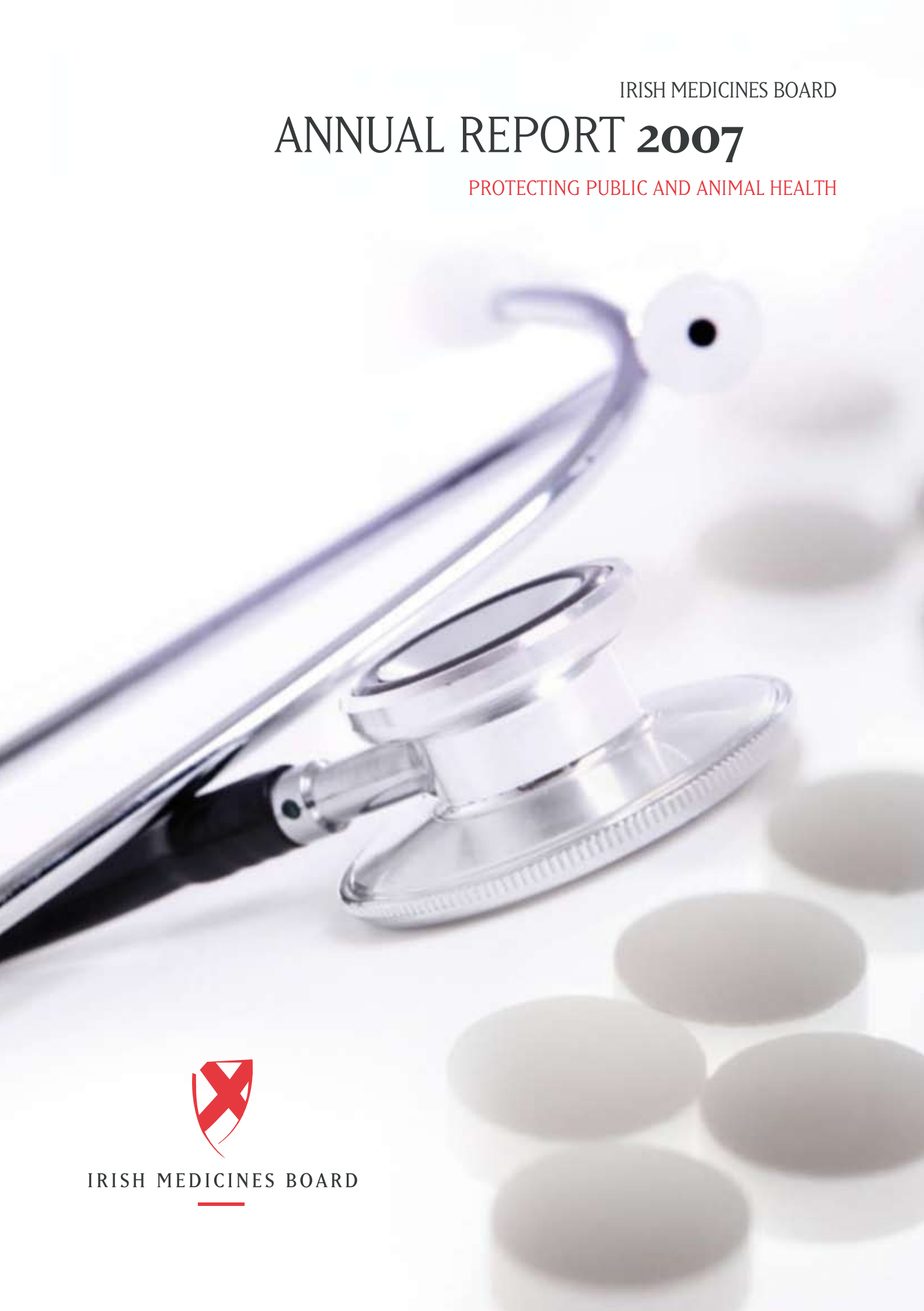
IRISH MEDICINES BOARD

ANNUAL REPORT **2007**

PROTECTING PUBLIC AND ANIMAL HEALTH



IRISH MEDICINES BOARD

CONTENTS

Mr. Pat O'Mahony, *Chairman*

CHAIRMAN'S STATEMENT

Once again 2007 proved to be another significant year of further development for the Irish Medicines Board (IMB) in relation to the organisation's primary objective of safeguarding public health. The breadth of our remit is extensive and continues to expand as new and important areas of regulatory policy come under our responsibility.

The IMB's core focus is to safeguard and enhance public and animal health through the regulation of human and veterinary medical products and medical devices on the Irish market. From a strategic planning position, this focus underpinned all our activities. One of the notable highlights in this regard took place during the year when we improved our facilities to assist direct communication with the IMB on potential adverse events. The IMB developed a sophisticated online reporting mechanism which facilitates healthcare professionals and members of the public to report any suspected adverse reactions or quality defects associated with medicines or medical devices directly to us. It is available on our redesigned website and our hope is that this new facility will further enhance our ability to monitor the safety of all medicinal products and medical devices on the Irish market.

The year under review witnessed the IMB undertaking a demanding programme of work across all departments. Against this background it is a pleasure to report that we increased outputs across all departments while achieving consistently high standards of quality throughout the period.

Our work involves the assessment and monitoring of some 6,000 human medicines, 1,200 veterinary medicines and over half a million medical devices on the Irish market. Our participation in a range of international and European groups is critical to our working in terms of having the fullest of available knowledge on all matters of relevance to products. We are significant participants in the European Medicines Agency (EMEA) and its working groups. Our Chief Executive, Mr. Pat O'Mahony, was elected Chairman of the Management Board of the EMEA in July, for a three-year term. We also participate in The World Health Organisation (WHO) in relation to monitoring medicines by supplying information on adverse reactions that occur in Ireland and assessing global safety information that can be of value to our fundamental role of protecting Irish consumers. We continue to consult closely with our EU counterparts and the US Food and Drug Administration (FDA), in sharing intelligence and information for mutual benefit.

During 2007, the number of enforcement cases initiated by the IMB rose substantially to some 1,400, almost tripling the 469 in 2006. This increase can be attributed to the continued co-operation with the Custom and Excise offices and An Garda Síochana, and increased levels of communication and intelligence-sharing with our international and European counterparts. There is no doubt that the increase in online purchasing of medicines and counterfeit medicines is a growing area and an issue for regulatory agencies throughout Europe. The IMB plays an active role in helping to protect consumers in this regard through its extensive activities both nationally and internationally.

A highlight of 2007 was the IMB's hosting of the international summit of heads of medicines regulatory bodies in December. This was the second time that this international meeting had taken place, with the inaugural event hosted by the FDA in Washington in 2006. It was a significant development for the IMB that Ireland played host to such an important forum. It involved over 20 countries including Australia, Canada, Germany, Singapore, UK and USA discussing and formulating approaches to important global issues such as counterfeit medicines and the regulation of clinical trials. The development of more streamlined links between agencies worldwide was also progressed.

During the year, our Board members and staff contributed to various working groups and sub-committees both at home and internationally. I would like to thank all individuals who gave up their time and expertise. It is very much appreciated.

I would also like to acknowledge the role of the many independent experts who have worked closely with the IMB this year and express my appreciation to them. They contribute enormously to our committees and give us their expert insights which assist us in formulating our opinions. These committees provide the IMB with the highest calibre of experience and knowledge across a wide range of disciplines allowing the IMB to fulfil its role as the protector of public and animal health in Ireland.

We acknowledge the continued support of the Minister for Health and Children, the Minister for Agriculture and Food and their staff. Their continued co-operation with the IMB has contributed immensely to the organisation and indeed will continue to contribute to its productive operation.

I would like to take this opportunity to thank the Chief Executive, the Management Team and all the staff of the IMB for their exceptional work, enthusiasm and dedication in 2007.

The IMB's role continues to expand bringing with it new challenges for us to meet while maintaining the highest standards of service. We look forward to the year ahead with the assurance that we are delivering excellence in our field while always keeping to our core focus of protecting public and animal health.

Pat O'Mahony
Chairman

Back row – (l-r): Brendan Buckley, Pat Brangan, Maureen Windle, Brendan McLaughlin.
Front row – (l-r): Cicely Roche, Ingrid Hook, Pat O'Mahony *(Chairman)*, Wilf Higgins.

BOARD MEMBERS

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

The Board members are:

Mr. Pat O'Mahony *(Chairman)*

Prof. Brendan Buckley

Mr. Pat Brangan

Mr. Wilfred Higgins

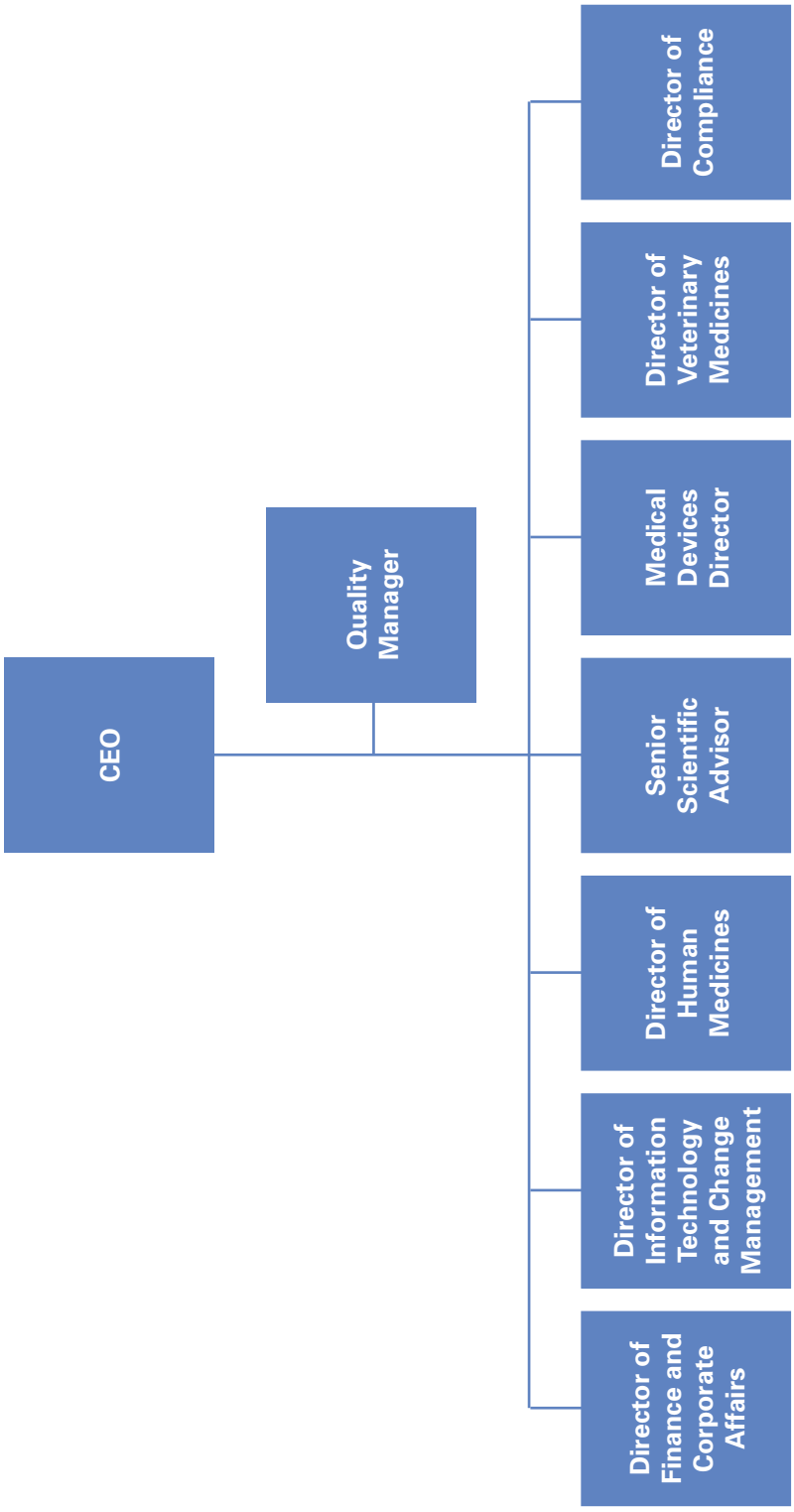
Ms. Ingrid Hook

Mr. Brendan McLaughlin

Ms. Cicely Roche

Ms. Maureen Windle

ORGANISATIONAL CHART



Mr. Pat O'Mahony, *Chief Executive*

CHIEF EXECUTIVE'S REPORT

OVERVIEW OF 2007

I am pleased to report that 2007 was another successful year for the Irish Medicines Board with sustained achievement in meeting the organisation's mission to protect and enhance public and animal health through the regulation of medicines, medical devices and healthcare products. Any public health issues within our remit which emerged during the year were handled efficiently and successfully with the protection of public health at the core of all our activities.

As we strove to continuously improve efficiencies and standards across the organisation whilst amalgamating new areas of responsibility, the implementation and management of change continued to be a key driver within the IMB. As a part of this ongoing organisational process we instigated change programmes in the Medical Devices and Veterinary Medicines areas. We also significantly enhanced the application of our quality management system and successfully managed the affairs of the IMB in line with our statutory obligation that income at least meets costs.

Ireland is an important global location for the pharmaceutical/biopharmaceutical and medical devices industries and products manufactured in Ireland are exported worldwide. Ireland is now the largest exporter of pharmaceuticals in the world. Over 6,000 human medicinal products and over 1,000 veterinary medicinal products are authorised by the IMB for use in this country at present. The IMB's regulation of the manufacture, marketing and distribution of medicinal products plays a very significant role in ensuring that appropriate standards are maintained in this sector.

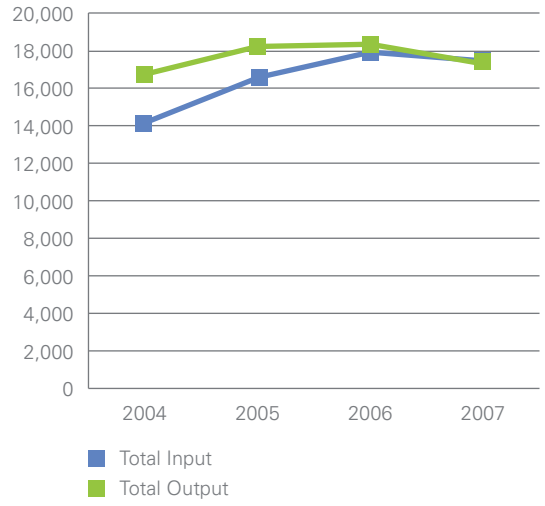
HUMAN MEDICINES

Our focus on the safety, quality and efficacy of human medicines extends throughout the full lifecycle of all products: from the provision of scientific advice, approval of clinical trials, through to the assessment of applications for granting, variation and renewal of marketing authorisations. A key focus in this area is post-marketing surveillance, which encompasses pharmacovigilance, investigating reports of quality defects and a programme of product sampling and analysis. At all stages, patient safety remains at the forefront of the IMB's focus. A wide range of safety

actions were implemented during the year across a variety of medicines. Notably, oral preparations of nimesulide were suspended in May and a full recall from the market was initiated as the IMB concluded that the products could no longer be considered safe under normal conditions of use. These products remain suspended at year end and a European-wide safety review is ongoing.

Output of applications matched input. During the year, the Human Medicines Department processed 14,502 variations to product authorisations, 1,082 new product applications and 1,011 renewals to product authorisations.

APPLICATION INPUT AND OUTPUT OVERVIEW

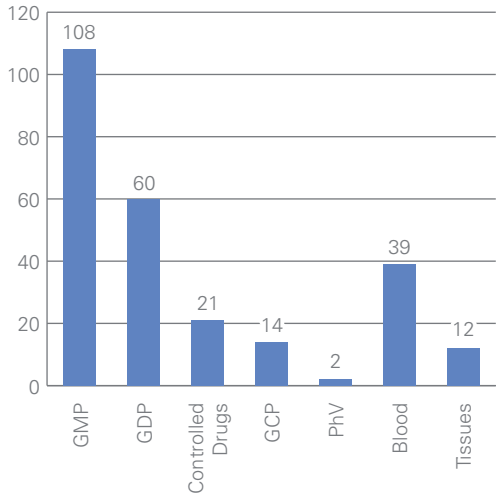


COMPLIANCE

The IMB's Compliance Department continued to carry out Good Manufacturing Practice inspections on the very substantial number of manufacturing sites operating in Ireland. It also contributed significantly to inspections of foreign sites on our own behalf, or on behalf of the European Union. Good Distribution Practices inspections were conducted on the supply chain while tissues and cells and blood establishment sites were also inspected. Licensing and export certification activities relating to Irish sites were carried out. Good Clinical Practice and Pharmacovigilance inspections were carried out as was a pilot programme of inspection of marketing authorisation holders.

During 2007, a total of 1,397 cases involving breaches of medicinal product legislation were initiated. The IMB seized 88,279 tablets, 106,443 capsules, 22.5 litres of liquids and 40 kg of creams containing a variety of active substances. Market surveillance programmes, encompassing investigation of quality defects and recalls, and sampling and analysis, were operated. These included 88 human medicines recalls and nine veterinary medicines recalls from the market. Where appropriate, the implementation of follow-up corrective and preventative actions was overseen. A total of 469 medicinal products were sampled for analytical testing and/or checks on labelling and packaging compliance.

NUMBER AND TYPE OF INSPECTIONS COMPLETED IN 2007

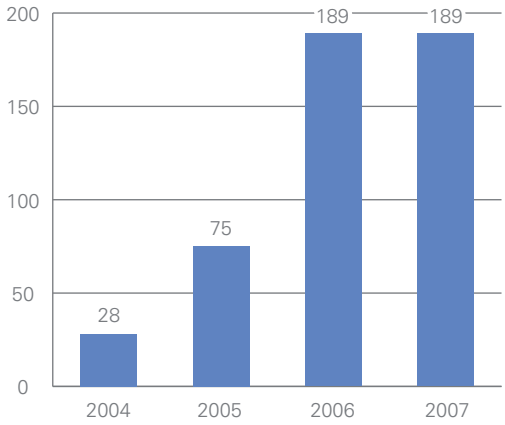


MEDICAL DEVICES

Activity in the medical devices area continues to be a significant part of the work of the IMB. During 2007, a total of 261 medical devices were registered, including 139 *in-vitro* diagnostic medical devices and 122 general medical devices. This area of our work continues to expand and provisions have been made to ensure the effective management of this growth through the restructuring of the department during 2007. The IMB is dependent on the availability of financial resources from the Department of Health and Children to fund this area of activity and continue to advocate for additional

resources. Any public health issues relating to medical devices arising during the year were handled effectively and efficiently.

NUMBER OF COMPLIANCE CASES OPENED

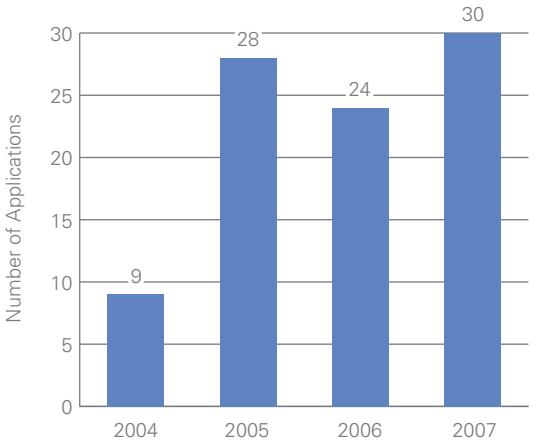


VETERINARY MEDICINES

Animal health and welfare is of critical importance to the Irish economy and its reputation in relation to producing quality produce. The food industry is a very important sector in the Irish economy with exports of €8.6 billion recorded in 2007. The regulation of veterinary medicines plays a significant part in assisting the prevention and treatment of disease, in enhancing animal welfare and in ensuring the safety of foods of animal origin. In 2007 the IMB implemented a change programme in our Veterinary Medicines Department to enable us to better deliver on our mission.

A record number of applications for authorisation of veterinary medicinal products were approved by the IMB in 2007, and despite Ireland being one of the smaller European Union countries we played a leading role acting as reference member state/ rapporteur in the centralised, mutual recognition and decentralised procedures. During the year, the department conducted a review of the distribution of veterinary vaccines which will form the basis of IMB policy henceforth. Any pharmacovigilance and public health issues relating to veterinary medicines arising during the year were handled efficiently and effectively.

APPLICATIONS AS REFERENCE MEMBER STATE



FINANCE AND CORPORATE AFFAIRS

In line with increased activity within the organisation in 2007, the Finance and Corporate Affairs Department expanded its output across its various activities. This department was responsible for the building renovation project which was substantially completed by year end. The Human Resources function had a busy year with an increase in recruitment and training provision. The internal financial audit function conducted reviews of systems and reported directly to the audit committee of the Board, in compliance with good corporate governance requirements.

IT AND CHANGE MANAGEMENT

The IMB's progressive programme of change, involving both an upgrade of our information technology and a programme of organisational change, reached some major milestones in 2007. Development continued in our IT systems with the launch of a new enhanced website which has been well received and which we hope will be seen as the definitive online information source relating to medicines and medical devices in Ireland. The new site includes a facility for online reporting of suspected adverse reactions relating to human medicines as well as quality defects. While only launched towards the later half of the year, it recorded

extensive usage by year end. Online reporting makes it easier for healthcare professionals and the public to report issues to the IMB in an efficient and convenient way. Stakeholders may subscribe for alerts from the website by email or text messaging. Another important advance in 2007 was the implementation of electronic reporting of details of adverse reactions to the EMEA.

The department also provided increased output during the year by way of staff training and IT support as required by the organisation.

IMPLEMENTATION OF THE NEW MEDICINES LEGISLATION AND QMS

A series of revised regulations on human medicines were enacted by the Department of Health and Children in 2007 and the IMB was fully prepared for the provisions of this new legislation. This was due to the carrying out of a significant programme to prepare for the implementation of revised medicines legislation since 2005. The Department of Agriculture, Fisheries and Food updated the Animal Remedies Regulations on two occasions during 2007 and the IMB fully implemented any relevant changes.

Photographed at the *International Summit of Heads of Medicines Regulatory Bodies.*

Meena Ballantyne, *Health Canada;* Andrew C. von Eschenbach, *FDA;* and Pat O'Mahony, *Irish Medicines Board.*

During 2007, we made significant progress in the implementation of an IMB-wide quality system which brings major benefits to efficient workings of the organisation.

THE EUROPEAN MEDICINES REGULATORY SYSTEM AND INTERNATIONAL AFFAIRS

In 2007, the IMB continued to participate actively in the European medicines regulatory system through its involvement in EU committees and working parties. We continued to contribute at EMEA level and in June 2007, the Management Board of EMEA elected me as its chairman, for a three year term. This is a significant honour and I look forward to assisting in the leadership and development of the European regulatory system. The IMB also continued to contribute very actively at the Heads of Medicines Agencies (HMA) level, providing part of the Permanent Secretariat to the HMA as well as co-chair and technical support to the process of quality improvement of the European network known as Benchmarking of European Medicines Agencies (BEMA). We were also engaged in the assessment of centralised applications for human and veterinary medicinal products as rapporteur and as reference member state in the mutual recognition and decentralised procedures. The IMB was the lead agency in Europe on the veterinary medicines side. We continued to meet all timelines in all these procedures in 2007.

The IMB also continued to represent Ireland at the European Pharmacopoeia, where Dr. Mike Morris, Senior Scientific Advisor, continued to mid-year in the role of President of the Pharmacopoeia Commission. During 2007, Dr. Morris delivered on a range of significant technical projects for the IMB.

Information technology continues to be an important topic on the EU agenda as it works to facilitate better access of patients to information on medicines and swift, accurate and efficient sharing of relevant information between regulatory authorities throughout Europe. During 2007, the IMB's Information Technology (IT) department was actively involved in EU IT implementation activities.

In November 2006, the US FDA, as part of its centenary celebrations, hosted an international summit of regulatory agencies in Washington. In 2007, the IMB took the initiative to convene a second international summit in Dublin. This summit was well attended by agency heads from around the globe. A number of important topics were discussed during the meeting ranging from the threat posed to patients from counterfeit medicines, the operation and supervision of clinical trials, increasing co-operation through enhancing exchange of information and efficient and effective use of

scarce regulatory resources. Substantial progress was made and agreement reached on the hosting of a third meeting in Singapore in December 2008.

THE EUROPEAN MEDICAL DEVICES REGULATORY SYSTEM

This was another active year in the European Medical Devices regulatory system with the IMB participating in a large number of meetings at EU level, including the Medical Devices Expert Group and the Classification and Borderline Working Group. Ireland was appointed to the chair of the Compliance and Enforcement working group of the EU Competent Authorities. The year also saw the publication of Directive 2007/47/EC amending Directive 93/42/EEC.

COMMUNICATIONS

In 2007, the Board continued to enhance its communication with various stakeholder groups with an interest in healthcare products. Information days for human medicines, veterinary medicines, medical devices and wholesaling industry stakeholders were held. These meetings attracted a large number of attendees and positive feedback was received.

A number of meetings with other organisations and individuals with particular interests in healthcare products were also hosted during the year. These included meetings with the Animal & Plant Health Association (APHA), the Association of Pharmaceutical Manufacturers of Ireland (APMI), the Irish Association of Health Stores (IAHS), the Irish Health Trade Association (IHTA), the Irish Medical Devices Association (IMDA), the National Standards Authority of Ireland, the Irish Pharmaceutical Healthcare Association (IPHA), Pharmachemical Ireland and the Pharmaceutical Distributors Federation.

PUBLICATIONS

During 2007 the IMB launched a number of valuable guidance documents as part of its communications efforts, all of which are available from our website (www.imb.ie).

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

FREEDOM OF INFORMATION

Nineteen requests were received under the Freedom of Information Act in 2007, compared with six in 2006, reversing the trend of recent years.

THE FUTURE

The IMB faces new challenges and new opportunities for development in 2008.

The overall workload for the organisation continues to increase and ensuring adequate staffing and resources to meet the various demands is an ongoing challenge. We intend to review our structures in the human products area; implement a system for notification of unauthorised medicines by wholesalers and manufacturers; conduct additional inspections in a range of areas including tissues and cells establishments; implement provisions relating to paediatric indications of human medicines; and report on implementation of regulation in the cosmetics sector.

Our objective will be to maintain the impetus for change across the organisation and continue to manage change to assist us in delivering higher standards of output to all stakeholders. In this regard, continuing to develop our performance management system will be a priority.

Our staff's expertise and experience are key assets to our organisation. We will continue to offer training and development opportunities in order to maintain and enhance the skills set required for the ever changing and increasingly complex areas under our remit. In this regard we will prepare for the implementation of the Advanced Therapies Regulation in 2009.

We will continue the roll-out of our ongoing innovation in IT development and linked organisational change during 2008. These will further develop our information technology systems and assessment activity with consequential major benefits to the IMB and its stakeholders.

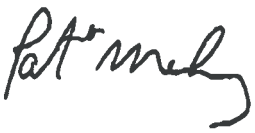
We will continue to review our funding provision and to look critically at our own cost base to ensure maximum use of resources.

BOARD AND STAFF MATTERS

In total, over 100 people contribute voluntarily to the work of the IMB through participation on the Board and various Committees. The Board and Committees had a very successful year in office and the access we have to this range of independent expertise and acumen is of immense value to the workings of our organisations. I thank each member for their individual contribution and commitment during 2007.

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

I welcome all new staff members who joined during 2007 and express my personal appreciation to all the staff of the IMB for their continued generous support in achieving the Board's objectives during the year. I look forward to the support of all staff in dealing effectively with the various challenges ahead, as we continue to strive for excellence in all aspects of our daily activities.



Pat O'Mahony
Chief Executive

Dr. Joan Gilvarry, *Director of Human Medicines*

HUMAN MEDICINES

INTRODUCTION

The Human Medicines Department had a very successful year in 2007. Safety monitoring of medicines on the Irish market continued to be a core priority and the key focus of the department's staff. Implementation of the revised pharmacovigilance structure continued during 2007, with further refinement of activities within the Market Surveillance and Pharmacovigilance assessment teams. This structure works closely with the technical assessment teams and has proven to be very beneficial. The department also managed and contributed to significant levels of safety assessments whilst witnessing a substantial increase in volume outputs related to licensing activities, all managed effectively by the staff of the department.

PHARMACOVIGILANCE

The IMB always places great emphasis on encouraging and promoting reports from a range of stakeholders in relation to suspected adverse reactions to medicines. These reports are important to signal potential safety issues from medicines in use and ultimately they assist the IMB to monitor medicines on the market. During 2007, the IMB continued to encourage adverse reaction reporting and provided regular reminders about reporting in the Drug Safety Newsletter and its regular publications in MIMS (Ireland) and the Irish Medicines Formulary (IMF). A number of presentations on pharmacovigilance and adverse reaction reporting were also made to healthcare professionals as part of undergraduate and postgraduate training courses as well as continuing education programmes.

During 2007 the IMB received a total of 1,751 suspected adverse reaction reports occurring in Ireland from healthcare professionals and pharmaceutical companies. The IMB greatly appreciates the contribution of healthcare professionals in reporting this information which facilitates the continued surveillance of the safety of medicines. The collection and evaluation of these reports is essential to ensure constant vigilance as to the safety of products and facilitates the IMB in ensuring that regulatory action/proposals take account of all available case report information.

The IMB recognises the sometimes burdensome nature of form-filling for suspected adverse drug reactions (ADRs) and values the time healthcare professionals and consumers give to this important

task. In 2007, the IMB established an online reporting system through its website which it is hoped will make it easier for participation in this process. This new online channel supplements the existing options for reporting suspected adverse reactions which include yellow cards and downloadable report forms. The new online option was introduced in November and over 60 online reports were submitted by year-end. It is hoped that uptake of this additional mechanism for reporting will continue to increase over the coming years. Access to the online reporting system is available through the IMB website at www.imb.ie.

In addition, the IMB's new website now also offers users the option of registering their contact information to enable them to receive direct and immediate notification of IMB alerts/updates by email or text message.

BREAKDOWN OF REPORTS BY SOURCE	
Marketing Authorisation Holders	964
General Practitioners	206
Hospital Doctors	172
Hospital Pharmacists	89
Community Care Doctors	71
Community Pharmacists	70
Nurses	67
Patient/Consumers	54
Clinical Trials	44
Dentists	7
Health Care Professionals (other)	7
Total	**1,751**

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

DRUGS WITHDRAWN/ SUSPENDED FOR SAFETY REASONS

Nimesulide

In May 2007, the IMB suspended the marketing authorisations for oral nimesulide products. This action was taken following evaluation of new and cumulative safety data related to hepatotoxicity, indicating that oral nimesulide could no longer be considered safe under normal conditions of use. Healthcare professionals and patients were informed of this urgent regulatory action through notices placed in the print media, as well as direct contact with a range of professional organisations. A freephone helpline dealt with some 1,500 enquiries, within the first few days of the suspension and the IMB's website was a resource for information through statements and a Q&A document.

At the time of suspension, nimesulide was authorised in 17 EU Member States. The national suspension of a product authorisation, by virtue of current European (EU) medicines legislation, automatically triggers a European procedure of review and assessment of the issues leading to the national regulatory action. In accordance with this procedure, scientific review is first carried out by the scientific Committee for Medicinal products for human use (CHMP) of the European Medicines Agency. This is followed by a European Commission review and its decision, once issued, is legally binding on EU Member States.

The CHMP review procedure for nimesulide concluded in September 2007 and the recommendation, which was agreed by a narrow majority, was that nimesulide-containing products for systemic use should be allowed to remain on the market in EU Member States, subject to further restrictions. This recommendation was communicated to the European Commission for consideration and the outcome of its deliberations was awaited at the end of 2007.

Notwithstanding the CHMP position, the IMB's view remains that the risk/benefit profile of nimesulide for systemic use is unfavourable and suspension of the authorisations for such products currently remains in place in Ireland.

INTERNATIONAL COLLABORATION

The CHMP Pharmacovigilance Working Party (PhVWP)

There were a total of 11 meetings of the CHMP's PhVWP during 2006. During these meetings, the PhVWP considered product-related issues at the request of CHMP. These included centrally-authorised products, products subject to referral procedures and nationally-authorised products. Other product-related issues were also considered at the request of the competent authorities of the Member States.

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

Following extensive update of EU pharmacovigilance guidelines to take account of both new and expanding responsibilities for marketing authorisation holders and national competent authorities, the European Commission issued Volume 9A of the Rules Governing Medicinal Products in the EU (Guidelines on Pharmacovigilance for Medicinal Products for Human Use) in January 2007.

PhVWP drafting groups continued to review and develop guidance on other organisational issues and to consider relevant class-related effects.

Information was provided by the IMB Pharmacovigilance Section in respect of all requests circulated via the Rapid Alert/Non-Urgent Information exchange system by other Member States.

WHO/ISOP

IMB staff participated in and presented at the annual meeting of national centres involved in the World Health Organisation (WHO) international drug monitoring programme and at the annual International Society of Pharmacovigilance (ISOP) conference, both of which were held in October, 2007.

Electronic Reporting

The IMB continued to report all suspected serious adverse reactions occurring in Ireland electronically via EudraVigilance to the EMEA and to those companies with which satisfactory testing has been completed. By the end of 2007, 59 companies (an increase from 21 companies at the end of 2006) were in production with electronic reporting to the IMB, with a further nine in active testing.

Detailed information and guidance on electronic reporting is available in the IMB Guide to Electronic Submission of ICSRs and SUSARs Associated with Use of Human Medicines, which can be located under the heading 'Publications' on the website.

During 2007, IMB staff participated at all EudraVigilance meetings and training courses organised by the EMEA.

Publications

Two issues of the IMB's Drug Safety Newsletter were circulated to doctors, dentists and pharmacists during 2007. These included a further update on experience with BCG vaccine; recommendations regarding safety and use of triamcinolone acetonide and terbinafine; the potential for interaction between glucosamine and warfarin; as well as the outcomes of several safety reviews related to neuroleptics, NSAIDs, piroxicam, desmopressin nasal spray and botulinum toxin. Copies of the newsletters and updates on safety issues considered to be of public health interest were published in the IMB's regular article in MIMS (Ireland) during the year and are available from the Publications section of the IMB's website www.imb.ie.

Company Liaison

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

Company/sponsor compliance with pharmacovigilance obligations was monitored on an ongoing basis. This was undertaken through review and monitoring of the timeliness and quality of individual adverse reaction reports, evaluation of the follow-up information provided for individual reports, assessment of the quality and comprehensiveness of periodic safety update reports and annual safety reports and responses to IMB requests for pharmacovigilance data.

Haemovigilance

The IMB continued to participate in the steering committee established by the Department of Health and Children (DoHC) to oversee implementation of relevant EU and national legislation. A report on the outcome of review and evaluation of the haemovigilance system in place in Ireland prepared by an independent expert at the request of the DoHC in 2006 was considered by the Committee. The DoHC indicated its intention to examine the report in detail, including proposed recommendations and to keep the Committee informed of progress in this regard.

The IMB continued its regular meetings with the National Haemovigilance Office (NHO). These meetings involve reviewing reported haemovigilance events, discussing issues of mutual concern and contributing to the development of guidance on haemovigilance reporting. In addition, consideration was given to further developments to facilitate monitoring and revised working practices necessary to meet the provisions of the EU and national legislation. The IMB collaborated with the NHO in the preparation of a Haemovigilance Handbook, which has been available on the NHO website since July 2007. The IMB also participated in a workshop arranged by the DoHC in June 2007 on haemovigilance issues which included reporting requirements. Presentations outlining the overall roles and responsibilities in relation to haemovigilance obligations and the inspection process were provided by the IMB.

The IMB attended the annual European Haemovigilance Network (EHN) conference, which took place in Dublin in March 2007. This was a useful forum at which issues regarding definitions and standards for reporting practice were discussed and developed, with a view to harmonising requirements across the EU. Harmonisation initiatives have since been progressed by the EU Commission which convened a Working Group on Haemovigilance, which met in December 2007 and which was attended by the IMB and NHO. The aim of this group is to determine a common approach to the provision of data by Member States to the European Commission.

Tissue and Cell Vigilance

In August 2007, S.I. 598 of 2007 was signed by the Minister for Health and Children which transposed Directives 2004/23/EC and 2006/86/EC into national law. This S.I. specifies the responsibilities regarding traceability requirements, notification of serious adverse reactions and events as well as certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells.

During 2007, the IMB attended and participated at relevant vigilance and surveillance meetings to facilitate monitoring and revising working practices as necessary to meet the provisions of the legislation. At national level, the IMB continued to participate in the steering committee established by the DoHC and to contribute to relevant workshops.

At European level, the IMB participated in relevant initiatives including the joint WHO/EU project for Standards and Training for the Inspection of Tissue Establishments (EUSTITE). This project aims to promote standardisation to best practice in the inspection of tissues and cells, and in partnership with the WHO, to develop optimal systems for the notification and management of adverse events and reactions relating to the quality and safety of tissues and cells. The IMB acted as co-rapporteur at the EUSTITE meeting on Vigilance and Surveillance of Human Tissues and Cells for Human Application in the European Union and Globally, which took place in Rome in July 2007.

During 2007, the IMB received 19 reports associated with use of tissues and cells, 14 of which met the reporting criteria, including one adverse reaction and 13 adverse events. Each report was followed up individually, with feedback provided to all reporters. An update on experience

with adverse reaction/event reporting was issued in August 2007, to all tissue and cell establishments, reflecting information received during the first year following introduction of the legislation.

Information on reporting requirements, including a 'Guide to Reporting SARs/SAEs' and downloadable/online versions of the report forms are available on the IMB's website.

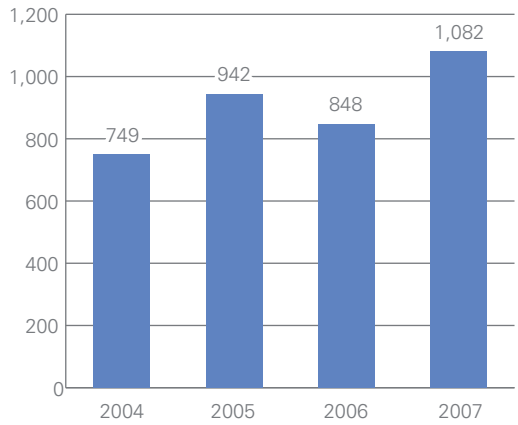
NEW PRODUCTS AUTHORISED

During 2007, the IMB output for new product applications was 1,082. This comprised 309 new national and parallel import applications, 340 new mutual recognition (MR) and new decentralised (DCP) applications, 188 new centralised* and 245 transfer applications.

(Total number of centralised applications complete in 2007, not all may be authorised by the European Commission at this point)*

The following table shows the distribution of these over the last number of years:

TOTAL OUTPUT FOR NEW APPLICATIONS

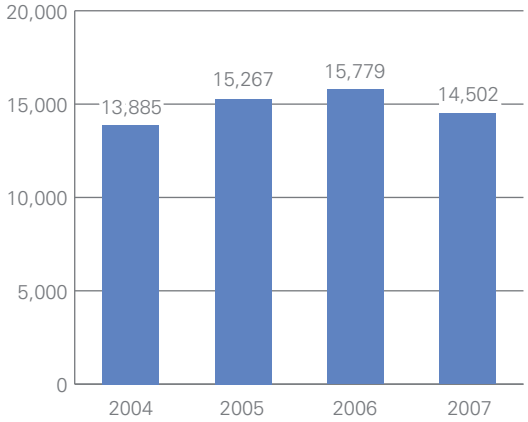


This total output figure displays an increase primarily due to an increase in the number of applications submitted through the centralised and decentralised procedures.

VARIATIONS AUTHORISED

During the year, there was an output of 14,502 variations to product authorisations for products authorised through the national or MR procedures. This was a slight decrease from 2006 due to a 5% decrease in the number of variations applications received which was 14,442.

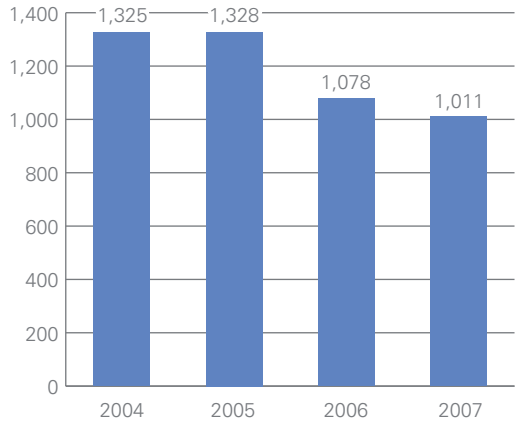
TOTAL OUTPUT FOR VARIATION APPLICATIONS



RENEWALS AUTHORISED

During the year, there was an output of 1,011 renewals to product authorisations for products authorised through the national or MR systems.

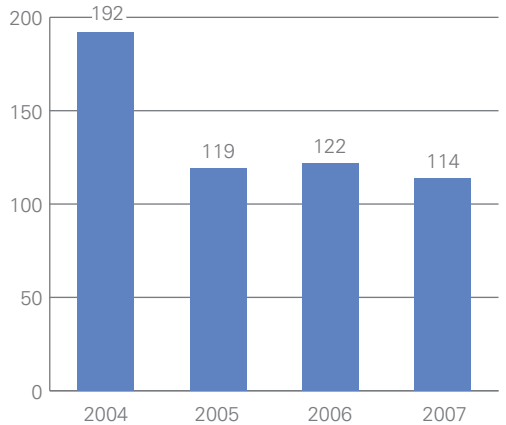
TOTAL OUTPUT FOR RENEWAL APPLICATIONS



CLINICAL TRIALS AUTHORISED

During 2007, 114 applications to conduct clinical trials were approved by the IMB. This represents a similar figure to that of 2006 and 2005 as depicted in the table below.

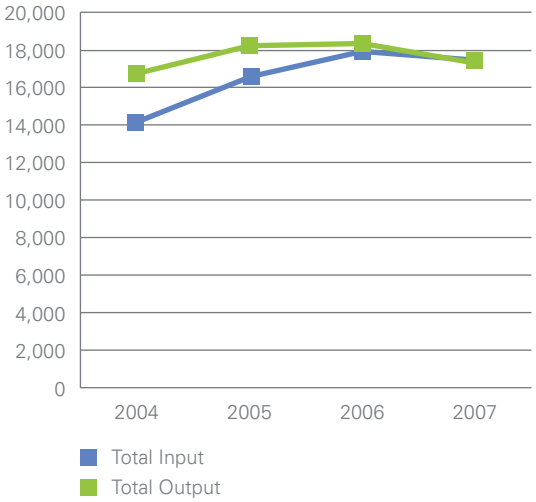
TOTAL OUTPUT FOR NEW CLINICAL TRIALS



Also in 2007 there was an output of 485 clinical trial amendment applications, which represents an increase from the 2006 figure of 409.

There was a slight decrease in the total input of new, variation, renewal and clinical trial applications in 2007 and the total output of these applications continued to meet the total input as shown in the graph below.

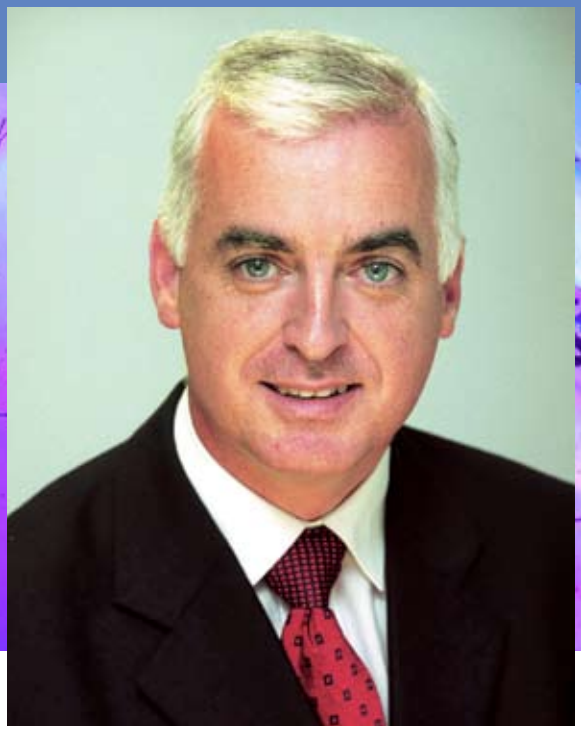
APPLICATION INPUT AND OUTPUT OVERVIEW

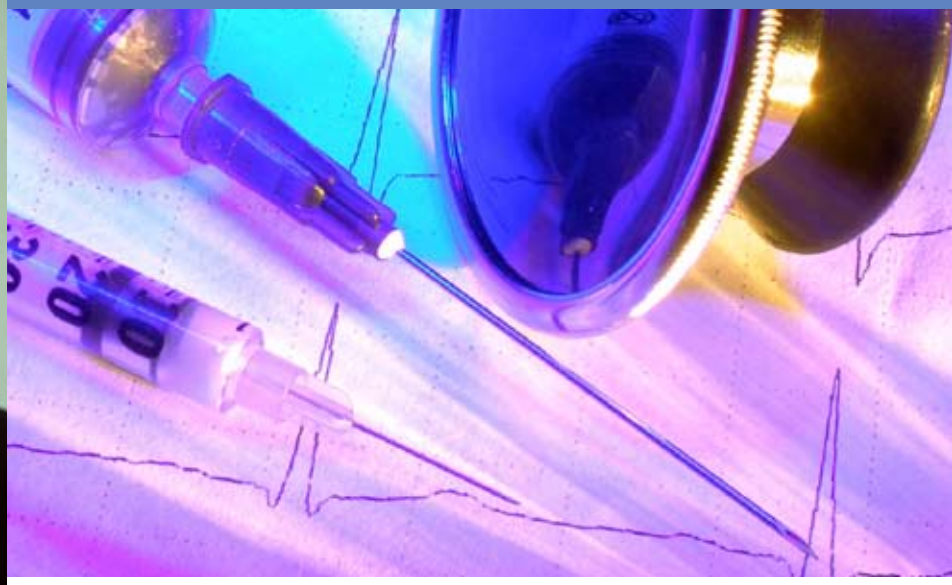


EUROPEAN COMMITMENTS

Our commitments to the European Regulatory process continued to be substantial in 2007. The department's technical staff serviced the following committees and working parties at the European Medicines Agency.

Committee/Working Party	Duration/Frequency
Committee for Human Medicinal Products (CHMP)	4 days/month
Committee for Orphan Medicinal Products (COMP)	2 days/month
Co-ordination Group for Mutual Recognition & Decentralised Procedures (CMD (h))	3 days/month
Committee on Herbal Medicinal Products (HMPC)	4 days/2 months
Paediatric Committee (PDCO)	3 days/month
Gene Therapy Working Party (GTWP)	6 days/year
Pharmacovigilance Working Party (PhVWP)	3 days/month
Safety Working Party (SWP)	2 days/3 months
Quality Working Party (QWP)	3 days/2 months
Vaccine Working Party (VWP)	3 days/2 months
Scientific Advisory Groups (SAG)	3 days/month
Efficacy Working Party (EWP)	2 days/3 months
Biological Working Party (BWP)	3 days/month





Dr. J.G. Beechinor, *Director of Veterinary Medicines*

VETERINARY MEDICINES

INTRODUCTION

The year under review marked a year of significant change for the department. A new management structure and workflow system were introduced into the department to improve efficiencies. Record outputs were achieved again in 2007. A further significant development, consequent to changes in national legislation on the distribution of veterinary medicines, was the development of a new policy in relation to the method of supply of veterinary vaccines.

PHARMACOVIGILANCE

A total of 92 reports of suspected adverse reactions associated with the use of authorised veterinary medicinal products were received by the IMB during 2007. Of those, 72 reports were received from marketing authorisation holders and 20 originated directly from veterinary practitioners. In those reports, a total of 62 veterinary pharmaceutical products and 40 immunological products were identified as possibly associated with adverse effects. While the majority of reports related to the use of a single veterinary medicinal product, two or more veterinary medicinal products were identified in ten reports.

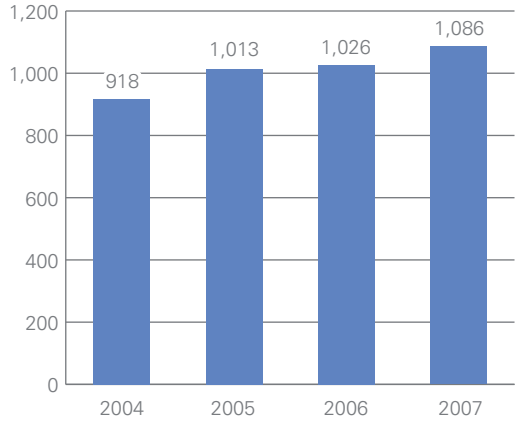
Suspected adverse events were reported in the following species: human (four reports), bovine (33), canine (35), ovine (five), equine (six), feline (seven), porcine (one) and rabbit (one).

Of the 92 reports associated with the use of veterinary medicinal products, 73 related to suspected adverse reactions in the treated animals, 14 related to lack of expected efficacy, one related to a suspected residue violation and four cases involved suspected adverse reactions in individual users following exposure to a veterinary medicinal product. No regulatory actions were taken in 2007 as a result of the safety information received in the form of spontaneous adverse reaction reports.

The IMB is committed to promoting veterinary pharmacovigilance in Ireland and gratefully appreciates and acknowledges the efforts of reporters in providing pharmacovigilance information to the IMB and responding to requests for clarification.

OUTPUTS

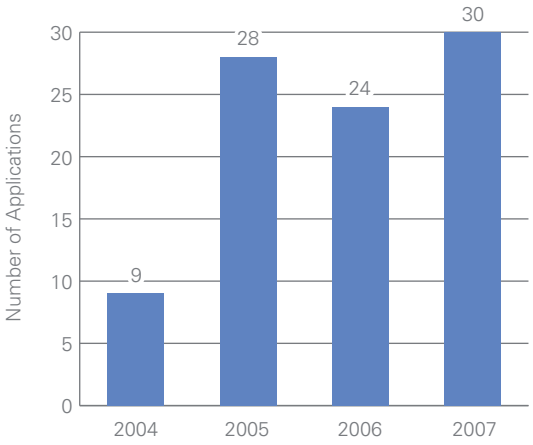
TOTAL OUTPUT OF THE VETERINARY MEDICINES DEPARTMENT 2004-2007



IMB personnel were active in centralised procedures both for new medicines and referral procedures during the year. Applications for variations to veterinary product authorisations continue to form the main bulk of total applications received, reaching 945 for the year and accounting for 73% of total outputs. A noticeable feature was the decline in the number of new applications submitted for evaluation using the national procedure; 13 such applications were received during 2007 compared to 47 in 2006. A corresponding increase in the number of applications submitted for assessment under the mutual recognition system was noted and reflects the growing importance of the procedures for joint assessments undertaken with the involvement of other Member States.

The department was very active as reference member state in the European mutual recognition and decentralised procedures, with more applications than all other member states in the European Community in 2005 and 2006. While official data on the IMB position relative to those of other EU member states for 2007 are unavailable at the time of writing, the department dealt with a record number of procedures during the year as seen from the following chart. The department continues to position itself so that it can continue to play a leading role acting as reference member state in the years ahead.

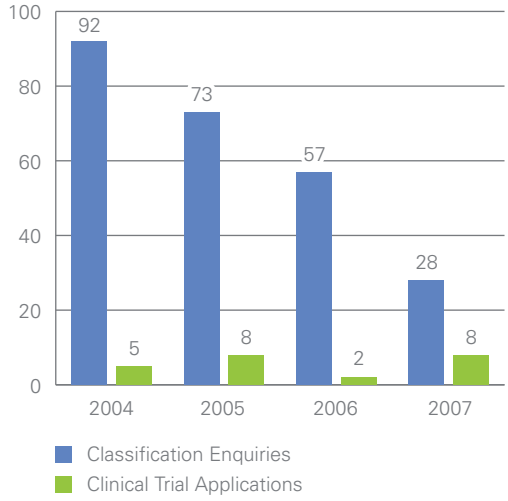
APPLICATIONS AS REFERENCE MEMBER STATE



During 2007, the number of applications for determination of a product as either within or outside the scope of the national legislation on animal remedies declined, continuing the trend of previous years. There were comparatively few clinical trial applications as seen in the chart on the next page.

Clinical trial applications are regulated by the Department of Agriculture, Fisheries & Food which seeks the advice of the IMB prior to granting approval for them.

APPLICATIONS FOR PRODUCTS FOR DETERMINATION OF THEIR MEDICINAL STATUS AND NUMBERS OF CLINICAL TRIAL APPLICATIONS



With a change to national legislation adopted in 2007, the IMB is now able to grant exemptions from the requirement for a marketing authorisation for animal remedies intended solely for aquarium fish, caged birds, homing pigeons, small rodents, ferrets and pet rabbits. In order to benefit from this legislation, applicants should apply to the IMB using the classification enquiry system. While no applications for exemption were received during 2007, it is expected that a number of such applications will be submitted to the IMB during 2008.

MANAGEMENT

A new management structure took effect in February 2007. This team is comprised of the Director of Veterinary Medicines and three section managers (Planning & Licensing, Quality, and Safety & Efficacy). This group spearheaded the development of new and significant changes in the business systems which underpin the management of applications within the department. Both pharmaceutical and immunological products now follow the same evaluation and management processes. New systems for the administrative management of applications and associated communications were also put in place. These new systems 'went live' in June and have proved highly effective. The department spent considerable time during the year updating its standard operating procedures which govern the authorisation procedures consequent to the changes in business processes and in accordance with corporate IMB standards. In addition, significant recruitment of scientific and non-technical personnel also took place. Notwithstanding the various internal initiatives within the department, an effective and successful year of outputs was recorded.

COMMUNICATIONS

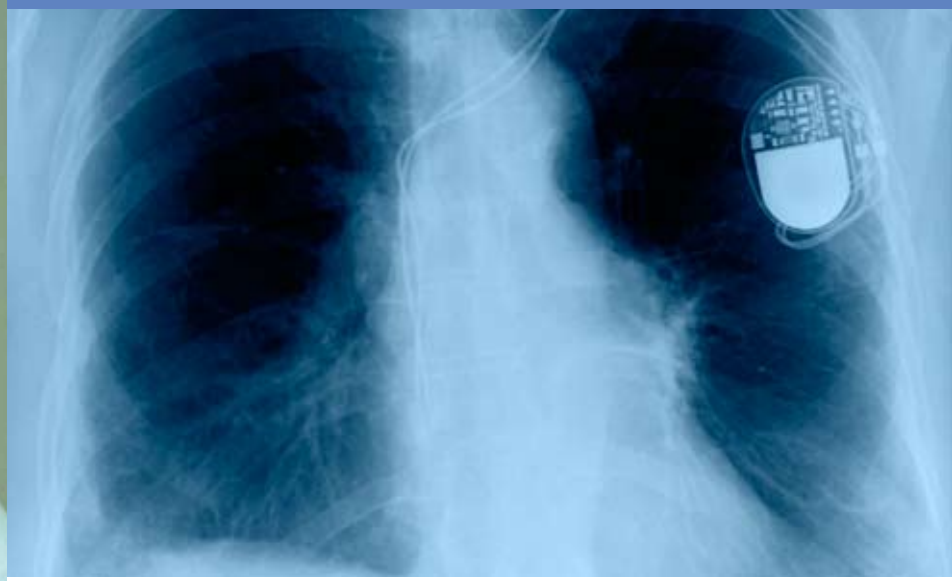
IMB staff held several meetings with the Department of Agriculture, Fisheries & Food, the Animal and Plant Health Association, other stakeholders and individual companies during 2007. The department also held a Vet Information Day and published four news articles relating to the regulation of veterinary medicines. The department participated in the development of a new IMB website. It hopes that this site will become the most authoritative and useful source of information on veterinary medicinal products in Ireland.

In December the department commenced a test phase of its automated email notification system for the validation and progression of applications to applicant companies. Emails generated from this system provide summary information on the status of the application as it progresses through various milestones of the evaluation procedure. On completion of the test phase, the system is expected to be rolled out to all applications in February 2008.

At an EU level, 2007 saw the publication of a report from the task force on availability of veterinary medicines in Europe http://www.hma.eu/203.html. This task force was chaired by the Director of Veterinary Medicines.

Through their involvement in committees of the European medicines network of regulatory agencies including the European Medicines Agency, personnel from the department played a useful role in influencing EU policies and in elaborating regulatory guidance. Recognising the strategic interest of the animal health industry in having as many shared products as possible between UK and Ireland, personnel from the department continued work with colleagues from the UK's Veterinary Medicines Directorate with the aim of achieving joint or dual labels of common products. Given the different legislation and structures which exist in the two territories, this remains a challenging but worthwhile objective for the IMB.

A significant development during the year was the elaboration of a revised IMB policy on the supply of veterinary vaccines. This policy was developed by a working group of scientific experts operating under the aegis of the IMB's Advisory Committee for Veterinary Medicines (ACVM). The objective of the working group was to review the available methods of supply of vaccines and prepare a guidance document on the most appropriate criteria to be considered when allocating vaccines to one of the available supply routes. The working group held consultations with interested parties and stakeholders. It received a total of 11 submissions and prepared a report for the ACVM in October. A further round of public consultation on the draft report yielded nine more submissions which were considered by the IMB before the final report was adopted in November. The report, together with a report on the outcome of the consultation process, is available on the IMB website. IMB policy on this matter will henceforth be in accordance with the conclusions of the report. The IMB wishes to thank the experts involved in developing the report and all those who took time to provide input into the process.



Ms. Ann O'Connor, *Medical Devices Director*

MEDICAL DEVICES

INTRODUCTION

The year 2007 was a busy and productive year for the medical devices department. Monitoring of safety issues on the marketplace continued to be a core focus of day-to-day activity. Significant activity took place in the areas of vigilance, compliance and clinical investigations.

During the year, the department implemented a major restructuring programme resulting in an organisational structure which more closely reflects its needs and facilitates further growth. A key element involved the introduction of a management team with responsibility for three core process areas, pre-market, post-market and audit. The new organisational model caters for an increased focus on operational management, supports increasing workload, improves the alignment of technical skills and resources, allows for an integrated focus on market compliance activities and facilitates the incorporation of new products and technologies.

The Advisory Committee for Medical Devices (ACMD) met three times in 2007. Topics under consideration included medical devices in the community setting, point-of-care testing, review of the medical devices directive and vigilance issues. The ACMD also assisted with the preparation of a safety notice in relation to medical devices prescribed for use in the community setting and it contributed to the development of the guidance note for ethics committees.

VIGILANCE

A total of 840 vigilance reports were received and assessed in 2007, representing a decrease on the 2006 figure of 993. This decrease was due to multiple factors including the continued low numbers of Competent Authority reports being circulated by Member States. It is anticipated that reports will increase significantly in 2008 as a result of the improved clarity in the revised guidance on the medical device vigilance system (MEDDEV 2.12-1 rev 5).

Some 456 vigilance reports were received from manufacturers, 308 were received from other regulatory agencies and 75 were received directly from medical device users. Class IIb general medical devices and general category *in-vitro* diagnostic medical devices (IVDs) represented the largest number of reports received, 243 and 159 respectively. An increase in the number of class I device issues was also noted.

Single use, non-active implantable and electro-mechanical medical devices represented the most common reports received per product family, which include devices such as, assistive technology devices, ophthalmic devices, e.g. contact lens solutions, and devices incorporating software, e.g. defibrillators. In the IVD area a large number of the reports related to clinical biochemistry and blood transfusion devices.

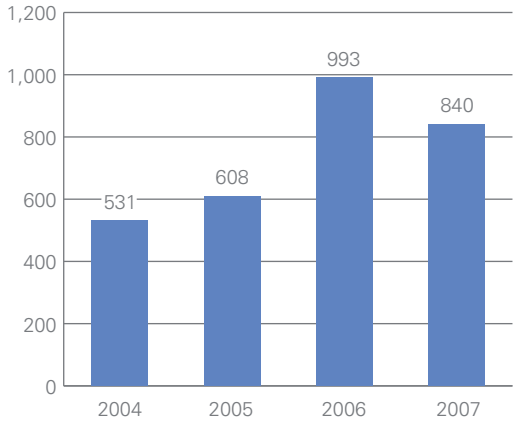
The principal issues encountered during 2007 included software problems and concern surrounding the maintenance and management of devices particularly in the area of technical aids for disabled people, walking frames and wheeled mobility devices. Other issues included mislabelling of IVDs.

RECALLS

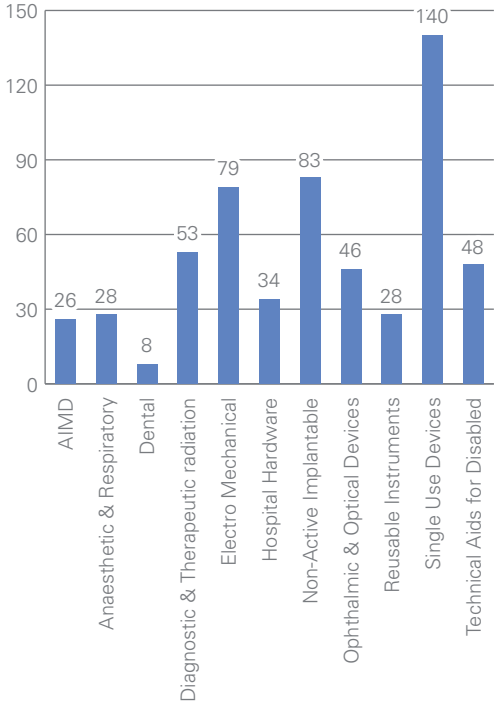
During 2007, the IMB received 333 field safety corrective actions relating to medical devices that directly impacted the Irish market. These resulted in a combination of 224 product removals, 119 field safety notices, 59 software upgrades and 29 hardware modifications. The implementation of corrective actions was closely monitored by the IMB.

In 2007, the IMB closely co-operated with other European Competent Authorities, the European Commission and medical device manufacturers on several major issues which needed input from a variety of stakeholders.

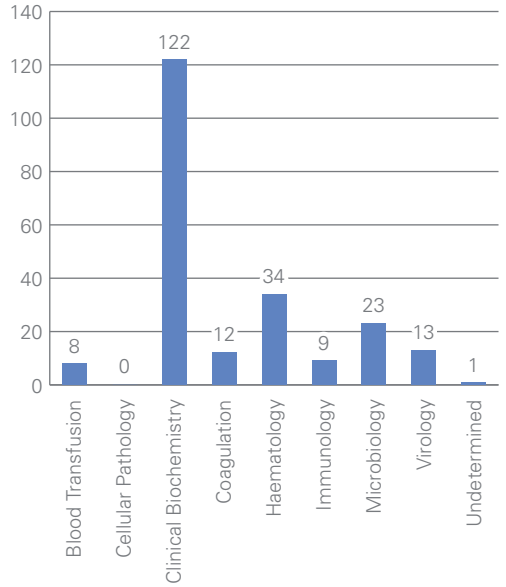
NUMBER OF VIGILANCE REPORTS RECEIVED DURING 2004 TO 2007



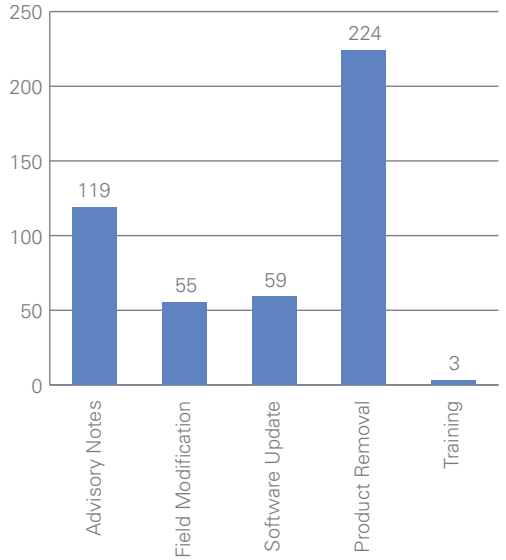
FAMILY GROUPS OF DEVICES IMPLICATED IN VIGILANCE REPORTS IN 2007 – GENERAL MEDICAL DEVICES AND ACTIVE IMPLANTABLE MEDICAL DEVICES



FAMILY GROUPS OF DEVICES IMPLICATED IN VIGILANCE REPORTS IN 2007 – *IN-VITRO* DIAGNOSTIC MEDICAL DEVICES



OUTCOME OF FIELD SAFETY CORRECTIVE ACTION IN 2007



NOTIFIED BODIES

The IMB conducted three surveillance audits on the Irish notified body, National Standards Authority of Ireland (NSAI), in 2007. The first audit conducted in early 2007 was a follow-up audit in relation to issues identified in audits of certification process and auditor performance in 2006. Two further surveillance audits to the medical device directive (MDD), the active implantable medical device directive (AIMDD) and the *in-vitro* diagnostic medical device directive (IVDD) took place. Of these two audits, one took place at the premises of NSAI in Ireland and the second at NSAI's office in the United States of America. All of the issues raised at these audits have been satisfactorily addressed.

Two satisfactory observed audits were conducted on the NSAI auditors to the MDD and IVD in 2007.

A peer review of the IMB performance was undertaken by the Danish Medicines Agency in 2007. This peer review system has been established by the European Union's Notified Body Operations Group, a group in which the IMB is an active participant. A report was completed and the findings were shared by the Danish Medicines Agency which revealed many common issues and approaches with regard to notified body management.

CERTIFICATES OF FREE SALE

In 2007, 432 certificates of free sale for medical devices were issued, which represented a 24% increase over 2006 figures. In 2007, the quality of the applications and related documentation for certificates of free sale received from medical device manufacturers were a cause for concern. The IMB highlighted these concerns to the trade federations and relevant manufacturers to seek rectification and improvements.

REGISTRATIONS

There were 261 new notifications/amendments in 2007 to the register for medical devices. A total of 139 IVD medical devices and 122 GMDs were registered. The number of new device manufacturers/ organisations registered was 32.

CLINICAL INVESTIGATIONS

During 2007, three new clinical investigation applications for general medical devices and amendments to four previous clinical investigation applications were received under S.I. No. 252 of 1994. One application for a device for use on compassionate grounds was received.

The IMB continues to promote an open and transparent approach to clinical investigation applications. It encourages clinical investigation sponsors to meet with the IMB prior to application to discuss the requirements and the process. During 2007, the IMB continued to work with clinicians interested in the area of medical device research to clarify legislative requirements and discuss issues relevant to Irish investigators. An informative guidance document on medical device investigations aimed at research Ethics Committees was completed and will be published in early 2008.

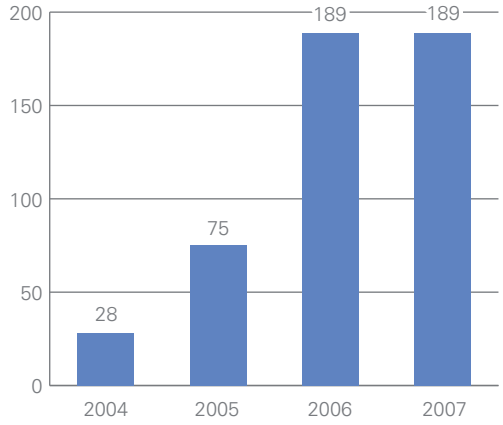
CLASSIFICATIONS

Fifty classification queries were received in 2007, 54% originating from other Competent Authorities and 20% originating from external stakeholders. A number of these queries require further discussion at the European Medical Devices Expert Group Classification/Borderline Working Group.

POST MARKET SURVEILLANCE ACTIVITIES

During 2007 there were 189 compliance cases opened, equal to the 2006 figure. Some 65% related to the withdrawal or suspension of a CE certificate by notified bodies throughout Europe for a variety of medical devices. Missing or incorrectly attached CE marking accounted for another 6% of cases. Other problems identified and investigated as part of compliance cases in 2007 included labelling, classification and registration issues. Requests for assistance from other European Competent Authorities accounted for 4% of cases. In 2007 there were also a small number of compliance cases relating to counterfeit medical devices investigated.

NUMBER OF COMPLIANCE CASES OPENED



The IMB's proactive compliance activities in relation to procedure packs and continuous positive airway pressure machines were concluded in 2007. From this recommendations were made to develop legislation governing the regulation of distributors of medical devices. Discussions are ongoing with the Department of Health and Children in this regard.

The second phase of this compliance activity relating to procedure packs focussed on medical device systems during 2007. A review of the IMB register to identify systems manufacturers was undertaken and compliance visits conducted. Non-compliances were raised with the manufacturers and corrective actions identified. It is expected that this activity will be completed during 2008.

The department also contributed to the European Commission study on distribution channels for medical devices: combating counterfeit medical devices and safe medical devices in the distribution chain.

In 2007, four post-market surveillance audits were carried out. Two manufacturers were audited following issues arising from the marketplace, while the remaining two audits were proactive post market surveillance audits. The programme of custom-made device audits continued in 2007 and a total of 20 audits took place.

PUBLICATIONS

In 2007, the following guidance documents were published or updated for stakeholders:

Guidance Note 7:
The Vigilance System for Medical Devices.

Guidance Note 8:
Field Safety Corrective Actions for Medical Devices and *In-Vitro* Diagnostic Medical Devices.

Guidance Note 13:
Incident Reporting for GMD's and AIMD's.

Guidance Note 18:
Guide to Adverse Incident Reporting for IVD's.

The IMB safety notices which were circulated in 2007 were:

IMB Safety Notice SN2007(01):
Shelhigh Implantable Devices

IMB Safety Notice SN2007(02):
Clearview HCG Pregnancy Test Kit

IMB Safety Notice SN2007(03):
Scholl Freeze Verruca and Wart Remover

IMB Safety Notice SN2007(04):
Mini lift stand Aid

IMB Safety Notice SN2007(05):
EVAQUA Breathing Circuits

IMB Safety Notice SN2007(06):
Medical Devices Recommended by Healthcare Institutions for Use in a Community Setting

A position paper was published in 2007 on the area of manufacturing/adaptation of splints and splinting material by professional users.

Three medical device newsletters were issued during 2007 which continue to be well received by stakeholders. Many contributions were received to newsletter articles from the academic and healthcare sectors and from industry, highlighting many different medical device issues.

COMMUNICATION

An information day was held on the 'Revisions to the Medical Devices Directive 93/42/EEC and Vigilance MEDDEV'. This event was attended by manufacturers, distributors, healthcare professionals and various other interested stakeholders. The mix of presentations from the IMB, the Industrial Development Agency, the European Commission and the German Competent Authority, BfArM, provided participants with some key practical information and advice.

In 2007 the IMB played an active role in the Consultative Group for point-of-care testing with the Faculty of Pathology, the Academy of Medical Laboratory Science and the Association of Clinical Biochemists in Ireland to develop guidance for the safe and effective management and use of point-of-care testing in the healthcare setting. The guideline will be published in Spring 2008.

EUROPEAN ACTIVITY

During 2007, the IMB participated in a number of European meetings of the Medical Devices Expert Group and its related working groups. It contributed to the development of the revised guideline on the vigilance system for medical devices MED.DEV 2.12-1 rev 5. This guidance document was published by the European Commission in April 2007 and is available on their website. The IMB proposed a new communication system between Competent Authorities in relation to vigilance issues. This was agreed, piloted and subsequently adopted.

The Classification and Borderline Working Group also met in 2007. Decisions emanating from this group were published and can be found on the EU Commission website. Contribution continued to the discussions in the group in relation to the appropriate classification of products used in *in-vitro* fertilisation and assistive reproductive therapies.

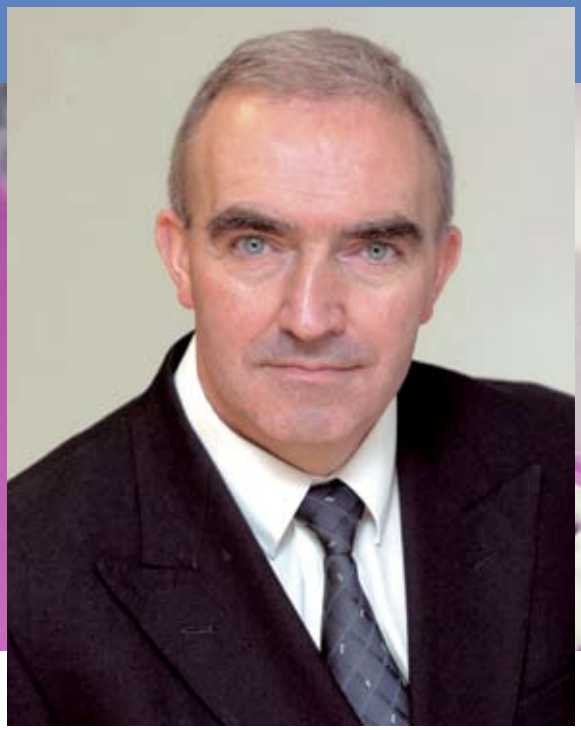
Ireland was appointed to the chair of the Compliance and Enforcement working group of the EU Competent Authorities for medical devices. The focus of this working group is to provide a forum for co-operation between Member States and encourage the development of harmonised best practice at EU level.

The IMB continued its participation in the Clinical Evaluation Task Force which included involvement in a small subgroup to draft a checklist for Competent Authorities regarding clinical investigation notification reviews. In 2007, contributions were made to the development of the task force's guidance document on clinical investigations involving coronary stents. The task force was also involved in discussions with the European Medicines Agency (EMEA) on a proposed document on requirements for medicinal substances when used in the context of drug-eluting stents.

The IMB participated in the EU Commission workshop and resulting working group which proposed to classify variant Creutzfeldt-Jakob disease (vCJD) assays as Annex II, List A devices in accordance with the IVD Directive 98/79/EC. This was broadly supported at EU level but requires the drafting of a minimum technical specification for all vCJD assays.

COSMETICS

In October 2007, a cosmetics project officer was appointed to the department to determine the legislative obligations and responsibilities of the IMB in assuming the role of Competent Authority for cosmetics in Ireland. This has involved close interaction with the current Competent Authority, the Department of Health and Children and other stakeholders. The activities of the European Council Working Group on cosmetics are being closely monitored, as a recast of the cosmetics directive is proposed for adoption which aims to strengthen the legislation in a number of key areas including definitions, good manufacturing practice and post market surveillance. The IMB also attended as an observer to a number of European meetings relating to cosmetics including the Standing Committee on Cosmetic Products, the Working Group on Cosmetic Products, and the Platform of European Market Surveillance Authorities in Cosmetics.



Mr. John Lynch, *Director of Compliance*

COMPLIANCE

INTRODUCTION

The year 2007 was a productive year for the department which witnessed increased activities across its five sections of Licensing, Inspection, Market Compliance, Enforcement and Planning.

Changes necessitated by the new Medicinal Products Regulations (Control of Manufacture, Control of Wholesale Distribution, Control of Placing on the Market and Control of Advertising) and by the European Communities (Animal Remedies) (No. 2) Regulations, 2007, were implemented. A further set of Regulations relating to the phased implementation of the Tissues and Cells Directive were also put in place.

Outlines of the key activities and relevant findings are set out below under each of the sections.

LICENSING

During 2007, there was an increase of 24% in licensing activities. The licence/authorisation applications received covered the range of manufacturers of human and veterinary medicines, wholesalers (human), manufacturers of investigational medicinal products, blood establishments and tissue establishments. In total, 30 new licences/authorisations were issued, four of which were blood establishment authorisations. One wholesaler's authorisation was revoked. In relation to tissue establishments, 20 applications were received in 2007.

A total of 781 variations were processed and issued, compared to 485 in 2006 and 452 in 2005. Technical variations increased by 82%.

The total number of licences/authorisations in force is presented below.

Total Number of Licences/ Authorisations	2005	2006	2007
Human	85	82	85
Veterinary	30	30	28
Investigational Medicinal Products	27	36	43
Wholesaler	139	148	127
Blood Establishments	0	1	4
Tissue Establishments	0	0	0
Laboratory Certificates	0	8	12

The licensing section continued to support the inspection section in relation to the issuing of GMP certificates within 90 days following an inspection.

Controlled Drugs Licensing

During 2007, a total of 1,665 controlled drugs licences were issued compared to 1,585 issued in 2006. Segmented activity levels are set out below.

Controlled Drugs Licensing Activity	2006	2007
Registration	26	19
Export & Import	944	964
Annual – New	20	19
Annual – Renewal	152	171
LONO	431	473
Pilgrims	12	14
Hemp	0	5

Export Certificates

There was an output of 1,758 export certificates as set out below.

Product Certification Activity	2005	2006	2007
Certification of Documents	305	389	316
Certificates of Free Sale	18	35	52
Certificate of Good Manufacturing Practice for Finished Product Manufacturers	181	224	200
Certificate of Good Manufacturing Practice for Active Substance Manufacturers	38	43	62
Certificate of a Pharmaceutical Product for Human Use	974	1193	941
Certificate of a Pharmaceutical Product for Veterinary Use	110	97	105
Other	103	69	82
Total	**1,729**	**2,050**	**1,758**

EU PROJECTS

During the year, the licensing section and the IT and Change Management Department continued to participate in the Eudra GMP EMEA project group. The purpose of this group is to establish a database of all manufacturers of medicinal products in the European Economic Area (EEA). The database was launched during April 2007 and contains information on all manufacturing importation authorisations (MIAs) issued by EEA competent authorities. It also contains information on GMP certificates, which Member States issue following each GMP inspection. EEA competent authorities currently have full access to the EudraGMP database.

Other features planned for future releases of the EudraGMP include:

- Member States will be alerted in cases of GMP non-compliance, faulty manufacture, suspension and/or revocation of MIAs.
- Access by the general public to MIAs and certain GMP certificates, with the exception of any information of a commercially and/or personally confidential nature
- Discussions with MRA partners are ongoing and the aim is to eventually eliminate the paper exchange of certificates
- Non-compliance information will also be included in the database if the outcome of the inspection is that the manufacturer does not comply with GMP.
- Sharing of information on planning inspection schedules in third countries (i.e. outside the EEA) will facilitate best use of resources and avoid duplication of inspections in third countries.

INSPECTION

Good Practice Inspection Activities

The inspection function carried out 256 inspections in 2007 across the four operational areas:

- Good Manufacturing Practice (GMP),
- Controlled Drugs and Good Distribution Practice (CD/GDP),
- Good Clinical Practice and Pharmacovigilance (GCP/PhV), and
- Blood and Tissues

Good Manufacturing Practice (GMP)

In 2007, 108 GMP inspections were carried out. These included ten inspections in third countries, six of which were carried out at the request of the European Medicines Agency (EMEA) for centrally authorised products, and one inspection at the request of the European Directorate for Quality of Medicines of an active substance manufacturing site named on a certificate of suitability to the monograph of the European Pharmacopoeia. The remaining sites are included on Irish manufacturers' authorisations as third country manufacturing sites.

Controlled Drugs

Twenty one controlled drugs inspections were conducted, extending the roll-out of the inspection programme to include all licensed distributors and manufacturers of controlled drugs.

Good Distribution Practice (GDP)

Sixty inspections were carried out at wholesale premises to evaluate compliance with the GDP requirements and to assess new authorisation applications and variations.

In October, the IMB hosted an Information Day for wholesalers and distributors involved in the distribution of medicinal products for human use in Ireland.

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 or EU marketing authorisations.

During the year, 14 GCP inspections were carried out. Nine of these were carried out at sponsor and investigator sites in Ireland and five were conducted at study sites abroad.

Pharmacovigilance Inspections

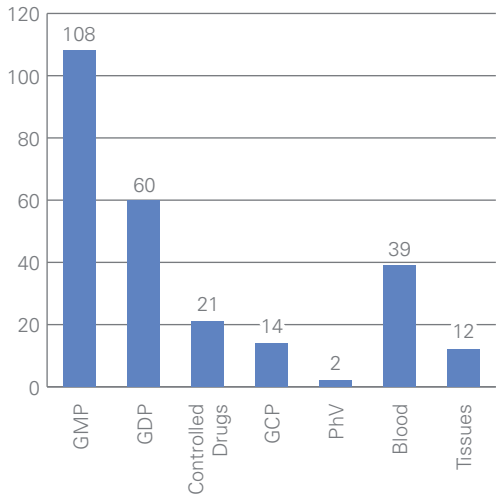
Two pharmacovigilance inspections were carried out in 2007: one at an Irish based marketing authorisation holder's facility and the other at the European site where the Qualified Person for Pharmacovigilance was located.

BLOOD ESTABLISHMENT AND BLOOD BANK INSPECTION

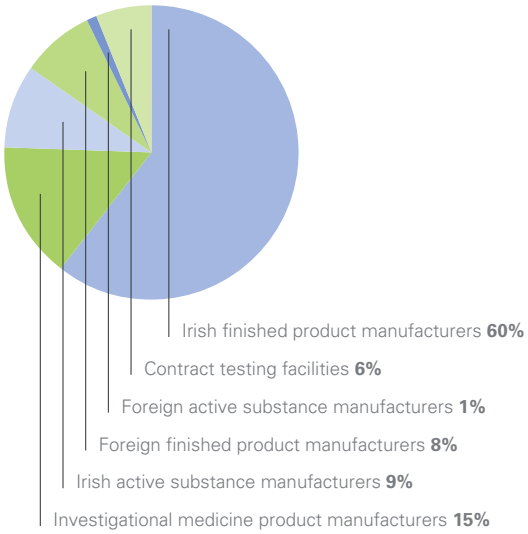
Nine blood establishment inspections were completed. The first hospital blood bank annual reports were submitted by 73 blood banks and facilities in January. Following a review of the reports, 30 blood bank inspections were completed by the IMB.

Tissues Establishment inspections

Twelve tissue establishment inspections were completed.



GMP INSPECTIONS BREAKDOWN – 2007



MARKET COMPLIANCE

In 2007, the quality defect and recall and the sampling and analysis programmes underwent significant expansion, and new areas of activity were also developed. These included a pilot programme of regulatory compliance inspections, and a notification system for the supply of exempt medicinal products.

REGULATORY COMPLIANCE INSPECTIONS

The purpose of this pilot programme was to facilitate the development in 2008 of a defined programme for inspecting the premises of marketing authorisation holder companies. This programme will enable the IMB to inspect key areas of activity at marketing authorisation holder companies.

During the pilot phase, two inspections were carried out, focusing on areas that had the highest potential to impact on the quality, safety and safe use of medicinal products. These included advertising and promotional activities, the management of registered product information, the management and communication of regulatory commitments and regulatory changes, implementation of changes to product information and product labelling in the marketplace and the provision of a medical information service for healthcare professionals.

Points for improvement identified by the IMB were communicated to pharmaceutical industry associations in 2007.

EXEMPT MEDICINAL PRODUCTS

In 2006, the Department of Health & Children provided funding to the IMB for a study into the use of unauthorised medicinal products in Ireland. A project officer was appointed and an extensive programme of research and stakeholder consultation undertaken.

The study, which continued throughout 2007, also encompassed the development of a notification system whereby companies and other parties importing unauthorised medicinal products into Ireland for supply as exempt medicinal products, are required to submit product information to the IMB. The primary purpose of this notification system is to facilitate the recall of exempt medicinal products when quality defect and other issues arise. The notification system was provided for in the Medicinal Product Regulations that were published in July 2007 and the system is due to be implemented from the beginning of 2008. A report on the project was at an advanced stage of drafting by year-end.

THE SAMPLING & ANALYSIS PROGRAMME

A risk-based approach is applied to sampling and analysis activities. This programme covers authorised human and veterinary medicinal products, active substances, products intended for export, enforcement-related samples, and borderline medicinal products. Products which are sampled are analytically tested and/or have their packaging and labelling examined.

In 2007, a total of 469 medicinal product and other product types were evaluated; 174 Irish marketplace medicinal products and 14 other samples were analytically tested, while examination of 281 samples focused on labelling examinations. This represented an increase of approximately 44% over 2006 figures.

Analytical Testing Activities

The table below provides details of the number and type of samples that were subjected to analytical testing during 2007.

Product categories subjected to Analytical Testing	Number of samples analysed
PHYSICO-CHEMICAL ANALYSIS:	
■ Active substances	2
■ Nationally-authorised medicinal products	44
■ Parallel import authorisations	3
■ Medicinal products authorised via the Mutual Recognition Procedure	20
■ Centrally-authorised medicinal products	5
■ Products manufactured for export	3
■ Borderline products	11
■ Enforcement-related samples	80
MICROBIOLOGICAL ANALYSIS:	
■ Nationally-authorised medicinal products	6
EU-collaborative Market Surveillance Samples	*9*
Icelandic Medicines Control Agency samples	*5*
Total	188

The analytical testing programme was assigned to pro-active market surveillance work (42%), analysis of enforcement-related samples (43%), and problem investigation work (15%).

Packaging and Labelling Examination

The table below shows that a total of 281 authorised medicinal and other products were sampled for packaging and labelling examination.

The programme was designed to reflect the fact that packaging and labelling errors and non-compliant labelling practices account for a large number of quality defect and recall issues on an annual basis. The programme also addresses medication error issues that may be related to product labelling, as well as checking for the presence of safety information and warning statements on product labelling.

Description of products examined	Number of samples examined
Medicinal and other products subjected to risk-based compliance monitoring for packaging and labelling attributes	210
Medicinal and other products subjected to Braille-compliance checks	27
Medicinal products associated with quality defects and/or recall issues	12
Medicinal and other products associated with IMB Classification Committee work	32
Total	281

Proactive market surveillance work accounted for 39% of the products sampled in this area.

The programme is also designed to rapidly react to product complaints and other marketplace compliance issues which may affect the safety and safe use of medicinal products. This accounted for 61% of the programme.

Participation in EU Co-ordinated Market Surveillance Activities

The IMB actively participated in various EU-wide sampling and analysis programmes. Samples from four batches of a centrally authorised product taken from other EU countries were analysed on behalf of the IMB by the Public Analyst's Laboratory, Galway, which is designated as an Official Medicines Control Laboratory (OMCL). Samples of five other centrally-authorised products were taken from the Irish market by the IMB for testing by OMCLs in other EU countries.

Five mutual recognition products were analysed by the Public Analyst's Laboratory, on behalf of other EU Member States, and the IMB also arranged for the analysis of 13 medicinal products, sampled from the Irish market, by other EU OMCLs.

Principal Findings from the 2007 Sampling and Analysis Programme

- Out-of-specification results affecting four nationally-authorised medicinal products. One product did not comply with its assay specification, and three failed to comply with their registered appearance specification
- Six analytical test methods, used to assess the quality of 11 medicinal products, were found to be deficient.
- Deficiencies were identified in packs of medicinal products examined for Braille compliance
- Deficiencies were identified in the quality of over-labelling associated with parallel imported products

Packaging and labelling complaints associated with medication errors were followed up with the marketing authorisation holders for the products concerned and, in several cases, changes were made to the product labelling.

ACKNOWLEDGEMENT

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 sampling and analysis programme.

THE QUALITY DEFECTS & RECALL PROGRAMME

Quality Defects in Human and Veterinary Medicinal Products

A total of 473 quality defects in human and veterinary medicinal products were reported to, or identified by, the IMB in 2007. This represents a substantial increase (27%) over the number of quality defects in 2006. This increase is largely due to work carried out by the market compliance section in promoting the reporting of quality defect issues, particularly at manufacturer/marketing authorisation holder level.

A total of 446 reports concerned medicinal products for human use, and 27 concerned veterinary medicinal products.

A total of 173 reports of critical quality defects were received, or identified in 2007. This represents an increase of 106% compared with 2006 figures. This increase was partly attributed to a sharp increase in the number of notifications of quality defects received from other Competent Authorities via the Rapid Alert network, as well as a significant increase in the number of reports received from pharmaceutical companies.

Of the 173 reports, 65 directly affected Ireland, meaning that the defective batch of product in question was either on the Irish market and/or manufactured in Ireland. This represented a threefold increase in the number of critical quality defects which affected Ireland compared with 2006 figures.

These 65 reports concerned medicinal products for human use. The issues of concern related to:

- Product contamination
- Various types of packaging and labelling issues
- Concerns in relation to efficacy
- Product mix-up
- Serious adverse reaction issues requiring marketplace actions
- Breach of cold chain controls in the product distribution system
- Lack of sterility assurance for products intended to be sterile
- The development of an unfavorable benefit/risk ratio as a result of new safety-related information
- Undeclared active constituent
- Other product safety concerns
- Counterfeit product issues*

** Two counterfeit products identified on markets other than Ireland were found to be genuine medicinal products manufactured at Irish manufacturing facilities, but the packaging components had subsequently been counterfeited/tampered with.*

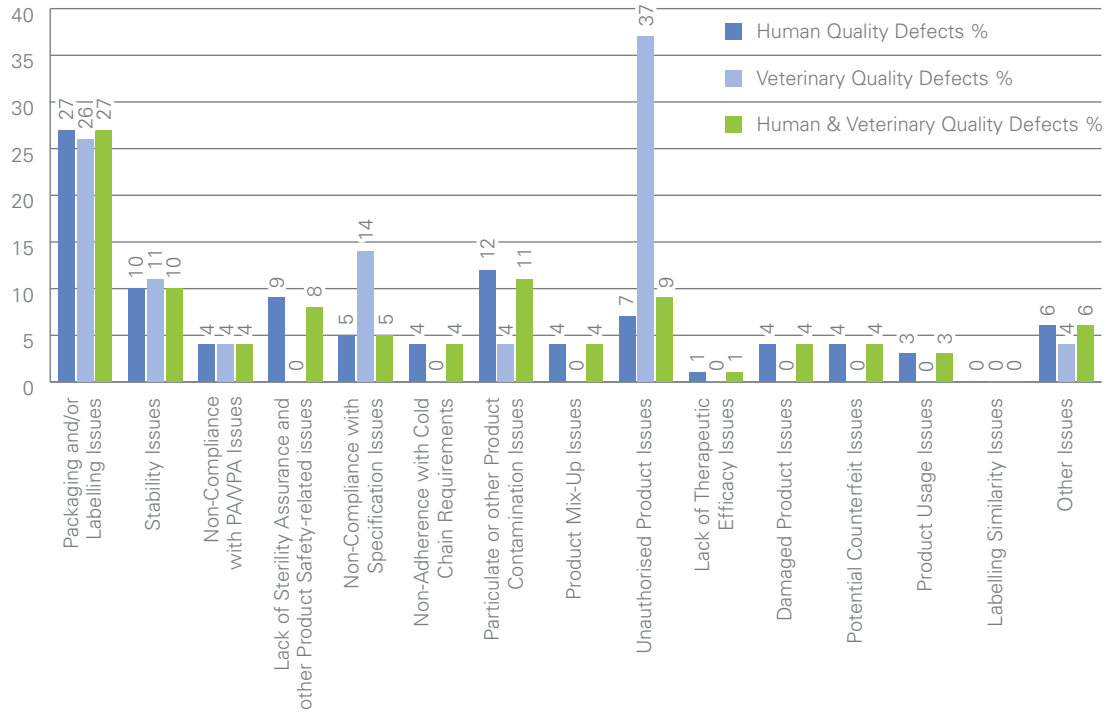
For 30 of the 173 critical quality defect reports, it was not possible to conclusively determine whether the reports concerned products that were on the Irish market. This was due to the nature of the products in question, and the manner in which they are often distributed, i.e. via the internet or other unauthorised supply routes. These cases concerned certain counterfeit-related reports, as well as unauthorised medicinal products containing undeclared active ingredients.

Year	2004	2005	2006	2007
Minor Quality Defects	80	40	40	80
Major Quality Defects	167	199	238	216
Critical Quality Defects	50	66	84	173
Number of Quality Defect Reports Not Justified	13	22	9	4
Total Number Quality Defects Reported/Identified for the Year	**310**	**327**	**371**	**473**

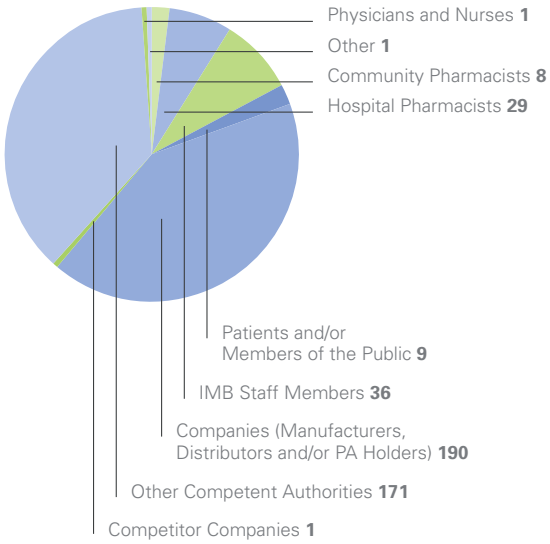
171 quality defect and recall notifications were received from Competent Authorities and OMCLs in other countries. Each of these reports was investigated to establish the potential implications of the report for the Irish market, and, where appropriate, risk-based follow up was undertaken.

AREAS OF QUALITY DEFECTS 2007

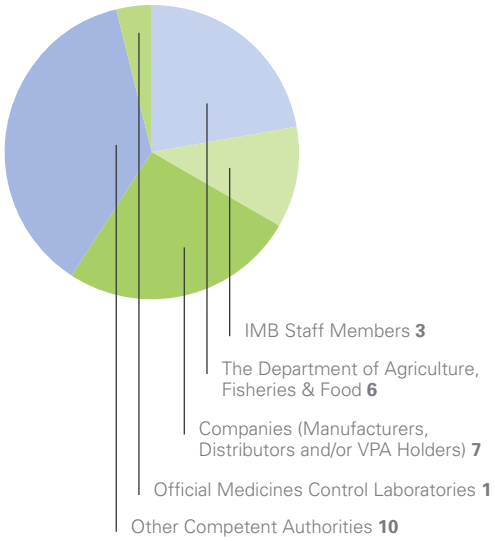
	Human Quality Defects %	Veterinary Quality Defects %
Packaging and/or Labelling Issues	27	26
Stability Issues	10	11
Non-Compliance with PA/VPA Issues	4	4
Lack of Sterility Assurance and other Product Safety-related issues	9	0
Non-Compliance with Specification Issues	5	14
Non-Adherence with Cold Chain Requirements	4	0
Particulate or other Product Contamination Issues	12	4
Product Mix-Up Issues	4	0
Unauthorised Product Issues	7	37
Lack of Therapeutic Efficacy Issues	1	0
Damaged Product Issues	4	0
Potential Counterfeit Issues	4	0
Product Usage Issues	3	0
Labelling Similarity Issues	0	0
Other Issues	6	4
	100	**100**



SOURCES OF HUMAN MEDICINAL PRODUCT QUALITY DEFECTS



SOURCES OF VETERINARY MEDICINAL PRODUCTS QUALITY DEFECTS



Online Reporting

In an effort to promote and encourage the reporting of quality defects, particularly by community pharmacists, the IMB established an online reporting mechanism on its website. www.imb.ie. It is hoped that this will make it easier for pharmacists to report quality defects to the IMB. The IMB wishes to also remind pharmacists that the postage paid quality defect report card is also a convenient option for reports and these report cards are available upon request from the IMB's Market Compliance section.

Recalls of Human and Veterinary Medicinal Products

Recalls from the Irish marketplace involving a batch or batches of a medicinal product occurred in approximately 21% of the quality defect cases. (This was similar to the 20% figure for 2006.)

A total of 97 recalls of medicinal products were carried out of which 88 related to human medicinal products, and nine related to veterinary medicinal products.

BREAKDOWN OF HUMAN MEDICINAL PRODUCT RECALLS FROM THE IRISH MARKET

Year	2004	2005	2006	2007
Packaging and/or Labelling Issues	19	10	14	21
Stability Issues	9	7	3	3
Non-compliance with MA Issues	4	6	0	5
Sterility Assurance issues and various other Product safety Concerns	5	13	8	13
Non-compliance with Specification Issues	2	3	4	1
Non-adherence with Cold Chain Issues	0	1	0	19
Particulate or other Contamination Issues	1	1	4	12
Product Mix-Up Issues	1	3	3	1
Unauthorised Product Issues	14	20	11	4
Lack of Therapeutic Efficacy Issues	0	0	0	3
Damaged Product Issues			3	1
Product Usage Issues			5	1
Other Issues	8	4	1	4
Total Number	**63**	**68**	**56**	**88**

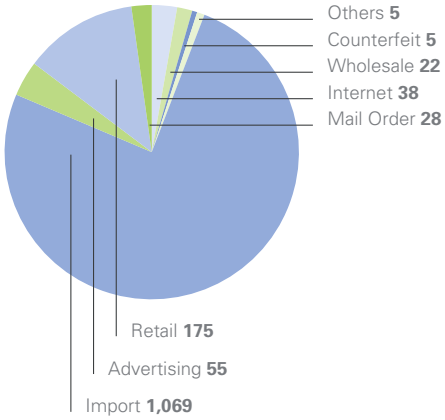
BREAKDOWN OF VETERINARY MEDICINAL PRODUCT RECALLS

Year	2004	2005	2006	2007
Packaging and/or Labelling Issues	8	3	1	2
Stability Issues	0	0	1	0
Non-compliance with VPA Issues	0	0	0	0
Sterility Assurance issues and various other Product safety Concerns	0	1	0	0
Non-compliance with Specification Issues	2	1	0	2
Particulate or other Contamination Issues	0	0	0	0
Product Mix-Up Issues	0	0	0	0
Unauthorised Product Issues	8	1	0	4
Other Issues	1	0	0	1
Total Number	**19**	**6**	**2**	**9**

ENFORCEMENT

The IMB's Enforcement section initiated 1,397 cases involving breaches of medicinal product legislation during 2007, compared to 469 in 2006. The number of enforcement cases closed in 2007 was 866 as compared to 797 in 2006.

ANALYSIS OF ENFORCEMENT CASE ACTIVITY



During 2007, the IMB detained a total of 88,279 tablets, 106,443 capsules, 22.5 litres of liquids and 40 kg of creams. The substances detained include diazepam, zopiclone, *tribulus terrestris*, ephedrine, yohimbine, sildenafil citrate, tadalafil and other erectile dysfunction formulations, anti-depressants, antibiotics, corticosteroids, weight loss products and skin lightening products.

In 2007, prosecutions were initiated at the District Court (Dublin) against six retail outlets for breaches in relation to the sale of paracetamol containing products. Three other prosecutions related to the supply of prescription only medicinal products. A conviction was recorded at Naas District Court for the unauthorised supply of anabolic steroids by mail order.

In a case resulting from a joint Garda – IMB investigation, and prosecuted by the Director of Public Prosecutions, a conviction on indictment was recorded at the Dublin Circuit Court and a custodial sentence handed down for the supply of unauthorised medicinal products (anabolic steroids) by mail order.

Authorised Officers from the IMB, Health Service Executive (HSE) and the Pharmaceutical Society of Ireland (PSI) carried out joint inspections in relation to a number of pharmacies.

National and international liaison between the IMB and other enforcement agencies, particularly Revenue Customs, in Ireland and abroad has enabled the IMB to co-operate to stem the unauthorised flow of illegal medicinal products and medical devices into and out of Ireland. The greatest levels of unauthorised supply into Ireland of unauthorised medicinal products were from India and China.

During 2007, the IMB contributed to the following international meetings in relation to enforcement matters: WHO/IMPACT (International Medical Product Anti-Counterfeiting Task Force) 2nd General Meeting; The Council of Europe Group of Specialist on Pharmaceutical medicines Anti-Counterfeiting; The Permanent Forum on International Pharmaceutical Crime; The Heads of Medicines Agencies Working Group of Enforcement Officers.

PLANNING

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

The main focus of the Planning section in 2007 related to the compilation of the inspection programme. It was also involved in the co-ordination of several training and information sessions including the GDP Information Seminar which took place in October 2007. This was attended by over 150 delegates from the industry.

Ms. Suzanne McDonald, *Director of IT and Change Management*

INFORMATION TECHNOLOGY AND CHANGE MANAGEMENT

INTRODUCTION

The Information Technology and Change Management Department plays a key role in supporting the IMB's objectives through the delivery of both technology and business services. The principal areas managed by this department are technology and communication services together with management of the IMB's change management programme.

The IMB has a well established change management programme with a strong focus on continuous improvement. Examining and implementing mechanisms to enhance business processes has been a fundamental activity within the organisation since 2003.

OVERVIEW – 2007

The department's primary focus is the provision of technical support services to over 200 staff. These support services include technology procurement, installation and management together with first and second line helpdesk functions. The department also has a clinical database administration role. Specialist skills in network, communication and security management also reside within the department along with project management, web and application development expertise.

The year 2007 saw further industry uptake on the Regulatory Information Online (RIO) system. This extranet service has proved very popular with online tracking and application submission functionality. Eight web-based training sessions for industry were held over the course of the year. Further development of the service is planned for 2008 and organisations are encouraged to register their interest in this system by contacting the IMB at helpdesk@imb.ie.

In line with plans for the year the IMB launched its new website www.imb.ie. The new site provides enhanced reporting mechanisms for adverse reactions and quality defects associated with medicines and medical devices.

The IMB is active at both national and European level and this involvement is reflected in the IT & Change Management Department's participation in a wide range of European technology initiatives. During 2007, the department was represented in eight different IT projects at EU level. These projects range from telecommunications projects (EudraNet) through to the development of centralised portals providing medicines information (EudraPharm).

The IMB's use of workflow technology to assist its operations has attracted the interest of many international regulatory bodies over the past number of years. This trend continued in 2007 with visits from a number of regulators keen to explore this option for their own organisations.

The provision of training to IMB personnel is an important aspect of the departments work and over 100 members of staff received training in 2007.

TECHNOLOGY ACTIVITIES

Drug Safety Management

The IMB continues to participate actively in the EudraVigilance Technical Implementation Group at the EMEA. Work commenced on the procurement of a new drug safety management system in 2007 with a view to development in 2008. New initiatives in pharmacovigilance reporting at EU level have brought challenges at national level with a consequent need to upgrade supporting systems.

Human and Veterinary Medicines

Workflow systems were subject to further upgrades in both the human and veterinary licensing areas during 2007. The RIO system continued to bring new opportunities for process improvement. The system allows registered users to submit applications to vary product authorisations via a secure web location. Some of the benefits of the online system include a significant reduction in the volume of paper generated and ease of use combined with an online tracking facility to determine the progress of ongoing applications.

The IMB plans to extend the RIO system to the veterinary medicines authorisation areas during 2008.

New IMB Website

The IMB website at www.imb.ie received a welcome upgrade in 2007. The new site has been redesigned to reflect the key activities within the organisation. In addition to the new 'look and feel' the site contains improved search functionality together with comprehensive information on licensed medicines for human and veterinary usage in Ireland.

The new site also includes online forms to assist in the reporting of adverse reactions and potential quality defects for medicines, medical devices, tissues and cells. Users are encouraged to register on the new website and to utilise the reporting forms wherever possible.

Websites are increasingly used as a mechanism to deliver important information in a timely fashion. The new IMB website has been designed with this in mind and the home page reflects current safety topics. Those interested in receiving the latest medicines or medical device safety notifications via email or SMS messaging should register with the new website.

Feedback from users has been very positive and comments or suggestions for further improvement are welcomed at helpdesk@imb.ie.

Medical Devices Department

Case management tools to assist in the tracking and review of medical device workload started development during 2007 with a view to implementation in early 2008.

Compliance Department

The procurement of new technology to support the work of the compliance department commenced in 2007. Systems to support the licensing of manufacturing and wholesale sites, inspection, market compliance and enforcement will be developed over the coming 12-month period.

Technical Support – External

In 2007, the IT & Change Management Department provided technical support to both the Maltese and Norwegian agencies.

EU Projects

The department was active in a wide range of EU Telematics projects during 2007. These included:

- EudraVigilance (Drug Safety)
- EudraPharm (Medicinal Product Information)
- EudraGMP (Good Manufacturing Practice)
- EudraCT (Clinical Trials)
- EudraNet (Secure network communications)
- eSubmissions (Electronic submissions)
- EU Datawarehousing/Reference Data Modelling
- Product Information Management (PIM)

Change Management Programme

The IMB's change management programme continued throughout 2007. The organisation has a strong focus on quality and remains committed to improvement via a process of continual review.

In 2007, the Medical Devices Department successfully implemented new organisational arrangements following on from an operational review conducted in 2006. The Veterinary Medicines Department also underwent a review in 2006 and the subsequent changes to the departmental structure went into operation in the first quarter of 2007.

In the human medicines area a review of the organisational arrangements for safety-related issues was undertaken in autumn 2007. The findings from the study were considered in November 2007 and it was decided to develop a new position with core responsibility for human product safety matters across the organisation. The implementation of this role and ancillary activities will take place in 2008 following the development of a comprehensive project plan.

Dr. Mike Morris, *Senior Scientific Advisor*

Dr. Caitríona Fisher, *Quality Manager*

CHIEF EXECUTIVE'S OFFICE

PERMANENT SECRETARIAT OF THE HEADS OF MEDICINES AGENCIES

The personal assistant to the Chief Executive continued as a member of the HMA Permanent Secretariat and is one of the two remaining original members of the group, giving 50% of her time to this task.

The HMA Management Group (MG) held 21 meetings in 2007 (mainly by teleconferences) which the Permanent Secretariat (PS) also attended and supported with agenda setting and minutes. The PS also held meetings on a regular basis between the MG meetings. The Permanent Secretariat also attended the four HMA meetings during the German and Portuguese Presidencies.

Among the many issues discussed by the HMA MG and PS at their meetings and which were presented to the HMA for discussion were:

- Product testing
- Resource planning for the network
- Availability of medicines
- Development of the HMA intranet
- Rules of Procedure for website editors
- Best Practice Guide updates
- Action Plan for the Continuous Development of the HMA Co-operation arsing from Strategic Day 1:
  - Redrafting the HMA mission/vision statement;
  - Restructure of the HMA Working Groups;
  - Revision of the mandates and rules of procedure for Working Groups;
  - Developed an induction package for all heads joining the network;
  - Revision of the rules of procedure for the management group and permanent secretariat;
  - Survey of all activities and responsibilities of each National Competent Authorities;
  - Database of the skills within the network.

The IMB's member of the Permanent Secretariat continues to act as the main contact point for the network and stakeholders worldwide.

The Permanent Secretariat continues to provide quality assurance for HMA minutes and documents.

BORDERLINE PRODUCT CLASSIFICATION

The Irish Medicines Board provides a service to stakeholders to assist in clarifying which products should be categorised as medicinal products and medical devices and thereby fall under the remit of IMB from a regulatory perspective and to distinguish such products from other products which are outside the scope of IMB's remit. Queries routinely are received in regard to human medicinal products, veterinary medicinal products and medical devices and in each of the three areas, relevant personnel within the organisation have provided on request, an IMB decision as to the status of a given product. During 2006, this service in each of the three areas was standardised and brought together under the umbrella of the developing IMB Quality Management System QMS and in 2007 has been the subject of an internal audit.

Human Medicines

A classification service is operated for products which are on the borderline of human medicines and other products such as food supplements, cosmetics and medical devices. Requests for classification whether external or internal are ultimately presented to an internal multi-disciplinary human medicines Classification Committee which meets once a month. The outcome of the decision is conveyed promptly to the enquirers and in turn is accompanied by a recommendation for any action arising depending upon the circumstances. In the event of an appeal to the Classification Committee decision, the matter will normally be referred to the Management Committee which may request the advice of the Advisory Committee for Human Medicines for arbitration. Full details of the procedure can be found in the guideline 'Definition of a Medicinal Product' which can be found on the IMB website. This was revised in 2007 following the implementation of the new legislation.

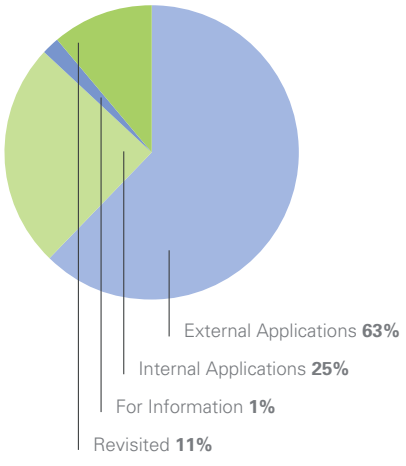
The IMB Classification Committee (human medicines) met 11 times in 2007 and considered a total of 167 new products. In addition, there were 21 products revisited from pre-2007. The Committee consists of appropriately experienced IMB staff from Human Medicines, Compliance and Medical Device departments and is chaired by Dr. J.M. Morris, Senior Scientific Advisor.

During 2007, the majority of the applications were external applications (120); and most of the internal applications emanated from the Compliance Department.

The Committee continues to work closely with representatives of the IMB Compliance Department – Market Compliance Section, which is represented on the Committee, and Enforcement Section. Externally, there is also a very close working relationship with Food Safety Authority of Ireland and a number of referrals were made in either direction during the course of 2007.

The Committee also engaged in regular dialogue with the Department of Health and Children and with the Advertising Standards Authority in regard to slimming products.

HUMAN MEDICINES –
SOURCE OF CLASSIFICATION QUERIES



Veterinary Medicinal Products

A classification service for veterinary medicinal products operates in a manner similar to that for human medicines and a decision is normally granted from within the Veterinary Medicines department of the IMB and conveyed promptly to the enquirers. In cases of appeal of the decision making process, the matter is normally referred to the Management Committee which may request the advice of the Advisory Committee for Veterinary Medicines.

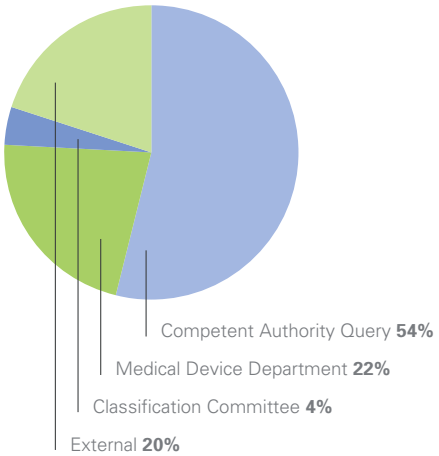
A total of 28 classification queries were processed by the Department in 2007.

Medical Devices

A classification service for medical devices operates in a manner similar to that for human medicines and a decision is normally granted from within the Medical Devices department of the IMB and conveyed promptly to the enquirers. In the event of a borderline issue the product may be referred to the IMB Classification Committee for an opinion. Classification issues may also be referred to the Advisory Committee on Medical Devices for advice and/or to the European Competent Authority enquiry system for opinion. Full details of the procedure can be found in the guidance note 15; 'Classification of Medical Devices'.

In 2007, 50 classification queries were received, 54% of which originated from other Competent Authorities in Europe. A number of these queries require further discussion at the Medical Devices Expert Group (MDEG) Classification Borderline Working Group. Two requests originated from the IMB Classification Committee (Human Medicines). There were ten external requests, six of which were subject to the classification review fee. The remaining queries were from within the Medical Devices Department, mainly arising from the post-market surveillance area. A total of six classification queries that were borderline products were referred to the IMB Classification Committee.

SOURCE OF MEDICAL DEVICE CLASSIFICATION QUERIES



QUALITY MANAGEMENT

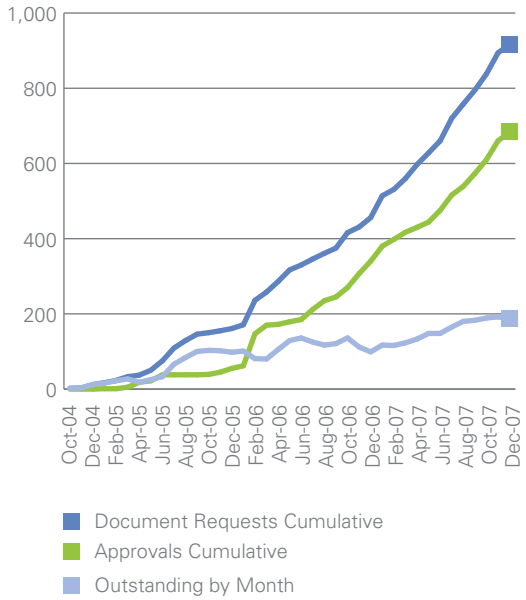
Implementation of the IMB-wide quality management system

During the year, further progress was made in the implementation of the organisation's quality system. Some 139 new documents and 165 requests for revision of documents were approved; six documents were withdrawn. At the end of the year, 187 document approvals were still in progress. Documents which are for external stakeholder use are posted on the IMB's website, while those for internal use are posted on an intranet for staff.

The graph on the next page shows the cumulative number of document control requests, document approvals and outstanding documents since system implementation began. At the end of the year, there were 372 documents approved within the organisation's system.

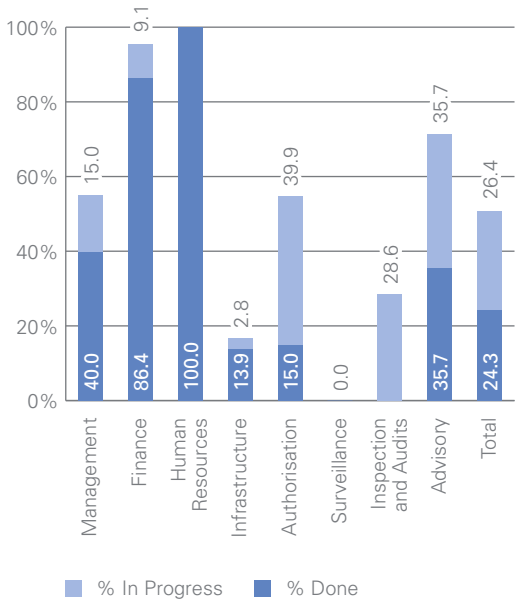
Little migration of current department quality systems to the organisation's system occurred during 2007. This was due in part to business process re-engineering in some departments and to the upcoming external audit of the Compliance Department under the EU's Joint Audit Programme. It is anticipated that migration of documents will start again in mid-2008.

DOCUMENT REQUESTS AND APPROVALS



At the end of the year, 51% of the estimated total implementation has been achieved or was in progress, as shown in the graph below. Progress in each system is shown below by system.

PERCENT IMPLEMENTED BY SYSTEM



Internal audit of the quality system began during 2007. Seven audits of the IMB's system were conducted in a range of areas using internal auditors drawn from the departments as well as QMS staff. The objective of the audits was to determine conformance to procedures, though opportunities for improvement were also identified. At year-end, corrective action plans were approved and actions had been taken for all but one audit. Staff in the areas being audited reported that the audits were constructive and contributed to quality assurance and improvement of their procedures.

Updates on the quality system were communicated to staff on an ongoing basis and induction training was carried out for all new staff.

In March, the QMS section carried out an internal customer survey, with responses received from about one-third of staff. A very high proportion (96%) commented that QMS documents are of value to them in their work: to provide instructions, assist in training, ensure consistency, and to identify areas for improvement. Overall satisfaction with the service of the QMS section was 4.1 on a scale of 1 (very dissatisfied) to 5 (very satisfied). The results of the survey showed a very positive attitude to QMS among those who responded.

Benchmarking of European Medicines Agencies

The IMB co-chaired and participated in the Heads of Medicines agencies Steering Group for the second cycle of Benchmarking of European medicines agencies (BEMA). While the method of benchmarking is primarily unchanged from the first cycle carried out from 2004 to 2006, the questionnaire for assessment was substantially revised during the year. Indicators were re-written to improve clarity and understanding, and the assessors' report format modified so as to highlight strengths/best practices for the benefit of the network and the visited agency. In order to improve the consistency of the process, guidance for each indicator has been agreed and documented; criteria for lead assessors and assessors have been defined; and significant training provided. The second cycle is due to commence in 2008 and run over a three-year period.

Ms. Rita Purcell, *Director of Finance and Corporate Affairs*

FINANCE AND CORPORATE AFFAIRS

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

- Management and safeguarding the finances of the IMB.
- Developing and managing the human resource needs of the organisation.
- Providing secretarial support to the Board and Committees and ensuring adherence to best practice in the area of corporate governance.
- Managing the building and accommodation requirements of the IMB
- Providing infrastructure requirements for the staff and visitors from cleaning, reception, canteen, travel service through to library services.
- Managing the Freedom of Information obligations
- Managing the legal issues for the IMB.

The year 2007 was another challenging and busy year for the department and some of the highlights are outlined below.

FINANCE

As outlined in the Financial Statements, the IMB experienced another year of financial growth. The finance section continued to successfully manage the high volumes of work while maintaining high standards of internal control. To further increase efficiency and control a new purchase order system and fixed assed register were implemented during the year. In 2007 internal auditors reviewed creditors, travel and subsistence and corporate governance with a satisfactory outcome. They also reviewed their recommendations from their audit in 2005 of payroll and human resources. All procedures were carried out using standard operating procedures under the IMB quality management system which has added real value to the operation of the department.

HUMAN RESOURCES

The Human Resources section had a significant year in the area of recruitment, training and the roll-out of the HR strategic aims throughout the IMB. The IMB has continued to develop best practice in all areas of human resources and during 2007 completed the roll-out of QMS in the unit. The time and attendance system was upgraded to provide enhanced reporting facilities and transfer to electronic recording of annual leave. The IMB has identified staff training and development as a key building block in the organisation's commitment to excellence and has continued to invest significantly in the area of providing support for the implementation of change programmes across the organisation.

Recruitment

Overall there were 34 external recruitment competitions in addition to 27 internal promotional opportunities resulting in the appointment of 19 additional technical personnel across a number of departments. (13 female and 6 male).

TRAINING

Courses 2007	No of Courses	No of training days
External courses/seminars	100	497.5
Internal – general	112	152.0
Internal – technical	21	105.5
Internal IT	56	72.25
% of employees supported in further education programmes	8.9%	

CORPORATE SERVICES

2007 was a busy year for corporate services as the increases in operations and staff outlined in all the other departments increase the level of services provided. In December 2007 the IMB hosted the International Summit for the Heads of Regulatory Agencies which was a considerable success. The hospitality and organisation of the conference was organised by Corporate Services and the dinner in Farmleigh provided a memorable night for the foreign delegates. In addition to the International Summit the section also facilitated four other conferences in 2007.

In the area of corporate governance revised terms of reference for all the committees and Board were completed and particular emphasis was given to the role of corporate governance in the organisation. Training in best practice for corporate governance was provided to the Board members.

There was a large number of Freedom of Information Act request in 2007. The IMB received 15 non personal requests and 4 personal requests for information. The outcome of these requests is outlined below:

Buildings

In 2005 the Board approved the complete renovation of Kevin O'Malley House following the purchase of the building in December 2004. This project was commenced in late 2006 and was successfully completed in December 2007. This was a very challenging project as every floor was completely stripped and fully renovated while the building was kept live, while at the same time managing the expectations of both our internal and external stakeholders.

2007	Number of FOI requests received	Granted/Part Granted	Refused	Withdrawn/ Handled outside FOI Act	Internal Reviews	Appeals to the Information Commissioner
	19	10	4	5	2	2

FINANCIAL STATEMENTS

for the year ended 31st December 2007

BOARD MEMBERS AND OTHER INFORMATION

Board Members:	Mr. Pat O'Mahony *(Chairman)* Mr. Pat Brangan Dr. Brendan Buckley Mr. Wilfrid Higgins Ms. Ingrid Hook Mr. Brendan McLoughlin Ms. Cicely Roche Ms. Maureen Windle The new Board was appointed by the Minister for Health & Children for a term of 5 years from 1st January 2006.
Bankers:	Allied Irish Bank Lower Baggot Street Dublin 2 Bank of Ireland Corporate Lower Baggot Street Dublin 2
Solicitors:	Eugene F. Collins Temple Chambers 3, Burlington Road Dublin 4
Head Office:	Kevin O'Malley House Earlsfort Centre Earlsfort Terrace Dublin 2
Auditor:	Comptroller and Auditor General Dublin Castle Dublin 2

CORPORATE GOVERNANCE

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

The IMB is committed to the highest standards of Corporate Governance and has implemented the Department of Finance "Code of Practice for the Governance of State Bodies". This Code of Practice, which was issued to the Irish Medicines Board in January 2002, incorporates many of the principles under which the IMB operates, taking account of the size and legal nature of the organisation. The IMB has in place an extensive code of conduct for all staff, committees and Board members. The IMB applies the highest standards of disclosure and transparency in respect of interests held by staff, committees and Board members.

Audit Committee

The IMB has an audit committee comprising two Board members, which met on three occasions during 2007. This committee is responsible for reviewing internal control matters, together with any other issues raised by the external auditors, the Board or management. The external auditor meets annually with the committee to brief them on the outcome of the external audit. In 2005 the IMB appointed Crowleys DFK as internal auditor to the Board under a three-year contract. During 2007 the internal auditors reviewed the areas of creditors, payroll/HR and expenses and reported their findings to the audit committee. The audit committee has also been involved with the review of the quality systems as described below.

Quality Systems

During 2007, the finance section of the IMB continued the process of implementing and reviewing standard operating procedures (SOPs) under the quality management system. This process involved a critical review and analysis of internal controls and processes throughout the section with particular emphasis on risk management. This system now underpins the internal control environment and feeds into the internal audit process and ultimately into the audit committee.

Remuneration Policy – Board Members and Executive Directors

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

Remuneration Committee

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

Internal Control

The Board is responsible for the IMB's systems of internal control. Such systems can only provide reasonable and not absolute assurance against material misstatement or loss. The systems of internal controls in use in the Irish Medicines Board are described more fully in the Chairman's report on page 53.

Going Concern

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

REPORT OF THE CHAIRMAN OF THE IRISH MEDICINES BOARD

regarding the assessment of internal financial controls of a State body for the year ended 31st December 2007

1. I, as Chairman, acknowledge that the Board is responsible for the body's system of internal financial control.

2. The IMB system of internal control can provide only reasonable and not absolute assurance against material error, misstatement or loss.

3. The Board confirms that there is an ongoing process for identifying, evaluating and managing the significant risks faced by the IMB. This process is regularly reviewed by the Board via the report of the Chief Executive.

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

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

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

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

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

4. The Audit Committee of the Board have satisfactorily reviewed the effectiveness of the system of internal control on behalf of the Board. The Audit Committee of the Board carried out a formal review of these systems in respect of 2007 at its meeting on 26th June 2008.

Mr. Pat O'Mahony
Chairman to the Board

STATEMENT OF BOARD MEMBERS' RESPONSIBILITIES

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

In preparing those statements the Board is required to:

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

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

On behalf of the Board

Chairman

Board Member

REPORT OF THE COMPTROLLER AND AUDITOR GENERAL

for presentation to the Houses of the Oireachtas

I have audited the financial statements of the Irish Medicines Board for the year ended 31 December 2007 under Section 18 of the Irish Medicines Board Act, 1995.

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

Respective Responsibilities of the Board and the Comptroller and Auditor General

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

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

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

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

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

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

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

Basis of Audit Opinion

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

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

Opinion

As explained in the Accounting Policies, the Board recognises the costs of superannuation entitlements only as they become payable. This policy does not comply with Financial Reporting Standard 17 which requires such costs to be recognised in the year the entitlements are earned. While non-compliance with Financial Reporting Standard 17 does not impact on the overall financial performance or position of the Board as disclosed in the financial statements, in my opinion compliance is necessary for a proper understanding of the costs of providing the superannuation benefits earned by employees during the year and of the value of the benefits that the Board has committed to providing in respect of service up to the year end.

Except for the non-recognition of the Board's superannuation costs and liabilities, which is not in accordance with Financial Reporting Standard 17, the financial statements give a true and fair view, in accordance with Generally Accepted Accounting Principles in Ireland, of the state of the Board's affairs at 31 December 2007 and of its income and expenditure for the year then ended.

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

Gerard Smyth
For and on behalf of the
Comptroller and Auditor General

3 September 2008

ACCOUNTING POLICIES

Historical Cost Convention

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

Income Recognition

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

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

Expenditure Recognition

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

Reporting Currency and Currency Translation

The financial statements are prepared in euros.

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

Tangible Assets

Tangible Assets excluding Premises

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

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

Leasehold Property:	Unexpired portion of the lease
Fixtures and Fittings:	5 years
Computer Equipment:	3 years
Improvements to Premises:	10 years

Premises

The IMB purchased its premises at Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2 on 22nd 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. An impairment review was carried out in April 2008 and the value of premises was considered to be appropriate.

Taxation

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

Debtors

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

Superannuation

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

The charge to salaries and wages is stated gross of superannuation deductions of €521,844 (2006 - €594,450). The surplus for the year on page 59 is then shown both before and after superannuation transactions for the year. The income and expenditure reserve on the balance sheet is split between retained reserves and superannuation reserves in note 11.

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

Provisions

It is the policy of the IMB to make adequate provision for any litigation that may arise. Due to the confidential nature of such transactions, it is not the policy of the IMB to disclose such information.

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 31st December 2007

	Note	2007 €	2006 €
Fee Income	*2*	**17,239,949**	15,965,921
Other Income	*3*	**5,073,029**	4,154,510
		22,312,978	20,120,431
Salaries and Wages	*4*	**13,239,398**	11,985,846
Other Operating Costs	*5*	**5,951,791**	5,399,854
Depreciation	*1*	**1,247,081**	1,086,383
		20,438,270	18,472,083
Surplus for the year before write back of Superannuation contributions		**1,874,708**	1,648,348
Staff Superannuation Contributions		**521,844**	594,450
Surplus for the year		**2,396,552**	2,242,798
Balance brought forward		**10,278,395**	8,035,597
Balance carried forward		**12,674,947**	10,278,395

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

Chairman

Board Member

The accounting policies on pages 57 to 58 and the notes on pages 63 to 69 form part of the financial statements.

STATEMENT OF TOTAL RECOGNISED GAINS AND LOSSES

for the year ended 31st December 2007

	2007 €	2006 €
Retained Surplus For The Year	**2,396,552**	2,242,798
Unrealised Gains For The Year	–	–
Total Recognised Gains	**2,396,552**	2,242,798

The accounting policies on pages 57 to 58 and the notes on pages 63 to 69 form part of the financial statements.

BALANCE SHEET

as at 31st December 2007

	Note	2007 €	2006 €
Tangible Assets	*1*	**24,657,277**	22,530,128
Current Assets			
Debtors and Prepayments	*6*	**1,703,351**	1,386,328
Stock of Stationery		**4,707**	5,040
Cash at Bank and in Hand	*12*	**1,711,782**	593,457
Short Term Deposits		**2,153,665**	3,263,387
		5,573,505	5,248,212
Creditors – Amounts falling due within one year			
Creditors and Accruals	*7*	**4,975,835**	4,579,945
Mortgage	*13*	**340,000**	340,000
		5,315,835	4,919,945
Net Current Assets		**257,670**	328,267
Long Term Liabilities			
Mortgage	*13*	**12,240,000**	12,580,000
TOTAL NET ASSETS		**12,674,947**	10,278,395
Financed by			
Income and Expenditure Reserve	*11*	**12,674,947**	10,278,395
		12,674,947	10,278,395

Chairman

Board Member

The accounting policies on pages 57 to 58 and the notes on pages 63 to 69 form part of the financial statements.

CASH FLOW STATEMENT

for the year ended 31st December 2007

	Note	2007 €	2006 €
Reconciliation of surplus to net cash inflow from operating activities			
Surplus for Year		**2,396,552**	2,242,798
Depreciation Charge		**1,247,081**	1,086,383
(Increase)/Decrease in Debtors		**(317,023)**	(105,156)
(Increase)/Decrease in Stocks		**333**	(591)
Increase/(Decrease) in Creditors – amounts falling due within one year		**395,890**	1,315,712
Deposit Interest		**(79,717)**	(35,580)
Bank Interest and Charges		**540,444**	572,430
Loss/(Gain) on Disposal of Fixed Assets		**44,092**	32,898
Net Cash Inflow from Operating Activities		**4,227,652**	5,108,894
Cash Flow Statement			
Net Cash Inflow from Operating Activities		**4,227,652**	5,108,894
Return on Investments and Servicing of Finance	*8*	**(460,727)**	(536,850)
Capital Expenditure	*8*	**(3,418,322)**	(1,476,327)
Management of Liquid Resources	*8*	**1,109,722**	(2,938,330)
Financing	*8*	**(340,000)**	(2,390,000)
Increase/(Decrease) in Cash		**1,118,325**	(2,232,613)
Reconciliation of net cash flow to movement in net debt			
Increase/(Decrease) In Cash		**1,118,325**	(2,232,613)
Increase/(Decrease) In Short Term Deposits		**(1,109,722)**	2,938,330
(Increase)/Decrease In Long Term Finance		**340,000**	2,390,000
Change In Net Debt		**348,603**	3,095,717
Net Debt at start of year		**(9,063,156)**	(12,158,873)
Net Debt at end of year	*9*	**(8,714,553)**	(9,063,156)

The accounting policies on pages 57 to 58 and the notes on pages 63 to 69 form part of the financial statements.

NOTES TO THE FINANCIAL STATEMENTS

for the year ended 31st December 2007

1 Tangible Assets

	Fixtures and Fittings €	Computer Equipment €	Leasehold Improve-ments €	Improve-ments to Premises €	Premises €	Total €
Cost						
Balance as at 1st January 2007	688,564	5,887,431	502,445	618,113	20,549,166	28,245,719
Additions for the year	395,592	912,098	–	1,155,974	954,690	3,418,354
Disposals for the year	(400,976)	(1,131,610)	–	–	–	(1,532,586)
As at 31st December 2007	683,180	5,667,919	502,445	1,774,087	21,503,856	30,131,487
Depreciation						
Balance as at 1st January 2007	538,924	4,989,915	99,233	87,519	–	5,715,591
Charge for the year	123,896	895,531	50,245	177,409	–	1,247,081
Disposals for the year	(370,988)	(1,117,474)	–	–	–	(1,488,462)
As at 31st December 2007	291,832	4,767,972	149,478	264,928	–	5,474,210
Net Book value at 31st December 2007	391,348	899,947	352,967	1,509,159	21,503,856	24,657,277
Net Book value at 1st January 2007	149,640	897,516	403,212	530,594	20,549,166	22,530,128

2 Income

	2007 €	2006 €
Fee Income		
Clinical Trials	**118,081**	114,326
Human Medicine – National Fees	**6,090,886**	6,818,243
Human Medicine – European Fees	**6,025,588**	4,601,466
Veterinary Medicine – National Fees	**1,150,323**	1,128,342
Veterinary Medicine – European Fees	**854,874**	478,963
Compliance Department	**2,853,490**	2,703,422
Medical Devices	**146,707**	121,159
	17,239,949	15,965,921
Other Income (Note 3)	**5,073,029**	4,154,510
Total Income	**22,312,978**	20,120,431

Certain fees, totalling €11,459,491, are required by law to be disposed of in accordance with the directions of the Minister for Finance.

3 Other Income

	2007 €	2006 €
Department of Health & Children Funding	**4,924,000**	4,025,000
IT Income	**13,000**	13,000
Conference Fee Income	**88,402**	98,828
Deposit Interest	**79,717**	35,580
(Loss)/Gain on Disposal of Fixed Assets	**(44,092)**	(32,898)
Miscellaneous	**12,002**	15,000
	5,073,029	4,154,510

4 Salaries and Wages

	2007 €	2006 €
Salaries and Wages	**12,113,971**	10,991,736
Social Welfare Costs	**1,125,427**	994,110
	13,239,398	11,985,846

The average number of staff employed during the year was 234 (2006 - 218).

Staff employed at 31st December 2007 can be analysed across the following departments:

	2007	2006
Medical Technical	**15**	15
Pharmaceutical Technical	**28**	25
Veterinary Technical	**11**	10
Compliance Technical	**18**	13
Medical Devices Technical	**14**	10
Enforcement Technical	**8**	8
Scientific Technical	**1**	1
Blood Directive Technical	**5**	5
Controlled Drugs Technical	**2**	1
Tissues Technical	**2**	–
Administrative and Operational Staff	**124**	129
Pensioners	**10**	8
	238	225

5 Operating Costs

	€	€
Accommodation Costs	**1,096,121**	1,005,524
Travel, Representation and Training	**1,153,890**	871,051
Bank Charges and Interest	**540,444**	572,430
Legal & Professional Fees	**591,150**	1,072,026
Stationery, Publications and Postage	**396,123**	306,771
Other Operating Costs	**2,174,063**	1,572,052
	5,951,791	5,399,854

6 Debtors (all due within one year)

	2007 €	2006 €
Trade Debtors	1,340,493	1,131,677
Prepayments	266,401	160,313
Other Debtors	96,457	94,338
	1,703,351	1,386,328

7 Creditors (amounts falling due within one year)

	2007 €	2006 €
Trade Creditors	702,718	555,876
Accruals	3,842,994	3,675,890
Revenue	430,123	348,179
	4,975,835	4,579,945

8 Gross Cash Flows

	2007 €	2006 €
Returns on Investment and Servicing of Finance:		
Deposit Interest	79,717	35,580
Bank Interest and Charges	(540,444)	(572,430)
	(460,727)	(536,850)
Capital Expenditure		
Payments to acquire Tangible Fixed Assets	(3,418,354)	(1,476,807)
Receipts from sales of Tangible Fixed Assets	32	480
	(3,418,322)	(1,476,327)
Management of Liquid Resources		
(Increase)/Decrease in Short Term Deposits	1,109,722	(2,938,330)
	1,109,722	(2,938,330)
Financing		
Increase/(Decrease) in Long Term Finance	(340,000)	(2,390,000)
	(340,000)	(2,390,000)

9 Analysis of Changes in Net Debt

	As at 01/01/2007	Cashflow	As at 31/12/2007
Cash at Bank and in Hand	**593,457**	1,118,325	1,711,782
Short Term Deposits	**3,263,387**	(1,109,722)	2,153,665
Debt Due Within One Year	**(340,000)**	–	(340,000)
Debt Due After One Year	**(12,580,000)**	340,000	(12,240,000)
	(9,063,156)	348,603	(8,714,553)

10 Administration Expenses

	2007	2006
Surplus for the year was calculated having charged:		
Auditor's Remuneration	**18,500**	15,800

11 Income and Expenditure Reserves

The Income and Expenditure Reserve disclosed in the Balance Sheet on page 61 comprises the following:

	2007	2006
Retained Reserves	**9,486,806**	7,612,098
Staff Superannuation Contributions	**3,188,141**	2,666,297
	12,674,947	10,278,395

12 Cash and Bank Balances

	2007 €	2006 €
Current Account Balances	**9,098**	91,281
Deposit Account Balances	**1,700,000**	500,000
Cash on Hand	**2,684**	2,176
	1,711,782	593,457

13 Long Term Liabilities

Mortgage

On 22nd 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:

	2007 €	2006 €
■ within one year	**340,000**	340,000
■ between one and five years	**1,360,000**	1,360,000
■ after five years	**10,880,000**	11,220,000
	12,580,000	12,920,000

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 a period of 10 years. The balance of the borrowings are fully offset by cash reserves. For 2008 it is estimated that the net borrowings for which an interest rate exposure may arise is €0.

15 Financial Commitments

	2007 €	2006 €
Operating Leases		
Amounts payable during the next twelve months in respect of leases which expire		
■ within one year	–	–
■ between one and five years	–	–
■ after five years (in respect of Alexandra House)	**236,000**	236,000
	236,000	236,000

The operating lease amount includes an annual commitment of €236,000 in respect of the Board's premises at Alexandra House, Earlsfort Centre, Earlsfort Terrace, Dublin 2. As shown in note 13 above, the IMB purchased Kevin O'Malley House on 22nd December 2004, which is why no further lease obligations exist in respect of that premises.

On 22nd December 2004 the IMB signed a leasehold interest with 17 years remaining in respect of the 5th floor, Alexandra House, Earlsfort Centre, Dublin 2.

16 Capital Commitments

	2007 €	2006 €
Contracted For (Contract Signed)	**110,000**	280,000
Not Contracted For	**65,000**	200,000
	175,000	480,000

17 Board Remuneration

	2007 €	2006 €
Chairman's Salary	**26,087**	25,822
Board Members' Travel Expenses	**8,645**	9,788
	34,732	35,610

18 Staff Remuneration

	2007 €	2006 €
Chief Executive's Remuneration	**157,747**	152,415
(Stated net of Superannuation Contributions)		
	157,747	152,415

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:

2007 €1 = STG £0.73335
2006 €1 = STG £0.6715

22 Approval of Financial Statements

The financial statements were approved by the Board on 26th June 2008.

APPENDIX I: MANAGEMENT COMMITTEE MEMBERS AND COMMITTEES

Management Committee

Mr. Pat O'Mahony – Chief Executive
Dr. J.Gabriel Beechinor –
Director of Veterinary Medicines
Dr. Joan Gilvarry – Director of Human Medicines
Mr. John Lynch – Director of Compliance
Ms. Suzanne McDonald – Director of Information Technology and Change Management
Dr. J. Michael Morris – Senior Scientific Advisor
Ms. Ann O'Connor – Medical Devices Director
Ms. Rita Purcell – Director of Finance and Corporate Affairs

Advisory Committee for Human Medicines

Dr. Brendan Buckley – Chairman
Dr. Mary Horgan
Dr. Kevin Connolly
Prof. John Kelly
Dr. Pat Sullivan
Dr. Brendan Silke
Prof. Ted Dinan
Mr. Tom McGuinn
Ms. Eugenie Canavan
Dr. Paul Browne
Dr. Desmond Corrigan
Dr. Íde Delargy

Advisory Committee for Veterinary Medicines

Mr. Pat Brangan – Chairman
Mr. Tom McGuinn
Mr. Rory Breathnach
Ms. Eugenie Canavan
Mr. Thomas Barragry
Dr. Anne Cullinane
Mr. Joseph Britton
Mr. Matt Browne
Mr. Michael Clancy
Dr. Hamish D. Rodger
Dr. Donal Sammin

Advisory Committee for Medical Devices

Mr. Wilfrid J. Higgins – Chairman
Dr. Geoffrey Chadwick
Ms. Maureen D'Arcy
Dr. John Keogh
Prof. Robert McConnell
Dr. Brendan Cormack
Dr. Tim McGloughlin
Ms. Aideen Murphy
Dr. John O'Mullane
Ms. Maebh Smith
Prof. W. Arthur Tanner
Prof. Wil van der Putten

Clinical Trial Sub-Committee of Advisory Committee for Human Medicines

Dr. Patrick Sullivan – Chairman
Dr. Liam. T. Bannan
Dr. Tom Pierce
Prof. David Bouchier-Hayes
Dr. John Taffe
Dr. Paul Browne
Dr. Pat Manning
Prof. Ted Dinan
Prof. Sidney Lowry
Dr. Brian Cantwell

Experts Sub-Committee of the Advisory Committee for Human Medicines

Dr. Brendan Buckley
Dr. Mary Horgan
Dr. Brion Sweeney
Dr. Colin Buckley
Dr. Íde Delargy
Dr. Stephen Flint
Dr. Lorraine Kyne
Dr. Owen Hensey
Dr. Owen Carey
Dr. Kevin Connolly
Dr. Frank Murray
Dr. Mary Keogan
Dr. Kevin Kelleher
Dr. Linda Fenelon
Dr. John McCaffrey
Dr. Noreen Dowd
Dr. Patricia McCormack
Dr. Stephen Eustace
Dr. Douglas Veale
Dr. Joseph Galvin
Prof. Michael Fitzgerald
Prof. Brian Shephard
Dr. Tim Fulcher
Prof. David Kerins
Dr. Donal Brosnahan
Dr. Mark Ledwidge

APPENDIX II: GLOSSARY

ADR:	Adverse Drug Reaction
ACMD:	Advisory Committee for Medical Devices
ACVM:	Advisory Committee for Veterinary Medicines
AIMDD:	Active Implantable Medical Device Directive
BEMA:	Benchmarking of European Medicines Agencies
BfARM:	German Competent Authority
BWP:	Biological Working Party
CETF:	Clinical Evaluation Task Force
CHMP:	Committee for Human Medicinal Products
CMD(h):	Co-ordination Group for Mutual Recognition & Decentralised Procedures
COMP:	Committee for Orphan Medicinal Products
DCP:	Decentralised Procedure
DOHC:	Department of Health and Children
EC:	European Commission
EHN:	European Haemovigilance Network
EMEA:	European Medicines Agency
EUSTITE:	EU Project for Standards and Training for the Inspection of Tissue Establishments
EWP:	Efficacy Working Party
FDA:	Food and Drug Administration
GMD:	General Medical Device
GTWP:	Gene Therapy Working Party
HMA:	Heads of Medicines Agencies
HMPC:	Committee on Herbal Medicinal Products
ICSRs:	Individual Case Safety Reports
IMB:	Irish Medicines Board
IMF:	Irish Medicines Formulary
ISOP:	International Society of Pharmacovigilance
IVDs:	*In-Vitro* Diagnostic
IVDD:	*In-Vitro* Diagnostic Medical Device Directive
MAHs:	Marketing Authorisation Holders
MDD:	Medical Device Directive
MDEG:	Medical Devices Expert Group
MEDDEV:	Medical Devices
MIA:	Manufacturing Importation Authorisation
MR:	Mutual Recognition
NHO:	National Haemovigilance Office
NSAI:	National Standards Authority of Ireland
NSAID:	Non Steroidal Anti Inflammatory Drug
OMCL:	Official Medicines Control Laboratory
PDCO:	Paediatric Committee
PEMSAC:	Platform of European Market Surveillance Authorities in Cosmetics
PhVWP:	CHMP Pharmacovigilance Working Party
PSUR:	Periodic Safety Update Report
QMS:	Quality Management System
QWP:	Quality Working Party
RIO:	Regulatory Information Online System
SAE:	Serious Adverse Event
SAG:	Scientific Advisory Groups
SAR:	Serious Adverse Reactions
SUSARs:	Suspected Unexpected Serious Adverse Reactions
SWP:	Safety Working Party
VCJD:	Variant Creutzfeldt-Jakob Disease
VWP:	Vaccine Working Party
WHO:	World Health Organisation

IRISH MEDICINES BOARD

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