Council and European Parliament. This will include the period of the Irish Presidency of the Council of the European Union from January to June 2013.

CONTRIBUTING TO THE EUROPEAN REGULATORY NETWORK

European Commission's Joint Plan for Immediate Actions on Medical Devices

In early February, the European Commissioner for Health and Consumers wrote to all European Ministers for Health outlining a 'joint plan of immediate actions' with the objective of reinforcing the existing regulatory system for medical devices. The plan outlined actions for Member States and the Commission in respect of the functioning of notified bodies, market surveillance, coordination, communication and transparency. The IMB believe that the plan is critical to reinforcing the existing regulatory system for medical devices across Europe and to ensuring that European consumers are appropriately protected in advance of the future revision of the medical devices legislation in Europe.

The planning and the practical implementation of the joint plan utilised significant resource across the IMB. The most significant work items arising from the joint plan during 2012 included:

1. Review of class III notified bodies for medical devices. This action was completed by the IMB by the deadline of September 2012.
2. Analysis and communication of resource and activities relevant to market surveillance of medical devices which was completed by the revised deadline of September 2012.
3. Significant input to the preparation of an implementing Regulation and a Commission recommendation on notified bodies for medical devices in advance of the plan's deadline.

European Commission Guidance Documents

During 2012, the IMB chaired the European taskforce to revise the guidelines on the medical devices vigilance system (MEDDEV 2.12-1) which specifically includes in-vitro fertilisation / assistive reproduction technologies devices within the scope of the vigilance system as well as greater detail regarding the reporting requirements for devices which do not generally come into contact with patients.

Resourcing the European Medical Devices Regulatory Network

The IMB continued to engage actively during 2012 in discussions with other European competent authorities, the European Commission and relevant stakeholders on how to optimise resourcing of the network for medical device regulation in Europe. These discussions, involving significant dialogue with the medical device industry associations, included examination of potential mechanisms for changing the current funding models for regulatory authorities to fee-based models. The IMB hosted two related workshops.

Co-operation between the HMA and the Competent Authorities for Medical Devices Networks

The IMB continued to promote discussions during 2012 on enhancing cooperation and partnership between the HMA and the Competent Authorities for Medical Devicess (CAMD). The HMA and CAMD are the respective regulatory networks of national competent authorities for medicines and medical devices. Although these networks represent distinct regulatory frameworks, there are many aspects and technologies that are of common interest. In addition, the systems and structures around these networks could be developed for mutual benefit.

ADVISORY COMMITTEE FOR MEDICAL DEVICES

The Advisory Committee for Medical Devices met four times in 2012. Regular updates were provided on key medical device issues, regulatory developments, the revision of the medical devices legislation and IMB activities in regulating medical devices. The committee also invited a number of external stakeholders, such as academic researchers, to make presentations to the Committee in respect of their activities.

ADVANCED THERAPIES

An advanced therapy medicinal product (ATMP) is a biological medicinal product which is a gene therapy medicinal product, a somatic cell therapy medicinal product or a tissue engineered product. This definition is set out in Directive 2001/83/EC, as amended to reflect new innovative therapeutic products. Given their innovative nature, applications for marketing authorisations for advanced therapy products proceed through the centralised procedure in accordance with Regulation 726/2004/EC.

During 2012, the IMB continued to actively participate in the European Medicines Agency's Committee for Advanced Therapies (CAT). The IMB's internal group on biological products and ATMPs also continued to meet regularly as a forum for information exchange and for discussion of areas of regulatory interest as relevant to ATMPs, blood, tissue and biological products.

Key developments in the ATMP area during 2012 included the IMB's participation in the planning and delivery of the ESOF Satellite Conference 'Making Gene and Cell Therapy a Reality'. The IMB also drafted a specific guidance document to provide regulatory information to hospital-based manufacturers of ATMPs. This guide clarifies the IMB's requirements for the manufacture and use of these medicines. The guide underwent public consultation during 2012. The outcome of consultation was positive and it is planned to formally publish the guide in early 2013.

HUMAN ORGANS FOR TRANSPLANTATION

This European Directive on standards of quality and safety of human organs intended for transplantation (Directive 2010/53/EC) was transposed into Irish legislation by Statutory Instrument (S.I. No. 325 of 2012). Signed by the Minister for Health on 27 August 2012, this legislation resulted in the appointment of the IMB and the HSE as the responsible Competent Authorities for implementation of different aspects of the Directive. In respect of the IMB, we are responsible for the inspection and authorisation of organ procurement and transplant centres and for the development of a system for reporting of serious adverse reactions and events.

During 2012, an internal multidisciplinary group continued to review the requirements of the directive from an IMB perspective and developed appropriate internal systems and procedures for implementation of these requirements. As part of this process, an initial report form for the notification of suspected adverse reactions and events associated with transplantation was developed and published on the IMB website.

The IMB also engaged with the HSE in respect of areas of mutual interest and contributed to the relevant competent authority meetings during the year.

COSMETICS

TEETH WHITENING PRODUCTS DIRECTIVE

Directive 2011/84/EU, concerning the use of hydrogen peroxide in teeth-whitening/oral care products, was transposed into Irish law in October by the European Communities (Cosmetic Products) (Amendment) Regulation 2012 (S.I. No. 396 of 2012). This permits products with less than 0.1% hydrogen peroxide (present or released) to be made available directly to consumers. However, products having between 0.1% to 6% hydrogen peroxide (present or released) may only be sold to dentists and used in individuals over 18 years of age. The IMB was involved in a range of activities both in advance of and subsequent to the introduction of this legislation. This included the publication of a information on its website specific to distributors, retailers and consumers. In addition, information was provided to regulatory bodies such as the Dental Council and the Pharmaceutical Society of Ireland.

SCIENTIFIC ANIMAL PROTECTION

The IMB implemented an extensive programme of work during 2012 in advance of becoming the competent authority responsible for the implementation of Directive 2010/63/EU on the protection of animals used for scientific purposes from 1 January 2013. The accompanying national Regulations are set out in SI No 543 of 2012. This authority was transferred from the Department of Health which regulated this area until 31 December 2012.

Directive 2010/63/EU is significant and complex legislation intended to improve the welfare of animals used for scientific purposes and to promote the principles of the 3Rs (replacement, refinement and reduction).

Among the primary functions of the IMB in respect of this legislation is the authorisation of establishments and monitoring of animal welfare at establishments where animals used for scientific purposes are kept. In addition to establishments, authorisations will also be required at project level and at individual level. The Department of Health continues to have responsibility for related policy and legislative developments.

IMB IMPLEMENTATION PROGRAMME

During 2012, a dedicated section was established within the Veterinary Sciences Department to advance preparations for the implementation of Directive 2010/63/EU. This section will now also be responsible for carrying out the assessment and inspection duties required. In addition, an internal steering committee and a cross-functional project team were established. The implementation plan included the development of the operational processes, authorisation procedures, policies, application forms and accompanying guidelines that are necessary to implement the requirements of the legislation. The project team also met with a broad range of stakeholders including representatives of the research institutions, the broader research community and the animal protection movement. In addition, relevant website content was developed and published on www.imb.ie.

Throughout 2012, the IMB worked closely with officials from the Department of Health on clarifying legal and operational issues arising from the implementation of Directive 2010/63/EU and on the development of the relevant national Regulations.

STAKEHOLDER ENGAGEMENT AND COMMUNICATIONS

A core strategic goal of the IMB is to ensure that all our stakeholders have timely access to relevant safety, licensing and regulatory information. We are committed to enhancing our communications and engagement activities and this will continue to be an area of focus and development for the IMB over the coming years.

Throughout 2012, there were a series of communications programmes and initiatives implemented.

STAKEHOLDER ENGAGEMENT

Consultative Panel on the Legal Classification of Medicines

The Consultative Panel on the Legal Classification of medicines held quarterly meetings during 2012. The aim of the Panel is to assist in developing the debate on policies in the area of legal classification of human medicines. It was established following a public consultation process which was held during 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 panel provides advice on external socioeconomic and policy issues that should be considered when determining the appropriate classification of medicines. During 2012, each representative was invited to present their views and perspectives to the panel. The final meeting of the panel was planned for early 2013 and it is anticipated that a report on its deliberations will be finalised later in the year.

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). Issues of mutual interest are discussed at these bi-annual meetings. In 2012, these included labelling, electronic submissions, new legislation, shortages of medicines and national timelines.

A number of meetings were also held with industry and company representatives in respect of the ongoing implementation of the Traditional Herbal Medicinal Products Directive. These meetings provided guidance and direction to stakeholders in an effort to improve the number and quality of applications received through the registration scheme.

Two meetings were held with the Pharmaceutical Distributors Federation. The main topics of discussion included updates to legislation and related guidance document as well as IMB expectations with regard to emerging issues such as the Falsified Medicines Directive, EU GDP guidelines, traditional herbal medicines and the regulation of cosmetics.

Meetings with Stakeholders – Veterinary Medicines

The IMB held several meetings during 2012 with interested parties, including the European Generics Group for Veterinary Medicines, the International Federation of Animal Health (Europe), the Environmental Protection Agency and the Health Protection Surveillance Centre. These meetings considered a wide variety of topics including the pending EU legislation on veterinary authorisation procedures, the inspection of establishments where animals for scientific purposes are kept and antibiotic resistance.

The IMB also held a number of meetings with the Department of Health in relation to the implementation of Directive 2010/63/EU and with the Department of Agriculture, Food and the Marine in relation matters of mutual interest. In addition, the IMB attended a tripartite meeting with the UK's Veterinary Medicines Directorate and the Department of Agriculture, Food and the Marine held in County Kildare with the goal of advancing the development of the new EU legislation on the authorisation and regulation of veterinary medicines.

Several meetings also took place in the past year with applicants to discuss ongoing or proposed applications where IMB is to be the reference member state in future European application procedures. The IMB also held a number of meetings with agricultural stakeholders on the subject of regulation of veterinary medicinal products.

Furthermore, in preparation for the implementation of Directive 2010/63/EU, the IMB met with a broad range of additional stakeholders including representatives of the research institutions, research funding bodies and the animal protection community.

Meetings with Stakeholders – Medical Devices

In 2012, four meetings were held with the Irish Medical Device Association (IMDA). These meetings focused on developments in the regulation of medical devices issues including developments at European level. In addition, the IMB participated in the IMDA two yearly Global Access Conference held in Galway in May.

There were four meetings held with the National Standards Authority of Ireland (NSAI), the sole notified body for medical devices in Ireland. Regular meetings allow for discussion on designation and monitoring activities and regulatory developments in respect of medical devices. In addition, a number of additional meetings were held with the NSAI during 2012 arising from the joint plan for immediate actions which included a review of the designations of notified bodies.

Meeting with Stakeholders – Cosmetic Products

As part of our co-operation with the HSE Environmental Health Service and Public Analyst's Laboratories regarding cosmetics regulation, a meeting of the National Cosmetics Surveillance Forum was held. The purpose of this meeting was to review and manage the national market surveillance strategy for cosmetic products.

Presentations to Stakeholders

As in previous years, 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.

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 2012 presentations is provided in Appendix 2.

EVENTS

Information Days

IMB information days and seminars 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. The following information sessions were held during 2012:

- A GMP and market compliance information day, aimed primarily at manufacturers of medicinal products and manufacturers of active substances, was held on 27 September. The event was focused on updating stakeholders on current regulatory topics and ongoing IMB activities and initiatives in this area. The programme was designed to allow greater opportunity for audience participation with smaller groups in parallel sessions and the use of interactive voting pads.
- A wholesale distribution information day was held on 28 September. This event was aimed primarily at distributors of medicines and again focused on providing up-to-date regulatory information and advice. The programme was similarly designed to allow greater opportunity for attendees to actively participate and engage with speakers.
- A clinical trials information seminar for academic sponsors and investigators was held at the IMB in June 2012. Presentations were given by IMB staff members who also contributed to the questions and answers session that followed. Approximately 90 people attended the seminar including medical practitioners, pharmacists and nursing staff from the main teaching hospitals, clinical academic units and members of the IMB's Advisory Committee for Human Medicines. The feedback received was very positive and has provided ideas for future seminars.
- A training seminar for distributors of cosmetic products was held in March. The seminar provided an overview of the current and future legislation with a particular emphasis on the distribution of cosmetics. The respective roles of the Department of Health, the HSE, the National Consumer Agency and the IMB were also outlined.

TOPRA Annual Symposium 2012

In October 2012, the IMB co-hosted The Organisation for Professionals in Regulatory Affairs (TOPRA) annual symposium which was held in University College Dublin. The event brought together over 600 representatives of industry, regulatory agencies and the European Commission to review and discuss current regulatory issues and to debate future planned developments.

The symposium, which is a key annual European forum for those working in healthcare regulatory affairs, consisted of 11 informative sessions covering topics such as clinical trials, the availability of medicines, falsified medicines, herbal medicines and the European pharmacovigilance legislation. There were also three parallel symposia focused on the regulation of medical devices, veterinary medicines and small to medium enterprises. A special session in relation to the roles and activities of the IMB was also held at this year's forum, to mark the co-hosting of the symposium.

Speakers over the course of the three day event included representatives from the European Commission, the European Medicines Agency, various European national authorities, the US FDA, industry and patient groups. IMB staff members also delivered a broad range of presentations.

City of Science ESOF Satellite Conference: Making Gene and Cell Therapy a Reality

The IMB and the Parenteral Drug Association (PDA) Ireland Chapter hosted a major two day scientific gathering entitled Making Gene and Cell Therapy Medicines a Reality on 10 and 11 July 2012.

The two day event, which was organised as a satellite event to the EuroScience Open Forum (ESOF2012), focussed on the regulatory framework and challenges of translating the basic scientific discoveries related to molecular and cell biology into novel, commercial gene and cellular therapies. The meeting brought together leading experts from regulatory authorities including the European Medicines Agency, the US FDA and the IMB with expert academic and industrial scientists. It afforded delegates the opportunity to discuss regulatory developments in advanced therapy medicines and the opportunities these products provide in meeting unmet medical needs for patients. IMB staff presented on a number of topics including clinical trial applications and the assessment process.

The IMB and PDA also presented a more publicly focussed session on the same theme on Thursday 12 July within the main ESOF event and this generated a lot of interest from conference attendees. This event was in-keeping with one of the aims of ESOF 2012 which was to bring science to the public.

BT Young Scientist and Technology Exhibition 2012

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 2012. The exhibition took place in mid-January in the RDS and it was the third year in succession the IMB was involved.

Our stand used interactive displays and other features to build awareness among attendees 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.

BRAND IDENTITY

The role and functions of the IMB have increased significantly over the 16 years since it was established in 1996. Consequently, our current name and brand identity does not accurately reflect the nature and character of our organisation and our identity has not evolved in step with our size and expanding new areas of responsibility. The current name of our organisation also contributes little to supporting our strategic objectives which now extend beyond medicines alone.

As a result, it has been decided by the Board of the IMB to change the name of the organisation to better reflect the range of services it provides. The new name to the replace the Irish Medicines Board is the Health Products Regulatory Authority (HPRA). The introduction of the new name is provided for in the Health (Pricing and Supply of Medical Goods) Bill 2012 and it is anticipated it will become operational in early 2014. We will also be launching a new corporate website at that time.

In preparation for the adoption of the new name, the IMB commenced a project to develop a new brand identity. This project, which will incorporate a logo and brand identity guidelines, will be completed in the first half of 2013.

PUBLICATIONS

Safety Warning and Notices

Throughout 2012, the IMB published various warning statements and notices on safety issues or benefit/risk evaluations of human medicines. There were 34 Direct Healthcare Professional Communications concerning human medicines published on the IMB website and issued to subscribers.

In respect of medical devices, 19 safety notices were sent to the relevant stakeholder groups and published online in 2012. In addition, 441 manufacturers field safety notices affecting the Irish market were highlighted on the IMB website.

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.

Among the new publications was a guidance document addressing cosmetic-biocide borderline products which was finalised in 2012 following collaboration between the IMB and the Department of Agriculture, Food and the Marine. This collaboration included the completion of a public consultation process which was initiated in 2011.

Further information concerning new and updated guidance documents published during 2012 is provided in Appendix 3.

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 2012. Topics covered included:

- Implementation of the new EU pharmacovigilance legislation;
- Guidance for marketing authorisation holders when dealing with pharmacy level recalls on the Irish market;
- Falsified Medicines Directive 2011/62/EU and API manufacturers, importers and distributors;
- Audits of Type IA variations: experience to date;
- Update on status of flukicides without an MRL for milk;
- Consumption of veterinary antimicrobials in Ireland;
- Tooth whitening products - new legislation on hydrogen peroxide.

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

Six issues of the IMB's Drug Safety Newsletter were distributed to doctors, dentists and pharmacists during 2012. The publication is circulated by a combination of post and email and is available to download from the IMB website.

The 50th edition of the newsletter, which highlighted the changes arising from the revised pharmacovigilance legislation, was published in November and was marked by a introduction from the Chief Executive. Additionally, an information leaflet for patients and consumers on the safety monitoring of medicines in the context of the revised legislative framework was also distributed to patient organisations and published on the IMB website. A 'Quick Guide to Medical Device Incident User Reporting' was included as an insert in the 51st edition of the newsletter.

A full list of all the safety topics and issues covered in this publication during 2012 is included 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.

During 2012, the IMB published three editions of the Medical Devices Newsletters including a special edition focused on the Commission's proposals to revise the legislative framework. The additional topics cover during the past year are listed in Appendix 3.

External Articles

Pharmacovigilance

There were 14 IMB articles published in MIMS Ireland. One article was published each month while the remaining two 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 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 Veterinary Ireland Journal and It's Your Field.

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

Cosmetic Products

An article was published in the Journal of the Irish Dental Association in relation to the new legislation on tooth whitening products. Additionally, a joint communiqué was issued to dentists by the Dental Council and the IMB regarding the same topic.

MEDIA COMMUNICATIONS

We continued to develop our proactive media communications programme to highlight important safety messages and to build awareness of the role of the IMB. We issued 38 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 press releases issued during the past year were:

- IMB urges continued vigilance of children's cosmetics ahead of Halloween
- IMB, Customs and Gardaí in global INTERPOL operation
- IMB advises against use of echinacea in children under 12 years
- IMB announces new dosage instructions for children's liquid paracetamol medicines
- IMB cautions consumers against purchase of illegal online medicines

In addition, we responded to 532 queries from national, local and specialist media during the year. This represents a 20% increase in the number of queries compared to 2011. Drafting 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 2012, the IMB completed public consultations on:

- Fees for 2013
- An updated enforcement strategy for 2012-2016
- Hospital-based advanced therapy medicinal products

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. In 2012, we provided comments in respect of 12 public consultations from the Department of Health, the HSE, HIQA, the Pharmaceutical Society of Ireland, and other bodies.

WEBSITE

The website www.imb.ie is a critical element 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. We are focused on its continued development and enhancement to ensure it remains an attractive and user-friendly resource. As part of this process, a user survey was completed in 2012 to identify potential areas for improvement.

2012 Statistics

- More 171,000 unique visitors accessed the website during the past twelve months representing an annual increase of 36%. There were close to 434,000 visits in total.
- Of those who accessed the site in 2012, 37% were new or first time visitors.
- Among the most popular sections of the website were the human and veterinary medicines product listings.

Pharmacovigilance

The dedicated webpage on the new pharmacovigilance legislation was further updated with additional information and guidance while the highlights from the PRAC meetings were also published online. A dedicated webpage, Resources for Healthcare Professionals, was also developed and includes specific information for healthcare professionals in respect of IMB pharmacovigilance activities. It features a link to the Irish Academy of

Continuing Medical Education (iaCME) website, where a CPD module based on the key messages and advice to healthcare professionals included in the IMB's Drug Safety Newsletter has been developed. The intention of the module is to help healthcare professionals to apply learnings from the newsletter to their individual practices.

New Website

In late 2012, the IMB also commenced a procurement process to appoint a website development company to plan for and develop a new corporate website (for early 2014). It is intended that the new website will better reflect the broad range of services delivered by the IMB as well as supporting new technologies. In addition, it will coincide with the introduction of the Health Products Regulatory Authority name and brand identity.

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 2012, the IMB received 11 Freedom of Information requests consisting of six non-personal requests and five personal requests.

PARLIAMENTARY AFFAIRS

Oireachtas Joint Committee on Health and Children

The IMB attended four meetings of the Joint Committee on Health and Children. These related to the PIP breast implants, DePuy ASR Articular Surface Replacement and ASR XL Acetabular system, the safety profile of the HPV vaccine Gardasil and the responsibilities of the IMB.

Meeting with Members of the European Parliament

A delegation from the IMB met with the Irish and Northern Irish Members of the European Parliament in Strasbourg to discuss regulatory developments relevant to the Irish Presidency of the Council of European Union in the first half of 2013.

Parliamentary Questions

During 2012, the IMB received and responded to 98 parliamentary questions, an almost trebling of the number received in 2011. There were also 57 other requests from the Department of Health, other government departments or members of the Oireachtas during the year. Of the total number of queries (155), the three largest categories related to human medicines (66), staff and payroll (33) and medical devices (16). Many of the queries relating to human medicines concerned the availability or supply of product, market shortages, or reimbursement issues.

CUSTOMER SERVICES

The customer services team responded to over 3,000 queries from industry representatives, healthcare professionals and members of the public. Queries were received primarily via email and by phone.

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.

RESEARCH

IMB Website – User Satisfaction Survey

In July 2012, the IMB carried an online survey among the users of our website. The goal of the survey was to identify potential areas for improvement as well as any new content or features that users feel should be included on the site. The survey was highlighted via the homepage while a link and request to participate were also sent to key stakeholder groups including patient, healthcare professional and industry representative bodies. The helpful and informative feedback we received from a total of 334 users will be used to guide the future development of our online presence.

Impact of Direct Healthcare Professional Communications

IMB research, conducted in collaboration with the School of Pharmacy in Trinity College Dublin, was presented at the Health Services Research and Pharmacy Practice (HSRPP) conference. The research involved the assessment of the impact of Direct Healthcare Professional Communications on pharmacy practice in Ireland.

Sources of Medicines Information and the Use of the Internet

In late 2012, the IMB commissioned research to examine how Irish consumers source information about the medicines they take. The research will also examine the use of the internet as a source of medicines information and supply. The results of the research will be published in the first half of 2013.

ORGANISATIONAL MANAGEMENT AND DEVELOPMENT

A key strategic goal of the IMB is to build the future capabilities of the organisation. In particular, there must be effective systems in place to manage quality and risk across all of our processes, to support learning and development of our staff and to provide information technology and telecommunications services to staff and stakeholders. 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 central to the achievement of our strategic goals and are designed to attract and retain the skills necessary to maintain organisation capability. Our policies are kept under continuous review and we adapt our work practices as required to enable us to manage our human resources with the flexibility necessary to respond to changing circumstances. Amongst the primary projects and statistics from 2012 were the following:

- The IMB's first leadership development programme commenced in 2012 based on requirements identified in our Learning and Development Strategy (2010). The eight participants in the programme engaged in a range of activities throughout the past year and this initial course will conclude in Q1 2013. The programme has been awarded external accreditation from the Institute of Leadership and Management (ILM). Also in 2012, arising from the Learning and Development Strategy, we maintained our commitment to staff continuous learning and development with the launch of a number of new initiatives throughout the year. These included access to a range of online courses and resources, language classes and a series of cross-departmental awareness sessions to facilitate greater staff engagement.
- We also maintained our focus on empowering line managers by providing proactive support to assist them with staff management. During 2012, 14 managers participated in IMB bespoke new manager training sessions.
- Project planning progressed in respect of the replacement of the human resources IT systems and this will continue throughout 2013.
- As in previous years, the business plans for each internal department provided the framework for performance management within the IMB. The PDP (Performance Development Programme) aims to ensure achievement of strategic and business goals, to develop employee skills and to promote clear two-way discussion between employees and their managers. As well as incorporating key performance indicators against which individuals are evaluated, there are organisational and personal competencies prioritised while specific training and development needs for the year ahead are also identified. This process recognises good performance as well as addressing any under-performance and/or training needs.
- During 2012, we recruited new specialist staff for those areas of additional competencies arising from the introduction of new EU legislation and assigned to the IMB by the Department of Health. This included the requirements arising from the EU pharmacovigilance legislation, the Directive on standards of quality and safety of human organs intended for transplantation and the Directive relating to animals used for scientific purposes.
- The IMB continued 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 regular management and Board reports. The overall absence rate for 2012 was maintained at 2.4%.

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

The IMB utilises a range of technologies to support the management of core activities such as product and establishment licensing together with ongoing safety monitoring and reporting. In addition, the IMB is also party to certain pan-European and international systems and provides data feeds into a number of databanks throughout the year.

During 2012, work progressed on the delivery of the IMB's IT Strategy (2011 to 2015). The requirement, identified as part of this strategy, to introduce more robust disaster recovery arrangements as well as enhanced online tools, highlight the growing dependence on information technology in delivering services to stakeholders.

In line with Government initiatives for shared services, in 2012 the IMB worked closely with bodies such as the Office of the Revenue Commissioner and the HSE. Our information technology team also provided support to a range of third party organisations seeking assistance in developing and implementing technology solutions during the course of the year.

The IMB is also part of the wider European regulatory network focussed on EU telematics. This work programme is designed to support licensing and safety related activities across the EU. One of the most significant IMB achievements in this regard during 2012 was our continued development of the Common European Submission Portal (CESP).

CESP Homepage

This system was launched in 2011 and widely adopted across the EU during 2012. As a result, multiple Member States are now utilising the services of the IMB to manage the secure delivery of medicines data. Over 20 Member States are scheduled to formally agree a three year contract with the IMB in respect of CESP usage during the Irish EU Presidency in early 2013. Additionally, the pharmaceutical industry has welcomed the introduction of a single portal to manage the medicines regulatory process.

The IMB was also active in a number of other EU information technology projects during 2012. These included projects associated with the new pharmacovigilance legislation as well as forthcoming falsified medicines and clinical trials legislation.

Throughout 2012, the IMB also acted in an advisory capacity to the Board of the European Medicines Agency and to the HMA.

Change Management

The IMB has a strong track record in change management. The adoption of best practice models, both for organisational structures and business processes, has been part of our corporate strategy for over 10 years.

In 2012, the IMB continued on this path of continuous improvement by introducing an organisational project management office (PMO) tasked with supporting the planning process, ensuring alignment with the organisational objectives, and developing consistent management and control mechanisms. While the PMO is in its infancy, a range of regulatory, organisational and technology programmes are already benefiting from the new model, offering improved prioritisation and project management services.

The development of a new IMB Enforcement Strategy was completed in 2012 following extensive stakeholder engagement both nationally and internationally. An associated public consultation document was also published in mid 2012. This new strategy is strongly focussed on targeting high risk areas in line with organisational capacity. Planning for the implementation of the strategy commenced in the last quarter of 2012.

The introduction of new EU pharmacovigilance legislation was a significant focus of the IMB throughout 2012 as a range of process changes were implemented to support the new requirements. Further details are provided on page 51.

The IMB also developed new processes and technology interfaces to assist with the introduction of generic medicines legislation. Once this legislation is introduced, the IMB website will include lists of interchangeable medicines that will be accessible to healthcare professionals and members of the public. New data feeds have also been established from the IMB's national database of licensed medicines to the HSE.

CHIEF EXECUTIVE'S OFFICE

The Chief Executive's Office is responsible for communication, strategy and planning, 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 with respect to the quality of the systems and practices in place in agencies and is a resource for sharing of best practices. The IMB's chief executive is co-chair of the BEMA steering group with the head of the Paul Ehrlich Institute in Germany. The IMB provides the secretariat for the group and is responsible for visit logistics. During 2012, we continued to lead the steering group as preparations for the third cycle were finalised and the first visits began.

Quality Management

During 2012, the IMB's quality management system continued to be extended with respect to a number of new functions and legislative requirements. Good progress was made with implementing the new pharmacovigilance activities (Directive 2010/84/EU) where GVP modules had been adopted, and systems and processes were in place at the European Medicines Agency. Full implementation in some areas will await the finalisation and adoption of the remaining GVP modules and the development and deployment of IT systems, including a repository for PSURs, and the corresponding processes at the European Medicines Agency. Other implementation areas included the development of the quality system for 'scientific animal protection' according to the European Union (Protection of Animals Used for Scientific Purposes) Regulations 2012, and for new and amended processes under the falsified medicines Directive, 2011/62/EU.

CORPORATE AFFAIRS

Corporate Affairs is responsible for the delivery of a number of core service areas to colleagues across the organisation. These include building and accommodation management as well as the provision of reception, canteen, travel, library and event management services. The department 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. 2012 was another busy and productive year across all these functions.

Event Management

The IMB held six events in 2012 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 four information days and two training seminars. The information days, which typically provide regulatory guidance and updates to interested parties, were focused on GMP, wholesale distribution, clinical trials and cosmetics distribution. The number of delegates attending these events ranged from 100 to 350.

In addition, the two training events consisted of a course (duration three days) in Substances of Human Origin Vigilance and Surveillance (SOHOV&S) and a course (duration 4½ days) under the Pharmaceutical Inspection Co-operation Scheme (PIC/S).

Freedom of Information

During 2012, the IMB received 11 Freedom of Information requests consisting of six non-personal requests and five personal requests (see also page 70).

Board and Committees

Corporate Services 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 IMB met six times in 2012 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 2011. 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 2012 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)	6	6
Mr. Pat Brangan	6	5
Mr. Wilfred Higgins	6	6
Ms. Ann Horan	6	5
Prof. Mary Horgan	6	5
Dr. Elizabeth Keane	1	1
Mr. Brendan McLaughlin	6	6
Mr. Noel O'Donoghue	6	5
Prof. Caitriona O'Driscoll	6	4

- The Audit Committee, a subcommittee to the Board, met four times in 2012. Further details are provided in the financial statements.
- Also during the year in review, the Advisory Committee for Human Medicines met four times, the Advisory Committee for Veterinary Medicines met three times and the Advisory Committee for Medical Devices met four times.
- The Herbal Medicines Committee, a subcommittee to the Advisory Committee for Human Medicines, met twice in 2012. The Clinical Trials Committee is also a subcommittee to the Advisory Committee for Human Medicines and it met twelve times in the past year.

FINANCE

It is the role of Finance section to safeguard the finances of the IMB while managing the day-to-day financial running of the organisation. 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 finance section also provides financial information and analysis to the Board and the Management Committee.

The 2012 financial statements presented in this report were prepared by the finance team 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 2012

Since 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. 542 of 2009. These regulations transpose the Energy End Use Efficiency and Energy Services Directive (Directive 2006/32/EC) into Irish law.

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

In 2012, the IMB consumed 648 MWh of energy, consisting of:

- 575 MWh of electricity;
- 0 MWh of fossil fuels;
- 73 MWh of renewable fuels.

Actions Undertaken in 2012

In the past year, the IMB continued to focus on energy performance by maintaining 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. The agreements are intended to maximise volume discounts and provide for reductions in administrative and transaction costs for suppliers and public sector purchasers. IMB cost savings were in the region of 6% for electricity and 5% for gas (compared to the cost of going directly to the market). Energy savings amounted to 103 MWh.

Total Energy Savings

In total, initiatives undertaken prior to 2010 and the measures outlined above are saving the IMB 117 MWh on average annually. The IMB used very little gas in 2012 as a result of a boiler upgrade which reduced total energy usage for 2012 by 15% compared to the year previous.

Actions Planned for 2013

In 2013, 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 to the public sector. It is anticipated that both these framework agreements, which will again be accessed via the National Procurement Service, will deliver savings when compared to the costs of going directly to the market. It is important to note that the National Procurement Service contract rates are fixed until the end of 2013. During next year, the IMB also intends to replace its single glazed windows on the upper floors to more energy efficient triple glazed windows which will result in greater energy savings.

FINANCIAL STATEMENTS

BOARD MEMBERS AND OTHER INFORMATION

Board Members:	Mr. Michael Hayes (Chairman) Mr. Pat Brangan Mr. Wilfrid Higgins Ms. Ann Horan Prof. Mary Horgan * Dr. Elizabeth Keane ** Mr. Brendan McLaughlin Mr. Noel O'Donoghue Prof. Caitriona O'Driscoll The Board was appointed by the Minister for Health on 18th January 2011. * Prof. Mary Horgan was appointed on 08/11/2011. ** Dr. Elizabeth Keane was appointed on 24/10/2012.
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 (as amended), 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 2012. 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 is invited annually to meet with the audit committee to brief them on the outcome of the external audit and the audit committee meets annually with the internal auditor. In 2010 the IMB re-appointed Crowleys DFK as internal auditor to the Board under a three-year contract. During 2012 the internal auditors reviewed the areas of procurement and payments, banking and finance, and financial and asset management 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 2012, 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 page 84.

STATEMENT ON INTERNAL FINANCIAL CONTROLS

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 financial 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. The IMB maintains a risk register which is reviewed and updated by management, considered by the audit committee and presented to the Board 3 times a year.

   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. These risks are recorded in the risk register.

   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 Board have carried out a review of the effectiveness of internal financial control, in order to demonstrate compliance with the Code of Practice. This review was carried out at its meeting on 22nd May 2013.

Mr. Michael Hayes
Chairman to the Board
24 June 2013

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.

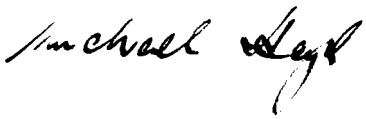
In preparing those statements the Board is required to:

- 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
24 June 2013

Board Member

Ms. Ann Horan

COMPTROLLER AND AUDITOR GENERAL
REPORT 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 2012 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 statements have been prepared in the form prescribed under Section 18 of the Act, and in accordance with 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.

In addition, I read the Board's annual report to identify material inconsistencies with the audited financial statements. If I become aware of any apparent material misstatements or inconsistencies, I consider the implications for my report.

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 2012 and of its income and expenditure for 2012.

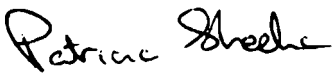
In my opinion, proper books of account have been kept by the Board. The financial statements are in agreement with the books of account.

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 money has not been applied for the purposes intended or where the transactions did not conform to the authorities governing them, or
- the information given in the Board's annual report is not consistent with the related financial statements, 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.



Patricia Sheehan

For and on behalf of the

Comptroller and Auditor General

30 June 2013

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 227 of the Taxes Consolidation Act, 1997.

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 €687,798 (2011 - €689,860). The surplus for the year on page 92 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 2012

	Notes	2012 €	2011 €
Fee Income	2	**20,065,633**	21,399,720
Other Income	3	**3,927,031**	3,546,480
		23,992,664	24,946,200
Salaries and Wages	4	**17,215,472**	16,433,330
Other Operating Costs	5	**5,190,035**	6,679,498
Depreciation	1	**1,027,957**	1,272,749
		23,433,464	24,385,577
Surplus for the year before write back of Superannuation contributions		**559,200**	560,623
Staff Superannuation Contributions		**687,798**	689,860
Surplus for the year		**1,246,998**	1,250,483
Balance brought forward		**21,626,901**	20,376,418
Balance carried forward		**22,873,899**	21,626,901

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

Chairman

Mr. Michael Hayes
24 June 2013

Board Member

Ms. Ann Horan

The accounting policies on pages 89 to 91 and the notes on pages 95 to 101 form part of the financial statements.

BALANCE SHEET

as at 31 December 2012

	Notes	2012 €	2011 €
Tangible Assets	1	**23,162,452**	23,019,503
Current Assets			
Debtors and Prepayments	6	**948,557**	1,420,295
Stock of Stationery		**2,703**	2,469
Cash at Bank and in Hand	12	**187,175**	36,890
Short Term Deposits		**15,500,825**	14,669,317
		16,639,260	16,128,971
Creditors - Amounts falling due within one year			
Creditors and Accruals	7	**7,407,809**	7,208,237
Mortgage	13	**793,332**	793,332
		8,201,141	8,001,569
Net Current Assets		**8,438,119**	8,127,402
Long Term Liabilities			
Mortgage	13	**8,726,672**	9,520,004
TOTAL NET ASSETS		**22,873,899**	21,626,901
Financed by			
Income and Expenditure Reserve	11	**22,873,899**	21,626,901
		22,873,899	21,626,901

Chairman

Mr. Michael Hayes
24 June 2013

Board Member

Ms. Ann Horan

The accounting policies on pages 89 to 91 and the notes on pages 95 to 101 form part of the financial statements.

Cash Flow Statement

for the year ended 31 December 2012

	Notes	2012 €	2011 €
Reconciliation of surplus to net cash inflow from operating activities			
Surplus for Year		**1,246,998**	1,250,483
Depreciation Charge		**1,027,957**	1,272,749
(Increase)/Decrease in Debtors		**487,014**	139,654
(Increase)/Decrease in Stocks		**(234)**	(103)
Increase/(Decrease) in Creditors - amounts falling due within one year		**203,671**	862,733
Deposit Interest		**(272,921)**	(256,205)
Bank Interest and Charges		**422,839**	460,323
Loss/(Gain) on Disposal of Fixed Assets		**(460)**	458
Net Cash Inflow from Operating Activities		**3,114,864**	3,730,092
Cash Flow Statement			
Net Cash Inflow from Operating Activities		**3,114,864**	3,730,092
Return on Investments and Servicing of Finance	8	**(169,293)**	(233,446)
Capital Expenditure	8	**(1,170,446)**	(539,463)
Management of Liquid Resources	8	**(831,508)**	(2,151,221)
Financing	8	**(793,332)**	(793,332)
Increase/(Decrease) in Cash		**150,285**	12,630
Reconciliation of net cash flow to movement in net debt			
Increase/(Decrease) In Cash		**150,285**	12,630
Increase/(Decrease) In Short Term Deposits		**831,508**	2,151,221
(Increase)/Decrease In Long Term Finance		**793,332**	793,332
Change In Net Funds/(Debt)		**1,775,125**	2,957,183
Net Debt at start of year		**4,392,871**	1,435,688
Net Funds/(Debt) at end of year	9	**6,167,996**	4,392,871

The accounting policies on pages 89 to 91 and the notes on pages 95 to 101 form part of the financial statements.

Notes to the Financial Statements

for the year ended 31 December 2012

1. Tangible Assets	Fixtures and Fittings €	Computer Equipment €	Leasehold Improvements €	Improvements Premises €	Premises €	Total €
Cost						
Balance as at 1 January 2012	978,235	8,606,936	502,445	3,551,410	20,383,000	34,022,026
Additions for the year	11,271	422,252	-	23,148	714,235	1,170,906
Disposals for the year	(1,025)	(24,986)	-	-	-	(26,011)
As at 31 December 2012	988,481	9,004,202	502,445	3,574,558	21,097,235	35,166,921
Depreciation						
Balance as at 1 January 2012	847,682	8,044,061	350,458	1,760,322	-	11,002,523
Charge for the year	77,215	543,041	50,245	357,456	-	1,027,957
Disposals for the year	(1,025)	(24,986)	-	-	-	(26,011)
As at 31 December 2012	923,872	8,562,116	400,703	2,117,778	-	12,004,469
Net Book value at 31 December 2012	64,609	442,086	101,742	1,456,780	21,097,235	23,162,452
Net Book value at 1 January 2012	130,553	562,875	151,987	1,791,088	20,383,000	23,019,503

2. Income

	2012 €	2011 €
Fee Income		
Clinical Trials	**148,326**	123,617
Human Medicine - National Fees	**6,875,259**	7,750,395
Human Medicine - European Fees	**5,943,402**	7,056,707
Veterinary Medicine - National Fees	**1,163,520**	1,104,294
Veterinary Medicine - European Fees	**1,564,656**	1,339,833
Compliance Department	**4,123,445**	3,773,733
Medical Devices	**247,025**	251,141
	20,065,633	21,399,720
Other Income (Note 3)	**3,927,031**	3,546,480
Total Income	**23,992,664**	24,946,200

Certain fees, totalling €16,725,422 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 2012

3. Other Income

	2012	2011
	€	€
Dept of Health Funding	**3,545,000**	3,230,479
Conference Fee Income	**108,650**	60,254
Deposit Interest	**272,921**	256,205
(Loss)/Gain on Disposal of Fixed Assets	**460**	(458)
	3,927,031	3,546,480

4. Salaries and Wages

	2012	2011
	€	€
Salaries and Wages	**15,822,480**	15,144,077
Social Welfare Costs	**1,392,992**	1,289,253
	17,215,472	16,433,330

The average number of staff employed during the year was 297 (2011 - 289).
Staff employed at 31 December 2012 can be analysed across the following departments:

	2012	2011
Chief Executive	**12**	10
Compliance	**60**	58
Finance & Corporate Affairs	**18**	16
Human Products Authorisation & Registration	**105**	108
Human Products Monitoring	**42**	36
Human Resources	**8**	7
IT & Change Management	**14**	13
Scientific Affairs	**2**	2
Veterinary Sciences	**23**	19
Pensioners	**24**	21
	308	290

Pension related deductions for Public Servants of €986,483 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 2012

5. Operating Costs

	2012	2011
	€	€
Accommodation Costs	**1,464,548**	1,347,919
Travel, Representation and Training	**734,240**	720,158
Bank Charges and Interest	**428,324**	460,323
Legal & Professional Fees	**151,892**	1,780,330
Stationery, Publications and Postage	**419,163**	438,945
Other Operating Costs	**1,991,868**	1,931,823
	5,190,035	6,679,498

Other operating expenses of €1,991,868 includes an amount of €4,185 related to staff hospitality.

6. Debtors (all due within one year)

	2012	2011
	€	€
Trade Debtors	**431,040**	788,523
Prepayments	**324,609**	357,405
Other Debtors	**192,908**	274,367
	948,557	1,420,295

7. Creditors (amounts falling due within one year)

	2012	2011
	€	€
Trade Creditors	**379,248**	540,975
Accruals	**6,519,183**	6,146,590
Revenue Commissioners	**509,378**	520,672
	7,407,809	7,208,237

Notes to the Financial Statements

for the year ended 31 December 2012

8. Gross Cash Flows

	2012	2011
	€	€
Returns on Investment and Servicing of Finance:		
Deposit Interest	**257,645**	226,521
Bank Interest and Charges	**(426,938)**	(459,967)
	(169,293)	(233,446)
Capital Expenditure		
Payments to acquire Tangible Fixed Assets	**(1,170,906)**	(539,663)
Receipts from sales of Tangible Fixed Assets	**460**	200
	(1,170,446)	(539,463)
Management of Liquid Resources		
(Increase)/Decrease in Short Term Deposits	**(831,508)**	(2,151,221)
	(831,508)	(2,151,221)
Financing		
Increase/(Decrease) in Long Term Finance	**(793,332)**	(793,332)
	(793,332)	(793,332)

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

	As At 01/01/2012	Cashflow	As At 31/12/2012
Cash at Bank and in Hand	36,890	150,285	**187,175**
Short Term Deposits	14,669,317	831,508	**15,500,825**
Debt Due Within One Year	(793,332)	0	**(793,332)**
Debt Due After One Year	(9,520,004)	793,332	**(8,726,672)**
	4,392,871	1,775,125	**6,167,996**

10. Administration Expenses

	2012	2011
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 2012

11. Movement on Income and Expenditure Reserves

	As At 01/01/2012	Movement	As At 31/12/2012
Retained Reserves	15,840,655	559,200	16,399,855
Staff Superannuation Contributions	5,786,246	687,798	6,474,044
	21,626,901	1,246,998	22,873,899

12. Cash and Bank Balances

	2012 €	2011 €
Current Account Balances	186,798	35,976
Cash on Hand	377	914
	187,175	36,890

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 :

	2012 €	2011 €
- within one year	793,332	793,332
- between one and five years	3,173,328	3,173,328
- after five years	5,553,344	6,346,676
	9,520,004	10,313,336

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 the mortgage duration. The balance of the borrowings are fully offset by cash reserves. For 2013 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 2012

15. Financial Commitments

	2012 €	2011 €
Operating Leases		
Amounts payable during the next twelve months in respect of leases which expire		
- within one year (in respect of Ormonde House)	**54,530**	-
- within one year (in respect of Longphort House)	**70,369**	-
- between one and five years (in respect of Longphort House)	**-**	167,056
- after five years (in respect of Alexandra House)	**285,984**	285,984
	410,883	453,040

Included in Accommodation Costs (Note 5) is expenditure of €476,250 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 2012 this lease had 9 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 2012 this lease had 5 months remaining.

On 1 September 2012 the IMB signed a leasehold interest in respect of the ground floor, Ormonde House, Earlsfort Centre, Dublin 2.

At 31 December 2012 this lease had 8 months remaining.

16. Capital Commitments

	2012 €	2011 €
Contracted For (Contract Signed)	**2,657,000**	145,000
Not Contracted For	**890,000**	5,212,000
	3,547,000	5,357,000

17. Board Remuneration

	2012 €	2011 €
Chairman's Salary	**20,520**	19,596
Board Members' Travel Expenses	**8,554**	4,723
	29,074	24,319

Notes to the Financial Statements

for the year ended 31 December 2012

18. Staff Remuneration

	2012 €	2011 €
Chief Executive's Total Remuneration		
Basic Salary	**156,386**	156,386
	156,386	156,386

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

19. Related Party Transactions

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

20. Prompt Payment Of Accounts

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

21. Exchange Rates

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

2012 €1 = STG £0.8174

2011 €1 = STG £0.838

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 and the issue of damages was referred back to the High Court. In advance of the High Court hearing the Board settled all outstanding matters through mediation. The provision was sufficient to cover all costs.

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 22 May 2013.

APPENDIX 1
COMMITTEE MEMBERS

MANAGEMENT COMMITTEE

Mr. Pat O'Mahony
Chief Executive

Dr. Gabriel Beechinor
Director of Veterinary Sciences

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

Mr. Wilfrid J. Higgins

Ms. Ann Horan

Prof. Mary Horgan

Dr. Elizabeth Keane (appointed October 2012)

Mr. Brendan McLaughlin

Mr. Noel O'Donoghue

Prof. Caitriona O'Driscoll

AUDIT COMMITTEE

Mr. Pat Brangan

Ms. Ann Horan

Mr. Brendan McLaughlin

ADVISORY COMMITTEE FOR HUMAN MEDICINES

Prof. Mary Horgan – Chairman

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

Prof. Richard Reilly

Ms. Mary Sharp

Ms. Maebh Smith

Dr. Declan Sugrue (resigned June 2012)

Mr. Sean Paul Teeling

Prof. Wil van der Putten

Dr. Vivion Crowley

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. Catherine Kelly (from December 2012)

Dr. Thomas Peirce

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 (resigned August 2012)

Mrs. Ingrid Hook

Ms. Claudine Hughes

Ms. Anna-Maria Keaveney

Dr. Celine Leonard

Dr. Diarmaid O'Connell (resigned July 2012)

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

Dr. Colin Buckley

Dr. Owen Carey

Dr. Kevin Connolly

Dr. Noreen Dowd

Dr. Stephen Eustace

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. Patricia McCormack (resigned June 2012)

Prof. Aidan McCormick

Dr. Frank Murray

Dr. Yvonne O'Meara

Mr. Ashley Poynton

Dr. Brion Sweeney

Dr. Jogin Thakore

Dr. Douglas Veale (resigned July 2012)

APPENDIX 2
PRESENTATIONS 2012

THIRD LEVEL PRESENTATIONS

College	Course	Presentation Title
Athlone IT	Veterinary Nursing	Regulation of Veterinary Medicines
DCU	Chemical and Pharmaceutical Sciences	Irish pharmaceutical Industry Regulation and the Role of the IMB
DIT	Pharmaceutical Validation Technology	Regulatory Inspectional Findings
Dundalk IT	Veterinary Nursing	Regulation of Veterinary Medicines (2 presentations)
Letterkenny IT	Veterinary Nursing	Regulation of Veterinary Medicines
RCSI	Nurse Midwife Prescribing	Role of the IMB (2 presentations)
RCSI	Nurse Midwife Prescribing	Pharmacovigilance (2 presentations)
RCSI	Pharmacy	Evolution of Medicines Regulation
Sligo IT	Medical Biotechnology and Pharmaceutical Science	IMB Inspections / Pharmacovigilance
Sligo IT	Industrial Pharmaceutical Science	The Role of the IMB, Manufacturers and the QP
St. Johns, Cork	Veterinary Nursing	Regulation of Veterinary Medicines
TCD	Pharmacy	Quality Defects & Drug Withdrawals
TCD	Pharmacy	Regulation of Medicines and the Role of the IMB
TCD	Pharmacy (QP Forum)	Manufacture of Sterile Medicinal Products – GMP Inspections
TCD	Biomedical Sciences	Biopharmaceuticals – Introduction to EU Regulation
TCD	Pharmaceutical Medicine	New EU Pharmacovigilance Legislation
TCD	Pharmaceutical Medicine	Communicating Drug Safety Data
TCD	Pharmaceutical Medicine	Role of the Pharmacopoeia in the Regulation of Medicines
TCD	Pharmaceutical Medicine	Regulation of Medical Devices
TCD	Pharmaceutical Medicine	The Role of the CMDh
TCD	Pharmaceutical Medicine	Pharmacovigilanc
TCD	Nursing/Midwife Prescribing	Role of IMB

THIRD LEVEL PRESENTATIONS

College	Course	Presentation Title
TCD	Nursing/Midwife Prescribing	Pharmacovigilance
TCD	Pharmaceutical Analysis	Specification Setting for Drugs
UCC	Pharmacy and Medicine	Adverse Reactions
UCC	Pharmacy and Medicine	Risk Minimisation Tools
UCD	Nursing - Prescription of Medication	Role of IMB (2 presentations)
UCD	Nursing - Prescription of Medication	Pharmacovigilance (2 presentations)
UCD	Veterinary Medicine	Regulation of Veterinary Medicines
UCD	Biotechnology	Biopharmaceuticals – Introduction to EU Regulation
UCD	Biotechnology	Regulation of Medical Devices
UCD	Pharmaceutical Management	Regulatory Environment and the Irish Pharmaceutical Industry
UCD	Clinical & Translational research	Medical Device Studies
UCG	Medical Physics	Regulation of Medical Devices

REGULATORY PRESENTATIONS

Event/Organiser	Presentation Title
Annual Risk and Safety Workshop	Medical Devices: The Role of the IMB
APIC Conference	International Inspection Collaboration
Association of Pharmaceutical Manufacturers in Ireland	E-submissions
BARQA Ireland Regional Forum	Regulatory Update
Biocides Symposium	Classification of Borderline Products
DIA Europe	EudraVigilance
DIA Europe	EU Pharmacovigilance legislation
Drug Safety Research Unit	Pharmacovigilance
EMA Stakeholder Days	Number of presentations on the implementation of the new pharmacovigilance legislation.
EU Pharmaceutical Law Forum	Regulatory Framework in Medical Technology Law
Health Services Research and Pharmacy Practice Conference	Impact of DHPCs on Pharmacy Practice: MC Kennedy (TCD), A Spooner, M Henman (TCD)
IBEC	Commercialisation of Drug, Device and Biologic Combination Products
Informa	Process Validation, Sampling and Control Strategy

Event/Organiser	Presentation Title
Informa	Validation Process
Informa	Pharmaceutical Labelling
Informa	Pharmacovigilance and Risk Management
Informa	Labelling Compliance for Medical Devices
Inter-Agency docuBridge User Group	IMB Experience
International Pharmaceutical Federation (FIP)	Dissolution Testing - Regulatory Consideration
International Pharmaceutical Federation (FIP)	Multinational Pharmacopoeial Harmonisation
Irish Cleanroom Society	GMP Inspections
Irish Medication Safety Network	Quality Defects and Recalls
Irish Pharmaceutical Healthcare Association	Compliance Monitoring through Adverse Reaction Reporting
Irish Society of Rheumatology	Clinical Trials
ISPE	Process Validation
IVT Validation Week	Qualification and Validation
Medical Device Directive and the Recast	Medical Devices Directive
Medicrime Convention	Significance of Medicrime Convention
Official Medicines Control Laboratories	Market Surveillance Project
PCI Conference	Variations (2 presentations)
PCI Conference	Deficiencies in CMC Part of Application
PDA / IMB ESOF 2012 Satellite Conference	Multiple IMB presentations on the regulation gene and cell therapy medicines
PharmaChemical Ireland	Quality Risk Management Activities (2 presentations)
Pharmigs Annual Irish Conference	Application of Annex 1 Principles to Biological Drug Substance Manufacturing
PHSS	Bio-contamination Control and Monitoring
PIC/S GMP Inspector Training Course	Multiple IMB Presentations
PIC/S New Inspector Training Course	Multiple IMB Presentations
Pompidou Group	Information Exchange Initiatives
Quality & OPEX in Pharma and Biotech	Compliance
RCPI – Rational and Safe Prescribing	The Role of the IMB
RCPI – St. Luke's Day Symposium	The Medicines Regulator
TOPRA Symposium 2012, Dublin medicines, and medical devoices	Multiple IMB presentations across human and veterinary
TOPRA Symposium Launch Event	Regulatory News
Vigilance and Surveillance of Substances of Human Origin	Effective Vigilance and Surveillance Systems

APPENDIX 3
PUBLICATIONS AND ARTICLES 2012

DRUG SAFETY NEWSLETTERS

Edition	Articles
February 2012 46th Edition	– Proton-pump inhibitors: Association with hypomagnesaemia – Metoclopramide: New Recommendations for treatment of children – Gonadotrophin releasing hormone-Risk of depression – HMG-CoA reductase inhibitors: Risk of new onset diabetes in patients already at increased risk of developing diabetes. – Varenicline (Champix) and cadiovascular safety – Adverse Drug Reaction Reporting Experience during 2010 – Adverse reaction and quality defect reporting including herbal medicines.
April 2012 47th Edition	– Aliskiren: New contraindications and warnings due to the risks of cardiovascular and renal adverse reactions – Proton pump inhibitors: Small increased risk of bone fractures with long term use in patients with risk factors. – Oral methotrexate: Risk of unintentional overdose due to medication errors. – Miconazole oral gel (Daktarin oral gel): Interaction with warfarin. – Childrens liquid paracetamol medicines: New dosage instructions.
June 2012 48th Edition	– Topical tacrolimus (Protopic): Important recommendations for appropriate use to minimise risks – Strontium (Protelos and Osseor): Updates to product information on risks of venous thromboembolism and severe allergic skin reactions – Vernakalant (Brinavess): Risk of severe hypotension and bradycardia – Fingolimod (Gilenya): Updated recommendations on cardiovascular monitoring during treatment initiation
August 2012 49th Edition	– Ondansetron (Zofran): Risk of QTc prolongation and new intravenous dose restriction – Levodopa, dopamine agonists and COMT inhibitors: Risk of impulse control disorders – Miacalcic (calcitonin, salmon) nasal spray: Association with malignancies with long term use. – Adverse Reaction Reporting Experience during 2011 – Donepezil: Risk of neuroleptic malignant syndrome – Dabigatran (Pradaxa): Furhter information on contraindications and management of bleeding

DRUG SAFETY NEWSLETTERS

Edition	Articles
November 2012 50th Edition	– Update on new pharmacovigilance legislation
December 2012	– Diclofenac: Further evidence that the cardiovascular risk with diclofenac is higher than other non-selective NSAIDs and similar to the selective COX-2 inhibitors – Valdoxan (agomelatine)-reports of serious hepatotoxicity – Evicel-Recommendations to minimise the risk of gas embolism during application – Exempt medicinal products-prescribing products that have been suspended in Ireland for safety reasons – User reporting of medical device incidents – Additional insert: Quick guide to medical device incident user reporting

IMB HUMAN MEDICINES ARTICLES – EXTERNAL PUBLICATIONS

Topic	Publication	Month
Domperidone: Risk of cardiac disorders	MIMS	January
Citalopram and Escitalopram: Risk of QT interval prolongation	MIMS	February
Direct Healthcare Professional Communications	IMF	February
Metoclopramide: New recommendations for treatment of children	MIMS	March
HMG-CoA reductase inhibitors: Risk of new onset diabetes in patients already at increased risk of developing diabetes.	MIMS	April
Aliskiren: New contraindications and warnings due to the risks of cardiovascular and renal adverse reactions	MIMS	May
Revlimid (lenalidomide): Risk of second primary malignancies in authorised indication (oncology supplement)	MIMS	May
Strontium (Protelos and Osseor): Updates to product information on risks of venous thromboembolism and severe allergic skin reactions	MIMS	June
Vemakalant (Brinavess): Risk of severe hypotension and bradycardia	MIMS	July
Topical tacrolimus (Protopic): Important recommendations for appropriate use to minimise risks	MIMS	August
HMG-CoA reductase inhibitors: Risk of new onset diabetes in patients already at increased risk of developing diabetes	IMF	August
Oral Methotrexate: Risk of unintentional overdose due to medication errors	MIMS	September
Ondansetron (Zofran): Risk of QYc prolongation and new intravenous dose restriction	MIMS	October
Valdoxan (agomelatine): New reports of serious hepatotoxicity	MIMS	November

IMB HUMAN MEDICINES ARTICLES – EXTERNAL PUBLICATIONS

Topic	Publication	Month
HMG-CoA Reductase Inhibitors: Risk of new onset diabetes in patients already at increased risk of developing diabetes (Diabetes Supplement)	MIMS	November
Updated Pharmacovigilance Legislation	MIMS	December

IMB VETERINARY MEDICINES ARTICLES – EXTERNAL PUBLICATIONS

Topic	Publication	Month
IMB Veterinary Medicinal Updates for 2011	Veterinary Ireland Journal	March
Suspected Adverse Events for Veterinary Medicinal Products 2011	Veterinary Ireland Journal	August
Forthcoming Changes to Labelling of Certain Wormers for Sheep	It's Your Field	Spring
Withdrawal Periods and Residue Controls on Yeterinary Medicines	It's Your Field	Summer
Veterinary Pharmacovigilance	It's Your Field	Autumn
Identifying Borderline Products which have been Judged by the IMB as not Requiring a Marketing Authorisation	It's Your Field	Winter

IMB MEDICAL DEVICES NEWSLETTER – SAFETY ARTICLES

Edition	Main Topics
June	– Medical devices joint action plan – User reporting – Unique device identifiers – E-labelling regulation
October	– MEDDEV 2.1/6 on stand alone software – Medical devices containing tissues of animal origin – Unique device identification – Medical devices containing mercury: New restrictions. – Transition from the Global Harmonisation Task Force (GHTF) to the International Medical Device Regulators Forum (IMDRF)
December	– A special edition focused on the proposals for new Regulations on medical devices.

INDUSTRY GUIDANCE DOCUMENTS

Document title	New/Revision	Date
Guide to Traditional Herbal Medicinal Products Registration Scheme	Revision	January
Guide for Suppliers of First Aid Kits, containing Medicinal Products, Supplying solely to the End-user	Revision	March
Guide to Invented Names of Human Medicines	Revision	April
Guide to Labels and Leaflets of Human Medicines	Revision	May
Guide to Submission of Risk Minimisation Plans	Revision	May

INDUSTRY GUIDANCE DOCUMENTS

Document title	New/Revision	Date
Guide to the In-vitro Diagnostic Medical Devices Legislation	Revision	June
Guide to Electronic Submissions - Human Medicines	Revision	June
Guide to Parallel Imports - Human Medicines	Revision	June
Guide for Custom-made Medical Device Manufacturers on Compliance with European Communities (Medical Devices) Regulations, 1994	Revision	June
Guide to Completion of the Tissue Establishment Annual Report for Reproductive Tissues and Cells	Revision	July
Guide to Completion of the Tissue Establishment Annual Report	Revision	July
Guide to Registration of Persons Responsible for Placing Medical Devices on the Market	New	July
Guide to Registration of Persons Responsible for Placing In-Vitro Diagnostic Medical Devices on the Market	New	July
Guide to Incident Reporting for General Medical Devices and Active Implantable Medical Devices	Revision	July
Guide to an Application for a variation to a Manufacturing/Importation Authorisation or Wholesaler's Authorisation	Revision	July
Guide to Notification of Marketing Status of Human Medicines	Revision	August
Guide to the On-line Registration System for Medical Devices	New	August
Guide to Field Safety Corrective Actions for Medical Devices and In-vitro Diagnostic Medical Devices	Revision	August
Guide to the Vigilance System for Medical Devices	Revision	August
Guide to Incident Reporting for In-vitro Diagnostic Medical Devices	Revision	August
Guide to Applications for Certificates of Free Sale for Medical Devices	Revision	September
Guide to Reporting of Quality Defects	Revision	October
Guide to the Registration of Homeopathic Veterinary Medicinal Products	Revision	November
Guide to Notification of Marketing Status of Veterinary Medicines	Revision	November
Guide to Withdrawal of Authorisations or Certificates for Veterinary Medicines	Revision	November
Guide to Renewal of Veterinary Product Authorisations	Revision	November
Guide to the Implementation of Packaging Changes to Authorised Veterinary Medicinal Products	Revision	November
Guide to the Definition of an Animal Remedy and the Classification Process	Revision	November
Guide to Registration for Brokers of Finished Medicinal Products	New	December
Guide to the Completion of the Hospital Blood Bank Annual Report	Revision	December

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 (CMC)	CAMD	2
Competent Authority for Medical Devices (CAMD)	CAMD	2
Notified Body Operations Group (NBOG)	CAMD	3
NBOG subgroup on joint assessment of notified bodies	CAMD	3
Medical Devices Recast Working Group	CAMD	2
Compliance and Enforcement Working Party (COEN)	CAMD	3
P-SC-COS (Committee of Experts on Cosmetics)	Council of Europe	1
Pompidou Group – Drug Precursors	Council of Europe	1
Official Medicines Control Laboratories Network	Council of Europe	2
Working Group on Anti-counterfeiting	Council of Europe	2
Medication Safety Forum	Department of Health	4
National Steering Group on Organs for Human Transplantation	Department of Health	5
Market Surveillance Forum	Department of Jobs, Enterprise and Innovation	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	11
Committee on Herbal Medicinal Products (HMPC)	EMA	6

Committee/Working Group	Organisation	Meetings Per Annum
Efficacy Working Party (of CVMP)	EMA	4
EudraCT (Clinical Trials Database)	EMA	3
GCP/Pharmacovigilance Inspectors Working Group	EMA	8
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 (Final meeting July 2012)	EMA	7
Pharmacovigilance Risk Assessment Committee (First meeting July 2012)	EMA	4
Quality Working Party (CHMP/CVMP)	EMA	4
Safety Working Party (of the CHMP)	EMA	2 (+ 8 virtual ½ day meetings)
Scientific Advice Working Party	EMA	11
Biologics Working Party	EMA	11
Working Group on Quality Review of Documents (QRD)	EMA	3
Telematics Committee - Management Board	EMA	4
New and Emerging Technologies Working Group	EU Commission	2
In-Vitro Diagnostic Technical Working Group	EU Commission	1
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	2
Clinical Investigation and Evaluation Working Group	EU Commission	3
Competent Authorities for (1) Blood, (2) Tissues and Cells and (3) Organs for Transplantation	EU Commission	6
Haemovigilance – Common Approach	EU Commission	1
Cosmetic Borderline Working Group	EU Commission	2
Cosmetic Standing Committee and Working Group	EU Commission	2
Cosmetics Sub-group on Skin Allergies	EU Commission	1
Drug Precursors Working Group	EU Commission	2
EUDAMED Working Group	EU Commission	3

Committee/Working Group	Organisation	Meetings Per Annum
MDEG Software Working Group	EU Commission	2
MDEG Working Group on Vigilance	EU Commission	2
Medical Device Expert Group	EU Commission	3
PEMSAC (Platform of European Market Surveillance Authorities for Cosmetics)	EU Commission	4
Regulatory Committee for Medical Devices	EU Commission	0
Unique Device Identifier Group	EU Commission	2
Guidance on Investigation and Reporting of SAR/E Associated with Tissues and Cells	EU Commission / SoHO V & S	3
Tissues and Cells – Common Approach	EU Commission / SoHO V & S	1
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
Working Group of Enforcement Officers (WGEO)	HMA	2
HMA ICT Working Groups	HMA	
Homeopathic Medicinal Products Working Group (HMPWG)	HMA	2
PSUR Work-Sharing Working Party	HMA	11
HMA-CAMD workshops	HMA/CAMD	3
Steering Group on Medicines for Older People	HSE	2
Anti-doping Committee	Irish Sports Council	4
Cosmetics Standards Advisory Group	NSAI	2
Permanent Forum on International Pharmaceutical Crime	PFIPC	1
Committee of Officials	PIC/S	2
GDP working group	PIC/S	2
Heads of Medicines Agency meetings – Human	Presidency	4
Heads of Medicines Agency meetings – Veterinary	Presidency	4
National Immunisation Advisory Committee	RCPI	6
Board of the UMC/WHO Collaborating Centre	WHO	3
WHO National Pharmacovigilance Centres Meeting	WHO	1

APPENDIX 5 GLOSSARY

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
CPD	Continuing Professional Development
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
ESOF	EuroScience Open Forum
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
HIQA	Health Information and Quality Authority
HMA	Heads of Medicines Agency

HMPC	Committee on Herbal Medicinal Products
HPRA	Health Products Regulatory Authority
HPSC	Health Protection Surveillance Centre
HPV	Human Papillomavirus
HSE	Health Service Executive
IBTS	Irish Blood Transfusion Service
ICH	International Conference of Harmonisation
ICSR	Individual Case Safety Report
IMDA	Irish Medical Devices Association
IMF	Irish Medicines Formulary
IPHA	Irish Pharmaceutical Healthcare Association
IVD	In-Vitro Diagnostics
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
PDA	Parenteral Drug Association
PDCO	Paediatric Committee
PDP	Performance Development Programme
PIC/S	Pharmaceutical Inspection Co-operation Scheme
POM	Prescription-only Medicine
PRAC	Pharmacovigilance Risk Assessment Committee
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

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