IRISH MEDICINES BOARD

ANNUAL REPORT 2013

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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Statistics at a Glance

753

THE TOTAL NUMBER OF NEW HUMAN MEDICINES AUTHORISED

10

APPLICATIONS FOR CLINICAL INVESTIGATIONS OF A MEDICAL DEVICE

188

NEW VETERINARY MEDICINE APPLICATIONS ASSESSED AND APPROVED

334

NOTIFICATIONS OF MEDICAL DEVICES TO THE IMB MEDICAL DEVICE REGISTER FOR CLASS I, IN-VITRO DIAGNOSTIC AND CUSTOM MADE MEDICAL DEVICES

30%+

RISE IN THE NUMBER OF CLINICAL TRIALS APPROVED WITH 102 IN TOTAL

5th

IMB RANK IN EU FOR RAPPORTEURSHIPS FOR CENTRALLY AUTHORISED HUMAN PRODUCTS

11

ACTIVE SUBSTANCES PUBLISHED TO THE INTERCHANGEABLE MEDICINES LIST ON THE IMB WEBSITE

133

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

2,835

SUSPECTED ADVERSE REACTIONS REPORTS FOR HUMAN MEDICINES RECEIVED AND EVALUATED

272 REPORTS OF SUSPECTED ADVERSE REACTIONS ASSOCIATED WITH USE OF VETERINARY MEDICINES RECEIVED AND EVALUATED

2,268 MEDICAL DEVICE VIGILANCE REPORTS RECEIVED AND ASSESSED

53 DIRECT HEALTHCARE PROFESSIONAL COMMUNICATIONS FOR HUMAN MEDICINES APPROVED

109 MEDICINES RECALLED DUE TO QUALITY DEFECTS

9 DISTRICT COURT PROSECUTIONS RESULTING FROM THE ILLEGAL MANUFACTURE, SUPPLY AND/OR SALE OF MEDICINES

€600,000 THE VALUE OF ILLEGAL MEDICINES DETAINED UNDER THE PANGEA VI ENFORCEMENT PROGRAMME

12th IMB RANK IN TERMS OF REPORTING RATES FOR ADVERSE REACTIONS AMONG 116 FULL COUNTRY MEMBERS PARTICIPATING IN THE **WHO** INTERNATIONAL DRUG MONITORING PROGRAMME

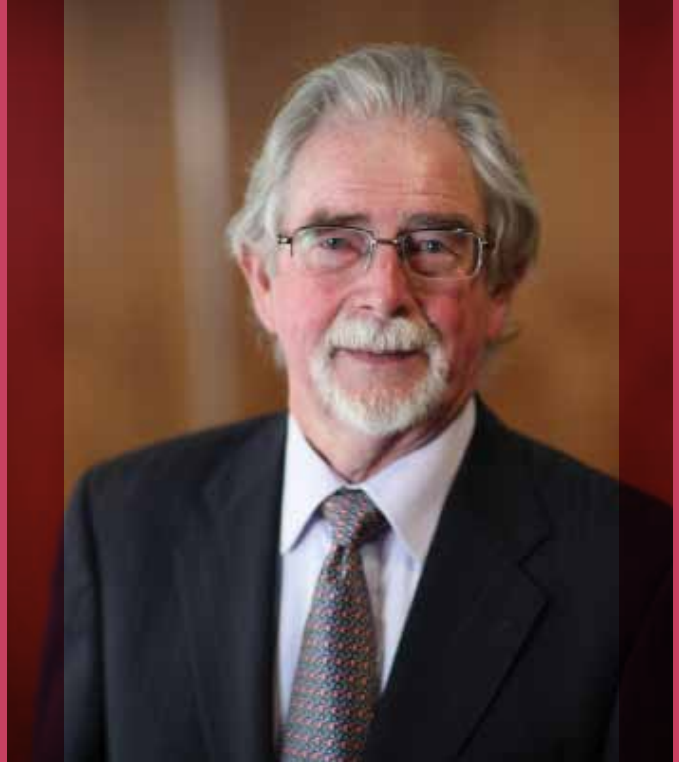
313 NATIONAL AND FOREIGN INSPECTIONS AND AUDITS PERFORMED

87% OF IRISH ADULTS CONFIRM THEY UNDERSTAND THE PRODUCT INFORMATION THAT COMES WITH THEIR MEDICINES

32% INCREASE IN THE NUMBER OF UNIQUE VISITORS TO WWW.IMB.IE

22 THE NUMBER OF INFORMAL MEETINGS HOSTED BY THE IMB UNDER IRELAND'S PRESIDENCY OF THE COUNCIL OF EUROPEAN UNION.

CHAIRMAN'S STATEMENT



The Irish Medicines Board (IMB) delivered on an extensive and challenging programme of work in 2013 and it is my pleasure, as Chairman, to present its annual report.

The IMB remains on target with the implementation of the five year strategic plan for 2011-2015 which sets out five high level strategic objectives and a clear roadmap to achieve these goals within the timeframe. This report outlines in detail the high level of activity and achievement by the IMB during year three of the plan as it remained focused on its core remit to protect human and animal health.

In 2013, the Board approved a new brand identity to accompany a name change for the IMB. Our new name, effective from mid-2014, is more reflective of the organisation's expanded and broader role since first established in 1996. Over the last 17 years, the IMB's regulatory remit has grown incrementally to include other health products as well as a number of health related functions. In addition to human and veterinary medicines, and clinical trials for human medicines, we now have a role in regulating a range of areas including medical devices, blood and blood components, tissues and cells, human organs intended for transplantation as well as cosmetic products. Our new name, the Health Products Regulatory Authority (HPRA), more clearly reflects the wider scope of our work, functions and responsibilities across the health products sector.

Health products can be life-saving and can improve the health and the quality of our lives. The IMB plays a unique and important role in national healthcare policy to safeguard human and animal health in relation to these products. Our fundamental aim, as always, is based on the need to make sure that health products used in Ireland or exported abroad, are as safe as possible and do what they are intended to do.

Our responsibility to regulate and monitor medicines, medical devices and healthcare products demands excellence across all areas of our operations with a clear focus by our staff to ensure the needs and best interests of our citizens and our animal population are at the forefront of our deliberations, actions and processes. At all times, the IMB's actions and decisions are influenced by the latest and best available clinical and scientific data at national and EU level. As a state agency in the current economic environment, we must, and indeed do, continually re-evaluate our processes and structures to ensure they deliver best efficiencies. At the same time we must have the flexibility to meet future requirements from a changing regulatory landscape across an industry where innovation and progression is a key driver.

The information presented throughout this report outlines the depth and breadth of our work programme across all departments and product areas. This impressive level of activity was achieved in a year in which the IMB also successfully hosted and managed some 22 high level EU meetings as part of Ireland's Presidency of the Council of the European Union. In addition, during 2013 the IMB commenced its new role for the establishment, maintenance and publication of a list for interchangeable medicines which supports increased levels of generic substitution. The first list was published in August 2013. A significant level of stakeholder engagement and communications was undertaken to support this national health policy initiative and we worked closely with our colleagues in the Department of Health and the HSE in its effective initial implementation and ongoing work programme.

Also during 2013, a key focus for the organisation was to highlight our concerns about the risk to public health from the purchasing of prescription medicines via the internet. Medicines sourced online are of dubious origin, may be falsified and could pose a health risk to those who use them. The increase in illegal medicines detentions as well as our successful court prosecutions in this area, and the subsequent publicity relating to these, continue to highlight this crucial message to the general public and other stakeholders. This will continue to be a constant area of vigilance for the IMB and, in time, the HPRA.

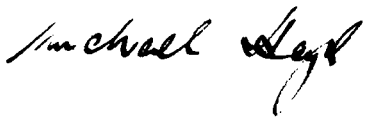
All our regulatory actions are grounded in legislative requirements and the application of scientific and regulatory expertise. The IMB and our partners at a European level review adverse reaction and clinical data on an ongoing basis to ensure that people continue to have access to products where the benefit of using that product outweighs the inherent risk. During the past 12 months there was, as in previous years, an intense focus and time investment on monitoring the safety of these products in use on the Irish market which is outlined further in this report. It is important to note the active role the IMB plays at EU level where new legislation is developed. Our experts continue to be active contributors in this area with an objective of ensuring that a strong patient centric regulatory system for human and veterinary products is maintained and enhanced.

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

The IMB has earned an enviable reputation internationally as a highly effective and strong regulatory agency. Its standing is a reflection of the quality of its organisational structure and policies. It is also due to the excellence of the work carried out by everyone at the IMB and I wish to thank the Chief Executive, management and all the staff for their continued professionalism throughout 2013.

I would like to thank my fellow Board members for their continued support and valuable expert guidance during the past year. I would also like to express my appreciation to those members who chair IMB advisory committees and sub-committees. The contribution of these committees is of immense value to the IMB and I wish to thank all members for their active participation and commitment.

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



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 up to 31 December 2013.

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

* Term ended 31 December 2013

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

Dr. Lorraine Nolan
Director of Human Products Authorisation and Registration

Ms. Rita Purcell
Director of Finance and Corporate Affairs

CHIEF EXECUTIVE'S REPORT

I am pleased to introduce the 2013 annual report of the Irish Medicines Board (IMB). This is a significant report as it is the last full-year review that will be submitted in the name of the IMB. From July next year, our organisation will become known as the Health Products Regulatory Authority (HPRA).

Established in 1996, the IMB name has served us well. However, over the last 18 years our regulatory remit has expanded to include other health products as well as a number of health related functions. Our new name will better reflect the wider scope of our work, functions and responsibilities across the health product sector, something that is evident from the significant level of activity outlined in this report.

STRATEGIC PLAN 2011 – 2015

The layout of the annual report for 2013 is structured to ensure that the main chapters are closely aligned with the IMB's five high-level strategic goals.

These goals are to:

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.

AUTHORISATION, REGISTRATION AND LICENSING ACTIVITIES

Our pre market activities are a core regulatory function of the IMB. We are committed to providing an efficient authorisation system to help ensure patients have timely access to appropriate treatments. The activities of note during 2013 included the following:

- There were 102 clinical trials for human medicines approved to commence in Ireland representing a significant annual increase of over 30%. While the IMB received 10 applications for clinical investigations of a medical device, the number of clinical investigations ongoing in Ireland remains lower than expected.
- In respect of human medicines, the IMB assessed 198 new national applications (including parallel product authorisations), 51 applications via mutual recognition procedures (MRP) and 280 via decentralised procedures (DCP).
- As part of our active contribution to the European human medicines licensing system during 2013, we acted as reference (lead) Member State for the assessment of 12 of the MRP and DCP procedures. The IMB was also allocated as rapporteur or co-rapporteur for 15 new marketing authorisation applications by the European Medicines Agency (EMA). Based on 2013 allocations, the IMB is ranked as fifth in the EU for rapporteurships for centrally authorised human products. We acted as lead in 38 scientific advice procedures for medicines proposed for the treatment of a broad range of conditions.
- We assessed and approved a total 188 applications for new veterinary medicines, representing an increase of 24% compared with 2012. In Europe, we issued 50 new marketing authorisations as the reference Member State while the IMB acted as the rapporteur or co-rapporteur for 7 centralised procedures (including extension applications to new target species).
- Over the course of 2013, the IMB issued 17,749 variations to marketing authorisations for human products authorised through the national or MR procedures. Of note, at a European level, we acted as rapporteur for two paediatric Article 45 procedures, one paediatric Article 46 procedure and 13 procedures relating to Paediatric Investigational Plans (PIPs). The IMB approved 1,364 variations to veterinary authorisations granted through the national, MR or centralised procedures.
- A total of 334 notifications of medical devices to the medical device register were received. In addition, 26 organisations registered with the IMB as Irish based manufacturers of medical devices.
- There were a total of 113 manufacturers' licences in place at year end for human and veterinary medicines.
- There were four blood establishments and 23 tissue establishments authorised at year end.

SAFETY AND COMPLIANCE MONITORING

Monitoring the safety of medicines, medical devices and other healthcare products that have been licensed or registered for use in Ireland is a core public health function of the IMB. We also monitor quality issues relating to how a product is manufactured, packaged, labelled, distributed or stored. Our regulatory decisions are always based on the best available information regarding benefit and risk.

- A key part of our monitoring efforts is the operation of a national pharmacovigilance scheme for adverse reactions, or side effects, associated with the use of human medicines. During the year under review, the IMB received a total of 2,835 valid new adverse reaction reports. This figure is consistent with the reporting rates seen in 2011 and 2012.

- The IMB continued to contribute to work-sharing for signal detection within the EU during 2013. We acted as the human medicine lead for the detection and management of signals for 58 active substances. We also retained responsibility for assessing any signals arising as a result of signal detection for 21 centrally authorised active substances (or combination of active substances) incorporating 34 authorised products for which IMB is rapporteur. In addition, the IMB acted as concerned Member State in 15 EU safety-related referrals and provided the lead on the assessment of two significant safety referral procedures at the EMA.
- Periodic safety update reports (PSURs) are vigilance reports submitted by marketing authorisation holders which are intended to provide an evaluation of the benefit-risk balance of a medicine. For human medicines, the IMB evaluated PSURs relating to 2,500 medicinal products, a figure which includes PSURs submitted as national, mutual recognition, centralised, EU single-assessment and PSUR work-sharing procedures.
- The IMB received 272 national reports of suspected adverse events to veterinary medicines in 2013 which compares with the 244 reports received the previous year. We completed the evaluation of 1,072 PSURs for veterinary medicines representing year-on-year increase of approximately 25%.

- Post-market surveillance and vigilance is important in ensuring the safety of those who use medical devices. A total of 2,268 medical device vigilance reports were received and assessed. A slight increase on 2012, this figure continues the upward trend in the number of vigilance cases received annually.
- Systems were put in place for reporting of serious adverse events and reactions relating to human organs intended for transplantation.

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

- 313 inspections and audits were performed in 2013 compared to 315 in 2012 and 300 in 2011. The 2013 figure included 115 Good Manufacturing Practice (GMP) inspections, 126 Good Distribution Practice (GDP) inspections, 17 Good Clinical Practice (GCP) inspections, 19 medical device audits and 29 inspections covering blood, tissues and organs.
- We sent 275 medicinal and other product samples for analytical testing. These included 156 samples sent to governmental laboratories in Ireland.
- During 2013, a total of 774 quality defects were reported to, or identified by, the IMB. This was a slight increase on the numbers reported for 2012.
- It may be necessary in certain cases to withdraw, or recall, products from the Irish market in order to protect public health. In 2013, 109 medicine recalls occurred. Of these, 107 related to human medicines and two to veterinary medicines.
- The IMB initiated nine prosecutions in the District Courts during the course of 2013 as a result of illegal activity involving the manufacture, supply and/or sale of medicines. The number of dosage units detained as part of our enforcement programme during 2013 was 919,965. This represents an annual increase of 20%.

LEGISLATIVE AND REGULATORY DEVELOPMENTS

As evidenced by the planned introduction of our new name in 2014, the remit and role of our organisation continues to change and expand due to changes in our operating environment. These include changes to national and European legislation and the addition of further competencies.

Presidency of the Council of European Union

A significant event in 2013 for the IMB was Ireland's Presidency of the Council of European Union. We had the honour of hosting 22 informal meetings of our regulatory peers from across the member states, EMA and European Commission in the various areas we regulate. Essential progress was made in respect of a number of important regulatory issues during the six months of the Presidency and, from an IMB perspective, we were very pleased with the positive feedback received from participants.

Among the highlights from the Irish Presidency was 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. The Irish Presidency also included the first ever combined meeting of both the Heads of Medicines Agencies (HMA) and the Competent Authorities for Medical Devices (CAMD).

The IMB also provided a high level of support to the Department of Health as it chaired the European Council's Working Party on Pharmaceuticals and Medical Devices. This working party had a substantial work programme during the Irish Presidency with two proposals for medical devices Regulations, the Regulation on clinical trials of medicinal products and the transparency legislation before the Council.

Benchmarking of European Medicines Agencies

The aim of the Benchmarking of European Medicines Agencies (BEMA) programme is to provide assurance to the heads of the EU medicines agency network with respect to the quality of the systems and practices in place in agencies for regulating medicines. I serve as co-chair of the BEMA steering group while the IMB provides the secretariat for the group and is responsible for visit logistics. We continued to lead the steering group throughout 2013 as assessment visits were undertaken in this the third benchmarking cycle.

The IMB's own benchmarking assessment visit took place in October 2013 when three assessors from the Austrian, Greek and UK agencies interviewed senior staff, reviewed evidence and rated the 'maturity' of the IMB's management and scientific quality systems. Several proposed 'best practices' were accepted by the assessors related to our project management office, leadership development programme and our contribution to the European network. The assessors also nominated a further best practice in the close link between our strategic and business planning objectives and the objectives in staff's individual performance development plan. As is to be expected, some 'opportunities for improvement' were highlighted and identified as actions to enhance the quality of our services. Overall, we were extremely pleased with the outcome of the IMB's assessment which reflected well on our progress and achievements in recent years. The assessors noted our strong dedication to quality in general and to the BEMA programme in particular.

Health (Pricing and Supply of Medical Goods) Act 2013

A significant regulatory development during 2013 was the commencement of the Health (Pricing and Supply of Medical Goods) Act. Under this Act, the IMB is responsible for the establishment, consultation, publication and maintenance of a list of interchangeable medicinal products which will be grouped together under their respective active substance, strength and pharmaceutical form(s). The purpose of the legislation is to provide for substitution of medicines that are considered interchangeable so that a pharmacist can dispense a less expensive medicine than the one prescribed.

Throughout 2013, the IMB worked closely with the Department of Health and HSE in the implementation of this legislation. Between August and December, we published 11 active substances to the interchangeable list which is maintained on the IMB website. In each case, the IMB consulted with the relevant marketing authorisation holders prior to adding a medicine or a group of medicines to the list. The IMB also supported the various communications initiatives introduced to raise awareness and understanding of generic and interchangeable medicines.

Ongoing Implementation of EU Pharmacovigilance Legislation

The new pharmacovigilance legislation is resulting in more systematic risk management planning, greater coordination of real time signal management, and faster assessment and decision-making. During 2013, the IMB continued its work with stakeholders including the EMA, other national regulators and industry to support the phased implementation of further elements of the legislation.

This included the publication by the EMA of the initial list of medicines that are subject to additional monitoring. The introduction of the symbol for these products (an inverted black triangle) is an important deliverable of the new pharmacovigilance legislation. Explanatory information was published on the IMB website and in relevant health publications while we also developed a national guideline for marketing authorisation holders.

Falsified Medicines Directive

The falsified medicines Directive aims to strengthen the protection of patients and consumers by preventing falsified (including counterfeit) medicines entering the legal supply chain. During 2013, as part of the continued implementation of the provisions of the falsified medicines Directive, the IMB established a registration scheme for manufacturers, importers and distributors of active substances and for brokers of medicines.

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

In February 2012, the European 'joint plan of immediate actions' was published with the objective of reinforcing the existing regulatory system for medical devices in advance of the proposed revision to the medical devices legislation. The plan outlined actions for Member States and the Commission in the areas of functioning of notified bodies, market surveillance, coordination, communication and transparency.

During 2013, in advance of the legislative proposal being finalised, the IMB focussed on the adoption of the joint plan.

- The performance of notified bodies for medical devices and their oversight which is highlighted in the joint plan was subject to significant attention and development at European level during 2013. The IMB helped establish a subgroup of the European Notified Body Operations Group (NBOG) to plan a joint assessment scheme, to develop common criteria, documents and guidance, and to coordinate the joint assessments. During 2013, 21 of the 23 countries responsible for class III notified bodies were subject to joint assessment while the remaining two will be completed in 2014. The IMB directly participated as experts in five joint assessments of EU notified bodies in 2013. This included the first mandatory joint assessment and further contributions are planned for 2014. The IMB was also subject to a successful joint assessment in their surveillance audit of the National Standards Authority of Ireland (NSAI) in December 2013.

- At EU level, the joint plan has also resulted in a review of activities conducted by Member States in the area of market surveillance. To ensure we fully contribute to these developments, the IMB has set out a re-development proposal for its market surveillance activities to include greater emphasis on proactive and reactive surveillance across the product life-cycle.

Cosmetics Regulation

The new Cosmetic Products Regulation, EU Regulation 1223/2009, came into effect in July 2013. In November, the European Union (Cosmetic Products) Regulations 2013 (S.I. No. 440 of 2013) came into force. The national regulations gave full effect to the EU Regulation, designated the IMB as competent authority and allocated powers to the IMB and HSE.

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.

Our participation and contribution to the European medicines regulatory system continues to be significant. IMB scientific and technical staff are members of a broad range of committees and working parties at the EMA, the European Commission, the HMA and via other platforms. The IMB also worked closely with relevant international organisations as necessary.

Significant contributions and achievements from an IMB perspective during 2013 include the following:

- The IMB attended the 7th International Summit of Heads of Medicines Regulatory Agencies. Significant progress was made in respect of adopting formalised procedures for international co-operation across a number of regulatory areas with agreement on the formation of the International Coalition of Medicines Regulatory Authorities (ICMRA) with the selection of Health Canada as chair with the IMB and PMDA Japan as vice Chairs. Seven priority projects were agreed including the development of terms of reference and rules of procedure which the IMB will lead. Additional projects involve communications, rapid sharing of information, mapping, inspections, generic medicines and capacity building.
- During 2013, the IMB was invited to join the management committee of the International Medical Device Regulators Forum (IMDRF). This forum seeks to promote the harmonisation of medical device regulation across the globe.
- The Irish PRAC delegate continued to fulfil the role of Vice-Chair of this important EMA public health committee. Our Pharmacovigilance and Risk Management Lead also acted as Regulatory Chair for the ICH Implementation Working Group on the new E2C R2 guideline on Periodic Benefit Risk Evaluation Reports.
- As in previous years, IMB experts contributed to initiatives to facilitate the transition from implementation to operation of the new EU pharmacovigilance legislation. This included participation in a three year pharmacovigilance project entitled SCOPE (Strengthening Collaborations for Operating Pharmacovigilance in Europe). The IMB will also lead the impact assessment topic in a work package on risk communications.
- The IMB Pharmacovigilance Manager for 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 during 2013.
- Negotiation on the two proposed regulations on medical devices and in-vitro diagnostics continued in 2013 during and after the Irish Presidency of the European Council. The

IMB continued its active contribution to the working groups and subgroups focused on the development of the expected new regulatory system and we will continue to support the Department of Health in this regard as required.

- As in previous years, the IMB also continued to engage actively in discussions on how to optimise resourcing of the network for medical device regulation in Europe. These discussions included significant dialogue with the medical device industry associations on possible fee-based funding models.

STAKEHOLDER ENGAGEMENT AND COMMUNICATIONS

As set out in our five year strategic plan, the IMB is committed to expanding and improving our communications activities and to ensuring that all our stakeholders have timely access to relevant safety and regulatory information. As well as our regular meetings and ongoing publication of safety and regulatory updates, newsletters and guidance documents, a number of significant communications initiatives were implemented during 2013.

Consultative Panel on the Legal Classification of Medicines

Established in 2011, the Consultative Panel on the Legal Classification of Medicines concluded its work in 2013. The Panel was independently chaired and consisted of external representatives drawn from a wide range of interested stakeholders including patients, healthcare professionals, the Department of Health and relevant government agencies. The focus of the panel was to review policies relating to the legal classification of human medicines and to develop recommendations to address current unmet needs in the availability of non-prescription medicines. The IMB is currently working to develop processes to address the issues and recommendations identified and this is an area of priority focus for 2014.

Events

- As outlined earlier, the Irish Presidency was a considerable area of focus for the IMB in the first half of 2013. We hosted a total of 22 meetings during this period with approximately 1000 delegates visiting Ireland for IMB organised events. The number of delegates attending each meeting varied with the largest events taking place in Dublin Castle and the Convention Centre Dublin. The logistics for all these meetings were organised and managed in-house by an IMB team. This included online registrations, venue management, onsite support and networking events.
- The IMB, in association with the Irish Presidency of the Council of the European Union and with the support of the King's Centre for Risk Management and the Nickel Institute, hosted the European Risk Summit in Trinity College Dublin on 11 and 12 June 2013. This successful and well-received event discussed the advantages of evidence and risk-based rulemaking as well as the challenges of formulating European directives / regulations and, by extension, national legislation on hazard classifications. Approximately 100 Irish and international experts comprising policy-makers, regulators, governing bodies, industry and academia from a range of industries attended the summit. It also presented an opportunity to foster dialogue and collaboration among the relevant stakeholder community to address the challenges in this area.
- IMB information days and seminars provide regulatory guidance and updates to a range of stakeholders. The events enable all attendees to submit questions, seek clarifications and network with colleagues. A webinar event outlining the IMB's approach to the development of the interchangeable list of medicinal products was held in February. The topics covered included an overview of the approach to stakeholder consultation and publication of the lists. A veterinary information day was held on 24 October. The programme was focused on

updating stakeholders on recent changes in the regulatory framework for veterinary medicines in advance of publication of the EU Commission's proposed new legislation in this area. An information day on the new Common European Submission Platform (CESP) took place on 20 November. This joint DIA/IMB event provided the latest information on the CESP system which is designed to enable the simultaneous delivery of applications to the various EU regulatory agencies.

- 2013 was the fourth year of the IMB's involvement at the BT Young Scientist and Technology Exhibition in the RDS. Thousands of students as well as teachers, parents and members of the general public from all over Ireland again visited the IMB's exhibition stand which was focused on the important issue of medicines and medical devices safety.

Research

The IMB published a series of research results during 2013 focused on consumer attitudes in respect of a number of medicines topics. These included:

- Sources of information and advice on medicines.
- The use of the internet as a source of medicines information and possible supply.
- Awareness of and attitudes towards generic medicine.

Among the key findings were:

- Two thirds of people (63%) state that they always read the product information when taking a prescription medicine.
- One in two people always seek advice from a healthcare professional before taking a new over the counter medicine.
- Almost 4 out of 10 people (37%) using online channels for information are attempting to diagnose health symptoms (self-diagnosis).
- Actual purchase of medicines online is low with 2% of all adults claiming to have done so which, nevertheless, equates to approximately 60,000 people.
- Nine out of ten consumers (92%) who had personally used generic medicines said that they had a positive experience overall.

Brand Identity

It has been decided by the Board of the IMB to change the name of the organisation to better reflect the range of products and processes we now regulate. The new name to the replace the Irish Medicines Board is the Healthcare Products Regulatory Authority (HPRA). It is anticipated that our new name will become operational in mid 2014. We will also be launching a new corporate website at that time. In preparation for the adoption of the new name, the IMB initiated a project to develop a new brand identity incorporating a logo and a style guide. The latter document provides clear direction on the application of the new brand across all platforms and publications. This project was completed during 2013.

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 32 press releases concerning safety and regulatory issues and responded to 449 queries from different media sources during the year.

Website

The IMB website continued to be updated with news, safety information and regulatory documents while further changes and improvements were made in response to stakeholder feedback. Almost 225,000 unique visitors accessed the website during the past twelve months representing an annual increase of 32%. Development of a new and more modern corporate website began in 2013 and this project will be completed during the first six months of 2014 coinciding with the launch of the Health Products Regulatory Authority.

DEVELOPING ORGANISATIONAL CAPABILITY

As an organisation the IMB must respond to changes in our operating environment to ensure we remain an effective and progressive regulatory body. We are committed to ensuring that we have the requisite structures, systems and supports in place to deliver on our public and animal health mission.

Information Technology and Change Management

Technology is recognised as a key component in supporting regulatory activities at both national and international levels. Throughout 2013, the IMB continued to contribute to, and actively lead, a number of key technology projects at a national and European level. This includes the ongoing development and management of the Common Electronic Submission Portal (CESP) on behalf of the wider EU regulatory community. In 2013, the CESP portal activity levels grew substantially, handling over 100,000 submissions on behalf of 20 European regulatory organisations and the pharmaceutical industry.

The IMB is also actively engaged at national level through its involvement with the National Health Data Standards Committee and works with other relevant agencies including the HSE, NSAI and HIQA. In addition, the IMB contributed to the development of the eHealth Strategy for Ireland and contributed technological support to the introduction of interchangeable medicines in co-operation with Department of Health and the HSE.

IMB technologies are also strategically positioned to support the effective and efficient operation of the organisation. During 2013, there was a strong focus on developing the key requirements for our new workflow technology solutions. Work also began on the implementation of a new HR solution and the development of the new hpra.ie website.

The IMB is committed to continuous improvement across all areas of our organisation. As part of our commitment to change management, it was decided to adopt a project management office model for all relevant activities. The Project Management Office came into full operation in 2013. It ensures that all organisational projects are fully aligned with corporate strategy and provides management with the necessary information to support the planning process.

Staff Developments

It is vitally important that the IMB has the human resources in place to deliver on our core regulatory functions for the benefit of all our stakeholders. During 2013, we continued to develop and adapt our work practices to enable us to manage our human resources with the flexibility necessary to respond to changing and challenging external factors.

Chief among these external issues was the introduction of the Haddington Road Agreement (HRA) which applied to all public sector bodies with effect from July 2013. The terms of this agreement included a further reduction to the salaries of staff as well as the deferral of payment of increments during the course of the agreement and extended working hours. Such demands on public sector workers clearly impact them in a number of ways and not just financially. In the IMB, our human resources colleagues provided extensive assistance and support around the introduction of the agreement. I commend the professionalism of all our staff across the IMB who were delivering the extensive programme of work outlined in this report while implementing the terms of HRA.

Another significant focus of activity during 2013 was completion of a business requirements phase for the replacement of the human resources IT system. The detailed planning and preparatory work being carried out at this stage will help ensure we deliver a greatly enhanced system by June 2014. This will result in greater efficiencies for the human resources department and will provide managers and staff with improved access to personnel and training records.

The organisation's first leadership development programme concluded in 2013 with all core objectives successfully achieved. The programme supports the development of managers within the IMB by helping to identify and evaluate the skills they have or need to have in order to become more effective managers and leaders. I am very pleased that following a review of the pilot programme during 2013, the commencement of a second programme was recommended and approved. The application and selection process for the second programme was concluded by the end of 2013 and it will commence in January 2014 with 10 participants.

Extension to the IMB Offices

Kevin O'Malley House, which accommodates the offices of the IMB, was extended upward by two floors during the course of 2012 and 2013 with the certificate of practical completion being granted on 12 July 2013. The extension of two new floors has ensured that all IMB staff can be housed in one building which reduces rental costs and will result in practical efficiencies over time. This was a complex build due to our requirement that the building remained fully in use throughout the duration of the project. I am pleased to confirm that the addition of the two new floors was completed on time and under budget.

Financial Performance

The IMB is largely self-funded by a system of fees which are approved annually by the Minister for Health, following a public consultation. This approach is in line with the typical funding model of healthcare products regulation worldwide. The IMB is committed to the highest standards of independence and governance so as to ensure quality of service combined with value for money. We continued in 2013 to successfully manage the affairs of the IMB in line with our statutory obligation that income at least meets costs.

THE FUTURE

As ever we can say that the immediate and medium term future will be interesting and challenging.

A major event for 2014 will be the rebranding of IMB to the HPRA. This will serve as a real visible indicator of the broad range of health products now regulated by the organisation. It will provide an opportunity to revitalise the organisation and by various means, including a new website, enhance our abilities to communicate directly with patients and consumers.

Staff recruitment and retention will be a challenge over the near and mid term and this will receive particular attention.

Our core work remains the protection and enhancement of public and animal health and we will continue to focus all our efforts to this end.

ACKNOWLEDGEMENTS

In total, over 100 people contribute voluntarily to the work of the IMB through participation on the Board and various advisory committees. On behalf of our management team and staff, I wish to thank the Chairman, his fellow Board members and the committee members for their invaluable contributions throughout 2013. The input of these independent experts is of immense value to the workings of our organisation.

Our ability to deliver on our public health mission is dependent upon the productivity and professionalism of IMB staff. I wish to express my personal appreciation to all my colleagues for their continued support throughout 2013. I look forward to working with you all into the future as we become the HPRA.

Finally, I would like to thank and acknowledge the support and co-operation 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 health products is a core public health function of the IMB. These are the regulatory actions which are carried out before a health product can be marketed and supplied in Ireland. The IMB is committed to the timely approval of new product applications in particular, following a positive assessment of their safety, quality and effectiveness.

The IMB is responsible for the authorisation of medicines and clinical trials and for the registration of certain medical devices. We also licence manufacturers and wholesalers of human medicines, manufacturers of veterinary medicines as well as blood and tissue establishments and organ transplant centres. In addition, we are responsible for issuing export certificates.

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

HUMAN MEDICINES

BORDERLINE PRODUCT CLASSIFICATION

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

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

The Committee, which met 11 times in 2013, 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 168 new products were considered consisting of 161 internal applications and seven external applications. In addition, there were 33 products revisited from pre-2013.

The Committee has a close working relationship with the Food Safety Authority of Ireland (FSAI) and there were a number of referrals between both organisations during the course of 2013. The FSAI notified the IMB of 62 products that it considered to fall more appropriately under the IMB's remit and these were reviewed and followed up as appropriate. The committee also engaged in regular dialogue with the Department of Health and with other European regulatory authorities.

The accompanying table outlines the numbers of classification queries for 2013 compared with previous years. Queries are generally evaluated within the normal 28 day timeframe and written explanations of the outcome are provided.

Number of Applications Received		**2009**	**2010**	**2011**	**2012**	**2013**
Source	Internal	114	72	132	127	161
	External	17	33	21	17	7
Classification Outcome	Medicinal Product	88	63	88	91	108
	Medical Device	4	4	9	6	7
	Food Product	13	24	36	26	28
	Cosmetic Product	3	6	4	10	19
	Biocide			2	1	1
	Pending	21	7	12	6	1
	Other	2	1	2	4	4
	Total	**131**	**105**	**153**	**144**	**168**

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 2013, 102 clinical trials were approved to commence in Ireland. This represents an increase of over 30% in clinical trial applications compared to 2012, which positively reflects increasing research and innovation conducted in Ireland. The key areas of interest continue to include oncology and haematology.

Voluntary Harmonisation Procedures

The IMB participated in 16 voluntary harmonisation procedures (VHP) during 2013 compared with five the previous year. A VHP is a co-ordinated work sharing assessment procedure for multinational clinical trials. This procedure was established by the national competent authorities for clinical trials from across the EU. In four of these VHPs, the IMB acted as lead Member State for the assessment. In addition, the IMB led in 17 VHP amendments during the year.

NEW MARKETING AUTHORISATION APPLICATIONS

Before a new medicine can be placed on the Irish market, it must be firstly assessed and authorised (licensed) by the IMB or the EMA. The assessment involves establishing that a medicine's public health benefits outweigh its known risks. Where this is the case, it may be granted a marketing authorisation.

There are a number of routes through which a product can be authorised by the IMB. These include the national procedure, the mutual recognition procedure (MRP) and the decentralised procedure (DCP). Both MRP and DCP involve the simultaneous submission of applications in a number of EU Member States. The assessment involves the input from all of the relevant competent authorities in evaluating the benefit / risk of the product(s). The DCP route differs from MRP in that the product has not previously been authorised within the EU.

During 2013, the following applications were assessed by IMB:

- 198 new national applications (including parallel product authorisations);
- 45 applications made under the MRP;
- 274 applications made under DCP.

The IMB acted as reference (lead) Member State for the assessment of 12 of the MRP and DCP procedures.

The centralised route is another mechanism whereby products can be authorised in Ireland. In this procedure, the assessment is carried out by the EMA while the authorisation is granted by the European Commission. The centralised route involves the submission of a single application to the EMA and the authorisation once granted is valid in all Member States. The IMB was allocated as lead assessor (rapporteur) or joint lead assessor (co-rapporteur) for 15 new marketing authorisation applications by the Committee for Medicinal Products for Human use (CHMP) at the EMA in 2013. These included the following application types and treatment areas:

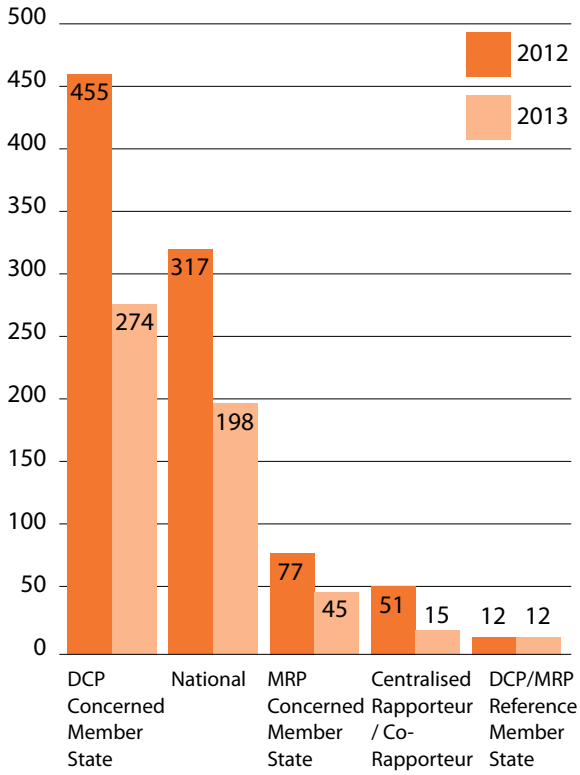
- Respiratory;
- Radiocontrast agent (ECHO);
- Treatment of bile acid metabolism disorders;
- Alcohol dependence;
- IVF media;
- Lysosomal storage disease.

Based on 2013 allocations, the IMB was ranked fifth in the EU for rapporteurships for centrally authorised human products.

The total number of new products authorised in 2013 was 752. This figure also includes 208 products authorised through the centralised route where IMB was not rapporteur or co-rapporteur. In overall terms, the number of products authorised has decreased

relative to previous years and this is reflective of a trend observed throughout the EU during 2013 which has been attributed to product patent lifecycles.

New Applications



TRADITIONAL HERBAL AND HOMEOPATHIC MEDICINAL PRODUCTS

During 2013, seven traditional herbal medicinal products (THMPs) were authorised by the IMB. This is a simplified registration scheme which takes into account the tradition of use of these products. Legislation requiring registration for THMPs came into effect in full in 2011. The number of applications received by the IMB since that time has remained low with a total of 19 THMPs authorised by the end of 2013.

There were seven homeopathic medicinal products registered during 2013 under the simplified rules scheme.

TRANSFER APPLICATIONS

The IMB processed a total 144 transfer applications in 2013. Of these, 103 related to the transfer of an existing marketing authorisation to a new marketing authorisation holder while the balance related to a transfer of a marketing authorisation holder prior to authorisation.

VARIATIONS

After a medicine has been authorised, the terms of the marketing authorisation may need to be changed and the process whereby these changes are implemented is known as a "variation". Examples of variations include the addition of a new indication, a new potential side effect, or updates to the company's manufacturing or contact details. In the past year, the IMB issued 17,749 variations to marketing authorisations for products authorised through the national or MR procedures.

Articles 45 and 46 - Variations to Update Product Information

The IMB acted as rapporteur for two paediatric Article 45 procedures, one paediatric Article 46 procedure and 13 procedures relating to Paediatric Investigational Plans (PIPs) during the past 12 months. These are important procedures from a public health viewpoint as they increase the availability of medicinal products specifically indicated for use in children.

RENEWALS

In 2013, 590 renewals to marketing authorisations for products authorised through the national or MR procedures were processed. The reduction of 10% on the previous year reflects the lifecycle of the products in question.

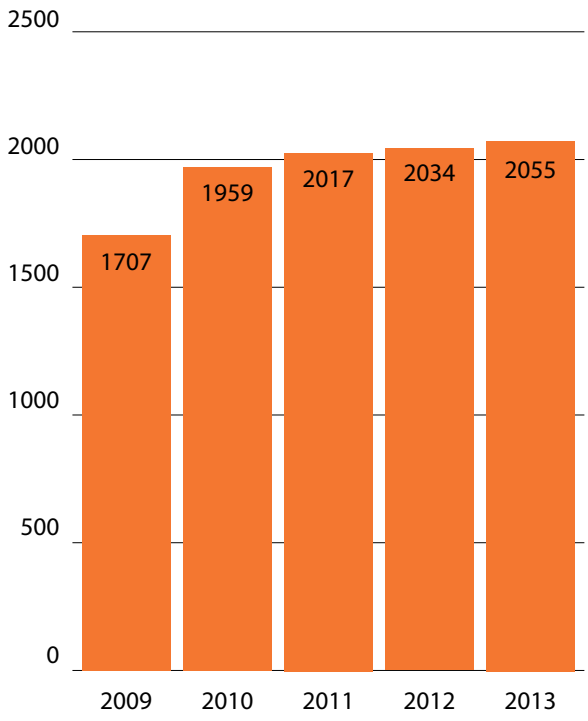
SCIENTIFIC ADVICE

Companies may also seek scientific advice from the CHMP. Scientific advice is a pre-authorisation activity which assists product and technology innovation and development. During 2013, the IMB acted as lead in 38 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.

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.

Controlled Drugs Licensing Activity 2009-2013



Licensing activity, which consists primarily of export and import licences and letters of no objection, has increased marginally during recent years.

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 which products should be categorised as veterinary medicines. 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 such as biocides and feeding stuffs.

During 2013, 33 product classification queries were received in respect of veterinary medicines. This represents a drop of more than 50% in the level of enquires compared to 2012.

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 preference of the marketing authorisation holder. When a company seeks an authorisation from the IMB for a new medicine, an assessment team of veterinary surgeons, pharmacists and other scientists will review the application to establish if the medicine's animal and public health benefits outweigh its known risks.

During 2013, the number of new product applications received by the IMB was 158 of which 16 were purely national applications. We assessed and approved 188 applications, which is an increase of 24% on last year.

The IMB continued to actively contribute to the European veterinary licensing system and issued 50 new marketing authorisations as the reference Member State. In total, including also those applications where the IMB was a concerned Member State, the number of MRP and DCP licenses issued was 139 while 124 such applications were received.

In the 'centralised' procedure, the EMA is responsible for conducting the initial assessment of veterinary medicines for which an EU-wide marketing authorisation is sought. Under this procedure, the Committee for Medicinal Products for Veterinary Use (CVMP) appoints members from two different EU countries to evaluate the application and these are known as the rapporteur and co-rapporteur. During 2013, the IMB acted as the rapporteur or co-rapporteur for seven centralised procedures (including extension applications to new target species).

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 2013, the IMB approved 1,364 variations to authorisations granted through the national, MR or centralised procedures while 1,416 variations applications were received, an increase of 15% on 2012.

RENEWALS

New marketing authorisations are valid for five years from the date of first issue, after which time they are usually renewed for an indefinite period.

In 2013, 95 renewals to marketing authorisations for veterinary medicines authorised through the national or MR procedures were received while 67 were issued. The number of renewals issued was in line with 2012 figures.

WORK-IN-PROGRESS APPLICATIONS

During 2013, the IMB reduced the overall work-in-progress at the end of the year relevant to veterinary medicines to 656 units (comprised of various application types). This represented a notable annual decline of 21%. The overall work-in-progress overdue figure was also reduced by over 70% during 2013.

SCIENTIFIC ANIMAL PROTECTION

The IMB became the national competent authority responsible for the implementation of Directive 2010/63/EU on the protection of animals used for scientific purposes on 1 January 2013. The accompanying national Regulations are set out in S.I. No. 543 of 2012. This authority was transferred from the Department of Health which regulated this area until 31 December 2012.

During its first year as the competent authority, the IMB issued a total of 81 project authorisations, 507 individual authorisations and one establishment authorisation. There were also 22 preliminary inspections and seven compliance inspections undertaken in 2013.

MEDICAL DEVICES

CLASSIFICATION REQUESTS

The IMB received 45 applications for classification of medical devices or products queried as medical devices. Of these enquiries:

- 48% were received from other medical device competent authorities in Europe or from the European Commission and related to complex classification questions;
- 34% of applications were received from external stakeholders such as medical device manufacturers or distributors;
- 16% were internal queries from within IMB;
- 2% were received from notified bodies.

The IMB circulated six enquiries on medical device classification issues to other European medical device competent authorities with a view to seeking a consensus opinion in Europe on the classification or qualification of a specific product.

In addition, four appeals to classification decisions taken by the IMB were received during 2013.

CLINICAL INVESTIGATION APPLICATIONS

The IMB received 10 applications for clinical investigations of a medical device to be conducted in Ireland comprising of nine new applications and one re-submission application. Five amendments to ongoing clinical investigations were received in 2013.

While there was an increase in the number of applications received in 2013 (compared with one in 2012), the number of clinical investigations of medical devices ongoing in Ireland remains lower than expected. The last revision of the European medical devices legislation (Directive 2007/47/EC) put greater emphasis on the conduct of clinical investigations. However, an increase in clinical investigation activity in line with this has not been seen in Ireland. 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. This is a specific type of medical device research. Other types of clinical research such as research involving CE marked devices are generally not required to be notified under national or European legislation. Therefore, 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

During 2013, the IMB conducted two surveillance assessments of the National Standards Authority of Ireland (NSAI). One of these surveillance assessments was carried out in its US-based office while the other was carried out in its Dublin headquarters. In addition, two observed audits were conducted by IMB of NSAI staff auditing medical device manufacturing sites.

The IMB received 183 certification notifications, including certificate issuance, modification and withdrawal, which were then uploaded as required to the European EUDAMED database.

TECHNICAL FILE REVIEWS

In 2013, the IMB increased its focus on review of technical documentation both in the context of market surveillance activities and notified body oversight. A total of 17 technical file reviews were opened in 2013. It is intended to further expand this activity during 2014.

PRODUCT REGISTRATIONS

The IMB received 334 notifications of medical devices to the medical device register. These relate to class I, in-vitro diagnostic and custom made medical devices as well as 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 as there is a self-declaration of conformity made by the manufacturer.

During 2013, 26 organisations registered with the IMB as Irish based manufacturers or authorised representatives of class I, custom-made, in-vitro diagnostic medical devices, as manufacturers of system or procedure packs or as sterilisers of medical devices.

QUERIES

During 2013, the medical devices team received 355 pre-market queries relating to medical devices, in addition to those received by the IMB's customer service team.

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. For the first half of the year, this could be done nationally (to the IMB and counterparts in other Member States) or via the European Commission's Cosmetic Product Notification Portal (CPNP). Notification via this centralised portal became mandatory on 11 July 2013.

The IMB received 819 cosmetic product notifications in the first six months of the year. The three most common categories of product notifications remained the same as in 2012 and were:

1. Lip products (20%)
2. Make-up products and make-up (20%)
3. 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, and wholesalers of human medicines as well as blood and tissue establishments and organ transplant centres. We are also responsible for the approval of contract laboratories.

Such sites and facilities are required to be authorised / licensed by the IMB for the activities which they carry out that fall within the remit of the relevant legislation. The IMB will grant an authorisation or licence subject to compliance with relevant European / National (as appropriate) legislation and guidelines. Compliance with these requirements is based on satisfactory outcomes of IMB inspections (see also the Safety and Compliance Monitoring section of this report – page 45).

The total number of licences / authorisations in place at year end for the past five years is presented by category in the accompanying table.

Total Number of Licences/Authorisations (Sites)	**2009**	**2010**	**2011**	**2012**	**2013**
Manufacturers of Medicines for Human Use	85	86	88	87	89
Manufacturers of Veterinary Medicines	25	27	24	23	24
Investigational Medicinal Products for Human Use	50	51	50	47	49
Wholesalers of Medicines for Human use	209	220	243	258	269
Blood Establishments	5	4	4	3	4
Tissue Establishments	13	16	22	21	23
Laboratory Approvals	13	16	16	17	16
Total	**400**	**420**	**447**	**456**	**474**

REGISTRATIONS FOR ACTIVE PHARMACEUTICALS INGREDIENTS AND BROKERS OF MEDICINAL PRODUCTS

Under amendments (via the so-called 'Falsified Medicines Directive') to the Medicines Directive, 2001/83/EC, that came into force at the beginning of 2013, manufacturers, importers and distributors of active substances were required to register with the IMB. Brokers of medicines were also required to register.

During 2013, the IMB accepted 95 registrations relating to active substances consisting of 22 manufacturer registrations, 35 importer registrations and 38 distributor registrations. There was also one registration accepted for a broker of medicines.

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 4,264 export certificates in 2012 as set out in the accompanying table:

Product Certification Activity	**2009**	**2010**	**2011**	**2012**	**2013**
Certification of Documents	235	234	239	272	223
Certificates of Good Manufacturing Practice for Active Substance and Finished Product Manufacturers	269	255	272	276	252
Certificates for Medicines	964	1200	1416	1350	1510
Medical Device Free Sale Certificates	977	2142	1780	1522	1987
Cosmetic Free Sale Certificates	n/a	174*	388	210	242
Other	56	28	51	16	50
Total	**2501**	**4033**	**4146**	**3646**	**4264**

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

SAFETY AND COMPLIANCE MONITORING

Post-market surveillance is a primary function of the IMB. This includes the ongoing monitoring of the safety of medicines, medical devices and other health products that have been authorised, licensed or registered for use in Ireland.

There are a range of tools employed to monitor the safety of health products including the assessment of 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. Quality issues concerning how a product is manufactured, packaged, labelled or distributed and stored may also arise at the post-market stage.

In certain 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. We work with all stakeholders impacted to ensure that 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.

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

During 2013, the IMB received a total of 2,835 valid new adverse reaction reports associated with the use of human medicines in Ireland, consistent with the reporting rates seen in 2011 and 2012. In addition, 3,304 follow-up reports were also received.

The majority of adverse reaction reports are notified to the IMB by pharmaceutical companies marketing the medicines, also known as marketing authorisation holders. Most of these reports will have been initially reported to the companies concerned 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.

Source of Suspected Adverse Reaction Reports	**%**
Pharmaceutical company	64
Community Care doctor	9
General Practitioner	5
Hospital Doctor	4
Hospital Pharmacist	4
Community Pharmacist	4
Nurse	5
Patient/Consumer	1
Other	4

In keeping with experience elsewhere, reporting rates were highest for newly authorised medicines. Reporting rates are also influenced by their ease of recognition and may be stimulated by publicity about a particular medicine or reaction. In addition, reporting rates are also influenced by proactive and repeated requests to healthcare professionals to submit reports on certain medicines as part of ongoing post marketing surveillance, as well as other promotional and data collection activities. All reports received are carefully evaluated and monitored, with reports of experience with use regularly highlighted and reinforced by IMB communications.

Reports submitted to the IMB in many instances arise from suspicions occurring during observation of an unexpected and/or unwanted event, in the context of use of a medicine. They also include adverse reactions known to occur in association with medicines, such as those described in the product information (summary of product characteristics and package leaflet) for a particular product.

The accompanying table indicates the medicines most frequently included in reports to the IMB. These account for almost 50% of the adverse reaction reports received during 2013. It is important to note that the inclusion of a medicine on this list cannot be taken as an indicator of safety or risk. The number of reports received cannot be used as a basis for determining the incidence of a reaction as neither the total number of reactions occurring, nor the number of patients using a medicine, is known. Reporting rates may also be stimulated by publicity about a medicine.

Of the reports received by the IMB during 2013, 143 patients were reported to have died while on treatment. In many of these cases, the patients concerned had significant underlying illness and were treated with multiple medicines and /or surgery, which may also have contributed to the outcome. In addition, many of these cases were influenced by disease progression or other complications unrelated to the medicine. The majority were associated with medicines used in the context of products subject to close monitoring, those used in the management of severe underlying medical conditions, in patient support programmes and special patient monitoring programmes such as those in place for clozapine. The following table outlines those medicines associated with the highest number of fatal outcomes.

Class of Medicines/Substance	Number of Reports in 2013
Monoclonal Antibodies	503
Vaccines used in the primary immunisation programme	234
Clozapine	214
Novel Anticoagulants (NOACs)	136
Human Papilloma Virus (HPV) Vaccine	131
Tyrosine Kinase Inhibitors	94
Fingolimod	74
Interferon Beta	55
Bortezomib	41
Selective Serotonin Re-uptake Inhibitor (SSRI) Antidepressants	40

Product(s)	Reports with a fatal outcome
Clozapine	14
Denosumab	9
Rivaroxaban	8
Dabigatran	5
Darbepoetin alfa	4
Mefloquine	4
Escitalopram	4
Pregabalin	4
Sorafenib	4
Palivizumab	4

Online Reporting

The online reporting system, available to healthcare professionals and patients / consumers, continued to be used during 2013 with some 459 reports submitted via our website by year end.

During 2013, the IMB continued to report all suspected serious adverse reactions occurring in Ireland electronically via EudraVigilance to the EMA.

Monitoring Compliance with Pharmacovigilance Obligations

Company / sponsor compliance with pharmacovigilance obligations is continuously monitored and the associated inspection programme continued in 2013. Inspections are jointly carried out by IMB pharmacovigilance and compliance colleagues with the pharmacovigilance team participating in four inspections during the year (see also Inspections and Audits on page 45).

VIGILANCE ASSESSMENT AND RISK MANAGEMENT

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, risk management plans, and protocols and reports related to post-authorisation safety studies. These activities also include signal management, the approval of direct healthcare professional communications and educational materials for use by healthcare professionals and patients. In respect of a number of these activities, the IMB acted as rapporteur or co-rapporteur via the EMA's Pharmacovigilance Risk Assessment Committee (PRAC).

Signal Management Activities

The IMB continued to contribute to work-sharing for signal detection within the EU during 2013 and acted as the lead in the detection and management of signals for 58 active substances. The IMB retained the responsibility for assessing any signals arising as a result of signal detection for 21 centrally authorised active substances (or combination of active substances) incorporating 34 authorised products for which IMB is rapporteur. The PRAC, which was established in July 2012, played a critical role in the prioritisation of potentially new or changing signals and in making recommendations for further investigation or for labelling changes. During its first 12 months of operation, the PRAC evaluated 92 signals and more than half of these led to labelling changes. The IMB was additionally responsible for the national implementation of these labelling changes for nationally authorised products following the PRAC recommendations.

The IMB also participated in the Signal Management Review Team at the EMA on a regular basis which focuses on tools, methods and processes for signal detection as well as methodological guidance.

Periodic Safety Update Reports

Periodic safety update reports (PSURs) are vigilance documents intended to provide an evaluation of the risk-benefit balance of a medicine. They are submitted by marketing authorisation holders at defined time points during the post-authorisation phase.

During 2013, a new format and content for PSURs was required under law and new assessment processes have been implemented nationally. The PSUR is now a cumulative benefit-risk report rather than an interval safety report, thus allowing continuing analysis of benefit-risk.

In addition, the European Union Reference Date (EURD) list became binding and further harmonised the frequency and dates of submission for PSURs.

The phased approach for implementation of the EU single-assessment procedure commenced in 2013 and now includes single assessments for products authorised centrally and where the active substance is authorised both centrally and nationally. The outcome of these procedures may lead to automatic regulatory action such as variation, suspension or revocation. The IMB also actively participated in the HMA PSUR work-sharing project, retaining our position in the top eight of national competent authorities in Europe in terms of lead Member State assessment responsibilities.

During 2013, the IMB evaluated PSURs relating to 2,500 medicinal products. This includes PSURs submitted as national, mutual recognition, centralised, EU single-assessment and PSUR work-sharing procedures.

Safety Referrals

2013 was a very active year in terms of EU safety-related referrals with IMB acting as concerned Member State in 15 of these procedures. The IMB provided the lead on the assessment (as PRAC (co-) rapporteur) for two of the major safety referral procedures. Experience to date has shown that the time taken to complete the assessment of referrals has fallen with the establishment of the PRAC. For example, for one type of EU referral the assessments have concluded in less than eight months compared to 15 months before July 2012. These prompter, high quality assessments allow faster optimisation of safe and effective use though drug labelling changes and restrictions when necessary.

Risk Management Plans and Risk Communications

Since July 2012, all applications for drug marketing authorisations have, by law, had to include a risk management plan (RMP) documenting the proposed risk management system to be implemented if a marketing authorisation is granted. This facilitates the balancing of access and evidence with proactive planning both of post authorisation studies and risk minimisation measures. EU guidance on the format of RMPs was revised during 2013 and new assessment processes were implemented nationally. In addition, applications for new or initial RMPs submitted outside another regulatory procedure to national competent authorities has changed in line with revised EU variations guidelines.

During 2013, the IMB evaluated 507 RMPs submitted as national, mutual recognition, decentralised and centralised procedures. The IMB demonstrated its continuing commitment to the new European pharmacovigilance processes by acting as PRAC rapporteur for five new marketing authorisation applications during the year.

As part of its role to promote and support the safe and effective use of medicines, the IMB reviewed and approved 53 Direct Healthcare Professional Communications (DHPCs) which provided new safety information or risk minimisation advice to prescribers. These communications were also published on the IMB website. The IMB also approved 71 sets of educational materials for distribution to healthcare professionals and/or patients.

Post Authorisation Safety Studies (PASS)

During 2013, the IMB provided assessment input into 120 post authorisation safety studies (PASS) protocols and reports. PASS are non-interventional studies carried out in order to obtain further information on the safety of medicinal products which are already authorised, or to measure the effectiveness of risk minimisation activities that have been introduced. The results of a PASS help to further evaluate the safety and benefit-risk profile of a medicine already in use and may have an impact on the marketing authorisation of the product.

BLOOD, TISSUES AND CELLS, ORGANS

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 2013, including discussion of issues of mutual interest and concern at bilateral quarterly meetings.

Following collaboration with the NHO, the IMB submitted an annual report on serious adverse reactions and events to the EU Commission during 2013. The report reflected information received during 2012 and included information on 129 serious adverse reactions and 117 serious adverse events which met the mandatory legislative reporting requirements. While these figures reflect a decrease of approximately 25% for serious adverse event reports compared with the previous year, the overall reporting rates remain largely consistent. These figures also reflect the impact of changes to agreed EU reporting criteria.

The EU Commission continued to progress harmonisation initiatives to develop a common approach to the provision of data by Member States through a Working Group on Haemovigilance first convened during 2007. During 2013, the IMB, 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 tissues and cells.

There were a number of tissue and cell vigilance activities progressed during 2013.

The three-year project co-funded by the EU Public Health group on Substances of Human Origin Vigilance and Surveillance (SOHOV&S) was brought to a conclusion. The IMB participated as a partner in this project which had a primary aim of supporting the establishment of effective vigilance and surveillance systems for tissues and cells used in transplantation and in assisted reproduction.

The IMB submitted an annual report on serious adverse reactions and events, associated with tissues and cells to the EU Commission during 2013. The report reflected information received in 2012 and consisted of some 42 reports associated with use of tissues and cells, 38 of which met the legislative reporting requirements, including two serious adverse reactions and 36 serious adverse events. Both these figures represented a very slight decrease in reporting rates compared to the previous year. 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 2013, the IMB continued to participate in the development of guidance for reporting which was updated during the year.

HUMAN ORGANS FOR TRANSPLANTATION

The IMB and the Health Service Executive (HSE) were appointed as the responsible national competent authorities for the legislation on standards of quality and safety of human organs intended for transplantation in 2012. During 2013, the IMB liaised with the HSE lead and colleagues responsible for this area in relation to the development of report forms and guidance to facilitate serious adverse reaction and event reporting. The IMB also shared information with the HSE in respect of reports received to date and supported appropriate follow up of relevant cases.

VETERINARY MEDICINES

PHARMACOVIGILANCE

Pharmacovigilance is a post-authorisation activity designed to ensure the ongoing production and use of high-quality veterinary medicines that are effective and as safe as possible. The primary inputs into the national pharmacovigilance system are reports of suspected adverse events received by the IMB from marketing authorisation holders, veterinarians and the general public.

During the 12 months under review, the IMB received 272 national reports of suspected adverse events to veterinary medicines. Reports received related to the following species:

- Bovine (116)
- Canine (81)
- Ovine (40)
- Feline (10)
- Equine (5)
- Poultry (5)
- Fish (2)
- Porcine (2)
- Caprine (1)

In addition, there were 10 reports of adverse effects in humans exposed to veterinary medicines.

Of the 272 reports of suspected adverse events received, a total of 135 involved pharmaceutical products and 137 involved immunological products. The majority of reports related to the use of a single medicine. However, two or more products were implicated in 71 reports of which 13 related to the use of both pharmaceutical and immunological products concurrently.

Overall, 144 reports involved suspected lack of expected efficacy with 114 involving suspected adverse reactions in the treated animals. Four reports related to violations of approved residue limits.

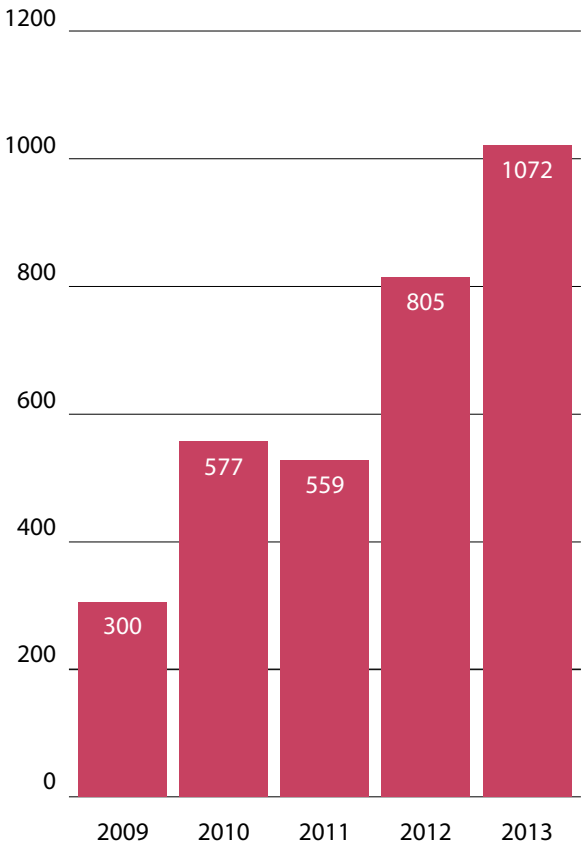
As a result of suspected adverse event information received during 2013, the IMB requested an amendment to information included in the summary product characteristics of one product.

Periodic Safety Update Reports

The IMB received 909 applications for periodic safety update reports (PSURs) for veterinary medicines in 2013. This represents a slight reduction of approx 5% compared to the 2012 data.

The IMB completed the evaluation of 1,072 PSURs in 2013. This represents year-on-year increase of approximately 25%.

Total PSURs Output 2009-2013



USE OF VETERINARY ANTIMICROBIALS IN IRELAND

Under a European programme known as the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC), the IMB collects annual information on the consumption of antibiotics from each marketing authorisation holder. The data for 2012 show that there was an apparent increase in the overall usage of veterinary antibiotics of 14% (although the 2011 baseline might be seen as low by historical standards). Medicated premixes and other oral formulations that are used primarily for the medication of pigs and poultry account for about two thirds of total consumption. This consumption pattern is relatively consistent with that of previous years.

The IMB continues to work with other EU veterinary medicines agencies and the EU Commission to help ensure that veterinary antibiotics are used responsibly in accordance with their approved conditions of use.

MARKET COMPLIANCE – HUMAN AND VETERINARY MEDICINES

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

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

SAMPLING AND ANALYSIS PROGRAMME

The IMB's risk based sampling and analysis programme is part of our monitoring of the quality and safety of medicines and our identification of borderline medicinal / non-medicinal products that may be on the Irish market. This is achieved through analytical testing and / or examination of packaging and labelling of medicines, active substances, borderline medicinal / non-medicinal products and enforcement-related samples.

A total of 437 product samples were sent for analytical testing / examination work during 2013. Details are provided in the accompanying tables.

Examination of Packaging and Labelling

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

The packaging and labelling of 162 medicines and other products available on the Irish market were examined. In total, 402 individual checks were carried out on the samples including a number relating to the safety information on package leaflets.

Description of products examined	Number of samples examined
Medicines subject to risk-based compliance monitoring for packaging and labelling attributes	65
Parallel imported medicines subject to risk-based compliance monitoring for packaging and labelling attributes	61
Borderline medicinal/non-medicinal products (associated with IMB Classification Committee work)	20
Samples obtained for other IMB work	10
Products subjected to usability checks	6
Total	**162**

Of the products examined, 86% were authorised medicines. All of these products were examined for signs of counterfeiting and tampering and no issues were identified. The remaining 14% concerned work on mainly borderline products. Braille compliance checks were carried out on 26% of products while 4% were subjected to usability checks.

Analytical Testing

There were 275 medicinal and other product samples sent for analytical testing. These included 156 samples sent to governmental laboratories in Ireland and 104 sent to Official Medicines Control Laboratories (OMCL) in other countries and to the European Directorate for the Quality of Medicines (EDQM) as part of European working-sharing programmes and other collaborations.

Approximately 49% were authorised medicines, while 35% related to enforcement and borderline medicinal / non-medicinal products. There were 17 products manufactured in Ireland for export tested while 29 samples were collected by our inspectors during inspections abroad. A small number of exempt medicines were tested.

Product categories selected for analytical testing in 2013	**Number of samples analysed**
Physico-chemical Analysis / Biological Analysis	
Enforcement-related products for human use	70
Nationally authorised medicines for human use	62
Biological active / intermediate pharmaceutical ingredients	35
Centrally authorised medicines for human use	33
Borderline medicinal / non-medicinal products for human use	18
Authorised veterinary medicines	14
Other product categories	20
Microbiological Analysis	
Nationally authorised medicines for human use	14
Nationally authorised medicines for veterinary use	5
Medicines for human use manufactured for export	4
Total	**275**

Participation in EU Co-ordinated Market Surveillance Activities

The IMB is an active participant in EU surveillance programmes that involve the sampling and analysis of medicines. This is achieved by participation in the OMCL network co-ordinated by the EDQM in Strasbourg.

The 2013 programme included:

- Centrally authorised medicines:
  - 29 sampled in Ireland for testing at OMCLs in other Member States and 5 tested at the IMB's OMCL (Public Analyst's Laboratory, Galway).
  - 21 of the 34 products were sampled as part of an anti-counterfeiting collaboration.
- MRP/DCP:
  - 8 MRP / DCP medicines sampled in Ireland and analysed at other Member State OMCLs.
  - 5 MRP/DCP products analysed at the IMB's OMCL.
- Other products:
  - A number were analysed at the IMB's request at OMCLs in other Member States. For example, 23 products underwent microbiological analysis at the Finnish and Czech OMCLs.
- As part of a European-wide project, the IMB organised the analysis of 29 biological samples that were obtained during an inspection in China. The analysis work was done in collaboration with OMCLs in Germany, Sweden, the UK, Denmark and Italy.

Acknowledgements

The IMB would like to thank the staff of the Public Analyst's Laboratory, Galway, and the staff of the State Laboratory, Young's Cross, Celbridge, Co. Kildare, for their invaluable contributions to the IMB's sampling and analysis programme in 2013.

Principal Findings

Analysis	Findings
Laboratory analysis	While the majority of samples tested were compliant with their specifications, 29 of out-of-specification results were also obtained. These included, for example, eight products that did not comply with the Ph. Eur. subdivision of tablets test and eleven products that did not comply with their assay specification. There were 21 deficiencies identified in the analytical methods and specification documents used by manufacturers of medicines. Appropriate follow-up actions were taken in each case.
Packaging and labelling	19 non-compliances were identified across 17 authorised medicinal products and in 2 borderline medicinal / non-medicinal products. Of these, 13 related to Braille non compliances while three related to incorrect information in package leaflets or in other product information, including the safety warning information. The final three related to unauthorised products that included medicinal claims on the packaging.

QUALITY DEFECTS AND RECALLS

The IMB's quality defects and recalls programme investigates, on the basis of risk to public and animal health, reports of suspected quality defects in both human and veterinary medicines and in their related active substances. The IMB also co-ordinates any subsequent recall actions on the Irish market. Reports are received both nationally and through a global network of regulators via a rapid alert system.

Number and Types of Quality Defects

A total of 774 quality defects were reported to, or identified by, the IMB during the past 12 months. Medicines for human use accounted for 743 quality defect reports with 31 reports concerning veterinary medicines.

The most common categories of defect were:

- Stability issues (14%);
- Non-compliance with marketing authorisation (11%);
- Contamination issues (11%);
- Reports of undeclared active ingredients in products (7%);
- Lack of sterility assurance (5%).

These categories are generally consistent with those reported in 2012.

The accompanying table illustrates how the various quality defect issues were classified in 2013. For comparison, the corresponding figures for the previous four years are also presented.

Of the total number of defects, 533 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.

Critical quality defects, which are those defects defined as potentially life-threatening or a serious risk to health, accounted for 235 of the total reports received. Of these, 56 were deemed to affect Ireland. These included 19 product contamination issues, 18 lack of sterility issues and five falsified medicine issues. However, in none of the cases was a falsified product identified on the Irish market. Of the remaining 15 critical cases affecting Ireland, one concerned a veterinary medicine, while the remainder related to human medicines.

Year	2009	2010	2011	2012	2013
Minor Quality Defects	147	241	314	236	230
Major Quality Defects	345	332	364	303	300
Critical Quality Defects	105	173	231	189	235
Number of Quality Defect Reports Not Justified	17	5	8	13	9
Total Number Quality Defects	**614**	**751**	**917**	**741**	**774**

Source of Reports	Human Medicines	Veterinary Medicines
Companies (Manufacturers, distributors and/ or marketing authorisation holders)	372	17
Other Competent Authorities (Regulators)	280	13
IMB Staff Members	49	1
Hospital Pharmacists	21	
Community Pharmacists	13	
Patients and/or Members of the Public	6	
Physicians and Nurses	2	

Sources of Quality Defects

As in previous years, pharmaceutical companies and other competent authorities accounted for the majority of reports of human medicine quality defects received.

Recalls of Human and Veterinary Medicinal Products

In order to protect the health and safety of patients, it is deemed necessary in certain cases to withdraw, or recall, products from the Irish market. During the year in review, 109 medicine recalls occurred. Of these, 107 related to human medicines and two to veterinary medicines.

As regards the level of recall, 16% were to patient/ user level, 48% to pharmacy/retail level and 37% to wholesale level.

Exempt medicines accounted for 21% of recalls of human medicines while compounded products for human use accounted for 11%. Of the total number of recalls from the Irish market, 26% related to products manufactured at an Irish facility.

The most common causes of a human medicine recalls were:

- Lack of sterility assurance (16)
- Non-compliance with GMP (15)
- Stability issues (14)
- Non-compliance with marketing authorisation (11)
- Printed packaging component (9)
- Non-printed packaging component (8)
- Contamination issues (7)

In respect of veterinary medicines, one recall related to a product mix-up issue and one to a non-printed packaging component issue.

RETAIL SALES MONITORING

Exempt Medicinal Products Programme

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

Under the medicinal products Regulations, wholesalers and manufacturers of medicines are obliged to notify 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. This information facilitates, when required, the effective recall of any defective exempt medicine from the Irish market.

During 2013, 1,290,347 packs of exempt medicines were notified. We continue to work with stakeholders in several areas to identify and develop solutions aimed at limiting the use of exempt medicines in Ireland.

General Retail Sale Investigations

The IMB monitors the sale of consumer healthcare products by retail outlets such as grocery shops, health food shops and, in some instances, pharmacies, using a proactive and reactive risk based programme. Of the 98 products investigated in the past year, 19 were removed from sale as they breached medicines legislation in various ways. For example, some were unauthorised products while others included medicinal claims.

Regulatory Compliance Inspections

These risk-based inspections are carried out at the premises of marketing authorisation holders. The inspection seeks to determine the level of compliance with the legal requirements for the marketing and advertising of medicines. Three inspections were carried out in 2013 and a number of non-compliances were identified. These were followed up and the IMB monitored the implementation of corrective actions at companies concerned. This inspection activity is linked to the IMB's advertising compliance programme.

Human Medicines Advertising Compliance Programme

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

Just under 400 advertisements were reviewed for compliance in 2013. While the majority were found to be compliant, a number of non-compliant advertisements were also identified. One was required to be withdrawn.

The five elements of the programme are shown in the table below:

	Total	Advertisements Reviewed	Non-Compliances Identified
Proactive Monitoring: Pre-planned Projects	12	271*	17 individual advertisements were non-compliant
Proactive Monitoring: Randomly Selected Projects	25	88*	16 individual advertisements were non-compliant
MAH Inspections Performed	3	Multiple	Nine major deficiencies identified across a number of areas. Two related directly to advertising activities.
Complaints Received	16	49*	Five advertisements were found to be non-compliant
Queries Received	60	45*	12 advertisements were found to be non-compliant

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

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

MEDICAL DEVICES

VIGILANCE

The IMB's reporting system for incidents and Field Safety Corrective Actions (FSCA) associated with medical devices is intended to protect the health and safety of patients, users and others by reducing the likelihood of the same type of incident or FSCA occurring elsewhere and to correct product problems.

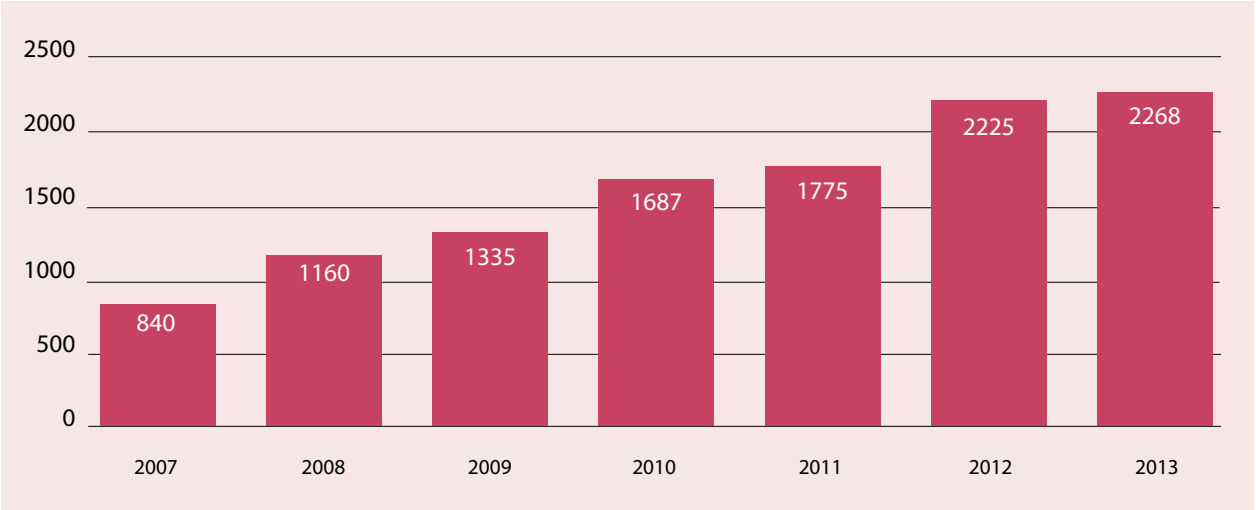
2013 Reports in Summary

A total of 2,268 medical device vigilance reports were received and assessed representing a slight increase on 2012. This continues the upward trend in the number of vigilance cases received annually.

Of the vigilance reports received in 2013, 58% were from manufacturers while 37% were received from competent authorities. In total, 38% of the reports received were as a result of an incident on the Irish market.

European regulatory action followed in respect of 58% of the reports received. In Ireland, the IMB published 543 manufacturer's field safety notices online which directly affected the local market representing a 23% increase compared with 2012. These notices are intended to inform users of safety issues relating to medical devices. A total of 182 product removals were conducted in Ireland in 2013. Safety information was also highlighted to the public through IMB safety notices. There were 16 such notices sent to relevant interest groups and published on the IMB website. During the year in review, the IMB issued 112 national competent authority reports which represents a 38% increase on 2012.

Number of Vigilance Reports - 2007 to 2013



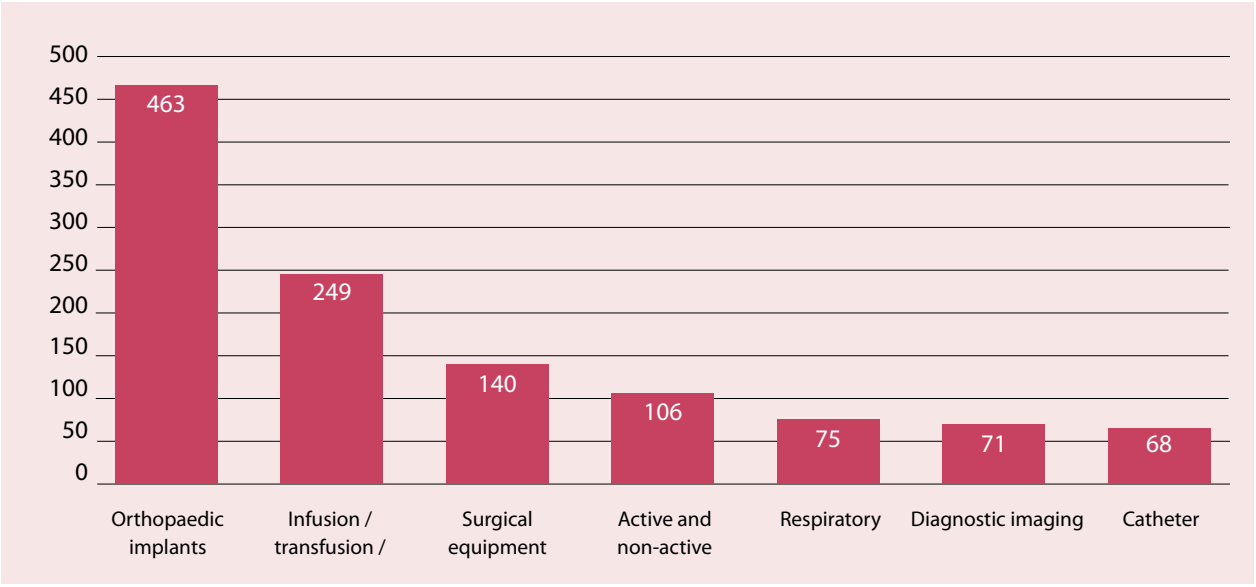
2013 Reports by Product Type

Orthopaedic implants, due to the continued reporting of revision procedures associated with the ASR Articular Surface Replacement and ASR XL Acetabular system manufactured by DePuy, and infusion and transfusion devices accounted for a large proportion of vigilance reports received. In addition, there were also a number of reported revision surgeries in relation to implanted defibrillation leads.

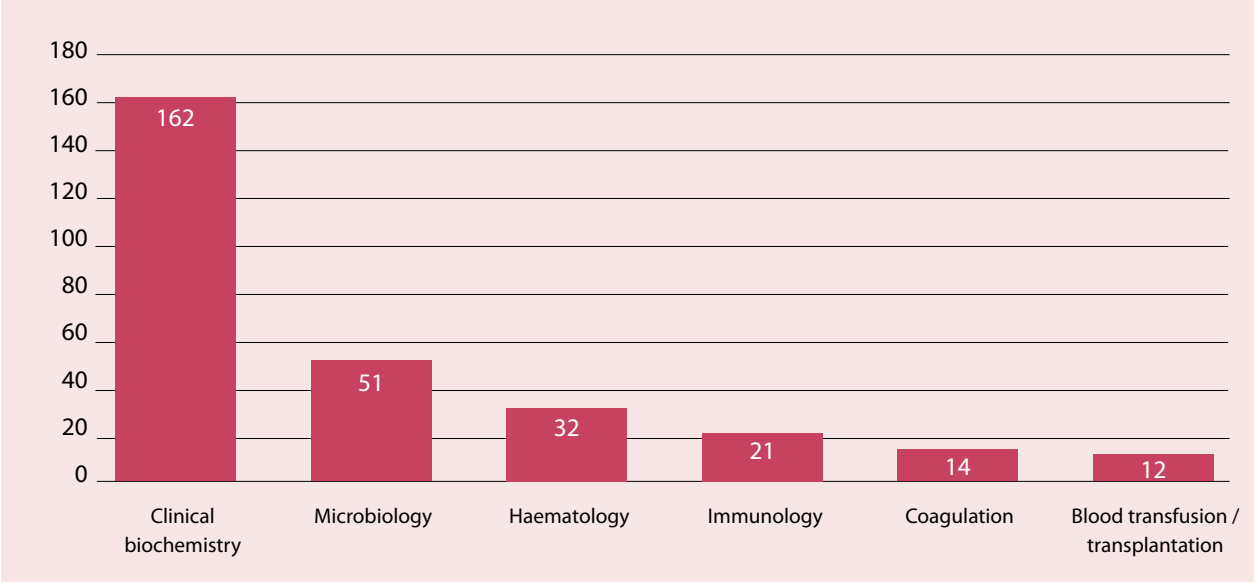
The accompanying chart outlines the types of general medical devices associated with the highest number of reports received.

In the area of in-vitro diagnostic medical (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.

Vigilance Reports Received - General Medical Devices



Vigilance Reports Received - IVD Medical Devices



COMPLIANCE

Medical device compliance activities are focused on protecting the health and safety of those who use medical devices by ensuring that all devices on the Irish market comply with the relevant European directives.

In 2013, a total of 665 compliance cases were reviewed and managed. Similar to previous years, issues identified in the past 12 months 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, 87% were from other competent authorities and mainly related to notified body certificate withdrawals.

The IMB finalised a retailer guide in late 2013 on key elements of legislation relating to the sale of medical devices in Ireland.

MARKET COMPLIANCE OF COSMETICS

PROACTIVE MARKET SURVEILLANCE

Post market surveillance of cosmetic products includes a national sampling programme and 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 proactive sampling and analysis of cosmetic products on the Irish market.

The new Cosmetic Products Regulation, EU Regulation 1223/2009, came into effect in July 2013 and introduced good manufacturing practice (GMP) requirements for cosmetic product manufacture in line with ISO 22716:2007. The IMB undertook a pilot GMP inspection programme where three manufacturers were inspected to this standard. Opportunities for improvement were highlighted as an output from these inspections.

There is no pre-market approval of cosmetic products on the European market and, therefore, the safety of cosmetic products is monitored through post market surveillance. This includes a review of product labelling and of the product information file (PIF). The requirement to have a product information file in place prior to placing a cosmetic product on the market is mandatory and is given legal status by Article 11 of the Cosmetic Products Regulation. A number of product information files were proactively requested by the IMB for technical review. Labelling reviews were also carried out as part of the proactive surveillance campaign.

REACTIVE MARKET SURVEILLANCE

Reactive surveillance includes investigation of quality related complaints (compliance cases) and reports of undesirable effects relating to the use of cosmetics (vigilance cases). During the year in review, 153 compliance cases were initiated and these accounted for the vast majority of investigations. There were 17 vigilance cases investigated, while seven products were recalled / withdrawn from the Irish market.

Reactive surveillance of cosmetic products also includes investigation of incoming RAPEX Alerts (EU safety alerts for cosmetic and other consumer products). The National Consumer Agency (NCA) is the national contact point for Rapex Alerts in Ireland. In conjunction with the HSE, the IMB investigated 111 alerts on the basis of risk and, where appropriate, market action was taken. In all, three of the products were found on the Irish market. In respect of each of these, a reaction report was submitted to the European Commission 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). The GCP inspection programme includes inspection of sponsor companies, investigators, contract research organisations and laboratories and applies to clinical trials approved in Ireland and those performed in support of national and EU marketing authorisations.
- Inspection for compliance with Good Pharmacovigilance Practice of the systems put in place by marketing authorisation holders for dealing with reports of adverse reactions to medicines.
- Regular audit of the NSAI, the notified body for medical devices that is designated by the IMB.
- Proactive audit of manufacturers of Class I medical devices and 'for cause' audits as required, for example, as part of the follow-up to a defect.
- Inspection of blood, tissue and cells, and organ establishments for compliance with applicable EU guidelines on the quality and safety of blood, blood products, tissues and cells, and human organs intended for transplantation.
- Inspection, often in conjunction with the Garda National Drugs Unit, of manufacturers and wholesalers of medicines containing controlled drugs (CD) and of precursors (chemicals that can be used in the preparation of illicit drugs) to check for compliance with security and record-keeping requirements for these controlled substances.

Performance Results and Statistics	2009	2010	2011	2012	2013
No. of national inspections and audits performed	238	293	271	289	279
No. of foreign inspections and audits performed	28	30	29	26	34
% inspections and audits closed on time (≤ 90 days)	58	62	66	61	63
Average time for close-out (days)	112	194	79	76	103

OVERVIEW OF THE 2013 INSPECTION PROGRAMME

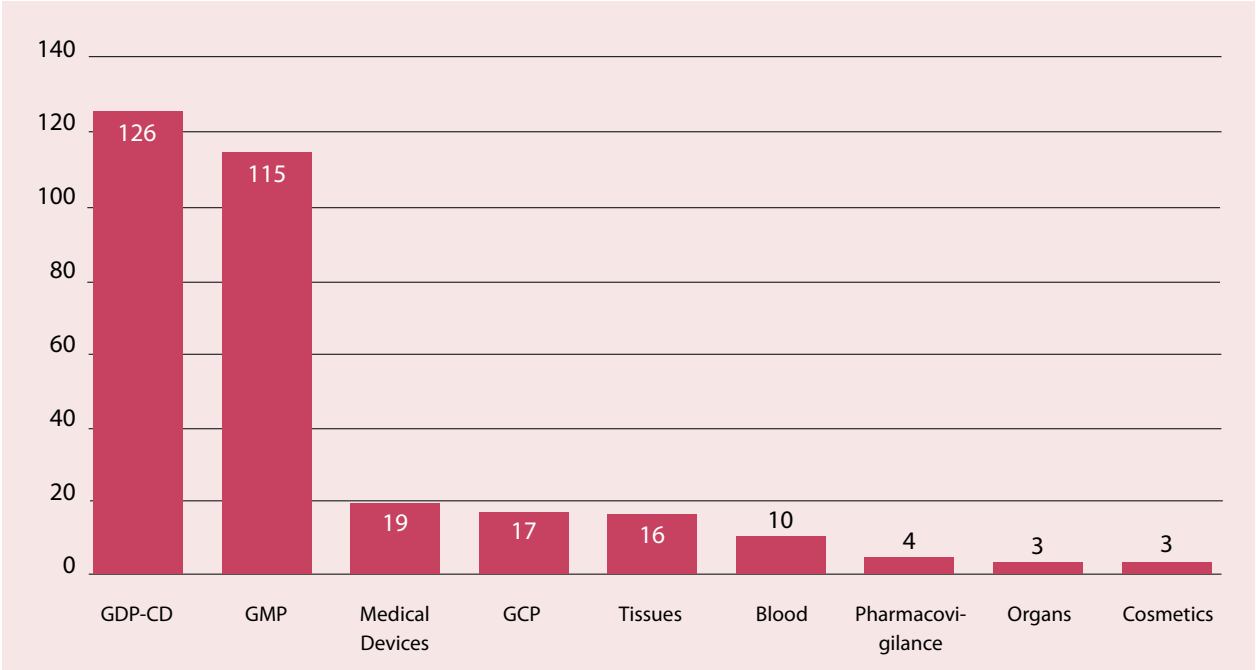
During the 12 months under review, 313 inspections and audits were performed compared to 315 in 2012 and 300 in 2011. The average number of days required to close-out inspections and audits conducted was 103.

In the past year, there were:

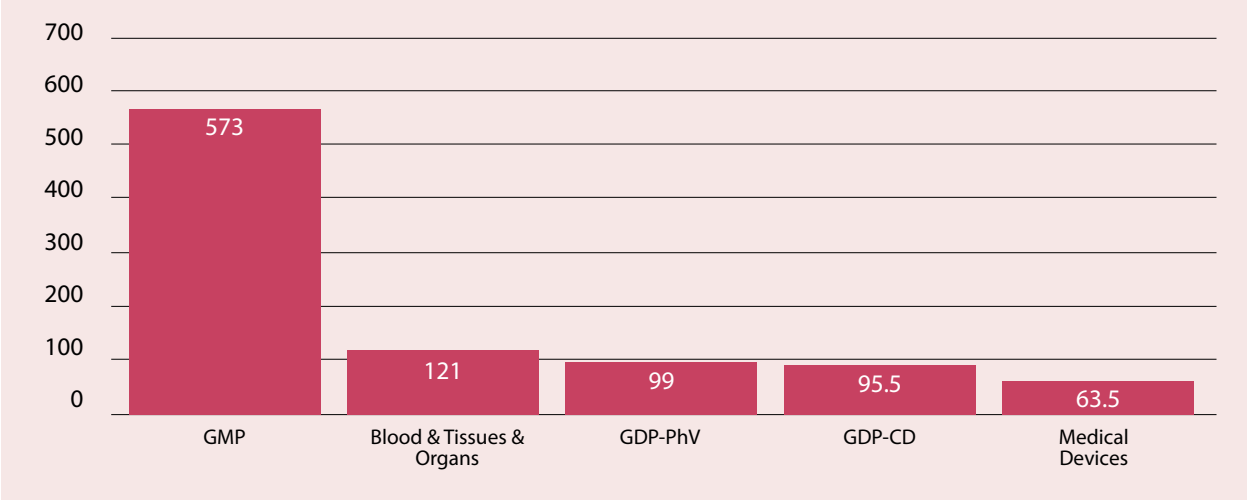
- 115 GMP inspections carried out at manufacturing sites. These included 24 inspections in non-EEA countries, 16 of which were carried out at the request of the EMA for centrally authorised products. Of the GMP inspections carried out, 16% were of active substance manufacturers.
- 126 inspections performed to assess compliance with GDP and controlled drugs (CD) requirements. Of these, 123 related to the distribution of medicines, including controlled drugs, and three related to the distribution of active substances.
- 17 GCP inspections completed, of which 12 were carried out at investigator sites in Ireland. Five inspections related to centrally-authorised medicines and were conducted at the request of the EMA. One of these took place at a contract research organisation (CRO) in Ireland.
- Four pharmacovigilance inspections carried out at the facilities of Irish based marketing authorisation holders.
- 19 medical device audits performed.
  - Two were surveillance audits of the NSAI, the notified body for medical devices in Ireland. One of these audits was carried at the NSAI's offices in Dublin and was observed by the European Commission's Food and Veterinary Office (FVO) while the other was performed in the NSAI's offices in New Hampshire, USA.
  - Three observed audits of the NSAI were performed at the premises of device manufacturers.
  - Two joint assessment audits were carried out by the IMB in conjunction with the FVO for assessment of designating authorities for medical devices outside of Ireland.
  - Three audits were performed of authorised representatives of medical device manufacturers and three were performed of manufacturers of custom made medical devices. There were also three audits of in-vitro diagnostic manufacturers and the remaining three audits were of general medical device manufacturers.

- 10 blood establishment inspections completed. These included six inspections of facilities maintained by the Irish Blood Transfusion Service (IBTS) and an inspection undertaken at the request of the Medicines Authority of Malta of its National Blood Transfusion Service.
- 16 tissue establishment inspections carried out.
- Three inspections carried out to assess applications for authorisation for establishments involved in organ transplantation.
- Three GMP inspections conducted at cosmetics manufacturers in Ireland as part of a pilot inspection programme.

Number of inspections and Audits Completed in 2013



Number of Inspection and Audit Days in 2013



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, medical device and the majority of other legislation within its remit. Where necessary, we will take the appropriate corrective action including possible legal proceedings.

ENFORCEMENT CASES AND DETAINED MEDICINES

In 2013, a total of 3,932 enforcement cases were initiated by the IMB, compared to 3,911 for 2012.

While this represents a stabilisation on the number of cases being initiated, the number of dosage units detained increased to 919,965. This represents a 20% increase in the numbers of units, such as tablets and capsules, when compared with 2012. The profile of the detentions changed in comparison to 2012 also with sedative products accounting for 51% (19% in 2012) of detentions and weight loss products and erectile dysfunction products accounting for 19% (20% in 2012) and 11% (6% in 2012), respectively. This may be partly explained by detections of larger quantities of sedative products during inter-agency operations by the IMB, Revenue's Customs Service and An Garda Síochána. The majority of these illegal supplies appeared to originate from China, USA, India and UK.

Summary of IMB 2013 enforcement data

Year	2009	2010	2011	2012	2013
Product detained	494,502 Dosage Units	822,484 Dosage Units	762,641 Dosage Units	758,276 Dosage Units	919,965 Dosage Units
Cases opened	3,729	3,936	4,549	3,911	3,932
Prosecutions	2	5	9	9	9
Product destroyed	2,601kg	1,400kg	4,519kg	1,065kg	4,194kg

INTER-AGENCY CO-OPERATION AND PANGEA VI

The IMB continues to liaise with other enforcement agencies, both nationally and internationally, to prevent and detect the unauthorised flow of medicines and medical devices. Co-operation with Revenue's Customs Service and with An Garda Síochána continued as evidenced by the joint approach in advance of Operation Pangea VI and during its execution in September. This global initiative, co-ordinated by INTERPOL, to identify and act against illegal websites supplying falsified and illegal medicines, involved 200 national agencies worldwide from 99 countries. It led to the detention in Ireland of nearly 200,000 tablets and capsules with an estimated value in excess of over €600,000.

DISTRICT COURT PROSECUTIONS

The IMB initiated nine prosecutions in the District Courts during the course of 2013. This is the same number of prosecutions as for 2011 and 2012.

The offences involved included the;

- Importation of medicines without manufacturing authorisations;
- Supply of prescription only medicines without prescriptions;
- Procurement and supply of prescription only medicines without marketing authorisations;
- Wholesale of medicines without a wholesaler's authorisation;
- Advertising of prescription only and unauthorised medicines.

Products containing active substances indicated for mood stabilisation, sports performance enhancement, erectile dysfunction and weight loss were included in these prosecutions.

LEGISLATIVE AND REGULATORY DEVELOPMENTS

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 the 2013 annual report outlines the most significant legislative and regulatory developments during the past year 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.

Details are also provided of the IMB's significant programme of work carried out under the Irish Presidency of the Council of European Union, a six month period during which Ireland was at the centre of decision-making in Europe.

IRISH PRESIDENCY OF THE COUNCIL OF THE EUROPEAN UNION

The Irish Presidency was a considerable area of focus for the IMB from January to June 2013. In total, we hosted 22 meetings during this period with approximately 1000 delegates visiting Ireland for IMB organised events.

Each meeting was focused on contributing to the overall Irish and European objective of ensuring public health through co-operation, consistency and development of standards throughout Europe. Overall, the IMB's contribution to the Presidency was considered highly successful with very positive feedback received from participants and, critically, essential progress made in respect of a number of important regulatory issues.

The IMB's Presidency programme included a number of joint meetings, which brought together key European committees and organisations to discuss a range of current regulatory issues. Of particular note, was the first joint meeting of CHMP, PRAC and CMDh which are the three key committees with responsibility for the authorisation and safety monitoring of human medicines. The Irish Presidency also included the first ever combined meeting of both the HMA and the Competent Authorities for Medical Devices (CAMD). During this meeting the IMB also facilitated medical devices and veterinary medicines stakeholder meetings.

In addition, the IMB's contribution to the Presidency included the provision of a high level of support to the Department of Health in its chairing of the European Council's Working Party on Pharmaceuticals and Medical Devices. This working party had a substantial work programme during the Irish Presidency with two proposals for medical devices Regulations, the Regulation on clinical trials of medicinal products, and the transparency legislation before the Council. A total of seven days of meetings of the Council working party were specifically dedicated to discussions of the medical devices proposals. In addition, the Irish Presidency, at the request of the Council working party, convened an additional seven days of meetings of an ad hoc group of experts in medical devices to discuss the technical aspects of the relevant Annexes to the proposals.

In relation to the Clinical Trials proposals, the Irish Presidency held 10 meetings of the Council Working Party on Pharmaceuticals and Medical Devices dedicated to the Clinical Trials dossier.

The IMB provided expert support to the Department of Health for its period as chair of the Council working party meetings, and directly chaired the additional expert group meetings.

HUMAN MEDICINES

HEALTH (PRICING AND SUPPLY OF MEDICAL GOODS) ACT 2013

The Health (Pricing and Supply of Medical Goods) Act 2013 came into effect in June. This Act outlines the circumstances under which medicines are considered interchangeable (often referred to as generic substitution). 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. During 2013, the IMB collaborated closely with the Department of Health and HSE in the implementation of this legislation.

The IMB is responsible for the establishment, consultation, publication and maintenance of a list of interchangeable medicinal products which will be grouped together under their respective active substance, strength and pharmaceutical form(s).

The process for publishing the list of interchangeable medicinal products was commenced in August 2013 and work on extending the list will continue for the foreseeable future. In conjunction with the Department of Health and the HSE, 40 priority substances for inclusion on the list have been identified. The approach to the generation of the list has been determined on the basis of maximising cost benefit to the State and to patients.

During 2013, the IMB published 11 active substances to the interchangeable list which is maintained on the IMB website. In each case, the IMB consulted with the relevant marketing authorisation holders prior to adding a medicine or a group of medicines to the list. The IMB also supported the various communications initiatives introduced to raise awareness and understanding of generic and interchangeable medicines.

The IMB continues to engage with the Department of Health and the HSE to ensure that the approach on interchanging medicines and generic substitution remains focused on the context of the wider national health system needs.

RESPONDING TO MEDICINES SHORTAGES

During 2013, the IMB continued to collaborate closely with the Department of Health and the HSE in relation to the management of shortages of medicines within the Irish market place. One of the mechanisms used by IMB to aid continuity of supply to the market place in the event of a shortage includes the granting of a temporary authorisation for a batch (or batches) of a product known as a 'batch specific request'. During 2013, IMB issued 152 such requests to prevent or alleviate shortages.

ONGOING IMPLEMENTATION OF EU PHARMACOVIGILANCE LEGISLATION

The IMB continued its work with stakeholders including the EMA, other national regulators and industry to support the phased implementation of the pharmacovigilance legislation. While still in the early stages of operation, the initial indicators from the introduction of this strengthened legislation and the establishment of the PRAC as a public health focused body are generally positive. The new legislation is resulting in more systematic risk management planning, greater coordination of real time signal management, and faster assessment and decision-making. As a result, there is a strengthening of the link between pharmacovigilance assessments and regulatory action such as labelling changes to optimise the safe and effective use of medicines.

Medicines Subject to Additional Monitoring

During 2013, the EMA published the initial list of medicines that are subject to additional monitoring. The introduction of the symbol for these products (an inverted black triangle) is an important deliverable of the new pharmacovigilance legislation. There is also a requirement for the inclusion of explanatory text in the product information and materials distributed to healthcare professional and patients. This information outlines why the symbol is present and encourages reporting of adverse reactions.

Specific information for healthcare professionals and patients was published on the IMB website and related articles were published in a number of health publications. A national guideline for marketing authorisation holders on the implementation of the additional monitoring scheme was finalised by the IMB and will be published in January of 2014.

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. During 2013, as part of the progressive implementation of the provisions of the Directive, the IMB established a registration scheme for manufacturers, importers and distributors of active substances and for brokers of medicines.

GUIDELINES ON GOOD DISTRIBUTION PRACTICE (GDP) OF MEDICINAL PRODUCTS FOR HUMAN USE

Revised EU GDP Guidelines were published by the EU Commission on the 7 March 2013 (2013/C 68/01) and replaced the GDP Guidelines published in 1994 (94/C 63/03). These updated guidelines, effective from 8 September 2013, were subsequently revised again to address a number of typographical errors. The updated version (2013/C 343/01) became applicable as of 24 November 2013. The guidelines, which form the basis for IMB inspections, apply not only to wholesalers and manufacturers of medicinal products but also incorporate specific requirements for brokers involved in activities relating to the sale or purchase of medicinal products.

ONGOING IMPLEMENTATION OF THE 2010 VARIATIONS REGULATION

The provision of the variations regulations which relates to the application of European requirements, such as timelines and work-sharing, to medicines authorised through the national route, came into effect in August 2013. The IMB is now applying these requirements.

NEW CLINICAL TRIALS LEGISLATION

The European Commission is proposing new legislation in an effort to increase the number of clinical trials being carried out in Europe. The IMB continued to contribute to the consultation process surrounding these new proposals during 2013. The new regulation is anticipated to be introduced in early 2014.

CONTRIBUTING TO THE EUROPEAN AND GLOBAL REGULATORY NETWORK

Europe

Throughout 2013, the IMB continued to actively participate in the European medicines regulatory systems. 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 Heads of Medicines Agencies, and at other fora.

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

- As part of the IMB's continued active contribution to the work of the PRAC, the Irish PRAC delegate continued to fulfil the role of Vice-Chair of the committee.
- The IMB's Pharmacovigilance and Risk Management Lead acted as Regulatory Chair for the ICH Implementation Working Group on the new E2C R2 guideline on Periodic Benefit Risk Evaluation Reports.
- IMB experts were significantly involved in initiatives to facilitate the transition from implementation to operation of the new EU pharmacovigilance legislation. This included participation in a three year EU-wide pharmacovigilance project entitled SCOPE (Strengthening Collaborations for Operating Pharmacovigilance in Europe). The project was launched in November 2013 with the aim of assisting Member States in operating the requirements of the legislation. The IMB will also lead the impact assessment topic in a work package on risk communications. In addition, the IMB is an active participant in a work package on lifecycle pharmacovigilance with a particular focus on risk management planning and benefit-risk evaluation through the product lifecycle.
- The IMB contributed to three EMA/Member State project teams (PT) concerned with collection of key information on medicines (PT1), better analysis and understanding of data and information (PT2), and committees and communications with stakeholders (PT3).
- The IMB continued its contribution to the development of Good Vigilance Practice Modules as a member of the project coordination group of the HMA European Risk Management Strategy Facilitation Group.

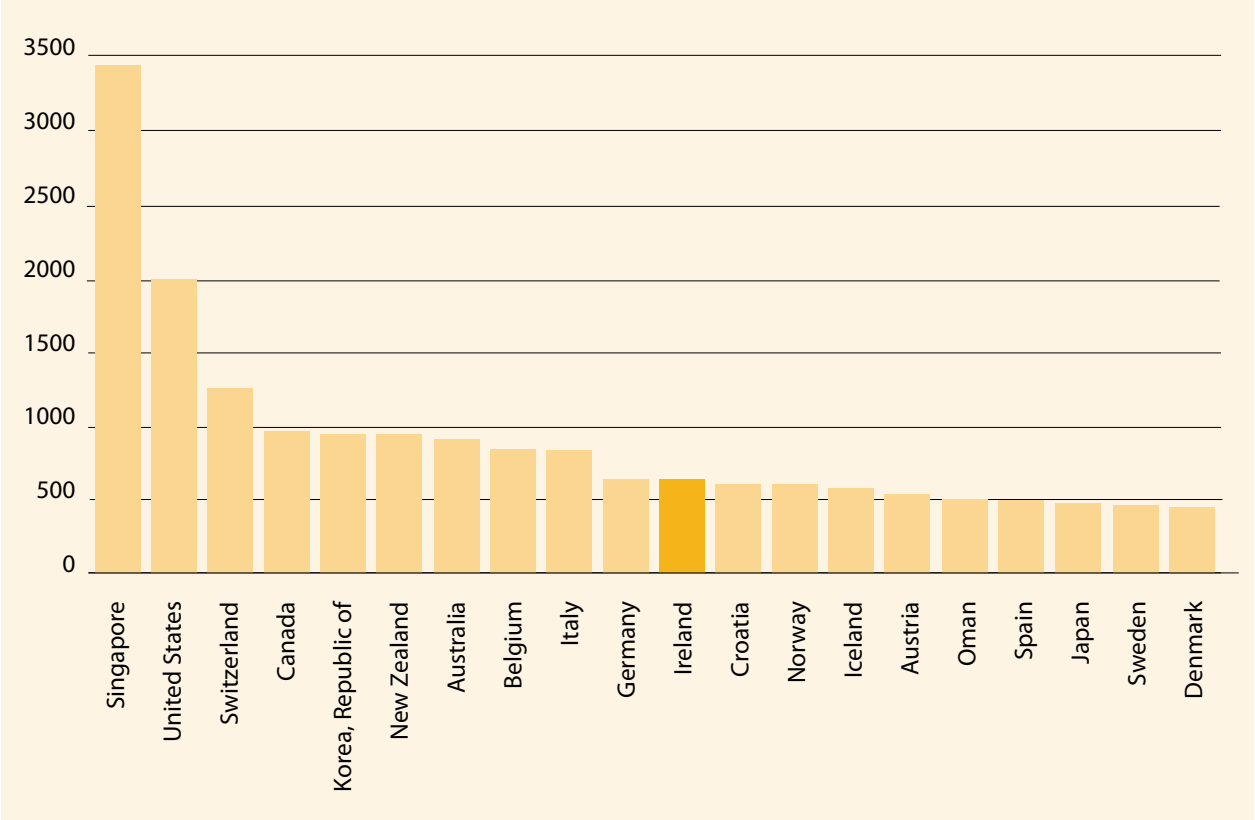
World Health Organization

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 2013.

IMB staff also participated at the annual meeting of national centres participating in the WHO international drug monitoring programme in September 2013 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 (116 full country members as of quarter four 2013). As can be seen from the accompanying graph, Ireland ranked as the twelfth highest reporter for the year during 2013.

Active ICSRs in the WHO global ICSR database per milion inhabitants - 2013



ADVERTISING COMPLIANCE PROGRAMME

IMB staff attended and presented at the second annual meeting of the Forum on Advertising of Medicines (FOAM), which was hosted in London by the MHRA. This forum comprises advertising regulators from 30 countries including all EU Member States. It was set up under the auspices of the HMA. FOAM aims to provide a platform to exchange information about regulatory practice and about advertising cases with cross-border relevance, and to share information about how regulatory challenges are addressed in different countries.

ADVISORY COMMITTEE FOR HUMAN MEDICINES

The Advisory Committee for Human Medicines, which is appointed by the Minister for Health, assists and advises the IMB Board in relation to any matters pertaining to the safety, quality or efficacy of medicines for human use. The committee met four times during 2013 and in addition to considering matters referred to it by the Board, it also reviewed the licenses for human medicinal products as approved by the IMB's Management Committee.

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

- The Clinical Trials Sub-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 Sub-Committee met twice in 2013. 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 EMA.

VETERINARY MEDICINES

CONTRIBUTING TO THE EUROPEAN REGULATORY NETWORK

The primary focus of the IMB is on our contribution to the work of the Heads of Veterinary Medicines Agencies (HMA-V). In addition to quarterly meetings of the HMA, there are a number of working groups including the European Surveillance Strategy group and the Antimicrobial Resistance group to which the IMB also contributes. The former is tasked with improving the co-operation between Member States in respect to work-sharing on periodic safety update reports and other pharmacovigilance initiatives. The latter group is tasked with implementing the HMA Strategy and Action Plan on veterinary antibiotics and related areas. The IMB was active also in other HMA groups, including those relating to new legislation and one dealing with timetabling of new applications in the centrally authorised system. Many of the meetings took the form of teleconferencing rather than physical meetings.

The European regulatory network continues to wait for new legislative proposal for veterinary medicines, which is being elaborated by the European Commission. In recognition that the new legislation might not be implemented before 2017, the HMA is continuing to examine ways to better cooperate under the existing legislative framework, including how to improve the efficiency of EU procedures as well as how best to control autogenous vaccines.

CONTRIBUTING TO NATIONAL HEALTH INITIATIVES

The IMB met with the Environmental Protection Agency (EPA) to discuss the disposal of veterinary medicines and spent product in this country. The IMB provided the EPA with information on the use of sheep dips. It is expected that the EPA will monitor the use of the products concerned over the coming years.

The IMB also participated in a working group of the Food Safety Authority of Ireland. The task of the group is to prepare a report on the risk of antibiotic resistance transfer posed by food.

ADVISORY COMMITTEE FOR VETERINARY MEDICINES

The Advisory Committee for Veterinary Medicines is the IMB's independent expert committee that advises on matters relating to the authorisation of veterinary medicines in Ireland. It met three times during the course of 2013 and considered such matters as:

- An improvement in the warnings of a vaccine for livestock;
- An application to switch a method of supply for an antiparasitic product for companion animals;
- The IMB policy on the supply of veterinary vaccines for cattle;
- The annual report of suspected adverse reactions to veterinary medicines in Ireland for 2012;
- The annual report on the consumption of veterinary antibiotics in Ireland for 2012;
- The peer review of various applications that had been considered previously by the IMB.

MEDICAL DEVICES

REVISION OF EUROPEAN MEDICAL DEVICES DIRECTIVES

Negotiation on the two proposed regulations on medical devices and in-vitro diagnostics continued in 2013 during and after the Irish Presidency of the European Council. The aim of the two proposals is to provide a legislative framework for the manufacture and placing on the market of medical devices and in-vitro diagnostic devices to ensure a high level of protection for patients and healthcare professionals. Both proposals are large and complex but represent significant development and improvement in comparison to the existing legislation.

It is not yet certain when agreement on the legislative proposals will be reached. The proposals are subject to the ordinary legislative process so require examination both at the European Council and the European Parliament levels.

The IMB has contributed extensively over the past number of years to working groups and subgroups focused on the development of the expected new regulatory system and we will continue to support the Department of Health in this regard as required.

EUROPEAN COMMISSION'S JOINT PLAN FOR IMMEDIATE ACTIONS ON MEDICAL DEVICES

In February 2012, 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 in advance of the proposed revision to the medical devices legislation. The plan outlined actions for Member States and the Commission in the areas of functioning of notified bodies, market surveillance, coordination, communication and transparency. In advance of the legislative proposal being finalised, the IMB remains committed to contributing to the joint plan.

Oversight and Performance of Notified Bodies for Medical Devices

Under the joint plan, the performance of notified bodies for medical devices and their oversight was subject to significant attention and development at European level during 2013.

In January, a joint assessment scheme for notified bodies for medical devices was implemented across Europe on a voluntary basis. The IMB helped establish a subgroup of the European Notified Body Operations Group (NBOG) to plan this scheme, develop common criteria, documents and guidance and coordinate the joint assessments. This scheme required the national authority in each Member State (that was responsible for the oversight of a notified body that certified the highest risk (class III) medical devices) to be accompanied during a notified body audit by a joint assessment team. The joint assessment team comprises of European expert assessors of notified bodies, experts from other Member State's national authorities and from the European Commission's health inspection division, the Food and Veterinary Office (FVO).

During 2013, 21 of the 23 countries responsible for class III notified bodies were subject to joint assessment while the remaining two will be completed in 2014. The IMB directly participated as experts in five joint assessments of EU notified

bodies in 2013. Further contributions are planned for 2014. The IMB was also subject to a successful joint assessment in their surveillance audit of NSAI in December 2013.

This joint assessment scheme will now continue on an ongoing mandatory basis in accordance with a new Regulation on notified bodies which was published and came into effect in the last quarter of 2013.

There has been extensive consultation with NSAI and with both the Department of Health and the Department of Enterprise, Jobs and Innovation, to discuss the implications for notified bodies of the near future and medium term legislative changes.

Market Surveillance

At EU level, the joint plan has also resulted in a review of activities conducted by Member States in the area of market surveillance. This has provided a platform from which a coordinated approach to surveillance can be developed and allows for enhanced co-operation and targeted proactive market surveillance, including joint activities. To ensure we fully contribute to these developments, the IMB has set out a re-development proposal for its market surveillance activities to include greater emphasis on proactive and reactive surveillance across the product life-cycle. This revised approach will be implemented in 2014.

Another area of focus for the IMB includes building capability to meet future requirements of the joint plan and Implementing Regulation 920/2013 in the medium term and the new legislative requirements in the longer term.

CONTRIBUTING TO THE EUROPEAN AND GLOBAL REGULATORY NETWORK

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

The IMB continued to promote discussions during 2013 on developing co-operation and partnership between the HMA and Competent Authorities for Medical Devices (CAMD) which are the inter-authority networks for medicines and medical device competent authorities respectively. 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.

Enhancing and Resourcing the European Medical Devices Regulatory Network

The IMB is participating in the inter-authority taskforce which was established under the Irish presidency and has been mandated to review the structures and functioning of the existing European devices regulatory system with a view to bringing further enhancements.

The IMB also continued to engage actively during 2013 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 included significant dialogue with the medical device industry associations and involved examination of methods to change current funding models for medical device regulatory authorities to fee-based models.

Enhancing the International Medical Device Regulatory Network

During 2013, the IMB was invited to join the management committee of the International Medical Device Regulators Forum (IMDRF). This forum includes regulators from Australia, Brazil, Canada, China, the EU, Japan, the Russian Federation and the US. It seeks to promote the harmonisation of medical device regulation across the globe. This is an important development in terms of the IMB's contribution to the international network.

The IMB also continued to actively participate in IMDRF and associated working groups during the past year. These working groups are focussed on progressing specific initiatives which are aimed at harmonising the global regulation of areas such as product submission and UDI requirements.

ADVISORY COMMITTEE FOR MEDICAL DEVICES

The Advisory Committee for Medical Devices met three times in 2013. 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 2013, the IMB continued to actively participate in the EMA'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 topics relevant to the regulation of ATMPs, blood, tissue and biological products. The IMB's guide to hospital based manufacturers of ATMPs was published in February 2013.

PRECURSOR CHEMICALS

During 2013, amendments were made to the two main European Regulations on precursor chemicals (Regulations (EC) No. 273/2004 and No. 111/2005). The amending regulations are Regulation (EU) No. 1258/2013 and Regulation (EU) No. 1259/2013 respectively. The main objective of these amendments is to strengthen the rules for registration and licensing of operators and users, in order to prevent diversion of scheduled substances towards the production of illicit drugs.

These amendments had an effective date of 30 December 2013 with the exception of one of the requirements relating to category 2A scheduled substances which will only become obligatory as of 30 June 2015.

COSMETICS

In November, the European Union (Cosmetic Products) Regulations 2013 (S.I. No. 440 of 2013) came into force. These gave full effect to Regulation (EC) No 1223/2009 on cosmetic products, which came into force in July 2013. These national regulations designated the IMB as competent authority for cosmetics, allocated powers to the IMB and the HSE and set out offences and penalties.

SCIENTIFIC ANIMAL PROTECTION

The IMB became the competent authority responsible for the implementation of Directive 2010/63/EU on the protection of animals used for scientific purposes on 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.

During 2013, the IMB further developed the operational processes, authorisation procedures, policies, application forms and accompanying guidelines necessary to implement the requirements of the legislation. There was a specific focus on the implementation of the 3R principles (reduction, refinement and replacement of animal testing). The IMB also completed the recruitment of the necessary expertise required to fulfil our role as national competent authority.

The IMB continued to interact with the Department of Health in relation to the overall implementation of the legislation and its potential impact on animal research in this country. There was also significant engagement with stakeholders within the research sector in order to highlight and explain what is required of them under the legislation. Engagement also commenced in respect of the development of an associated fee model for the future.

STAKEHOLDER ENGAGEMENT AND COMMUNICATIONS

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

A number of significant communications programmes and initiatives took place during 2013.

STAKEHOLDER ENGAGEMENT

Consultative Panel on the Legal Classification of Medicines

The Consultative Panel on the Legal Classification of Medicines was established in 2011 to consider policies relating to the legal classification of human medicines and to encourage consultation and debate in this area. The Panel was independently chaired and consisted 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 concluded its work in 2013 and made recommendations to address current unmet needs in the availability of non-prescription medicines. The IMB is currently working to implement processes to address these issues and this is an area of priority focus for 2014.

Meetings with Stakeholders – Human Medicines

During 2013, there were a number of meetings held with industry representative groups including the Association of Pharmaceutical Manufacturers in Ireland (APMI), the Irish Pharmaceutical Healthcare Association (IPHA), the Irish Health Trade Association (IHTA) and Pharmachemical Ireland. These provide a forum for discussion of items of mutual interest. Among the main topics of discussion were timelines and deliverables, interchangeable medicines, increasing the submission of THMP applications, improving the quality of submissions, GMP and market compliance.

There was also one meeting of the Advertising Compliance Technical Group which includes representatives from the IMB and industry. Issues of mutual interest were discussed including clarification of the IMB's interpretation of a number of aspects of the Medicinal Products (Control of Advertising) Regulations 2007 and anonymised feedback on findings from our advertising compliance programme.

Meetings with Stakeholders – Veterinary Medicines

The IMB held several meetings with applicants in relation to ongoing or proposed applications where IMB is to be the reference member state in future European application procedures. We also held a number of meetings with the Department of Agriculture, Food and the Marine in relation to matters of mutual interest and met with a number stakeholders from the agricultural sector throughout the year.

Meetings with Stakeholders – Medical Devices

Regular meetings with key industry stakeholder groups continued during 2013. These included meetings with the Irish Medical Devices Association (IMDA) and the Irish Medical and Surgical Trade Association (IMSTA). These meetings provide the IMB with an opportunity to update stakeholders on regulatory developments at national and European level. They also allow the IMB to be kept up-to-date on issues affecting the medical devices industry.
A key topic for discussion during 2013 was the European Commission's joint plan for immediate actions and the ongoing revision of the medical devices legislation.

Presentations to Stakeholders

As in recent 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.

Such presentations contribute to the IMB goal of providing stakeholders such as healthcare professionals and regulatory professionals with access to relevant, up-to-date information. The presentations are delivered by IMB staff from across the organisation and cover all products and functions

under our remit. While some are general in nature and primarily focused on explaining the role of the IMB, others were more specific and dealt with specialist areas and/or new regulatory developments.

A full list of all presentations delivered during 2013 is provided in Appendix 2.

EVENTS

Irish Presidency of the Council of the European Union

As outlined earlier in this report, the Irish Presidency was a considerable area of focus for the IMB in the first half of 2013. We hosted a total of 22 meetings during this period with approximately 1000 delegates visiting Ireland for IMB organised events. Important progress was made across a range of key regulatory issues during the Irish Presidency which also included a number of joint meetings bringing together key European committees and organisations.

European Risk Summit

The IMB, in association with the Irish Presidency of the Council of the European Union and with the support of the King's Centre for Risk Management and the Nickel Institute, hosted the European Risk Summit in Trinity College Dublin on 11 and 12 June 2013.

This significant event was attended by approximately 100 Irish and international experts comprising policy-makers, regulators, governing bodies, industry and academia from the chemicals, food, environmental, healthcare and pharmaceuticals sectors.

The purpose of the Risk Summit was to discuss the advantages of evidence and risk-based rulemaking as well as the challenges of formulating European directives / regulations and, by extension, national legislation on hazard classifications.

The programme included a series of panel discussions that highlighted the challenges for risk-based policy making in a number of distinct regulatory areas/ issues including:

- Promoting science based regulation in Europe – challenges & opportunities;
- The role of smart and better regulation: Lessons from the Member States;
- Hazard classifications and risk assessments – implications for regulation;
- Applying the substitution principle – a scientific analysis with regard to its use in European directives and regulations;
- Institutional oversight for risk-based policy making – The establishment of the European Parliamentary working group on risk.

The meeting also encouraged a fostering of dialogue and collaboration among the relevant stakeholder community to address the challenges in this area.

Information Days and Seminars

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 events were held during 2013:

- A webinar event outlining the IMB's approach to the development of the interchangeable list of medicinal products was held in February. The topics covered included an overview of the approach to stakeholder consultation and publication of the lists. The event attracted a wide range of industry stakeholders with an interest in this area.
- The IMB hosted a Topra networking event in October 2013. This was an evening seminar focussed on a number of topics of regulatory interest including DCP submissions, the new clinical trial regulation and the IMB's role in the development of a list of interchangeable medicines.
- A veterinary information day was held on 24 October 2013. The programme was focused on updating stakeholders on recent changes in the regulatory framework for veterinary medicines in advance of publication of the EU Commission's proposed new legislation in this area. Attendees were encouraged to actively contribute to discussions and the event also provided an opportunity for networking.
- DIA Europe held an information day on the new Common European Submission Platform (CESP) on 20 November 2013 in co-operation with the IMB. CESP provides a simple and secure mechanism for the exchange of information between applicants (companies) and regulatory agencies. This joint DIA/IMB event provided the latest information on the CESP system. It focused specifically on the practical use of this newly implemented solution designed to enable the simultaneous delivery of applications to the various EU regulatory agencies.
- A PDA Conference, in co-operation with the IMB, was held in Dublin on 9 and 10 July. The Conference was entitled 'Current and Emerging EU Regulations and Inspection Trends' and included a number of IMB presentations.

BT Young Scientist and Technology Exhibition 2013

For the fourth 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 and Technology Exhibition. The exhibition took place in mid-January in the RDS.

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

PUBLICATIONS

Guidance Documents

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

During 2013, ten new guidance documents were published while a large number of existing documents were updated. A full list of these documents 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.

Four Medicinal Product Newsletters were published during 2013. Topics covered included:

- List of Interchangeable Medicinal Products (Generic Substitution);
- Clinical Trials – Reference Safety Information (RSI);
- Revisions to EU GMP Guidance;
- New laws regulating the retail of cosmetic products;
- Clarification of the requirements for marketing authorisation holders regarding communications to healthcare professionals;
- Implementation of text highlighting additional monitoring requirements;
- Report on veterinary antimicrobial consumption in 2012;
- General sale wholesale distributors - update to the annual compliance assessment report and changes to the inspection process and its frequency;
- Update on the Variations Regulation;
- Controlled drugs – Licence endorsement requirements;
- New EU Regulation for cosmetic products.

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

Seven issues of the IMB's Drug Safety Newsletter were distributed to doctors, dentists and pharmacists during 2013. The publication was disseminated via both post and electronically until the end of 2013, with arrangements made to facilitate electronic only distribution from the start of 2014. All issues of the Drug Safety Newsletter are also published on the IMB website. Topics covered in the past year included a wide range of safety issues a full list of which is provided in Appendix 3.

Medical Devices Newsletter

This newsletter provides regulatory and safety updates for those working in the medical devices sector and professionals working in the health area who regularly use or purchase medical devices. It provides updates on Irish and European legislation, on safety issues as well as details of IMB medical devices publications and stakeholder events. A list of the main topics covered during 2013 is included in Appendix 3.

External Articles

Human Medicines

There were 17 articles published in MIMS Ireland by the IMB during 2013. One article was published each month with the remainder included in special supplements. A further two articles were published in the Irish Medicines Formulary. In addition, two articles on the topic of medicines under additional monitoring were published in the IPU Review and the Irish Medical Times respectively.

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 - It's Your Field.

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

Safety Warning and Notices

Throughout 2013, the IMB published various warning statements and notices on safety issues or benefit/risk evaluations of human medicines. There were 53 Direct Healthcare Professional Communications concerning human medicines published on the IMB website and issued to subscribers. Separately, 16 medical devices safety notices were sent to the relevant stakeholder groups and published online.

In excess of 500 manufacturers field safety notices concerning medical devices on the Irish market were also published on the IMB website.

The PRAC published agendas, minutes, meeting highlights, notifications of safety reviews and signals throughout 2013 and these were all made available via the IMB website. Such transparency in medicines regulation is essential in building trust among stakeholders, promoting engagement in the processes, and aiding understanding of the rationale and evidence supporting recommendations and actions impacting drugs and care.

Selling Cosmetic Products in Ireland: A Guide for Retailers

In October, the IMB published a guide for retailers informing them of their responsibilities under recently introduced European legislation governing the sale of cosmetics. The leaflet includes guidance on understanding label information, the storage and transportation of cosmetics, and the checks to perform when buying from suppliers. Advice on product recalls and actions to take if a consumer experiences a side effect after using a cosmetic product is also included.

All retailers who sell cosmetic products should be aware of these new laws. The purpose of the leaflet is to bring the changes to their attention and, in doing so, assist retailers to meet their legal obligations.

Retailers can download copies of the leaflet from www.imb.ie while printed versions can be ordered from brochures@imb.ie

MEDIA COMMUNICATIONS

Throughout 2013, we continued our media communications programme to proactively communicate important safety messages and to build awareness of the role of the IMB. We prepared 32 press releases and statements concerning safety and regulatory issues to ensure consumers, healthcare professionals and other stakeholders received timely and accurate information and advice. In a number of instances, these communications resulted in national and regional media interviews with an IMB spokesperson.

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

- Irish consumers have increased awareness of generic medicines
- 3 out of 5 people read product information for prescription medicines
- Publication of initial list of interchangeable medicines containing groups of atorvastatin products
- Operation Pangea VI targeting the online sale of falsified and illegal medicines
- Advice on seasonal maintenance of automated external defibrillators (AED)

The IMB also published a number of press releases to highlight successful prosecutions related to the illegal supply of unauthorised medicines.

In addition, we responded to a total of 449 queries from national, local and specialist media during the year. Drafting responses to such queries involves subject matter experts from across the organisation.

BRAND IDENTITY

The role and functions of the IMB have increased significantly over the 17 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 products and processes we now regulate. The new name to the replace the Irish Medicines Board is the Healthcare Products Regulatory Authority (HPRA). The introduction of the new name is provided for in the Health (Pricing and Supply of Medical Goods) Act 2013 and it is anticipated it will become operational in mid 2014. We will also be launching a new corporate website at that time.

In preparation for the adoption of the new name, the IMB initiated a project to develop a new brand identity incorporating a logo and a style guide. The latter document provides clear direction on the application of the new brand across all platforms and publications. This project was completed during 2013.

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 2013, the IMB completed public consultations on:

- Fees proposed for 2014
- Draft Guide to Cosmetics for Responsible Persons
- Draft Guide to Distribution of Cosmetic 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 2013, we provided comments in respect of 8 public consultations from the Department of Health, HIQA, the Pharmaceutical Society of Ireland, and other bodies.

WEBSITE

The website www.imb.ie is a key component of our communications programme. The site includes information about the primary functions and activities of the IMB while it also facilitates the dissemination of information to a wide variety of audiences including patients and consumers, healthcare professionals and industry personnel.

We are committed to the continued development and enhancement of the website to ensure it is easy to navigate and allows users to quickly find the content they require. For the second successive year, we completed a user feedback survey to identify areas for improvement. The results of this research are also being utilised in the development of our new website – www.hpra.ie – which will be a key element of the project to change the name of the Irish Medicines Board to the Health Products Regulatory Authority. Development of the new site began in 2013 with the appointment of a project team involving representatives from across the organisation. This project will be completed during the first six months of 2014.

2013 Statistics

- Almost 225,000 unique visitors accessed the website during the past twelve months representing an annual increase of 32%. There was in excess of half a million visits in total.
- Of those who accessed the site, 39% were new or first time users of the site.
- Among the most popular sections of the website were the human and veterinary medicines listings, and the new interchangeable medicines listing.

Interchangeable and Generic Medicines

The Health (Pricing and Supply of Medical Goods) Act 2013 provides for the introduction of a system of generic substitution and reference pricing for authorised medicines. This legislation was commenced on 24 June 2013.

The role of the IMB under this legislation is to establish, publish and maintain a 'List of Interchangeable Medicines' on our website. Following completion of a consultation process, the initial list including interchangeable atorvastatin medicines was published on www.imb.ie on 7 August 2013. For the remainder of the year, the IMB added a number of other active substances to the list and this will continue during 2014. Active substances are being added incrementally following the appropriate consultation process.

Products are grouped together according to their active substance, strength, pharmaceutical form and the route of administration. Users of the list can also download pdf documents listing the interchangeable products for each active substance. The publication of this list on our website coincided with the development of an easier to use search function.

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 2013, the IMB received 12 Freedom of Information requests all of which were non personal.

PARLIAMENTARY AFFAIRS

Oireachtas Joint Committee on Health and Children

During 2013, the IMB was invited to attend the Oireachtas Joint Committee on Health and Children on three occasions. Discussion areas included medical devices and the IMB's role in respect of interchangeable medicines.

Parliamentary Questions

In 2013, the IMB received and responded to 46 parliamentary questions, half the number received in 2012. There were also 76 other requests from the Department of Health, other government departments or members of the Oireachtas during the year. Of the total number of queries (122), the three largest categories related to human medicines (52), staff and payroll (26) and cosmetics (10). Many of the queries relating to human medicines concerned the availability or supply of product, market shortages, or personal importation.

CUSTOMER SERVICES

Approximately 3,000 queries were received and dealt with by the customer services team during 2013. These included 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. A large number of pre-market queries relating to medical devices are also received each year. In total, 355 queries were received that related specifically to medical devices during 2013.

RESEARCH

How Consumers Source Medicines Information and Related Use of the Internet

This Behaviour & Attitudes commissioned research involved face to face interviews with 1,000 adults and focused primarily on consumers' views and behaviour in respect of:

- Sources of information and advice on medicines.
- The use of the internet as a source of medicines information and possibly supply.

Among the key findings were:

- Two thirds of people (63%) state that they always read the product information when taking a prescription medicine.
- One in two people always seek advice from a healthcare professional before taking a new over the counter medicine.
- GPs and consultants are the most trusted sources of information on medicines for some six out of 10 people (64%) with three out of 10 people (31%) citing pharmacists.
- Nine out of 10 people (87%) confirm they understand the product information (leaflets and packs) accompanying their medicines.

In relation to the internet, the results showed that:

- One in three adults (36%) with internet access uses the internet as an information source on medicines.
- Over half (59%) use it to research a particular health problem.
- Almost 4 out of 10 people (37%) using online channels for information are attempting to diagnose health symptoms (self-diagnosis).
- Actual purchase of medicines online is low with 2% of all adults claiming to have done so which equates to approximately 60,000 people.

Consumer Awareness of and Attitudes Towards Generic Medicines

Also part of the Behaviour & Attitudes commissioned research, the results of this survey showed that there is a high level of consumer awareness and acceptance of generic medicines. Overall:

- Eight out of ten respondents (82%) would accept a generic medicine if offered it by their doctor or pharmacist.
- Nine out of ten consumers (92%) who had personally used generic medicines said that they had a positive experience overall.
- Three quarters (72%) of consumers said they were familiar with the term 'Generic Medicine'.

ORGANISATIONAL MANAGEMENT AND DEVELOPMENT

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

HUMAN RESOURCES

The IMB's people management practices and policies continue to be central to the achievement of our strategic goals and are designed to attract and retain the skills necessary to maintain organisation capability. The impact of the Haddington Road Agreement in 2013 required that we adapt our work practices to enable us to manage our human resources with the flexibility necessary to respond to changing national circumstances. Amongst the primary projects and statistics from 2013 were the following:

- A significant focus of human resources activity during 2013 was completion of a business requirements phase for the replacement of the human resources IT system. Following selection of a suitable vendor via a public procurement process, dedicated resources were assigned to undertake preparatory work on data extraction and cleansing in Q3 2013 in advance of the data migration deadline of January 2014. Training on the replacement system was scheduled to commence in January 2014 with the expectation that the system replacement would 'go live' by June 2014.
- The organisation's first leadership development programme concluded in 2013. The objectives of the programme were:
  - To support the development of managers within IMB, to evaluate the skills they have and how they are applying them in order to become more effective managers and leaders, currently and in the future to further IMB's mission;
  - To develop skills and behaviours in line with the IMB's Leadership Capability Framework;
  - To foster collaboration across different functions and promote an understanding of cross functional roles and projects.

  As this first programme was conducted on a pilot basis, a full review was completed following its conclusion. This review recommended the commencement of a second programme. The subsequent application and selection process was concluded in November 2013 and the second programme is to commence in January 2014 with 10 participants.
- The Human Resources department undertook a review of the operation of the performance management programme (PDP) process in the second half of 2013 which included feedback via an all staff survey. An action plan was prepared to progress the implementation of outcomes and recommendations and this will commence in January 2014.
- Recruitment of staff in specialist areas related to new competencies undertaken in 2012 was completed in 2013 in line with Department of Health approvals.
- Members of the Human Resources team were heavily engaged in the management of the impact on staff of the introduction of changed working hours mandated by the terms of the Haddington Road agreement which applied to public sector bodies. These changes also included the reduction of salaries for staff with effect from July 2013 as well as ongoing deferral of incremental payments during the course of the agreement. Explanatory workshops and individual face-to-face meetings gave rise to increased workload between June and September 2013. In addition, preparatory work was completed in advance of the introduction of the Public Service Sick Leave Scheme which introduced changes to sick leave arrangements for public sector employees scheduled to apply with effect from 2014.

- The IMB for the first time introduced an employee assistance programme in September 2013 to provide confidential employee support through telephone support, face to face counselling and the provision of specialist information across a broad range of issues.
- 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 monitored routinely and recorded in both management and Board reports. The overall absence rate for 2013 was 2.07%.

INFORMATION TECHNOLOGY AND CHANGE MANAGEMENT

The Information Technology and Change Management department is responsible for all aspects of organisational technology, data and telecommunications. The department also manages the IMB Project Management Office and delivers specialist business services, including business analysis and project management support, both within, and external to the organisation.

The organisational Project Management Office (PMO) came into full operation in 2013. The PMO formally manages projects and provides IMB management with the necessary information to support the planning process while ensuring that organisational initiatives are fully aligned with corporate strategy.

Technology is recognised as a key component in supporting regulatory activities at both national and international levels. Over recent years, the IMB has played a leading role in developing standards and technologies through its engagement with programmes at the EMA, the European Commission and the HMA forum. The IMB is represented on the EU Telematics Management Board and also leads a number of key initiatives relating to electronic submissions and data standards. The IMB is also actively engaged at national level through its involvement with the National Health Data Standards Committee and in liaison with other relevant agencies, such as the HSE, NSAI and HIQA. During 2013, the IMB also contributed to the development of the eHealth Strategy for Ireland and was recognised for its role in developing the national medicines catalogue. The IMB also committed to engagement with the European Commission's Horizon 2020 research programme and will actively seek opportunities to contribute over the lifetime of the programme.

IMB technologies are strategically positioned to support the effective and efficient operation of the organisation. Many of the key systems are designed to interface with both national and EU systems. An example of this is the European EudraVigilance system designed to collate adverse reactions to medicinal products. In addition, the IMB provides data to the HSE to support its pricing and medicines substitution processes. In keeping with the

government strategy for shared service provision, the IMB also provides hosting services to a number of organisations, and works closely with organisations such as the Office of the Revenue Commissioners.

European legislation is increasingly focussed on the technology elements required to satisfy legal requirements. In this context, the IMB must continuously review its capability to develop appropriate solutions.

During 2013, there was a strong focus on developing the key requirements for the IMB's new workflow technology solutions. This work was completed by the end of 2013, with a tender process for the new technology due for publication in early 2014. This technology is designed to consolidate and replace a number of legacy solutions. Work also commenced on the selection and implementation of a new HR solution and the development of a new website which is due for launch in mid-2014. The IT and change management team was also very active in the development of processes and technology interfaces to support the introduction of the interchangeable medicines and generic substitution programme by Government.

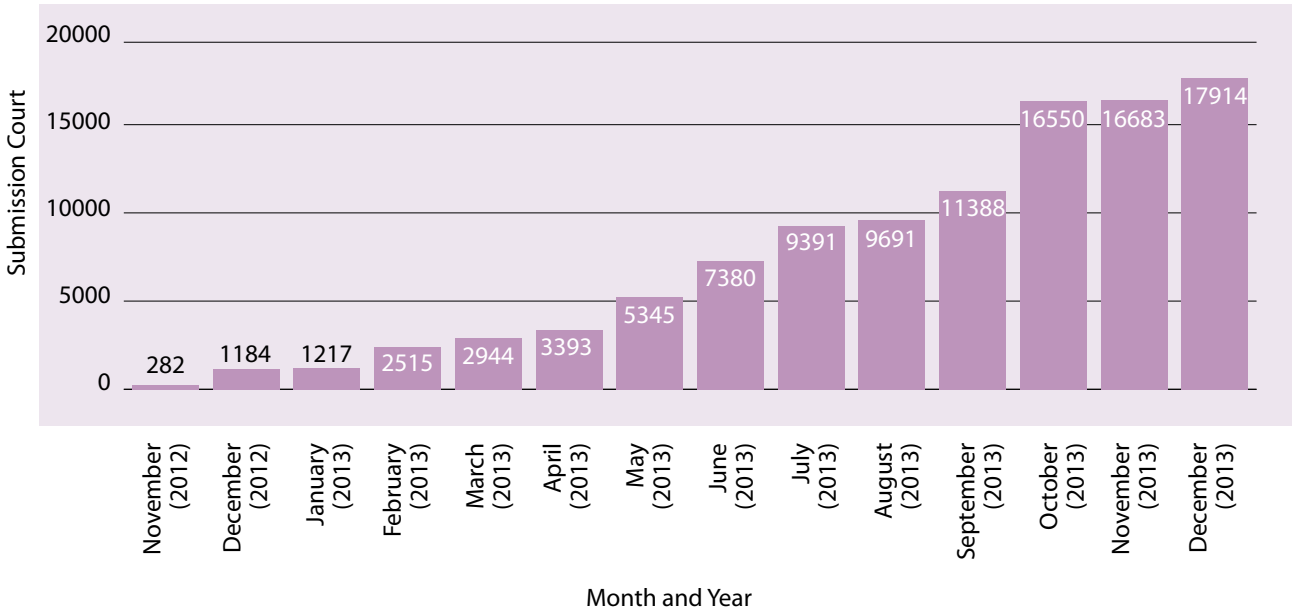
In 2013, work was undertaken on developing IMBs stakeholder engagement mechanisms together with potential process improvement initiatives relating to medical devices, veterinary science and compliance areas.

Common Electronic Submission Portal

A key activity for the IMB is the development and management of the Common Electronic Submission Portal (CESP) on behalf of the wider EU regulatory community. We provide technical support through the operation of a helpdesk facility and we work with all relevant stakeholders throughout the year to deliver an optimum solution.

In 2013, the CESP portal activity levels grew substantially, handling over 100,000 submissions on behalf of 20 European regulatory organisations and many hundreds of pharmaceutical companies.

CESP Submissions by Month



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 for regulating medicines 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 2013, we continued to lead the steering group as assessment visits were undertaken in this benchmarking cycle.

The IMB's own benchmarking assessment visit took place in October 2013. It was preceded by a self-assessment using the BEMA questionnaire, the results of which were sent to the assessors in August. The completed self-assessment report formed the basis for the assessor's focus during the visit, during which the three assessors from Austrian, Greek and UK agencies interviewed senior staff, reviewed evidence and rated the 'maturity' of the IMB's management and scientific quality systems according to a predefined capability maturity model. Several proposed 'best practices' for our project management office, leadership development programme, and contribution to the European network were accepted by the assessors, who also nominated a further best practice in the close link between our strategic and business planning objectives and the objectives in staff's individual performance development plan. Some 'opportunities for improvement' were highlighted as actions to enhance the quality of our services.

The IMB is pleased with the outcome of the visit which reflected well on the achievements of recent years, and with the assessors' overall compliment to the IMB's strong dedication to quality in general and to the BEMA programme in particular.

Quality Management

During 2013, the IMB's quality management system continued to be extended with respect to a number of new functions and legislative requirements. These included new and amended processes under the falsified medicines Directive, 2011/62/EU, our functions for scientific animal protection according to the European Union (Protection of Animals Used for Scientific Purposes) Regulations 2012, and the new competence given to the IMB during 2013 for the establishment and maintenance of lists of interchangeable medicines under the Health (Pricing and Supply of Medical Goods) Act 2013.

CORPORATE AFFAIRS

2013 was another busy and productive year for Corporate Affairs which is responsible for the delivery of a number of key service areas to the organisation. These include building and accommodation management as well as the provision of reception, canteen, travel, library and event management services. The department also manages legal matters, international co-operation 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.

Extension to the IMB Offices

The IMB building, Kevin O'Malley House, was extended upward by two floors during the course of 2012 and 2013 with the certificate of practical completion being granted on 12 July 2013. The extension of two new floors has ensured that all IMB staff can be housed in one building. The project was completed to satisfaction on time and under budget with four of the existing floors remaining fully in use throughout the duration of the build.

Event Management

As outlined earlier in this report, the IMB hosted 22 meetings involving approximately 1000 delegates during the Irish Presidency of the Council of the European Union. The number of delegates attending each meeting varied with the largest events taking place in Dublin Castle and the Convention Centre Dublin. The logistics for all these meetings were organised and managed in-house by an IMB team. This included online registrations, venue management, onsite support and social events. This approach ensured cost effective delivery of all these meetings while also allowing IMB staff to deal directly with delegates which resulted in very positive feedback from attendees.

In addition, the IMB held three events in 2013 which were not related to the European Presidency. These were also organised and managed in-house.

Freedom of Information

During 2013, the IMB received 12 Freedom of Information requests (as outlined on page 70).

Board and Committees

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

- The Board of the IMB met seven times in 2013 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 2012. The Board also reviewed update reports from the Statutory Advisory Committees and the Audit Committee. In addition, it noted the licences for all medicinal products as approved by the Management Committee.

  The number of meetings attended by each Board member during 2013 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 D. Hayes (Chair)	7	7
Mr. Pat Brangan	7	7
Mr. Wilfred J. Higgins	7	6
Ms. Ann Horan	7	6
Prof. Mary Horgan	7	4
Dr. Elizabeth Keane	7	5
Mr. Brendan McLaughlin	7	7
Mr. Noel O'Donoghue	7	3
Prof. Caitriona O'Driscoll	7	4

- The Audit Committee, a subcommittee to the Board, met four times in 2013. Further details are provided in the IMB's Financial Statements for 2013.
- Also during the year in review, the Advisory Committee for Human Medicines met three times, the Advisory Committee for Veterinary Medicines met three times and the Advisory Committee for Medical Devices met three times.

- The Herbal Medicines Sub-Committee, a sub-committee to the Advisory Committee for Human Medicines, met once in 2013. The Clinical Trials Sub-Committee is also a sub-committee to the Advisory Committee for Human Medicines and it met twelve times in the past year.
- The Legal Supply Classification Committee, which is a specially constituted temporary subcommittee to the Board, met twice in 2013.

FINANCE

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

The 2013 financial statements presented in conjunction with 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 2013

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 2013, the IMB consumed 887 MWh of energy, consisting of:

- 605 MWh of electricity;
- 0 MWh of fossil fuels;
- 282 MWh of renewable fuels.

Actions Undertaken in 2013

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 Office of Government Procurement (formerly 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 5.3% for electricity and 5% for gas (compared to the cost of going directly to the market). The organisation consumed 27% more energy in 2013 than 2012 as a result of extending a live building upwards by two floors, populating the floors and some IMB electricity being consumed in the building process.

In 2013, the IMB replaced its single glazed windows on the upper floors to more energy efficient double glazed windows. On the two new floors, PIR lighting and photo sensitive lighting have been installed in all areas. In addition, the ventilation system is a heat recovery system and the air conditioning is an energy efficient three pipe simultaneous heating and cooling system incorporating inverter motor control. Dyson hand dryers have been installed in seven bathroom areas. All of the above will result in greater energy savings.

Total Energy Savings

In total, initiatives undertaken prior to 2010 and the measures outlined above have saved the IMB 117 MWh on average annually up to and including 2012.

2013 was an unusual year for the organisation with regard to expansion of the building and the energy used in the construction phase. It is anticipated that the energy savings from the building work undertaken will become visible in 2014.

Actions Planned for 2014

In 2014, 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 Office of Government Procurement, will deliver savings when compared to the costs of going directly to the market. It is important to note that the Office of Government Procurement contract rates are fixed until the end of 2014 for electricity and January 31 2015 for gas.

FINANCIAL STATEMENTS

BOARD MEMBERS AND OTHER INFORMATION

Board Members:	Mr. Michael Hayes (Chairman) Mr. Pat Brangan *term expired 31/12/2013; re-appointed 22/05/2014* Mr. Wilfrid Higgins *term expired 31/12/2013; re-appointed 22/05/2014* Ms. Ann Horan Prof. Mary Horgan * Dr. Elizabeth Keane ** *term expired 31/12/2013; re-appointed 22/05/2014* Mr. Brendan McLaughlin *term expired 31/12/2013* Mr. Noel O'Donoghue Prof. Caitriona O'Driscoll Dr. Diarmuid Quinlan ***
	The Board was appointed by the Minister for Health on 18/01/2011. * Prof. Mary Horgan was appointed on 08/11/2011. ** Dr. Elizabeth Keane was appointed on 24/10/2012. *** Dr. Diarmuid Quinlan was appointed on 22/05/2014.
Bankers:	Allied Irish Bank 1-3 Lower Baggot Street Dublin 2 Bank of Ireland Corporate 2 Burlington Plaza Burlington Road 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 2013. 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 2013 the internal auditor reported to the audit committee on the areas of procurement and payments, banking and finance, and financial and asset management.

In 2010 the IMB re-appointed Crowleys DFK as internal auditor to the Board under a three-year contract. This contract expired during 2013 and following a competitive tendering process, BDO were appointed as internal auditor in January 2014 under a three year contract. The audit committee has also been involved with the review of the quality systems as described below.

QUALITY SYSTEMS

During 2013, 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 4.

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.

   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 5 June 2014.

Mr. Michael Hayes
Chairman to the Board
Date: 30 June 2014

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.

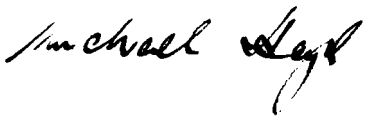
In preparing those statements the Board is required to:

- 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
Date: 30 June 2014

Board Member

Mr. Wilf Higgins

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 2013 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 accounts for 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.

In my opinion, except for the accounting treatment of the Board's superannuation costs and liabilities, the financial statements have been properly prepared in accordance with generally accepted accounting practice in Ireland and give a true and fair view of the state of the Board's affairs at 31 December 2013 and of its income and expenditure for 2013.

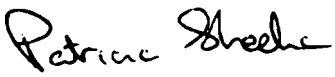
In my opinion, proper books of account have been kept by the Board. The financial statements are in agreement with the books of account.

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

10 July 2014

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 € 749,418 (2012 - € 687,798). 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. The balance on the superannuation reserve represents the cumulative superannuation deductions made since 1996.

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

for the year ended 31 December 2013

	Notes	2013 €	2012 €
Fee Income	2	**20,225,400**	20,065,633
Other Income	3	**4,430,585**	3,927,031
		24,655,985	23,992,664
Salaries and Wages	4	**17,765,250**	17,215,472
Other Operating Costs	5	**4,823,934**	5,190,035
Depreciation	1	**1,150,820**	1,027,957
		23,740,004	23,433,464
Surplus for the year before write back of Superannuation contributions		**915,981**	559,200
Staff Superannuation Contributions		**749,418**	687,798
Surplus for the year		**1,665,399**	1,246,998
Balance brought forward		**22,873,899**	21,626,901
Balance carried forward		**24,539,298**	22,873,899

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

Chairman

Mr. Michael Hayes
30 June 2014

Board Member

Mr. Wilf Higgins

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 2013

	Notes	2013 €	2012 €
Tangible Assets	1	**25,890,663**	23,162,452
Current Assets			
Debtors and Prepayments	6	**644,387**	948,557
Stock of Stationery		**2,407**	2,703
Cash at Bank and in Hand	12	**160,832**	187,175
Short Term Deposits		**12,940,623**	15,500,825
		13,748,249	16,639,260
Creditors - Amounts falling due within one year			
Creditors and Accruals	7	**6,372,942**	7,407,809
Mortgage	13	**793,332**	793,332
		7,166,274	8,201,141
Net Current Assets		**6,581,975**	8,438,119
Long Term Liabilities			
Mortgage	13	**7,933,340**	8,726,672
TOTAL NET ASSETS		**24,539,298**	22,873,899
Financed by			
Income and Expenditure Reserve	11	**24,539,298**	22,873,899
		24,539,298	22,873,899

Chairman

Mr. Michael Hayes
30 June 2014

Board Member

Mr. Wilf Higgins

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 2013

	Notes	2013 €	2012 €
Reconciliation of surplus to net cash inflow from operating activities			
Surplus for Year		**1,665,399**	1,246,998
Depreciation Charge		**1,150,820**	1,027,957
(Increase)/Decrease in Debtors		**228,197**	487,014
(Increase)/Decrease in Stocks		**296**	(234)
Increase/(Decrease) in Creditors - amounts falling due within one year		**(1,035,225)**	203,671
Deposit Interest		**(183,195)**	(272,921)
Bank Interest and Charges		**393,502**	422,839
Loss/(Gain) on Disposal of Fixed Assets		**(1,290)**	(460)
Net Cash Inflow from Operating Activities		**2,218,504**	3,114,864
Cash Flow Statement			
Net Cash Inflow from Operating Activities		**2,218,504**	3,114,864
Return on Investments and Servicing of Finance	8	**(133,976)**	(169,293)
Capital Expenditure	8	**(3,877,741)**	(1,170,446)
Management of Liquid Resources	8	**2,560,202**	(831,508)
Financing	8	**(793,332)**	(793,332)
Increase/(Decrease) in Cash		**(26,343)**	150,285
Reconciliation of net cash flow to movement in net debt			
Increase/(Decrease) In Cash		**(26,343)**	150,285
Increase/(Decrease) In Short Term Deposits		**(2,560,202)**	831,508
(Increase)/Decrease In Long Term Finance		**793,332**	793,332
Change In Net Funds/(Debt)		**(1,793,213)**	1,775,125
Net Debt at start of year		**6,167,996**	4,392,871
Net Funds/(Debt) at end of year	9	**4,374,783**	6,167,996

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 2013

1. Tangible Assets	Fixtures and Fittings €	Computer Equipment €	Leasehold Improvements €	Improvements Premises €	Premises €	Total €
Cost						
Balance as at 1 January 2013	988,481	9,004,202	502,445	3,574,558	21,097,235	35,166,921
Additions for the year	163,538	916,361	-	740,330	2,058,802	3,879,031
Disposals for the year	(17,136)	(71,487)	-	-	-	(88,623)
As at 31 December 2013	1,134,883	9,849,076	502,445	4,314,888	23,156,037	38,957,329
Depreciation						
Balance as at 1 January 2013	923,872	8,562,116	400,703	2,117,778	-	12,004,469
Charge for the year	62,277	606,809	50,245	431,489	-	1,150,820
Disposals for the year	(17,136)	(71,487)	-	-	-	(88,623)
As at 31 December 2013	969,013	9,097,438	450,948	2,549,267	-	13,066,666
Net Book value at 31 December 2013	165,870	751,638	51,497	1,765,621	23,156,037	25,890,663
Net Book value at 1 January 2013	64,609	442,086	101,742	1,456,780	21,097,235	23,162,452

2. Income

	2013 €	2012 €
Fee Income		
Clinical Trials	**152,714**	148,326
Human Medicine - National Fees	**6,597,201**	6,875,259
Human Medicine - European Fees	**5,809,092**	5,943,402
Veterinary Medicine - National Fees	**1,226,329**	1,163,520
Veterinary Medicine - European Fees	**1,682,126**	1,564,656
Compliance Department	**4,406,871**	4,123,445
Medical Devices	**351,067**	247,025
	20,225,400	20,065,633
Other Income (Note 3)	**4,430,585**	3,927,031
Total Income	**24,655,985**	23,992,664

Certain fees, totalling €16,623,534 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 2013

3. Other Income

	2013	2012
	€	€
Dept of Health Funding	**3,937,000**	3,545,000
Conference Fee Income	**6,100**	108,650
Deposit Interest	**183,195**	272,921
(Loss)/Gain on Disposal of Fixed Assets	**1,290**	460
IT Income	**303,000**	-
	4,430,585	3,927,031

4. Salaries and Wages

	2013	2012
	€	€
Salaries and Wages	**15,948,022**	15,448,788
Pensions	**359,984**	373,692
Social Welfare Costs	**1,457,244**	1,392,992
	17,765,250	17,215,472

The average number of staff employed during the year was 317 (2012 - 297).
Staff employed at 31 December 2013 can be analysed across the following departments : -

	2013	2012
Chief Executive	**10**	12
Compliance	**62**	60
Finance & Corporate Affairs	**19**	18
Human Products Authorisation & Registration	**103**	105
Human Products Monitoring	**46**	42
Human Resources	**9**	8
IT & Change Management	**14**	14
Scientific Affairs	**2**	2
Veterinary Sciences	**25**	23
Pensioners	**25**	24
	315	308

Pension related deductions for Public Servants of €1,011,911 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 2013

5. Operating Costs

	2013	2012
	€	€
Accommodation Costs	**1,281,687**	1,464,548
Travel, Representation and Training	**920,613**	734,240
Bank Charges and Interest	**398,152**	428,324
Legal & Professional Fees	**124,286**	151,892
Stationery, Publications and Postage	**409,221**	419,163
Other Operating Costs	**1,689,975**	1,991,868
	4,823,934	5,190,035

Operating costs of €4,823,934 includes an amount of €5,665 related to staff hospitality.

6. Debtors (all due within one year)

	2013	2012
	€	€
Trade Debtors	**336,335**	431,040
Prepayments	**186,716**	324,609
Other Debtors	**121,336**	192,908
	644,387	948,557

7. Creditors (amounts falling due within one year)

	2013	2012
	€	€
Trade Creditors	**268,817**	379,248
Accruals	**5,563,837**	6,519,183
Revenue Commissioners	**540,288**	509,378
	6,372,942	7,407,809

Notes to the Financial Statements

for the year ended 31 December 2013

8. Gross Cash Flows

	2013	2012
	€	€
Returns on Investment and Servicing of Finance:		
Deposit Interest	**259,169**	257,645
Bank Interest and Charges	**(393,145)**	(426,938)
	(133,976)	(169,293)
Capital Expenditure		
Payments to acquire Tangible Fixed Assets	**(3,879,031)**	(1,170,906)
Receipts from sales of Tangible Fixed Assets	**1,290**	460
	(3,877,741)	(1,170,446)
Management of Liquid Resources		
(Increase)/Decrease in Short Term Deposits	**2,560,202**	(831,508)
	2,560,202	(831,508)
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 01/01/2013	Cashflow	As At 31/12/2013
Cash at Bank and in Hand	187,175	(26,343)	**160,832**
Short Term Deposits	15,500,825	(2,560,202)	**12,940,623**
Debt Due Within One Year	(793,332)	0	**(793,332)**
Debt Due After One Year	(8,726,672)	793,332	**(7,933,340)**
	6,167,996	(1,793,213)	**4,374,783**

10. Administration Expenses

	2013	2012
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 2013

11. Movement on Income and Expenditure Reserves

	As At 01/01/2013	Movement	As At 31/12/2013
Retained Reserves	16,399,855	915,981	**17,315,836**
Staff Superannuation Contributions	6,474,044	749,418	**7,223,462**
	22,873,899	1,665,399	**24,539,298**

12. Cash and Bank Balances

	2013 €	2012 €
Current Account Balances	**160,302**	186,798
Cash on Hand	**530**	377
	160,832	187,175

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 :

	2013 €	2012 €
- within one year	**793,332**	793,332
- between one and five years	**3,173,328**	3,173,328
- after five years	**4,760,012**	5,553,344
	8,726,672	9,520,004

14. Interest Rate Exposure

The IMB have 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 2014 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 2013

15. Financial Commitments

	2013 €	2012 €
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
- after five years (in respect of Alexandra House)	**285,984**	285,984
	285,984	410,883

Included in Accommodation Costs (Note 5) is expenditure of €410,883 under operating leases.

On 28 January 2005 the IMB signed a leasehold interest in respect of the 5th floor, Alexandra House, Earlsfort Centre, Dublin 2. At 31 December 2013 this lease had 8 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. This lease terminated on 31 May 2013.
On 1 September 2012 the IMB signed a leasehold interest in respect of the ground floor, Ormonde House, Earlsfort Centre, Dublin 2. This lease terminated on 31 August 2013.

16. Capital Commitments

	2013 €	2012 €
Contracted For (Contract Signed)	**440,000**	2,657,000
Not Contracted For	**2,600,000**	890,000
	3,040,000	3,547,000

17. Board Remuneration

	2013 €	2012 €
Chairman's Salary	**20,520**	20,520
Board Members' Travel Expenses	**6,710**	8,554
	27,230	29,074

Notes to the Financial Statements

for the year ended 31 December 2013

18. Staff Remuneration

	2013 €	2012 €
Chief Executive's Total Remuneration		
Basic Salary	**151,186**	156,386
	151,186	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 :

2013 €1 = STG £0.8348

2012 €1 = STG £0.8174

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.

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 5 June 2014.

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

Dr. Lorraine Nolan
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*

Mr. Brendan McLaughlin*

Mr. Noel O'Donoghue

Prof. Caitriona O'Driscoll

* Term ended 31 December 2013

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. Tom Fahey

Prof. David Kerins

Ms. Marita Kinsella

Prof. Patrick Murray

Dr. Brian O'Connell

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

Dr. Jonathan Lyne

Prof. Fergal O'Brien

Prof. Richard Reilly

Ms. Mary Sharp

Ms. Maebh Smith

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

Dr. Thomas Peirce

Dr. John Taaffe

Dr. Bryan Whelan

Dr. Lee Helman (CT Expert)

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Dr. Jogin Thakore

APPENDIX 2
PRESENTATIONS 2013

THIRD LEVEL / EDUCATIONAL PRESENTATIONS

Institution	Course	Presentation Title
Athlone IT	Veterinary Nursing	Regulation of Veterinary Medicines
DIT	Biomedical Science	European Blood Directive – The IMB Perspective
HSE	Medicines Management Seminar for Nurse Educators	The role of the IMB / Quality and Safety Reporting
HSE	Medicines Management Seminar for Nurse Educators	IMB Role in Interchangeable / Generic Medicines
RCSI	Nurse Midwife Prescribing	Role of the IMB (2 presentations)
RCSI	Nurse Midwife Prescribing	Pharmacovigilance (2 presentations)
RCSI	Pharmacy	Regulation of New and Generic Medicines
RCSI	Pharmacy	Regulatory Affairs and Regulatory Authorities
RCSI	Pharmacy	The Regulation of Biotechnology
RCSI	Pharmacy	Advanced Therapy Medicinal Products
Sligo IT	Medical Biotechnology and Pharmaceutical Science	IMB Inspections / Pharmacovigilance
St. Johns, Cork	Veterinary Nursing	Regulation of Veterinary Medicines
TCD	Pharmacy	Authorisation of Medicines
TCD	Pharmacy	Reporting Quality Defects
TCD	Pharmaceutical Medicine	The Role of the Pharmacopoeia in the Regulation of Medicines
TCD	Pharmaceutical Medicine	Non Clinical Drug Development
TCD	Pharmaceutical Medicine	Quality Defects and Recalls
TCD	Pharmaceutical Medicine	Overview of Pharmacovigilance in the EU

THIRD LEVEL / EDUCATIONAL PRESENTATIONS (CONTINUED)

Institution	Course	Presentation Title
TCD	Pharmaceutical Medicine	New EU Pharmacovigilance Legislation
TCD	Pharmaceutical Medicine	Pharmacovigilance Communications
TCD	Pharmaceutical Medicine	Traditional Herbal Medicinal Products
TCD	Hospital Pharmacy	Pharmacovigilance and Risk Management
TCD	Biomedical Sciences	Biopharmaceuticals - Introduction to EU Regulation
TCD	Last-Ireland	Implementation of Directive 2010-63-EU (2 presentations)
UCC	Pharmacy and Medicine	Adverse Reactions
UCC	Pharmacy and Medicine	Notification of Adverse Events
UCD	Nursing - Prescription of Medications	Role of the IMB (2 presentations)
UCD	Nursing - Prescription of Medications	Pharmacovigilance (2 presentations)
UCD	Veterinary Medicine	Regulation of Veterinary Medicines
UCD	Veterinary Nursing	Regulation of Veterinary Medicines
UCD	Biotechnology	Biopharmaceuticals – Introduction to EU Regulation (2 presentations)
UCD	Biopharmaceutical Engineering	Biopharmaceuticals – Introduction to EU Regulation
UCD / SVUH	Nurse Education Centre	Medical Device Incident User Reporting

REGULATORY PRESENTATIONS

Event/Organiser	Presentation Title
British Herbal Medicine Association (BHMA)	The Borderline Interface – An Irish Perspective
Biomedical / Clinical Engineering Association of Ireland	Medical Devices Vigilance System and User Reporting
DIA	Impact of Revised Pharmacovigilance Legislation on Regulatory Communications
DIA	Quality Update – Current Developments – Process Validation
DIA	The Risk Management Plan as a Post-Authorisation Dossier
EPA / GMO Technology Conference	The Regulation of Clinical Trials
European Forum for Qualified Person for Pharmacovigilance	PRAC: The Experience to Date
HSE Vaccine Preventable Diseases Conference	Vaccine Licensing and Safety
IPHA	Communication with Stakeholders - The Regulators Perspective
International Pharmaceutical Federation (FIP)	Draft EMA Guideline on Process Validation

REGULATORY PRESENTATIONS (CONTINUED)

Event/Organiser	Presentation Title
International Society of Pharmacovigilance	The Pharmacovigilance Risk Assessment Committee
International Symposium on Medicinal Products and Medical Devices	Medical Devices Vigilance
Irish Clinical Research Infrastructure Network (ICRIN)	EU Regulation of Clinical Trials
Irish Clinical Research Infrastructure Network (ICRIN)	National Impact of Proposed Regulation and Experience to Date with VHP
Irish Fertility Society	Eurocet Coding / Regulatory Updates
National Haemovigilance Office Conference	Blood Legislation and Haemovigilance
National Haemovigilance Office Conference	Medical Devices Regulation, Vigilance and User Reporting
National Haemovigilance Office Conference	Blood Legislation and the Role of the IMB
NSAI	Medical Devices Vigilance
National Symposium on Biologic Medicines (NIBRT)	The Regulatory Process for Biosimilars
Parenteral Drug Association	Role of the IMB / Future Challenges
Parenteral Drug Association	EU Draft CHMP Guideline and Expected changes to GMP Annex 15 on Process Validation
Parenteral Drug Association	Presentations relating to 'Current and Emerging EU Regulations and Inspection Trends'
PharmaChemical Ireland	Innovation and Excellence – The Contribution of the Regulator
Royal Victoria Eye and Ear Hospital – Corneal Stem Cell and Tissue Engineering Symposium	Regulation of Advanced Therapies
SOHOV&S (Vigilance and Surveillance of Substances of Human Origin) Project	Communication Issues in Tissues and Cells
SOHOV&S (Vigilance and Surveillance of Substances of Human Origin) Project	European Training of Vigilance Officers
TOPRA	Module 3 – An Agency Perspective
Voluntary Hospitals Risk Management Forum	Medical Devices Legislation and the Role of the IMB

APPENDIX 3
PUBLICATIONS AND ARTICLES 2013

RETAILER INFORMATION LEAFLETS

Topic	Published
Selling Cosmetic Products in Ireland – A Guide for Retailers	October

DRUG SAFETY NEWSLETTERS

Edition	Articles
February 52nd Edition	- Tredaptive (Nicotinic Acid/Laropiprant) – Suspension of Marketing Authorisation - Restriction of indications for trimetazidine (Vastarel) - Use of the IMB online ADR report forms and Drug Safety Newsletter (DSN) for CPD purposes - INSERT: New guidance on treatment of paracetamol overdose with intravenous acetylcysteine
May 53rd Edition	- Changes to arrangements for Drug Safety Newsletter distribution - The Pharmacovigilance Risk Assessment Committee (PRAC) - Medicines Subject to Additional Monitoring Requirements: Update - Metoject solution for injection, pre-filled syringes: Caution in use
May 54th Edition	- Strontium ranelate (Protelos): Restricted indications, new contraindications, and warnings due to risk of serious cardiac disorders - Lenalidomide (Revlimid): Risk of serious hepatic adverse reactions-routine monitoring of liver function now recommended - Methylphenidate-containing medicines: Availability of web-based educational tools - Cinacalcet (Mimpara): Risk of QT prolongation/ventricular arrhythmias
July 55th Edition	- Diclofenac: The same cardiovascular precautions now apply for diclofenac as for selective COX-2 inhibitors - Codeine: Restricted use as an analgesic in children and adolescents - Dianette (Cyproterone acetate 2mg/ethinylestradiol 35mcg): New risk minimisation measures to further mitigate the known risk of thromboembolism - Lariam: Updated product information and availability of guidelines for healthcare professionals/alert cards for patients - Hydroxyethylstarch (HES) infusion solutions: PRAC recommends suspension of licenses - PRAC recommendations

DRUG SAFETY NEWSLETTERS (CONTINUED)

Edition	Articles
October 56th Edition	- Novel Oral Anticoagulants (NOACs) and risk of bleeding: Reinforcement of risk minimization advice for dabagatrin (Pradaxa), rivaroxaban (Xarelto) and apixabab (Eliquis) - Metoclopramide-containing medicines: Update on outcome of review and revised recommendations for use
December 57th Edition	- Ondansetron for intravenous use - updated information on posology to mitigate dose-dependent risk of QT interval prolongation - Agomelatine (Valdoxan): New contraindication and a reminder of the importance of liver function monitoring - Restrictions to the use of Short Acting Beta Agonists (SABAs) in obstetric indications - Trazodone: Reminder of the risk of postural hypotension and somnolence in the elderly particularly in the context of polypharmacy
December 58th Edition	- Intravenous iron-containing medicines: New recommendations to manage and minimise risk of allergic reactions - Cabazitaxel (Jevtana): Potential for medication error due to incorrect reconstitution - Medicines subject to additional monitoring requirements-update - Use of the IMB online adverse reaction reporting system for the DSN for CPD purposes - INSERT: Quick guide to medical device incident user reporting

IMB HUMAN MEDICINES ARTICLES – EXTERNAL PUBLICATIONS

Topic	Publication	Month
Diclofenac: Further evidence that the cardiovascular risk with diclofenac is higher than other non-selective NSAIDs and similar to COX-2 inhibitors	MIMS	January
Acetylcysteine: New guidance on treatment of paracetamol overdose	MIMS	February
Updated Pharmacovigilance Legislation	IMF	February
Tredaptive: Suspension of MA	MIMS	March
Restriction of indications for trimetazidine-containing products (CV supplement)	MIMS	March
iaCME: Use of the IMB online ADR report forms and DSN for CPD purposes.	MIMS	April
Methylphenidate: Availability of web-based educational tools	MIMS	May
Revlimid (lenalidomide): Risk of serious hepatic adverse reactions (oncology supplement)	MIMS	May
Strontium ranelate (Protelos and Osseor): Updates to product information on risks of venous thromboembolism and severe allergic skin reactions	MIMS	June

IMB HUMAN MEDICINES ARTICLES – EXTERNAL PUBLICATIONS (CONTINUED)

Topic	Publication	Month
Dianette (cyproterone acetate 2mg /ethinylestradiol 35 micrograms) – New risk minimisation measures to further mitigate the known risk of thromboembolism	MIMS	July
Diclofenac: The same cardiovascular precautions now apply for diclofenac as for selective COX-2 inhibitors	MIMS	August
Changes to arrangements for DSN distribution	IMF	August
Codeine: Restricted use as an analgesic in children and adolescents	MIMS	September
Medicines subject to additional monitoring	Irish Medical Times	September
Medicines subject to additional monitoring	IPU Review	October
Lariam (Mefloquine): Updated product information and availability of guidelines for healthcare professionals/alert cards for patients	MIMS	October
Medicines subject to additional monitoring	MIMS	November
Medicines subject to additional monitoring (Diabetes Supplement)	MIMS	November
Restrictions to the use of Short Acting Beta Agonists (SABAs) in obstetric indications	MIMS	December
Medicines subject to additional monitoring December 2013 (Compendium)	MIMS	December
Diclofenac: The same cardiovascular precautions now apply for diclofenac as for selective COX-2 inhibitors (Supplement-Rheumatology)	MIMS	December

IMB VETERINARY MEDICINES ARTICLES – EXTERNAL PUBLICATIONS

Topic	Publication	Month
Flukicides update	It's Your Field	Spring
Classification of the method of supply of veterinary medicines in Ireland.	It's Your Field	Summer
Functions of the IMB in relation to animal remedies	It's Your Field	Autumn
Applying for a marketing authorisation – the process	It's Your Field	Winter

IMB MEDICAL DEVICES NEWSLETTER

Edition	Main Topics
April	– Irish Presidency of the Council of the European Union and the impact on medical devices regulation
	– The Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR)
	– Harmonised standards
	– The medical device vigilance system and revision of Vigilance Guidelines MEDDEV Rev. 8
September	– Introduction to volumetric arc therapy in Ireland
	– Safe use of automated external defibrillators
	– New EU Commission Implementing Regulation on the designation and supervision of notified bodies
	– European Commission recommendation on unique device Identification of medical devices

IMB MEDICAL DEVICES ARTICLE – EXTERNAL PUBLICATION

Topic	Publication	Month
Focus on role of in-vitro diagnostic scientific officer in IMB	AMLS Converse magazine: Partners in Pathology	December

INDUSTRY GUIDANCE DOCUMENTS

Document title	New/Revision	Date
Guide to Good Distribution Practice of medicinal products for human use	New	December
Guide to wholesaling and brokering of medicinal products for human use in Ireland	Revision	December
Guide to the completion of the Hospital Blood Bank Annual Report	Revision	December
Guide to labels and leaflets for human medicines	Revision	December
Guide to transfers of product authorisations and parallel product authorisations for human medicines	Revision	December
Guide to the attainment of Qualified Person status in Ireland	Revision	November
Guide to applications for establishments regulated by Directive 2010/63/EU	New	November
Guide to preparation of a site master file for establishments regulated by Directive 2010/63/EU and S.I. No. 543 of 2012	Revision	November
Guide to applications for individuals regulated by Directive 2010/63/EU and S.I. No. 543 of 2012	Revision	November

INDUSTRY GUIDANCE DOCUMENTS (CONTINUED)

Document title	New/Revision	Date
Guide for custom-made dental device manufacturers on compliance with European Communities (Medical Devices) Regulations 1994	New	November
Guide to the Definition of a Human Medicine	Revision	November
Guide to the quality system for general sale wholesale distributors	Revision	November
Guide to ethics committee assessment of project applications under Directive 2010/63/EU and S.I. No. 543 of 2012	Revision	October
Guide to Renewal of Marketing Authorisations - Human Medicines	Revision	September
Guide to cosmetic products for Responsible Persons	Revision	September
Guide to interchangeable medicines	Revision	September
Guide to Cosmetics	Revision	September
Guide to the decentralised and mutual recognition procedures for veterinary medicinal products using Ireland as RMS	Revision	August
Guide to registration requirements for active substance manufacturers, importers and distributors in Ireland	Revision	June
Guide to distribution of cosmetic products in Ireland	Revision	June
Guide to completing a non-technical project summary for a project under Directive 2010/63/EU and S.I. No. 543 of 2012	Revision	May
Guide to practices exempt from the scope of Directive 2010/63/EU and S.I. No. 543 of 2012	Revision	May
Guide to completion of tissue establishment annual report	Revision	May
Guide to completion of the tissue establishment annual report for reproductive tissues and cells	Revision	May
Guide to electronic submissions - human medicines	Revision	May
Guide to interchangeable medicines	New	May
Guide to applying for a variation to a blood establishment authorisation	New	April
Guide to applying for a variation to a tissue establishment authorisation	New	April
Guide to display of chemical group symbols on product literature of sheep anthelmintics	New	April
Guide to electronic transmission of ICSRs and SUSARs associated with the use of human medicines	Revision	March
Guide to refusals and appeals	Revision	March
Guide to parallel imports - human medicines	Revision	March
Guide to hospital-based advanced therapy medicinal products	New	February
Guide to invented names of veterinary medicines	New	February
Guide to electronic submissions - veterinary medicines	Revision	January
Guide to parallel imports for veterinary medicines	New	January
Guide to the regulatory requirements for the procurement of human tissues and cells intended for human application	Revision	January

APPENDIX 4 EUROPEAN AND NATIONAL COMMITTEE / WORKING GROUP PARTICIPATION

EUROPEAN AND NATIONAL COMMITTEE/WORKING GROUP PARTICIPATION

Committee/Working Group	Organisation	Meetings Per Annum
Competent Authority for Medical Devices (CAMD)	CAMD	2
Notified Body Operations Group (NBOG)	CAMD	3
Compliance and Enforcement Working Party (COEN)	CAMD	3
Committee Of Experts on Minimizing Public Health Threats Posed by Counterfeiting of Medical Products and Similar Crimes	Council of Europe	2
European Pharmacopoeia Commission	Council of Europe	3
Pompidou Group – Drug Precursors	Council of Europe	1
P-SC-COS (Committee of Experts on Cosmetics)	Council of Europe	1
Implementation Group on Generic Substitution and Reference Pricing	Department of Health	6
Medication Safety Forum	Department of Health	4
Market Surveillance Forum	Department of Jobs Enterprise & Innovation	4
Market Surveillance Regulation & Consumer Product Safety Regulation for Cosmetic Products DJEI	Department of Jobs Enterprise & Innovation	1
Official Medicines Control Laboratories Network – European Directorate for Quality of Medicines (EDQM)	EDQM	8
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/Working Group	Organisation	Meetings Per Annum
ECommittee for Orphan Medicinal Products (COMP)	EMA	11
Committee on Herbal Medicinal Products (HMPC)	EMA	6
GMDP Inspectors Working Group	EMA	4
Pharmacovigilance Inspectors Working Group (Human)	EMA	2
Pharmacovigilance Inspectors Working Group (Veterinary)	EMA	2
GCP Inspectors Working Group	EMA	4
Paediatric Committee (PDCO)	EMA	12
Pharmacovigilance Risk Assessment Committee (PRAC)	EMA	13 (includes informal meetings)
Scientific Advice Working Party	EMA	11
Biologics Working Party	EMA	11
Telematics Committee - Management Board	EMA	4
New and Emerging Technologies Working Group	EU Commission	2
In-Vitro Diagnostic Technical Working Group	EU Commission	1
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
Drug Precursors Working Group	EU Commission	2
MDEG Working Group on Vigilance	EU Commission	2
Medical Device Expert Group	EU Commission	3
Unique Device Identifier Group	EU Commission	2
Vigilance and Surveillance of Substances of Human Origin (SoHO V & S)	EU Commission / SoHO V & S	1
European Commission Sub-working Group on Cosmetovigilance	European Commission	2
PEMSAC (Platform of European Market Surveillance Authorities for Cosmetics) Market Surveillance	European Commission	2
PEMSAC (Platform of European Market Surveillance Authorities for Cosmetics) Analytical Methods	European Commission	2

Committee/Working Group	Organisation	Meetings Per Annum
Competent Authority for Medical Devices	European Commission	1
HTA Advisory Committee	HIQA	2
Medicines Reconciliation Advisory Group	HIQA	3
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	HMA	2
Working Group of Quality Managers	HMA	2
Working Group of Communications Professionals	HMA	2
HMA ICT Working Groups	HMA	
Homeopathic Medicinal Products Working Group (HMPWG)	HMA	2
PSUR Work-Sharing Working Party	HMA	11
Steering Group on Medicines for Older People	HSE	3
IMB – UK Department for Business Innovation & Skills	Ireland/UK Working Group	5
Anti-doping Committee	Irish Sports Council	4
Healthcare Standards Consultative Committee	National Committee	4
IMB – HSE – National Organ Donation and Transplant Office (NODTO)	National Working Group	2
Cosmetics Standards Advisory Group	NSAI	2
EPA Health Advisory Committee	EPA	3
Permanent Forum on International Pharmaceutical Crime	PFIPC	1
Committee of Officials	PIC/S	2
GDP Working Group	PIC/S	2
Heads of Medicines Agencies meetings – Human	Presidency	4
Heads of Medicines Agencies 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

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

H1N1	Abbreviation for the influenza virus associated with the 2009 Flu Pandemic
HIQA	Health Information and Quality Authority
HMA	Heads of Medicines Agencies
HMPC	Committee on Herbal Medicinal Products
HPSC	Health Protection Surveillance Centre
HPV	Human Papillomavirus
HSE	Health Service Executive
HTA	Health Technology Assessment
IAHS	Irish Association of Health Stores
IBTS	Irish Blood Transfusion Service
ICH	International Conference of Harmonisation
IHTA	Irish Health Trade Association
IMDA	Irish Medical Devices Association
IMDRF	International Medical Device Regulators Forum
IMF	Irish Medicines Formulary
IMSTA	Irish Medical and Surgical Trade Association
IPHA	Irish Pharmaceutical Healthcare Association
IVD	In-Vitro Diagnostics
JIDA	Journal of the Irish Dental Association
MAH	Marketing Authorisation Holder
MEDDEV	Medical Devices Guidance Document from the European Commission
MIMS	Monthly Index of Medical Specialities
MRA	Mutual Recognition Agreement
MRLs	Maximum Residue Limits
MRP	Mutual Recognition Procedure
NBOG	Notified Body Operations Group
NCA	National Consumer Agency
NHO	National Haemovigilance Office
NODTO	National Organ Donation and Transplantation Office
NSAI	National Standards Authority of Ireland
OMCL	Official Medicines Control Laboratories
OTC	Over-the-Counter
PCI	Pharmachemical Ireland
PDCO	Paediatric Committee
PDP	Performance Development Programme
PFIPC	Permanent Forum on International Pharmaceutical Crime
PIC/S	Pharmaceutical Inspection Co-operation Scheme
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

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