IRISH MEDICINES BOARD

ANNUAL REPORT **2006**

PROTECTING PUBLIC AND ANIMAL HEALTH

IRISH MEDICINES BOARD

CONTENTS

Mr. Pat O'Mahony, *Chairman*

CHAIRMAN'S STATEMENT

2006 was another significant year for the IMB in terms of progress across a wide range of activities. There was an overall increase in the outputs of the IMB set against a background of new corporate structures being implemented and an expansion of the Board's remit. It is a tremendous endorsement of the commitment of the staff that, whilst every department witnessed increased activities, all challenges were met and indeed exceeded without any aspect of quality being compromised.

During 2006, we became the Competent Authority for the regulation of the safety and quality of tissues and cells in Ireland. The appropriate Commission Directives in relation to this area were transposed into Irish legislation (SI 158 of 2006) and thus activated our new role. As stipulated by this legislation, an application for an establishment authorisation is required from the operator of any site involved in the procurement, testing, processing, preservation, storage and distribution of human tissues and cells intended for human use for an authorisation to perform such activities. This new area has been integrated into our operations swiftly and effectively.

Our core focus is to protect and enhance public and animal health through the regulation of human and veterinary medical products and medical devices on the Irish market. There is no doubt that there is a growing appetite from all levels of society in relation to information on health issues. Of course we are also witnessing this increased interest, which presents itself to our organisation through increased queries and requests for information, all of which we welcome and strive to respond to in a timely fashion.

International developments in relation to medicinal products and medical devices impact on the day to day workings of the IMB. Our role in assessing all emerging issues in relation to products as well as supplying safety information from an Irish perspective is fundamental to the monitoring of safety issues across some 6,000 human medicines, 1,200 veterinary medicines and 500,000 medical devices. The IMB actively participates in a wide range of international groups including the EMEA, the EU Commission and the WHO in relation to keeping an up to the minute monitoring brief on safety and regulatory issues

in relation to its areas of responsibility. In addition, the IMB works in close consultation with its EU counterparts in sharing intelligence and information for mutual benefit.

The tangible benefits of our restructuring and Information Technology programme were demonstrated in all departments in 2006 – Human Medicines, Veterinary Medicines, Medical Devices, Compliance, IT and Change Management, Finance and Corporate Affairs. It allowed these departments to maintain high quality in an environment of increasing work levels. The robustness and flexibility of our new structure, combined with our new innovations on electronic processing of information, all assisted in achieving excellence in outputs without detracting from our core remit of health protection. It is a tribute to the calibre of our expert staff that they have embraced all the changes and new challenges with such professionalism.

Throughout 2006, the Board members of the IMB continued to demonstrate their commitment and dedication to the progress of the IMB through their application and depth of expertise. The work of our various expert sub-committees and of the individuals who give so generously of their time is very much appreciated. Through these committees, the IMB has unique access to the very best experience and knowledge across a wide range of disciplines. This access ensures the most appropriate decisions and controls are applied to maximise consumer and animal health in relation to medicinal products and devices.

To safeguard public and animal health, the sharing of information on human and veterinary products is crucial. It is particularly important thus to acknowledge the valuable contribution of various scientific bodies, professional groups and representative organisations, as well as industry, the EU and international scientific organisations whose co-operation is vital in ensuring the highest standards of all medicinal products and medical devices on the Irish market.

We acknowledge with great gratitude the ongoing support from the Minister for Health and Children, as well as the Minister for Agriculture and Food and the officials of both departments. The continued co-operation of the dedicated professionals in these departments has and will continue to contribute to the productive operation of the IMB.

I would like to thank the Chief Executive, the Management Team and all the staff of the IMB for exceptional work and application in 2006. Our remit is continually expanding as the IMB is given new areas of responsibility. This expansion is welcomed and it is only through the flexibility and enthusiasm of our staff that, while our work load expands, our high standards of quality service are maintained.

We look forward to the future with confidence. We have a strong organisation peopled with experts in their field delivering excellence in standards to ensure public and animal health in relation to medicinal products and medical devices. The IMB's role and remit continues to evolve and expand in line with the new responsibilities it is asked to oversee. We envisage this continuing and welcome further opportunities fulfil our important role in relation to protecting public and animal health.

Pat O'Mahony
Chairman

Back row – (l-r): Brendan Buckley, Pat Brangan, Maureen Windle and Brendan McLaughlin.
Front row – (l-r): Cicely Roche, Ingrid Hook, Pat O'Mahony (chairman) and Wilfred 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

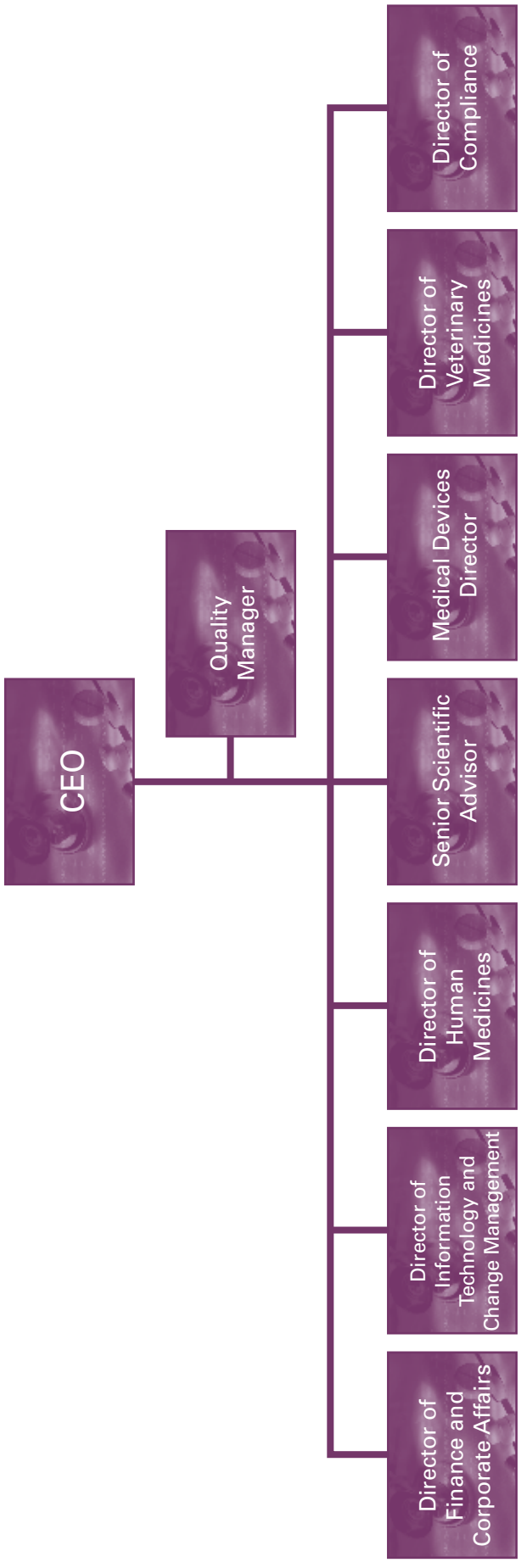
Ms. Ingrid Hook

Mr. Brendan McLaughlin

Ms. Cicely Roche

Ms. Maureen Windle

ORGANISATION CHART



Mr. Pat O'Mahony, *Chief Executive*

CHIEF EXECUTIVE'S REPORT

OVERVIEW OF 2006

During 2006, considerable progress was achieved 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 which emerged during the year were handled efficiently and successfully with the protection of public health at the core of all our activities.

The implementation and management of change continued to be a key driver within the IMB as we strove to improve efficiencies and standards across the organisation. We consolidated improvements of previous years in the Human Medicines and Compliance Departments and conducted reviews in the Medical Devices and Veterinary Medicines areas. We 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 industry and is now the largest exporter of pharmaceuticals in the world. Over 7,000 human medicinal products and over 1,000 veterinary medicinal products are presently authorised by the IMB for use in this country. 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.

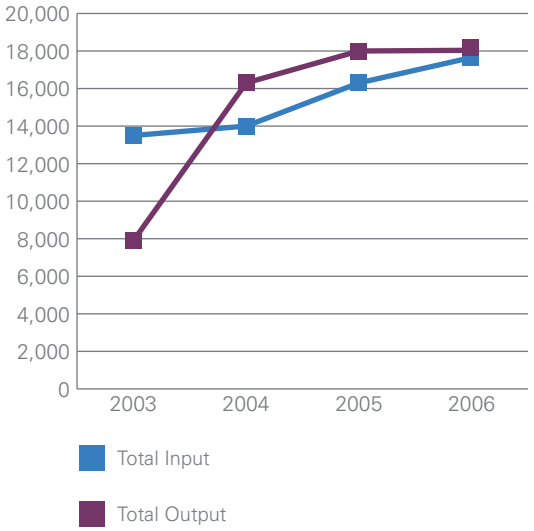
Our focus on the safety of medicines extends throughout the full lifecycle of all products from the provision of scientific advice, approval for the conduct of clinical trials through to the assessment of applications for granting, variation and renewal of marketing authorisations. A key focus in this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

HUMAN MEDICINES

The Human Medicines Department, which was restructured in 2003, continues to achieve consistent improvements in performance. The backlog in new national applications was dealt with by the middle of 2006 and followed on from the elimination of the historical backlog in variation and renewal applications during 2005.

Input of applications continued to increase during the year, and this increased input was matched by increased output. During the year, the IMB processed 15,799 variations to product authorisations, 848 new product applications and 1,078 renewals to product authorisations. This enhanced output level will be maintained as the IMB's structures and processes are consolidated and IT support further developed within the organisation.

TOTAL INPUT AND OUTPUT OF ALL ASSESSMENT TYPES IN THE HUMAN MEDICINES DEPARTMENT FROM 2003 TO 2006.



COMPLIANCE

The IMB's Compliance Department carried out a total of 99 Good Manufacturing Practice inspections, 128 Good Distribution Practices inspections. The European Communities (Quality and Safety of Human Tissues and Cells) Regulations 2006 came into force during 2006 and nine inspections of tissue establishment sites were carried out. A total of 469 cases involving breaches of medicinal product legislation were initiated. The IMB seized a total of 96,487 tablets, 41,361 capsules, 52,873 ml of liquids and 5,652 g of creams containing a variety of active substances. Market surveillance and compliance programmes continued to operate throughout the year.

BLOOD AND BLOOD COMPONENTS

The IMB has specific responsibilities for regulating services for the collection, processing and quality control of blood and blood components. In 2006, our first full year of responsibility for this new legislation, significant progress was made in inspecting sites and requesting enhancements in processes where deemed appropriate. Ten inspections of blood establishment sites were conducted in Ireland in 2006. Haemovigilance monitoring continued and included regular liaison with the National Haemovigilance Office.

MEDICAL DEVICES

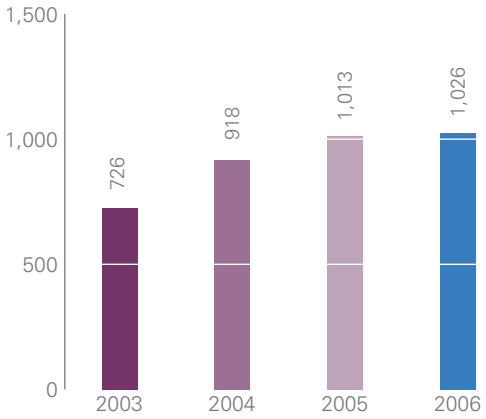
Activity in the medical devices area continues to be a major part of the work of the IMB and these products are also a major part of the Irish economy. During 2006, a total of 343 medical devices were registered, including 172 *in-vitro* diagnostic medical devices and 171 general medical devices. The IMB sees this area expanding in the future, and we have made provisions accordingly to ensure the effective management of this growth. Any public health issues relating to medical devices arising during the year were handled effectively and efficiently.

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 over €5 billion. The regulation of veterinary medicines plays a very significant role in supporting this sector in assisting in the prevention and treatment of disease, in enhancing animal welfare and in ensuring the safety of foods of animal origin. In 2006, the IMB was involved in addressing significant challenges surrounding the availability of certain medicines in Ireland for minor uses or for minor species (MUMS).

A record number of applications for authorisation of veterinary medicinal products was approved by the IMB in 2006. Any health issues relating to veterinary medicines arising during the year were handled efficiently and effectively.

TOTAL OUTPUT OF ALL APPLICATIONS IN THE VETERINARY MEDICINES DEPARTMENT 2003 TO 2006



FINANCE AND CORPORATE AFFAIRS

In line with increased activity within the organisation, the Finance and Corporate Affairs Department provided an increased output in its various activities during 2006. This department is responsible for the building renovation project which is currently underway. The Human Resources function had its busiest year ever in recruitment and training. The internal financial audit function conducted reviews of systems and reported directly to the audit sub-committee of the Board in compliance with good corporate governance requirements.

IT AND CHANGE MANAGEMENT

The IMB's progressive programme of change, involving both upgrading our information technology and a programme of organisational change, achieved some major milestones in 2006. Development continued in our IT systems, and a review of the future needs of the Medical Devices Department was approved by the Board in June and then referred to the Department of Health and Children (DoHC), which funds this activity. Implementation will begin in 2007, depending on resource provision.

A review was also initiated in the Veterinary Medicines Department. The outcome of this review was approved by the Board in October, and will be implemented in 2007. The IT and Change Management Department also provided increased output during the year by way of staff training and IT support as required.

IMPLEMENTATION OF THE NEW MEDICINES LEGISLATION AND QMS

During 2005, the IMB carried out a very significant programme to prepare for the implementation of new revised medicines legislation. The Department of Agriculture and Food implemented revised Animal Remedies Regulations by November 2005. A series of revised Regulations on human medicines were at an advanced stage at the end of 2006, and the IMB had completed the planning process for the implementation of the new legislation.

During 2006, significant progress was also made in the implementation of an IMB-wide quality management system.

THE EUROPEAN MEDICINES REGULATORY SYSTEM

In 2006, 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 very actively at the Heads of Medicines Agencies (HMA) level and at the EMEA Management Board. We continued to provide part of the Permanent Secretariat to the HMA. 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, and continued to meet all timelines in these procedures in 2006.

The IMB also continued to represent Ireland at the European Pharmacopoeia, where Dr. Mike Morris, Senior Scientific Advisor, continued in the role of President of the Pharmacopoeia Commission. During 2006, 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 facilitates swift, accurate and efficient sharing of relevant information between regulatory authorities throughout Europe. During 2006, the IMB's IT and Change Management Department was actively involved in EU IT implementation activities.

THE EUROPEAN MEDICAL DEVICES REGULATORY SYSTEM

2006 was another busy year for the European Medical Devices regulatory system with the IMB participating in a large number of meetings at EU level. The demands in this area are under review at European Commission level. During 2006, significant progress was made in relation to proposed amendments to the medical devices directives and on amendments to the guidance on the medical device vigilance system. Agreement was reached on guidance for electronic labelling of *in-vitro* diagnostic medical devices. The IMB contributed to all these initiatives.

STRATEGIC PLAN

The IMB's three-year Strategic Plan for the years 2007 to 2010 was finalised at year end. The plan sets out the following primary objectives:

- Effective risk management and improving consumer safety
- Effective regulation through ongoing development of our work force and non-staff resources
- Effective communication with all stakeholders and empowering consumers through better information

This document is published on our website (www.imb.ie).

OFFICE ACCOMMODATION

As reported in 2005, the Board completed the purchase of our present building in December 2004 with the approval of the Department of Health and Children and Department of Finance, In May 2005, the building was named Kevin O'Malley House to honour Professor Kevin O'Malley for his very considerable contribution to medicines regulation in Ireland through his participation over 27 years on the Board and Committees of the IMB and as Chairman of its predecessor, the National Drugs Advisory Board. Refurbishment of the building commenced in 2006 and is expected to be completed in 2007.

COMMUNICATIONS

During the year, 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 manufacturing 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 Irish Pharmaceutical Healthcare Association (IPHA) and Pharmachemical Ireland.

PUBLICATIONS

During 2006, 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 the IMB web site.

FREEDOM OF INFORMATION

Six requests were received under the Freedom of Information Act in 2006, compared with nine in 2005.

THE FUTURE

2007 offers new challenges and new opportunities for the development of the IMB. We await the formal enactment of the revised medicines legislation in relation to human medicines. A considerable amount of effort is still required to implement all the various provisions, and we will have to monitor critically the efficient use of resources with respect to any additional requirements. The overall workload, including the numbers of applications, continues to increase and ensuring adequate staffing and resources to meet all these demands is a particular challenge. The increasing number of meetings at EMEA and European Commission level continues to pose challenges, the impact of which we strive to reduce by maximising the use of tele-conferencing and video-conferencing facilities.

We look forward to completing the implementation of the development study in the Medical Devices Department. Ensuring adequate resources for the revised structure will be a challenge as funding for the medical devices department is provided by the Department of Health and Children.

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. Continuing to develop our performance management system and implementation of the outcome of the review we conducted in 2006 will be a priority.

New responsibilities are exciting and challenging. We will be examining the area of regulation of cosmetics following a request from the Department of Health and Children for the IMB to become the competent authority. This will involve the IMB looking at resource requirements and best management of this new area to ensure maximum protection of consumers. The formal transfer of responsibilities from the Department of Health and Children in the area of controlled drugs had been anticipated for a number of years. While we are already delivering services in this area, we now expect this to be formally transferred in 2007.

In relation to our staff, which are our key asset, we will continue to train and develop staff so that we maintain and enhance the skills sets required for the ever changing and ever more complex areas under our remit.

We will continue the roll-out of our IT strategic plan and related organisational change during 2007. This will transform our IT systems and assessment activity, resulting in 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 we are maximising the use of resources.

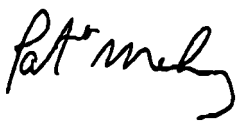
BOARD AND STAFF MATTERS

In total, over 100 people contribute voluntarily to the work of the IMB through the Board and Committees. At the end of 2005, a new Board and Advisory Committees for Human and Veterinary Medicines were appointed by the Tánaiste and Minister for Health and Children for the period of five years from 2006 to 2010. Sub-committees were also established. The new Board and Committees had a very successful first year in office, and I thank each member for their contribution during 2006.

The term of office of the Advisory Committee for Medical Devices overlaps with those of the other committees and the existing committee continues in office for a further year. I express my appreciation and gratitude for the help and advice of all these colleagues during the year.

I acknowledge the support of the staff of the Department of Health and Children and the Department of Agriculture and Food for the work of the IMB.

I wish to welcome all new staff members who joined during 2006 and to 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

The Human Medicines Department had a very successful year in 2006. Safety monitoring of medicines on the Irish market continued to be a core priority and a key focus of the workings of the department. During the year, the department witnessed an increase in work volumes and outputs for new product licensing, licence variations, licence renewals and pharmacovigilance activities. This increase was effectively managed due to the benefits of the major change programme initiated during 2003 which strengthened the structure, efficiencies and systems within the department. The change programme undertaken proved highly beneficial as it facilitated an increase in the number of licence applications processed in 2006 as compared with previous years.

During 2006, a new structure for the Pharmacovigilance Section was implemented. This coincided with its integration into the Human Medicines Management team as well as the subdivision of its core activities into Market Surveillance and Pharmacovigilance Assessment teams. This commenced in June 2006 and has already proven to be very successful with a seamless integration now fully in place.

Some of the drivers for this change included additional requirements arising from the revised pharmaceuticals legislation which came into force in October 2005 in addition to vigilance-related activities arising from implementation of the Blood Directive and the Tissues and Cells Directive.

PHARMACOVIGILANCE

The IMB places a major emphasis on promoting the importance of receiving reports on suspected adverse reactions to medicines. Fundamentally, this assists the IMB monitor the safety profile of medicines on the market. While Ireland is among the top seven countries in the World Health Organization's (WHO) adverse reaction reporting system, the IMB continues to actively encourage healthcare professionals to report any incidents in relation to medicines to the Board.

During 2006, the IMB engaged in a number of specific communications to remind a range of audiences of the importance of adverse reaction reporting. It provided regular reminders about reporting in its Drug Safety Newsletter and through its regular presence in MIMS (Ireland).

A number of presentations on pharmacovigilance and adverse reaction reporting were also made to healthcare professionals as part of undergraduate and postgraduate training courses and continuing education programmes.

During 2006, the IMB received a total of 1,907 suspected adverse reaction (ADR) reports occurring in Ireland from healthcare professionals and pharmaceutical companies. The IMB greatly appreciates and acknowledges the important contribution of busy healthcare professionals in reporting suspected ADRs which in turn assists in the overall continued surveillance of the safety of medicinal products. While the burdensome nature of form-filling is recognised, the collection and evaluation of these reports is essential to ensure continuous surveillance of the safety of marketed medicinal products.

BREAKDOWN OF REPORTS BY SOURCE	
Marketing Authorisation Holders	1119
General Practitioners	212
Hospital Doctors	148
Nurses	125
Community Care Doctors	105
Hospital Pharmacists	72
Clinical Trials	62
Community Pharmacists	61
Dentists	2
Healthcare Professionals (other)	1
Total	**1907**

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

Implementation of Revised Pharmacovigilance Structure

Further to the Board's approval of the new structure for the Pharmacovigilance Section within Human Medicines in 2005, recruitment and training of staff continued during 2006 with appointments made for key posts by the end of the year.

Drugs Withdrawn for Safety Reasons

No authorised medicines were withdrawn from the Irish market for safety reasons during 2006.

International Collaboration

There were a total of 11 meetings of the CHMP's Pharmacovigilance Working Party (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 US FDA through tele/videoconferences held during PhVWP meetings.

The IMB actively participated in the post-consultation review and update of Volume 9A of the Rules Governing Medicinal Products in the EU (Guidelines on Pharmacovigilance for Medicinal Products for Human Use) which addresses the revised and additional pharmacovigilance responsibilities arising from EU legislation that came into force in 2005. This revised and comprehensive guidance now also includes the guideline on Direct Healthcare Professional Communication.

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.

Electronic Reporting

The IMB continued its active participation in the EudraVigilance project, reporting all suspected serious ADRs occurring in Ireland electronically to the EMEA and to those companies with whom satisfactory testing had been completed. By the end of 2006, 21 companies were in production with electronic reporting to the IMB, with a further 22 in active testing. Scheduling of testing is ongoing and completion of all MAH testing is anticipated in 2007. The IMB staff participated at all EudraVigilance meetings organised by the EMEA throughout the year.

Publications

Three issues of the IMB's Drug Safety Newsletter were produced and circulated to doctors, dentists and pharmacists during 2006. These provide valuable information on the most up to date research or reviews across a range of medicines. In 2006, a comprehensive range of areas was outlined in the newsletter including:

- an overview of the safety issues associated with enoxaparin and clopidogrel;
- propofol infusion syndrome;
- the outcome of the retrospective review of reports associated with BCG Vaccine SSI;
- the outcome of EU reviews on the safety of antidepressants in children and adolescents, paroxetine and pregnancy and topical tacrolimus;
- co-amoxiclav and hepatobiliary reactions;
- bisphosphonates and osteonecrosis;
- atomoxetine and psychiatric effects;
- tamsulosin and intraoperative floppy iris syndrome (IFIS);
- issues related to the interchangeability of inhaled corticosteroids.

Copies of the Drug Safety Newsletters as well as updates on other safety issues considered to be of public health interest are published on the IMB's regular page in MIMS (Ireland) and are also available from the publications section of the IMB's website (www.imb.ie).

Company Liaison

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

Company/sponsor compliance with pharmacovigilance obligations was monitored on an ongoing basis. This was undertaken through continuous review and monitoring of the timeliness and quality of individual ADR reports, through evaluation of the follow-up information provided for individual reports as well as through evaluation of the quality and comprehensiveness of PSURs/ASRs 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 to oversee the implementation of relevant EU and national legislation.

During 2006, the Minister for Health & Children signed SI 547 of 2006 and SI 562 of 2006, which transposed into national law Commission Directives 2005/61/EC and 2005/62/EC, specifying the requirements for quality systems, traceability and notification of serious adverse reactions and events.

The IMB continued to participate and co-chair the expert group established with the Irish National Accreditation Board (INAB) during 2005 to define areas for addition to ISO 15189 (a standard for medical laboratories to which hospital blood banks are required to be accredited by November 2008) to address the requirements of Articles 14 and 15 (Traceability and Haemovigilance) of the Blood Directive. This Group concluded its work in June 2006 with guidance issued in August 2006.

In addition to discussion of haemovigilance activities by the Department of Health and Children's Steering Committee, the IMB continued its regular meetings with the National Haemovigilance Office (NHO). The key areas of work here involved reviewing haemovigilance events reported, discussion of issues of mutual concern, contributing to the development of guidance on haemovigilance reporting and consideration of further developments to facilitate monitoring and revised working practices necessary to meet the provisions of the above EU and national legislation.

Tissues and Cells Vigilance

The Minister for Health and Children signed SI 158 of 2006, which transposed into national law Directives 2004/23/EC and 2006/17/EC. This Statutory Instrument specifies the responsibilities regarding quality standards and certain technical requirements in relation to tissue and cells legislation. In addition, Directive 2006/86/EC implementing Directive 2004/23/EC, which covers traceability requirements, notification of serious adverse reactions and events and certain technical requirements, was published in 2006 and is awaiting transposition in 2007.

From April 2006, the IMB has established a reporting system for the notification of serious ADRs and events. *An Adverse Reaction/Event form* and a *Guide to Reporting Serious Adverse Reactions and Serious Adverse Events* have been developed, and were distributed to all centres potentially dealing with tissues and cells. Copies of these documents are also available on the IMB's website. In 2006, five adverse events were reported in association with use of tissues and cells, four of which satisfied the reporting requirements. No adverse reactions were reported.

LICENSING

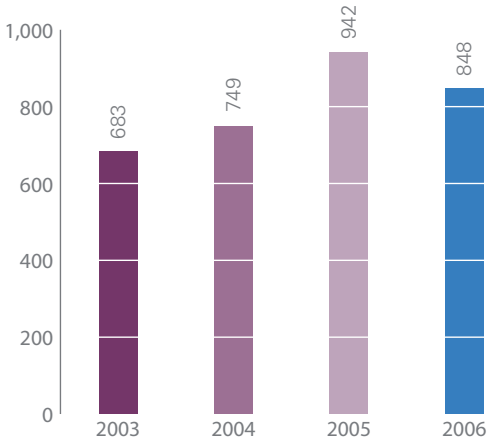
New Products

During 2006, the IMB processed 848 new product applications. This comprised 338 national, 268 EU mutual recognition (MR), 63 EU centralised* and 179 transfers applications.

*(*Total number of centralised applications completed in 2006, not all may be authorised by the European Commission at this point)*

The following table shows the distribution of new applications processed over the last number of years:

TOTAL OUTPUT FOR NEW APPLICATIONS



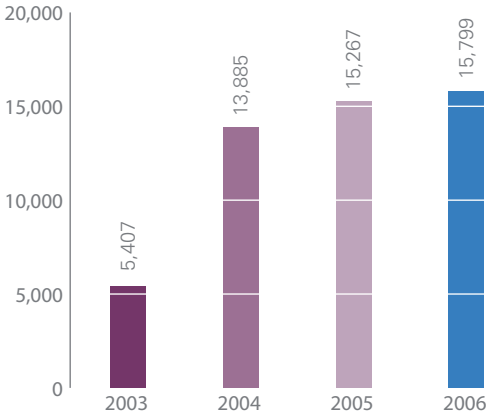
The total figure represents a slight decrease compared with 2005 and is due to a decrease in transfers and EU applications received and issued. There was an increase on previous years in relation to national applications issued. The total number of applications still in progress decreased to 285 in December 2006 from a total of 318 applications in progress in December 2005.

The median time for new product authorisations issued (excluding transfers) in 2005 was 30 weeks.

Variations

In 2006, 15,799 variations to authorisations for products authorised through the national or MR systems were processed. This was an increase over previous years as indicated below.

TOTAL OUTPUT FOR VARIATIONS

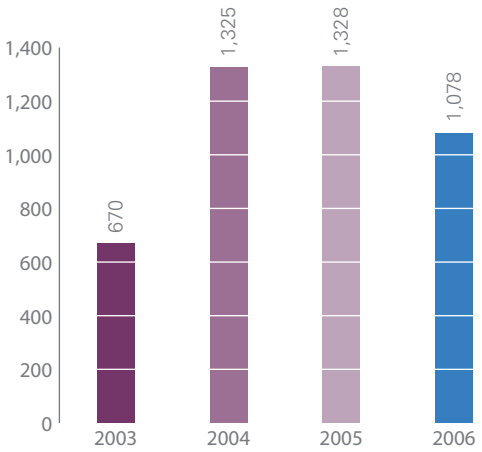


There was an increase in variation applications received in 2006 with an average growth of 16% in Type II applications.

Renewals

During 2006, there was an output of 1,078 renewals to product authorisations for products authorised through the national or MR systems.

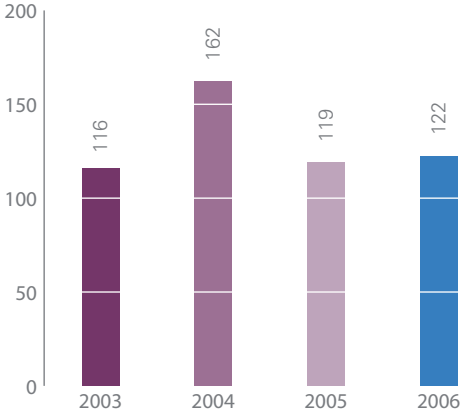
TOTAL OUTPUT FOR RENEWALS



Clinical Trials

During 2006, 122 applications to conduct clinical trials were approved by the IMB. This represents a similar figure to that of 2005 as depicted in the table below.

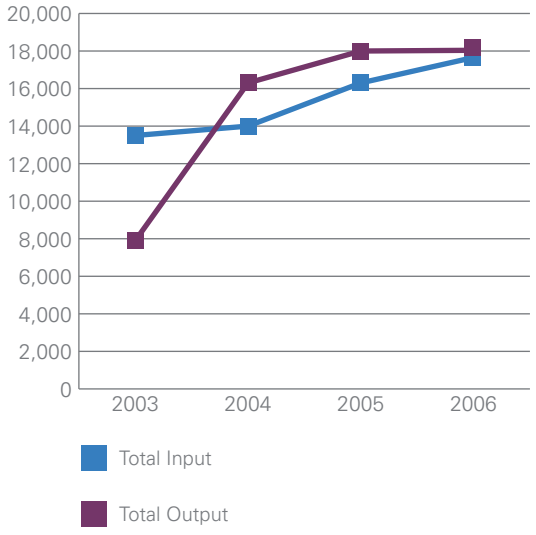
CLINICAL TRIALS APPROVED



In 2006, there was an output of 409 clinical trial amendment applications, which represents a minor increase from the 2005 figure of 368.

The total input of all applications continued to rise significantly in 2006 and this was matched by an increase in the output as depicted by the graph below.

APPLICATION INPUT AND OUTPUT OVERVIEW



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

VETERINARY MEDICINES

INTRODUCTION

2006 was highly productive for the Veterinary Medicines Department. Sustained efforts from staff, in addition to continued collaboration with other regulatory bodies, ensured fulfilment of the departmental aim: to have in place a self-sufficient, efficient system for licensing veterinary medicines in Ireland which operates to the highest European standards.

This was reflected in a number of key achievements throughout the year including:

- Assessment of a record number of applications.
- Publication of Irish public assessment reports on the IMB website.
- Development of new initiatives in relation to the assessment and licensing of immunological veterinary medicinal products.
- Publication of a pharmacovigilance guide to reporting ADRs in animals.

PHARMACOVIGILANCE

The IMB received 70 national reports of suspected ADRs to veterinary medicinal products in 2006. There were 59 reports from MAHs and 11 directly from veterinary practitioners.

Of the 70 reports, a total of 41 veterinary pharmaceutical products and 33 immunological products were identified as possibly associated with adverse effects. While the majority of reports related to the use of an individual veterinary medicinal product, two or more veterinary medicinal products were identified in four reports. A total of 42 reports related to suspected ADRs in the treated animals while 25 related to lack of expected efficacy and three cases involved suspected ADRs in individual users following exposure to a veterinary medicinal product. No regulatory actions were required to be taken in 2006 as a result of the safety information received in the form of spontaneous ADR reports.

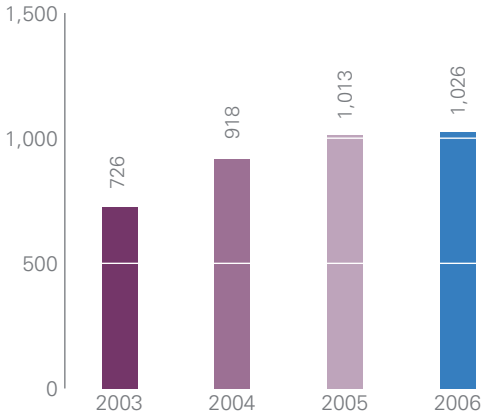
Suspected ADRs were reported in the following species: human (3), bovine (25), canine (24), ovine (8), equine (6) and feline (4).

The IMB is committed to promoting veterinary pharmacovigilance in Ireland. During 2006, the Veterinary Medicines Department, in conjunction with the EMEA, developed a *Simple Guide to Reporting Adverse Reactions*. This was sent out to all veterinary practitioners registered with the Veterinary Council of Ireland.

Licensing

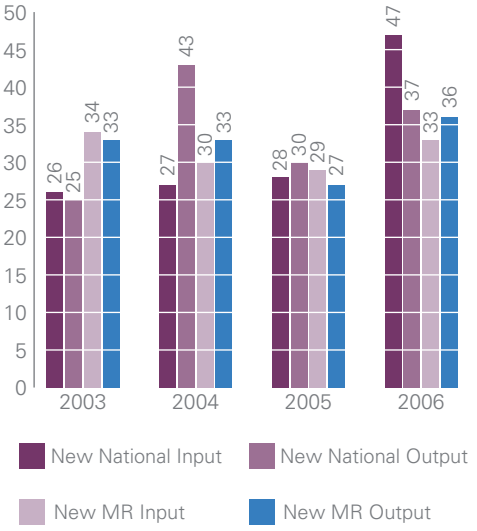
2006 was another record year for the Veterinary Medicines Department with continual improvement visible in relation to the total number of applications processed. This upturn in productivity was a result of the continued dedication of all individuals involved with assessment of applications and also the availability of additional resources.

TOTAL OUTPUT OF VETERINARY DEPARTMENT 2003-6

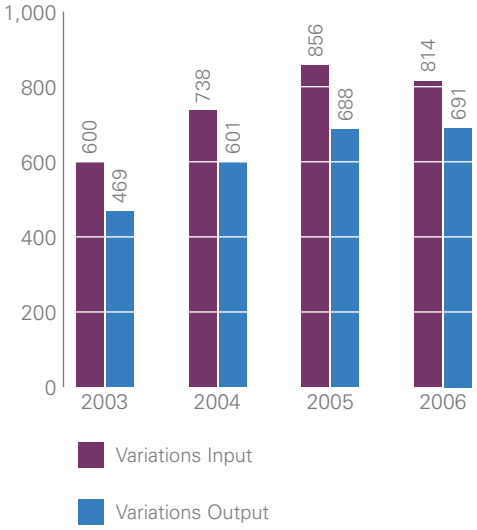


The number of new applications submitted during 2006 increased across the range of application types. The IMB continues to play a significant role in acting as reference member state in the European decentralised and mutual recognition procedure and is highly regarded in this role. IMB staff were also active in centralised procedures both for new medicines and referral procedures.

ACTIVITY LEVELS ON NEW APPLICATIONS 2003-6



ACTIVITY LEVELS ON VARIATIONS 2003-6



Other activities included:

- Staff from the department acting as co-rapporteur and national experts for three new or extension applications under the centralised procedure of the European Medicines Agency.
- Processing of 57 classification enquiries, compared to 73 in 2005 and 92 in 2004.
- Processing of two applications for clinical trials, compared to eight in 2005 and five in 2004.
- Completion of 15 review applications for immunological veterinary medicines during the year, compared to 17 in 2005 and 23 in 2004.

Income derived from the European decentralised, mutual recognition and centralised applications currently accounts for approx 30% of total receipts for the Veterinary Medicines Department, underscoring the importance of these activities in financing the Irish regulatory system.

Communications

A number of new initiatives aimed at developing this area were piloted during the year, the most significant being:

- Publication on the IMB website of Irish public assessment reports (IPARs) relating to new applications.
- Development of a secure system to encourage communication with applicant companies exclusively by email.
- Provision to service providers of indirect external access to information contained within the IMB database of authorised veterinary medicinal products for such purposes as population of data fields for veterinary prescriptions and product comparisons.
- Implementation of a scheme for electronic signing and storing of product literature aimed at improving efficiency in processing and accessing product literature.

The department also hosted a Veterinary Medicines Information Day, which afforded the opportunity to convey to stakeholders updates relating to changes in legislation. Other relevant updates relating to internal regulatory procedures were also presented. Feedback received indicated that this was a useful informative channel for communication with interested parties. Another event is planned for late 2007.

Staff from the department continued to liaise with a number of external organisations including the Department of Agriculture and Food and the Animal and Plant Health Association (APHA). There was a slight increase from 2005 in the number of meetings held with applicant companies which was in part related to the continued efforts of staff to address the availability of veterinary medicines in Ireland.

As in previous years, IMB personnel published several articles on the regulation of veterinary medicines in Ireland and attended meetings with stakeholders on topical issues. An updated *Guide to the definition of an animal remedy and the classification process* was also published during the year.

Other Activities

During the year, discussions were held with the Veterinary Medicines Directorate in the UK to examine the issue of potential loss on 'review' of immunological veterinary medicinal products (IVMPs) to the Irish market. This was due to the requirement for Irish and UK specific packaging for IVMPs to be available in both countries. The two authorities subsequently met with industry and, as a result, a new harmonisation procedure termed the 'Alignment Procedure' was developed for immunological products.

Following on from this, another initiative was developed for harmonising labels in Ireland and UK at the end of an EU procedure i.e. mutual recognition and decentralised procedures. Work commenced on the development of a procedural document in relation to this initiative and it was also proposed to trial the procedure for the joint assessment of packaging for new products.

The IMB continued to aid other regulatory agencies with the enforcement of relevant legislation by conveying to industry and other interested parties the impact of new amendments. Examples included:

- New provisions under Directive 2001/82/EC, as amended by Directive 2004/28/EC, regarding the consideration of effects on the environment in the risk/benefit assessment of veterinary medicinal products and on the data requirements regarding such effects.
- Implementation of the change to the supply categorisation of intramammary antibiotics as 'Prescription Only Medicines' (POM).

The IMB successfully chaired the European Task Force on the Availability of Veterinary Medicines, which intends to provide a report and recommendations to the Heads of Medicines Agencies (HMA) in the EU by February 2007. This report will help chart the future availability of veterinary medicines in Europe.

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

MEDICAL DEVICES

INTRODUCTION

2006 was a productive year for the Medical Devices Department. Monitoring of safety issues on the market place continued to be a key activity. Trends indicate a significant increase in activity particularly in relation to the areas of vigilance, compliance and clinical investigations.

In the first six months of 2006, a development study of the Medical Devices Department was carried out focusing on future activity levels within the department and the resources required to deliver essential services. This culminated in a proposal recommending appropriate resources to manage projected activity being adopted by the Board of the IMB and subsequently forwarded to the Department of Health and Children (as the agency funding these activities) for consideration.

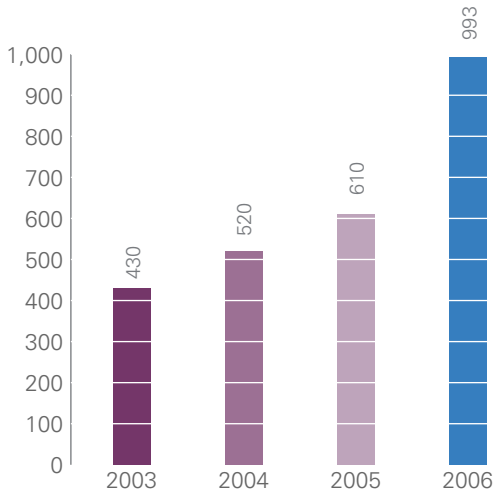
The Advisory Committee for Medical Devices met three times in 2006. Areas discussed included devices in the community setting, point-of-care testing, review of the Medical Devices Directive (MDD) and vigilance issues. The committee also assisted with the preparation of a safety notice in relation to the procurement and commissioning of medical equipment for hospitals.

The Dublin Area Teaching Hospitals vigilance pilot system was successfully concluded in 2006 and resulted in an increase in user reporting. It is expected that the model will now be implemented throughout the Dublin area.

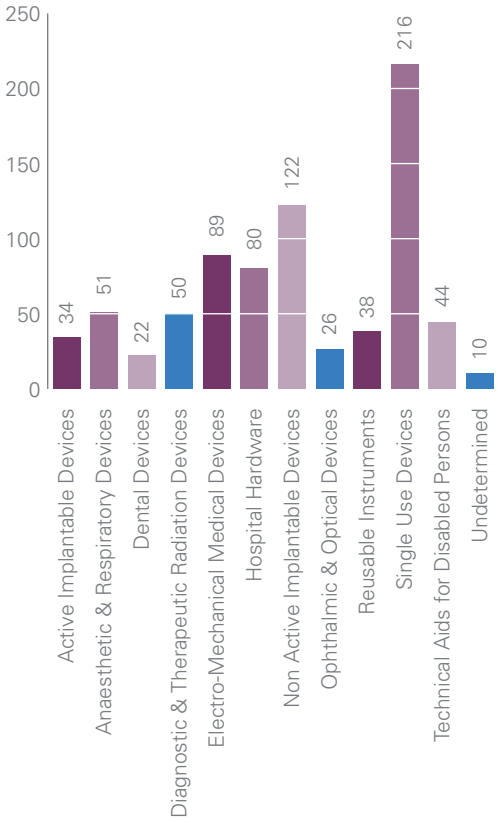
Vigilance

The number of vigilance reports received for medical devices continues to increase substantially, with an overall increase of 67% seen in 2006 as highlighted below. This increase was noted across all medical devices, with increases of 69% for general medical devices (GMDs), 100% for active implantable medical devices (AIMDs) and 42% for *in-vitro* diagnostic medical devices (IVDs) being recorded. Higher risk classes of general medical devices continue to represent a significant number of the reports received. General category IVDs represent the majority of vigilance reports received for IVDs with a large proportion relating to clinical chemistry as highlighted below. In 2006, there was a 14% increase in the number of user reports received by the IMB.

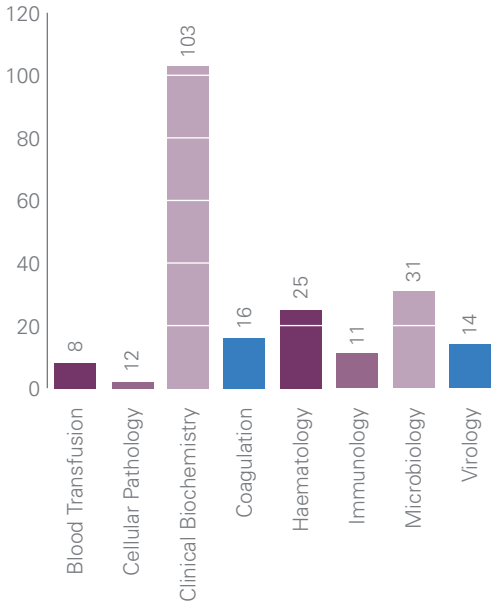
NUMBER OF VIGILANCE REPORTS RECEIVED DURING 2003 TO 2006



FAMILY GROUPS OF DEVICES IMPLICATED IN VIGILANCE REPORTS IN 2006 – GENERAL MEDICAL DEVICES AND ACTIVE IMPLANTABLE MEDICAL DEVICES



FAMILY GROUPS OF DEVICES IMPLICATED IN VIGILANCE REPORTS IN 2006 – *IN-VITRO* DIAGNOSTIC MEDICAL DEVICES



The principal issues encountered during 2006 included reports relating to single use devices, implantable devices, blood glucose meters and various devices used in cardiovascular interventions.

Quality issues and software problems were found to be the root causes of many of the vigilance issues relating to electro-mechanical medical devices and *in-vitro* diagnostic medical devices. Device maintenance and management problems have been identified as important causes of reports in relation to technical aids for disabled people and wheeled mobility.

Recalls

During 2006, there were a number of major recalls of medical devices. These included a recall of a contact lens solution which was thought to be associated with an increased incidence of a serious eye infection and the recall of three automatic external defibrillators due to component problems. A large replacement programme of various manufacturers' blood glucose meters was undertaken in Ireland during 2006, further to incidents associated with the unit of measurement inadvertently changing from mmol/l to mg/dl. In all instances, the IMB had considerable involvement in overseeing the manufacturers' recalls.

The IMB also co-operated closely with other European Competent Authorities, the European Commission and the device manufacturer in relation to a major field safety corrective action associated with an infusion pump.

A debate arose amongst the global clinical community about drug-eluting coronary stents and their appropriate use. At present, the international consensus remains that the benefits gained from using drug-eluting stents outweigh the potential risks. The IMB continues to monitor and evaluate this situation.

Notified Bodies

The IMB conducted a surveillance audit of the MDD, the Active Implantable Medical Device Directive and the *In-vitro* Diagnostic Medical Device Directive (IVDD) at the premises of the Irish Notified Body i.e. the National Standards Authority of Ireland (NSAI). Several issues arose from these audits, specifically the certification process and auditor performance, which are being addressed by the NSAI. A follow-up audit is scheduled for early 2007. Two satisfactory observed audits were conducted on the Notified Body Auditors to the MDD and IVDD.

A peer review of the Danish Competent Authority Notified Body audit process was conducted as part of the European peer review programme. A report was completed and the findings were shared with the Danish Medicines Agency.

Certificates of Free Sale

In 2006, 348 certificates of free sale were issued by the Medical Devices Department, which was a 15% increase over 2005. Concerns were raised with the Irish Medical Devices Association regarding the quality of the applications for certificates of free sale and the accompanying documentation. Incomplete applications and documentation are being returned to the applicants for completion.

Registrations

The number of new notifications/amendments in 2006 in relation to the register for medical devices was 343. A total of 172 *in-vitro* diagnostic medical devices (IVDs) and 171 general medical devices (GMDs) were registered. The number of new organisations registered was 48.

Clinical Investigations

During 2006, six clinical investigation applications of general medical devices were received under SI 252 of 1994 and one clinical investigation of an active implantable device was received under SI 253 of 1994. While reviews of some of these applications remain in process (three instances), no objection was raised to the investigation proceeding. Two applications were withdrawn and postponed while further data are collated. One application was withdrawn altogether. Another investigation was referred to the IMB's Advisory Committee for Medical Devices.

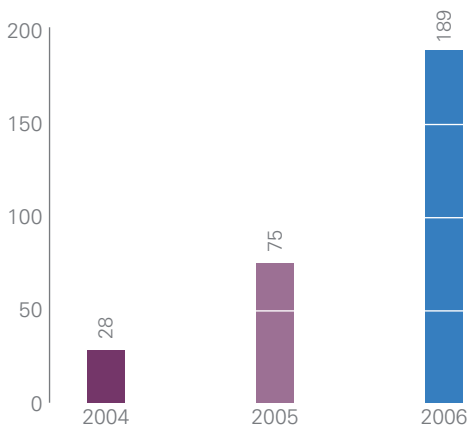
An application was approved to make a novel non-CE marked device used in paediatric cardiology applications available for use on compassionate grounds.

The IMB continues to promote communication with manufacturers and other investigation sponsors. This consultative approach, including pre-submission meetings, helps to clarify data requirements and may facilitate the review process. During 2006, the IMB consulted with and delivered presentations to many of Ireland's clinical research ethics committees with a view to developing a guidance document for ethics committees relating to medical device legislation and the investigation review process.

Post Market Surveillance Activities

A significant increase in the number of compliance cases handled was noted in 2006. The number of cases increased from 70 to 172, which represents an increase of 246% between 2005 and 2006. This increase was due to more focused compliance activities carried out by the department as well as increased awareness in the marketplace. The majority of cases were related to reactive issues.

NUMBER OF COMPLIANCE CASES OPENED



A number of proactive compliance activities were undertaken in 2006, including projects relating to systems and procedure packs and continuous positive airway pressure machines (CPAP). These proactive projects identified issues in relation to lack of understanding and knowledge of the requirements of the legislation. As a consequence, a considerable number of manufacturers became compliant in 2006. A total of 46 compliance visits, both proactive and reactive, were conducted.

A critical issue also arose in relation to the sale of various illegal IVD test kits via internet sources. Concern was focused on the fact that the kits were supplied by an Irish source. A press release and safety notice were issued by the IMB in the interests of public health. Investigations are still underway.

The Market Surveillance Operations Group monitored and followed up compliance communication requests coming from European countries.

In 2006, seven post-market surveillance audits were carried out. Four manufacturers were audited following issues arising from field safety corrective actions. One of these manufacturers required a follow-up audit due to inadequate product design. Two audits were conducted with the compliance section of the department relating to flammability concerns. The program of custom-made device audits continued this year and a total of 23 audits took place.

The area of splinting was also looked at in relation to classification as custom-made or class I medical devices. A position paper will be published in early 2007.

Publications

A number of guidance documents were published for stakeholders. In addition, the department continued to issue a monthly circulation of safety and advisory notices for medical devices to the health services in Ireland. Eight IMB safety notices and 68 Medicines & Healthcare Products Regulatory Agency (MHRA) safety notices were circulated.

Four medical device newsletters were issued and these continue to be well-received by stakeholders. Contributions are being received from both the healthcare sector and industry in relation to topics of interest.

All publications are available on the IMB website.

Communication

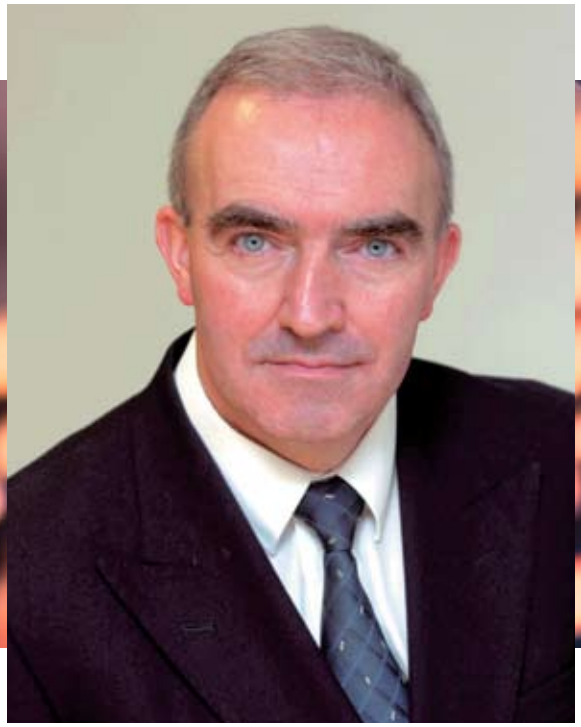
During 2006, the IMB held an information day on the 'Safe Management of Infusion Devices' at the Adelaide & Meath Hospital incorporating the National Children's Hospital, Tallaght, Dublin. This event was well attended by nursing staff, clinical engineers, risk managers and other healthcare professionals involved in the use and management of infusion devices. The mix of presentations from the IMB, the MHRA and representatives from hospitals in Ireland and the United Kingdom provided participants with some key practical information and advice.

The IMB also participated in a Consultative Group 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. It is anticipated that this guideline will be published in 2007.

European Activity

The IMB participated in a number of European meetings of the Medical Devices Expert Group (MDEG) and related working groups. The IMB led a subgroup of the European Electronic Labelling Working Group to develop a MED.DEV guidance document outlining the requirements for manufacturers to provide information in electronic format on the use of IVDs by healthcare professionals. This guidance document is now published by the Commission on its website. The IMB also actively participated in revision of the MED. DEV guidelines on the medical devices vigilance system which are due to be published in 2007.

The IMB continued its participation in the European Commission's Clinical Evaluation Task Force (CETF) including involvement in a small subgroup to draft a checklist for Competent Authorities regarding clinical investigation application reviews. Ireland presented and participated at two meetings of the Presidencies of the EU namely, Austria and Finland.



Mr. John Lynch, *Director of Compliance*

COMPLIANCE

INTRODUCTION

2006 was the first full year of operation for the Compliance Department's new structure. The department has five sections and summaries of the activities of four of these are set out below: Licensing, Inspection, Enforcement and Market Compliance. The fifth section, Planning, is responsible for planning and reporting.

LICENSING

During 2006, the Licensing Section processed all applications received. This included the licensing of manufacturers of human and veterinary medicines, pharmaceutical wholesalers, grocery wholesalers and manufacturers of investigational medicinal products. A total of 36 new licences/authorisations were issued. No licences were revoked and a total of 485 variations were processed and issued, compared to 452 in 2005 and 429 in 2004.

The total number of licences in force is presented below by category.

Total Number of Licences	2004	2005	2006
Manufacturers of Medicinal Products for Human Use	81	85	**82**
Manufacturers of Medicinal Products for Veterinary Use	29	30	**30**
Manufacturers of IMPs	12	27	**36**
Wholesalers	141	139	**148**
Blood Establishment Authorisation	0	0	**1**
Tissue Establishment Authorisation	0	0	**0**
Laboratory Certificates	0	0	**8**

The Licensing Section continued to support the Inspection Section with regard to the issuing of a GMP certificate within 90 days following a satisfactory inspection.

As per the requirements of Parliament and Council Directive 2002/98/EC, all five blood establishments submitted applications for blood establishment authorisation. The first blood establishment authorisation was issued in July 2006 and inspections are ongoing in the remaining four with a view to recommending authorisation during 2007.

On the 7th of April 2006, the requirements of Parliament and Council Directive 2004/23/EC with regard to the quality and safety of human tissues and cells came into force. By year end, 17 applications for tissue establishment authorisation had been received.

Controlled Drugs Licensing

The formal transfer of responsibilities to the IMB for controlled drugs licensing functions from the Department of Health and Children has been anticipated since 2003. While services in this area are already being delivered by the IMB, these responsibilities are expected to formally transfer during 2007. Controlled drug licences include annual licences which authorise the relevant sectors of the pharmaceutical and healthcare industries and other sectors to produce, supply and/or possess a controlled drug as appropriate. Other licences include import and export licences which authorise the international trading activities of these sectors. During 2006, a total of 1,585 controlled drugs licences were issued. Activity levels are set out below.

Controlled Drugs Licensing Activity	2006
Registration	**26**
Export and import	**944**
Annual – New	**20**
Annual – Renewal	**152**
Letter of no objection	**431**
Pilgrams	**12**
Hemp	**0**

EU Projects

During the year, the Licensing Section and the IT and Change Management Department continued to participate actively in the Eudra GMP EMEA project group, the purpose of which is to establish a database of all manufactures of medicinal products in the European Economic Area (EEA). This is an important forum as it will provide the IMB with up-to-date information on the good manufacturing practice (GMP) status of manufacturers across all Member States. This project will continue throughout 2007.

Export Certificates

There was an output of 2,050 export certificates as set out below, representing an increase of 16% on the total for 2005.

Product Certification Activity	2004	2005	2006
Certification of Documents	265	305	389
Certificate of Free Sale	11	18	35
Certificate of Good Manufacturing Practice for Finished Product Manufacturers	187	181	224
Certificate of Good Manufacturing Practice for Active Substance Manufacturers	66	38	43
Certificate of a Pharmaceutical Product for Human Use	1026	974	1193
Certificate of a Pharmaceutical Product for Veterinary Use	102	110	97
Other	37	103	69

INSPECTIONS

Good Manufacturing Practice (GMP)

The GMP inspection group carried out 99 GMP inspections in Ireland in 2006. These included inspections relating to new applications and changes to manufacturers' authorisations as well as routine and follow-up re-inspections, inspections of active substances manufacturers and contract testing laboratories. A total of six foreign inspections were performed in the year, four of which were carried out on behalf of the European Medicines Agency (EMEA).

A successful Information Day was held in November for manufacturers and marketing authorisation holders (MAHs) with over 220 participants attending.

Inspector cross-training was also an area of continued focus within the Inspections section during 2006.

Good Distribution Practice (GDP)/ Controlled Drugs

During 2006, 128 GDP inspections were conducted in Ireland. The focus of inspection for controlled drugs was to follow-up on the implementation of corrective actions identified in 2005. These inspections were incorporated into the GDP and GMP inspection programmes for 2006.

An information meeting on various aspects of controlled drugs licensing and regulations relating to the manufacture distribution and storage of controlled drugs, was held in November.

Good Clinical Practice (GCP)/ Pharmacovigilance Inspections

A requirement for competent authorities to carry out GCP inspections is stated explicitly in the Clinical Trials Directive 2001/20/EC and in the transposing national legislation, the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations, 2004 (S.I. 190 of 2004) and subsequent amendments.

The scope of the IMB's activities in evaluating compliance with GCP includes inspections of sponsors, investigators, contract research organisations and laboratories. It does not include supervision of the activities of ethics committees.

During the year, the IMB carried out 17 GCP inspections in Ireland of pharmaceutical companies (sponsors) and clinical research sites, including commercial and non-commercial research investigators. One pharmacovigilance systems inspection of an MAH was also performed in 2006.

Blood, Tissues & Cells

The IMB is the designated Competent Authority for national legislation in relation to blood establishments. SI 360 of 2005, which transposed the requirements of EU Directive 2002/98/EC on quality and safety for blood, SI 360 of 2005, came into force in November 2005. This legislation required that all sites involved in the collection, testing, processing, storage and distribution of blood be inspected and authorised. In 2006, the IMB carried out 10 inspections of blood establishment sites.

Directives 2004/23/EC and 2006/17/EC were transposed by SI 158 of 2006 "European Communities (Quality and Safety of Human Tissues and Cells) Regulations 2006. This SI came into force in two phases; the first on the 7th April 2006 and the second on the 1st November 2006. Prior to 7th April 2006 there was no Irish legislation covering the quality and safety of tissues and cells intended for human application. Nine inspections of tissue establishment sites were carried out in 2006.

Developing Standards

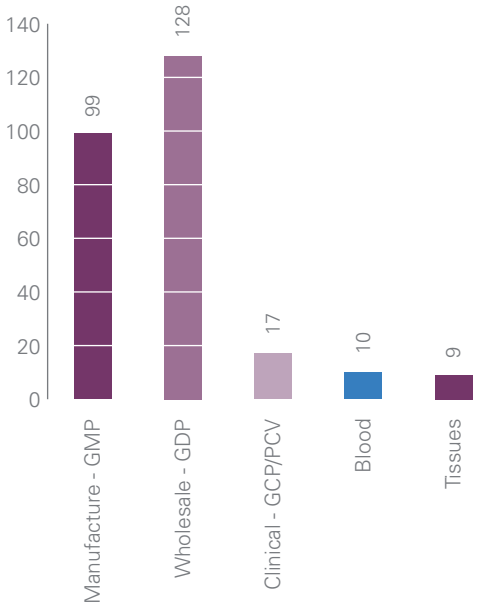
The GCP and GMP sections continued to play a significant part in the Ad Hoc Inspectors' Meetings (GCP and GMP) at the EMEA and within the Pharmaceutical Inspection Co-operation Scheme (PIC/S). Inspectors participated in expert circles on subjects such as computerised systems. The primary aim of these activities is to contribute to the harmonisation of inspection standards.

The IMB also participated in the development and review of new legislation for the manufacture and wholesaling of medicinal products.

The GDP section continued to be proactively involved in various EU and other international regulatory meetings for controlled drugs and medicinal product distribution. Activities included participation in the PIC/S joint visit programmes and attendance at relevant international meetings including the EU Drugs Precursor Committee and United Nations Office on Drugs and Crime working groups.

During the year the GCP section actively participated in the development of procedures for EU GCP inspections. The Working Party of GCP Inspection Services at the EMEA discussed appropriate inspection frequencies for determination of GCP compliance. However, there is no EU wide policy at this time.

NUMBER OF INSPECTIONS COMPLETED IN 2006



ENFORCEMENT

Overview

The IMB's Enforcement Section initiated 469 cases involving breaches of medicinal product legislation during 2006, compared to 561 in 2005. The number of enforcement cases closed in 2006 was 797, compared to the 430 cases number closed in 2005.

During 2006, the IMB seized a total of 96,487 tablets, 41,361 capsules, 52,873 ml of liquids and 5,652 g of creams. The active substances contained in the products seized include co-amoxiclav, diazepam, bendrofluazide, sildenafil citrate, tadalafil and other erectile dysfunction formulations, anti-depressants, prescription-level vitamins, antibiotics, corticosteroids, weight-loss products, skin lightening products and ephedrine.

A number of legal proceedings were undertaken in 2006 with a successful outcomes. These included a conviction recorded in the District Court recorded against a holistic practitioner, a legal entity and an employee for the procuring and administering (by parenteral means) of an unauthorised prescription-only medicinal product. In addition, a joint IMB/Garda operation around the supply of anabolic steroids resulted in the Director of Public Prosecutions initiating a prosecution on indictment in relation to this matter in 2006.

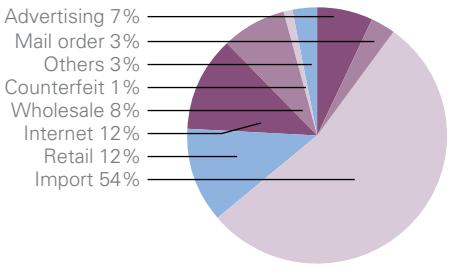
Authorised officers from the IMB, the Health Service Executive (HSE) and the Pharmaceutical Society of Ireland carried out joint operations in the retail pharmacy sector to assess compliance with the wide range of legislation that applies to pharmacies.

The majority of unauthorised supplies into Ireland of unauthorised medicinal products originated from within the EU, followed by the USA.

Liaison between the IMB and other enforcement agencies 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 IMB contributed to the WHO Organising Committee for the International Conference on Medicines Counterfeiting held in Rome and a follow-on conference held in Geneva. In addition, the IMB attended Council of Europe seminars relating to counterfeiting of medicinal products and a Council of Europe Anti Doping Conference. The IMB also attended the annual conference of the Permanent Forum on International Pharmaceutical Crime (PFIPC).

BREAKDOWN OF BREACHES BY SECTOR



MARKET COMPLIANCE

The Market Compliance Section runs two main market surveillance and compliance programmes – the Quality Defect and Recall Programme and the Sampling and Analysis Programme. In 2006, work was initiated to develop a third compliance programme for the inspection of marketing authorisation holder companies. The section was also active in the area of stakeholder education.

The IMB commenced a research project on the supply and usage of unauthorised medicinal products in Ireland. It is expected that this project will be completed in 2007.

Quality Defects in Human and Veterinary Medicinal Products

A total of 371 quality defects in human and veterinary medicinal products were reported or identified. This represents an increase of 13% over the number for 2005.

In 2006, 336 reports of quality defects concerned medicinal products for human use and 35 reports concerned veterinary medicinal products.

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

A number of the quality defect reports received or identified in 2006 resulted in batch and product recalls being requested by IMB, and a number resulted in the issuance of 'Rapid Alert Notifications of a Quality Defect' to other Competent Authorities by IMB. A number of 'Caution in Use Notifications' and 'Dear Doctor Letters' were also issued to health care professionals in cases where cautionary advice on the use of a medicinal product was required.

In addition, a number of IMB safety alerts were issued to various professional bodies and trade representative groups in Ireland as a precautionary measure in order to alert these parties and their membership to the fact that potentially harmful, unauthorised medicinal products had been notified to IMB by other Competent Authorities and that these could be on the market in Ireland.

Some 84 reports of critical quality defects were received or identified. This represents a 27% increase over 2005 figures and is attributed to both the nature of the reports in 2006 and the high level of reporting of quality defects. A total of 15 of the 84 reports were relevant to Ireland, in that the batch of product concerned was either on the Irish market or was manufactured in Ireland. The remaining 69 reports, which were determined as not affecting Ireland, were received mainly from other Competent Authorities through the rapid alert notification system.

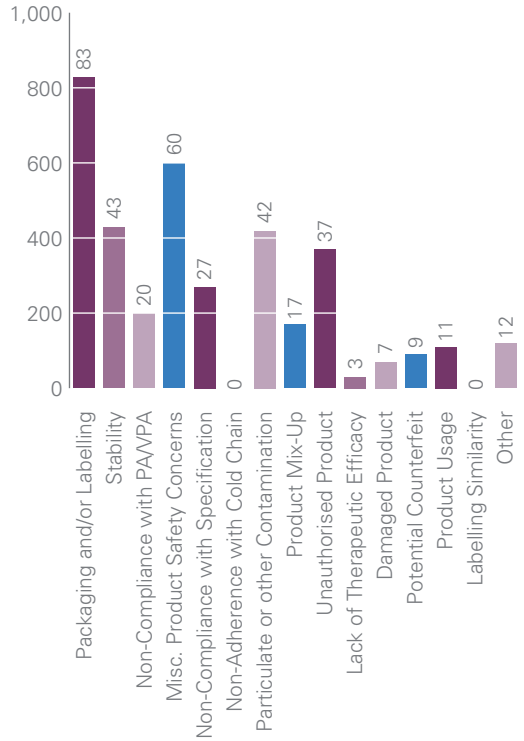
All 15 critical quality defects which affected Ireland concerned medicinal products for human use. These critical defects, which gave rise to product safety concerns, are summarised below:

- Sterility assurance issues with medicinal products for injection or infusion.
- Faulty gauges on medicinal gas cylinders.
- Potential for over-concentrated packs of a product for injection.
- Errors in product composition for compounded infusion products.
- Microbial contamination issues with non-sterile products.
- Product mix-up issues.
- Unauthorised herbal medicinal products on the Irish market which were potentially harmful.

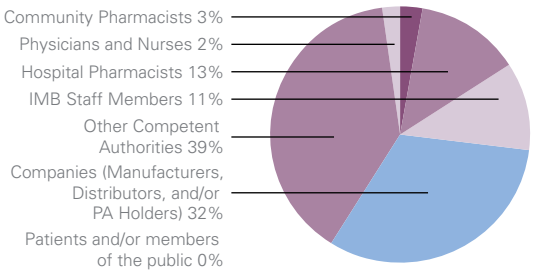
In 2006, 22% of the total number of quality defects concerned packaging and labelling issues. Product safety concerns, which included issues such as lack of sterility assurance, incorrect labelling with potential medical consequences, and product contamination issues, were also a large contributor to the total. Appropriate corrective action was taken in the interests of public health.

The level of reporting of quality defects by pharmacists increased by 65% over the previous year. This is seen as a positive development, as the IMB has been working to encourage the reporting of quality defects by pharmacists.

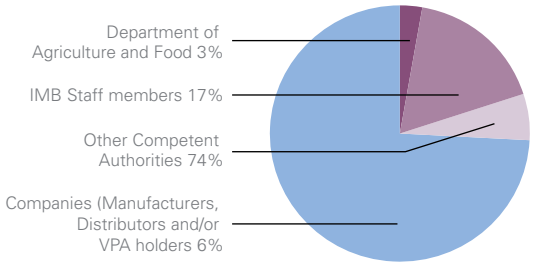
AREAS OF QUALITY DEFECTS 2006



REPORTS OF HUMAN MEDICINAL PRODUCT QUALITY DEFECTS



REPORTS OF VETERINARY QUALITY DEFECTS



Recalls of Human and Veterinary Medicinal Products

The IMB was involved in a total of 58 recalls of medicinal products during 2006: 56 for human medicinal products and two for veterinary medicinal products. Packaging and labelling issues, the distribution of unauthorised products and product safety concerns were the largest individual contributors to the total.

Some 149 recall notifications were received from Competent Authorities and Official Medicines Control Laboratories in other countries. Each of these reports was investigated to establish the potential implications for the Irish market and, where necessary, appropriate follow up action was undertaken.

BREAKDOWN OF HUMAN MEDICINAL PRODUCT RECALLS			
Year	**2004**	**2005**	**2006**
Packaging and/or Labelling	19	10	**14**
Stability	9	7	**3**
Non-compliance with MA	4	6	**0**
Product safety Concerns	5	13	**8**
Non-compliance with Specification	2	3	**4**
Non-adherence to Cold Chain	0	1	**0**
Particulate or other Contamination	1	1	**4**
Product Mix-Up	1	3	**3**
Unauthorised Product	14	20	**11**
Lack of Therapeutic Efficacy	0	0	**0**
Damaged Product	New category for 2006		**3**
Product Usability	New category for 2006		**5**
Other	8	4	**1**
Total Number	63	68	**56**

BREAKDOWN OF VETERINARY MEDICINAL PRODUCT RECALLS			
Year	**2004**	**2005**	**2006**
Packaging and/or Labelling	8	3	**1**
Stability	0	0	**1**
Non-compliance with VPA	0	0	**0**
Product safety Concerns	0	1	**0**
Non-compliance with Specification	2	1	**0**
Particulate or other Contamination	0	0	**0**
Product Mix-Up	0	0	**0**
Unauthorised Product	8	1	**0**
Other	1	0	**0**
Total Number	19	6	**2**

Sampling and Analysis

The sampling and analysis programme operates through the collection of samples of authorised medicinal products, active substances and other products (for example borderline products and unauthorised products making medicinal claims) from the marketplace or from the site of manufacture and as a result of enforcement activities. These products are analytically tested and/or reviewed internally. A risk-based approach is taken when carrying out planned sampling and analysis work.

In 2006, human and veterinary vaccines as well as one biotechnology-based medicinal product were tested. This is the first time such products were tested as part of the IMB's market surveillance work, and this was made possible via active participation in the Official Medicines Control Laboratory (OMCL) network and via co-operation with OMCL laboratories in specific countries. A formal programme of braille related market surveillance work was also initiated.

A total of 316 medicinal products and other product samples were analysed or reviewed. This is an increase of approximately 18% over 2005 figures. Of these, 140 samples were sent for laboratory analysis and 176 samples were reviewed internally for packaging and labelling compliance.

Participation in EU Sampling and Analysis Activities

The IMB actively participated in the sampling and analysis programme for centrally-authorised medicinal products and in the sampling and analysis programme for medicinal products authorised via the EU mutual recognition procedure. The IMB sampled five centrally authorised medicinal products from the Irish market place for testing by OMCLs in other EU countries. The IMB also analysed eight batches of a centrally authorised product sampled from the markets of a number of Member States. Six medicinal products authorised via the mutual recognition procedure were sampled and analysed in Ireland while a further 15 products, sampled from the Irish marketplace, were analysed by other OMCLs on the IMB's behalf. This latter work included the testing of the vaccine and biotechnology products mentioned earlier.

Principal Findings from the 2006 Sampling and Analysis Programme

- Thirteen authorised medicinal products were not fully compliant with their registered specifications.
- In relation to the suitability of analytical test methods, five were found to be deficient in several respects.
- All of the above issues were the subject of investigative and follow-up activities with the marketing authorisation holders or manufacturers concerned.

Acknowledgements

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

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

INFORMATION TECHNOLOGY AND CHANGE MANAGEMENT

INTRODUCTION

The Information Technology and Change Management Department supports the IMB's organisational activities through its role as a key service provider. The department's responsibilities include the development, maintenance and support of all hardware, communications systems and software used by the organisation. The department is also responsible for the management of the IMB's change management programme. The change management function is focused on reviewing operational activities in order to achieve greater effectiveness and efficiency.

In 2006, the IT and Change Management Department provided systems support services to over 200 staff on a wide range of specialised systems. These services range from business analysis through to end-user training.

Training is an important aspect of the department's work and over 106 members of staff received training in 2006. The department also provides technical support to all staff through its helpdesk function.

2006 was a very active year for the programme management section. A range of projects were on-going, including the RIO (Regulatory Information On-Line) system. This section is also responsible for co-ordinating the various EU IT projects, of which there are over ten, including EudraPharm, EudraVigilance, E2B, EudraNet, eSubmissions.

The department is also responsible for the management of the IMB's website (www.imb.ie), with a large number of updates throughout the year. In 2006, work commenced on the redevelopment of the IMB website and its replacement will be made available in 2007.

Infrastructure management was an important topic for the department throughout 2006 as refurbishment work on the IMB's buildings was undertaken. A new computer room facility with upgraded networking facilities was established, and staff worked closely with the various contractors to ensure minimum disruption to the business activities during this period.

TECHNOLOGY ACTIVITIES

Human Medicines Department

As the largest business area within the IMB, the Human Medicines Department operates a number of key support systems, including the internal workflow application (NIMBUS) together with various pharmacovigilance applications.

Work on the development of enhanced web services to industry continued throughout 2006 with a number of workshops and training sessions hosted by the IMB. In 2006, the RIO system went into production with the testing group. The RIO system provides registered applicants with an opportunity to complete and submit human medicines variation applications on-line. In addition, the system provides tracking and messaging functionality for the applicant. To date, feedback has been very positive. The roll-out of the system to interested pharmaceutical companies will continue throughout 2007.

Human Medicines Drug Safety

In 2006, E2B (exchange of structured drug safety information) became more widely used as many of the pharmaceutical companies successfully completed the testing phase of the system. The IMB plans to examine opportunities to enhance the functionality of its drug safety systems in 2007. The IMB continues to participate actively in the EudraVigilance Technical Implementation Group at the European Medicines Agency.

Knowledge Management Systems

Further improvements to the organisational document management systems were undertaken at the end of 2006. In line with the IMB's wish to capture and retrieve information in a more dynamic way, the system has now been extended to provide more comprehensive knowledge management functionality. The system will be implemented throughout the IMB in 2007.

Quality Management Systems (QMS)

Quality was a strong focus for the organisation in 2006. Enabling technology to support the implementation of the organisational quality management system was developed. The quality management section worked closely with the IT function on the development of the new system throughout the year.

Veterinary Medicines

The Veterinary Medicines Department fully implemented work management technology. This technology provides opportunities for operational efficiencies within the department and provides improved decision making information. The department also enhanced its authorised veterinary medicines listing available via the IMB website (www.imb.ie) to include the method of sale and supply for each authorised product.

IMB Website

Stakeholders continue to use the internet to access essential information relating to regulatory affairs and to access information on authorised medicines. In order to provide a more valuable resource to stakeholders, the IMB website was targeted for redevelopment in 2006.

The new website will include improved search functionality and more intuitive navigation for users. In addition, the extranet services will be incorporated into the site providing a useful portal for industry users. The new enhanced site will be launched in 2007.

Technical Support – External

The IT and Change Management Department provides technical support to a small number of external agencies. In 2006, both Malta and Norway received support services from the IT and Change Management department. The EMEA, Icelandic and German regulatory authorities visited the IMB to review its use of various systems. A number of other authorities have expressed interest in visiting during 2007.

EU Projects

The IMB is an active member of a wide range of European working groups in the technology area. As part of the IMB's commitment to the EU telematics strategy, it is essential that its core systems are compatible with initiatives in this area.

EU TELEMATICS PROJECTS

EudraPortal				
EudraServices EudraNet. EudraLink. Web Services. SSO				
EudraDataWarehouse				
Subm.	Eudra pharm	Eudra CT	Eudra Vig.	Eudra GMP
EU Telematics Controlled Terminology				
Reference Data Model				

There are currently 13 priority projects ongoing in this area. These include projects concerned with:

- Drug safety (EudraVigilance)
- Repository of medicinal product information (EudraPharm)
- Good manufacturing practice (EudraGMP)
- Clinical trials (EudraCT)
- Secure network communications (EudraNet)
- Electronic Submissions (eSub)

2006 proved to be a significant year for this area and, with plans to provide a wide range of scientific data to the central database located at the EMEA, this trend is likely to continue for a number of years.

Change Management

The IMB remains committed to ensuring quality and continuous improvement. In order to support this commitment, a comprehensive change management programme has been developed. In 2006 both the Veterinary Medicines and Medical Devices Departments were involved in projects to examine their performance and to identify potential opportunities for improvement.

An operational review of the Medical Devices Department was completed with proposals for improved structural arrangements being made in October 2006. It is anticipated that the new organisational arrangements focussing on improved service levels will commence implementation in 2007.

The Veterinary Medicines Department also underwent a review during the summer of 2006. This review resulted in a proposal to realign the key processes within the department and take on a small number of additional resources. The new management team will take up their positions in early 2007 with the implementation of the new arrangements following thereafter.

Dr. Mike Morris, *Senior Scientific Advisor*

Dr. Caitriona Fisher, *Quality Manager*

CHIEF EXECUTIVE'S OFFICE

The Chief Executive, Pat O'Mahony, is a member of the Management Board of the EMEA and attends all meetings. The Chief Executive is also a member of the Heads of Medicines Agencies (HMA), which meets four times a year hosted by the European Presidency of the day. During 2006, the Chief Executive chaired a working group on visibility which oversaw the development of a new identity and website for the HMA. At HMA/EMEA level, the Chief Executive also chaired a group on QP Discretion which agreed a revised interpretation for application in all Member States.

Permanent Secretariat of the Heads of Medicines Agencies

The personal assistant to the Chief Executive continued as a member of the Permanent Secretariat of the HMA and devoted 50% of her time to this task.

The HMA Management Group (MG) held 19 meetings during 2006 (most by teleconference) which the HMA Permanent Secretariat (PS) also attended. The Permanent Secretariat also held meetings approximately every fortnight (again, mostly by teleconference). In addition, the Permanent Secretariat member from the IMB also held the position of key-holder for the Benchmarking of European Medicine Agencies (BEMA) exercise which required attendance at BEMA Steering Group meetings on two occasions. In addition to these meetings, the Permanent Secretariat also attended the four HMA meetings held during the Austrian and Finnish Presidencies.

Among the issues discussed at HMA MG/PS meetings during 2006, many of which were brought forward for discussion and adoption by HMA, were the following:

- Benchmarking of European Medicines Agencies
- Observer status at HMA meetings
- Product testing
- EMEA/Member States Competent Authority Memorandum of Understanding on telematics
- Communication Tracking System Agreement
- Resource planning
- HMA website
- Working methods of HMA MG and PS

- Best practice guide updates
- HMA guideline updates
- Tandem Support Working Group
- HMA Working Group of Enforcement Officers
- Quality assurance of HMA minutes including development of a standard operating procedure.

The IMB's member of the Permanent Secretariat acts as the main contact point for those wishing to contact the HMA network and also as the central circulation point for the network itself. The Permanent Secretariat is also central to the quality assurance of the HMA minutes, editing for content and grammar.

BORDERLINE PRODUCT CLASSIFICATION

The IMB 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 the IMB. Queries are routinely received in regard to human medicinal products, veterinary medicinal products and medical devices. In each of these three areas, relevant staff within the organisation 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 IMB quality management system (QMS) to ensure consistency, clarity and clear recording of the decision making process in each case. Although the staff involved and the processes differ slightly, all are captured within the overall IMB QMS.

Human Medicines

A classification service is operated for products that 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 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 is accompanied by a recommendation for any necessary action depending upon the circumstances. In the event of an appeal to the Classification Committee's decision, the matter is referred to the Management Committee in order to seek the advice of the Advisory Committee on Human Medicines. Full details of the procedure can be found in the guideline – *Definition of a Medicinal Product,* which can be found on the IMB website.

The IMB Classification Committee (human medicines) met 11 times in 2006 and considered a total of 111 new products. In addition, there were 27 products revisited from before 2006. 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 2006, the majority of requests for classification were internal applications and most of these arose from the Compliance Department.

The Committee continues to work closely with representatives of the Market Compliance section and the Enforcement section within the IMB. Externally, there was a very close working relationship with the Food Safety Authority of Ireland and a number of referrals were made between the two agencies during the course of 2006.

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.

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 and conveyed promptly to the enquirers. In cases of appeal to the decision, the matter is referred to the Management Committee, which may request the advice of the Advisory Committee on Veterinary Medicines. In 2006, 57 classification queries were processed by the Veterinary Department.

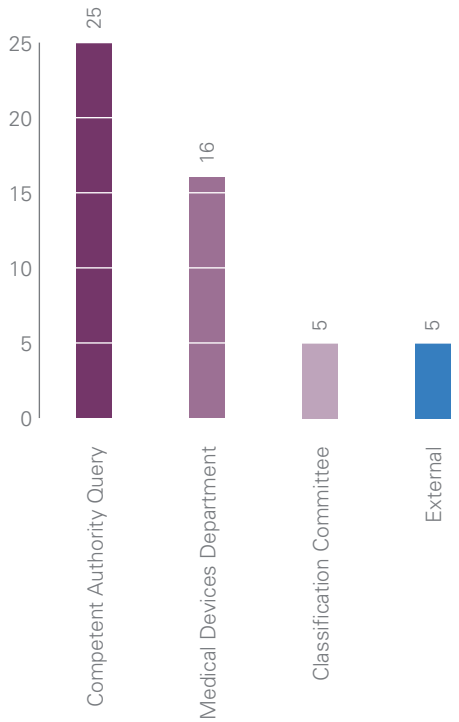
Medical Devices

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 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 *Guidance note 15: Classification of Medical Devices*.

In 2006, 51 classification queries were received. Half of the queries originated from other Competent Authorities in Europe. A number of these queries required further discussion at the Medical Devices Expert Group's Classification Borderline Working Group. Five requests originated from the IMB Classification Committee for human medicines. There were five external requests. The remaining queries were from within the Medical Devices Department, mainly arising from the post-market surveillance area. A total of 10 classification queries on 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 2006, good progress was made in the implementation of the organisation's quality system and the migration of the current department systems into it.

- Implementation was extended to authorisation processes in January and, by the end of the year, 72 authorisation documents were approved in a number of processes/areas, with a further 62 documents outstanding, many due for approval early in 2007.
- All human resources guidelines and forms were brought within the system, and new standard operating procedures were approved.
- The finance system, brought within the system in 2005, was further developed during 2006 with additional processes defined and documented.
- Procedures for an organisation-wide internal audit and corrective and preventive actions were approved with internal auditing to start in 2007.
- A total of 337 documents were approved within the system by year end.

This work is supported by a team of representatives from all departments and directed by a steering group of senior management.

Implementation progress was communicated to all staff on an ongoing basis and at department meetings, with induction training for new staff commencing during the year. A new intranet for improved document workflow and storage was developed and was in testing phase at the end of the year.

Benchmarking of European Medicines Agencies

In April, the IMB took part in an EU benchmarking exercise, termed BEMA. The objective of this exercise, which was agreed by the Heads of Medicines Agencies in 2004, is '*to contribute to the development of a world class pharmaceutical regulatory system, based on a network of agencies, working to best practice*'. The process involved self-assessment by each agency against agreed indicators of best practice, followed by an assessment and rating of the agency by assessors from other EU medicines agencies. The exercise was completed in all Member States by June and the results were compiled into an anonymised database, which is available to the Member States for review, along with a report on the outcome of the exercise.

BEMA assessors from the UK, Italy and Spain visited the IMB in early April and spent a week interviewing directors and senior staff, examining a sample of supporting documents and then assigning a rating for each indicator. At the end of the week, they presented the report of their findings and their overall conclusions. They complimented the IMB highly on the change management programme, the integration between departments, the workflow technology, the work ethic of staff and the friendly 'family' atmosphere. One area where they recommended further improvement was the integration of all departments into the quality management system to strengthen and support the IMB's work.

The benchmarking exercise was extremely useful to the IMB. The preparation and organisation for the visit involved extensive collaboration both within and between departments. During the self-assessment, attention was focussed on evidence to support achievement of best practice, revealing both strengths and opportunities for improvement in the areas under assessment. The emphasis on supporting evidence showed the usefulness of an integrated quality management system while the successful outcome reinforced the organisation's confidence in its capabilities.

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:

- Managing 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 IMB's Freedom of Information obligations.
- Managing legal issues for the IMB.

The highlights for 2006 are outlined below.

FINANCE

As outlined in the financial statements, the IMB experienced another year of significant financial growth. The Accounts Section continued to successfully manage the high volumes of work while maintaining high standards of internal control. In 2006, internal audit reviewed debtors, fee income, bank and cash and treasury management with a satisfactory outcome. All procedures were carried out using standard operating procedures under the IMB's 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 HR software implemented in 2005 was fully populated in 2006 and provided important HR strategic information to assist in the running of the organisation. The IMB has identified training as a key building block in the organisation's commitment to excellence and has invested significantly in this area.

Recruitment

2006		**Technical**	Male	Female	**Non-technical**	Male	Female
Total Appointments	86	**39**	12	27	**47**	5	42
External Recruitment	66	**26**	8	18	**40**	5	35
Internal Recruitment	20	**13**	4	9	**7**	0	7
Total number of interviews	350						

Training

Detail 2006	**No. of Courses**	**No. of days**
External Courses/Seminars	100	105
Internal – general	118	310
Internal – technical	9	77.5
Internal IT	35	125
% of employees supported in further education programmes	14.5%	

CORPORATE AFFAIRS

2006 was a milestone year for corporate services as the increases in operations and staff outlined in all the other departments increased the level of services provided. The new legislation in blood and tissues, the pending legislation in human medicines and the IMB Act have impacted on legal services. Following a review of parallel imports and a public consultation via the website, a new process for certain parallel imports was introduced. In 2006 for the first time there was a full public consultation in respect of the IMB fees and it is planned to use the Internet for further public consultations in 2007. In the area of corporate governance, the terms of reference for all the committees and Board were reviewed and particular emphasis was given to the role of corporate governance in the terms of reference for the Audit Committee and Audit Charter.

Activity under the Freedom of Information Act was relatively quiet, with only 6 requests being received.

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 commenced in 2006 with the completion of budgets, tender documents and appointment of contractors. The building work commenced in August 2006 with the refurbishment of the offices of the Veterinary Medicines Department, which moved back into the new offices in October 2006. The second phase, involving the renovation of the fourth floor was substantially completed at year end. The renovation of the building is particularly challenging as the building is being kept operational throughout the project. The challenges that this project have posed are being actively managed and service to all the stakeholders, both internal and external, is being maintained.

FINANCIAL STATEMENTS CONTENTS

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 McLaughlin 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 two occasions during 2006. 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 2006, the internal auditors reviewed the areas of debtors and banking and finance 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 2006, 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 44.

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 2006.

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 is 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 Board of the IMB carried out a formal review of these systems in respect of 2006.

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 2006 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.

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 the failure to comply 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 failure to recognise the Board's superannuation costs and liabilities in accordance with Financial Reporting Standard 17, the financial statements give a true and fair view, in accordance with Generally Accepted Accounting Principles in Ireland, of the state of the Board's affairs at 31 December 2006 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
25th June 2007

ACCOUNTING POLICIES

Historical Cost Convention

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

Income Recognition

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

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

Expenditure Recognition

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

Reporting Currency and Currency Translation

The Financial Statements are prepared in euros.

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

Tangible Assets

Tangible Assets excluding Premises

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

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

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

Premises

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

No depreciation has been calculated on the value of premises, as the remaining useful economic life is estimated to be greater than 50 years. An impairment review was carried during 2006 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 €594,450 (2005: €319,701). The surplus for the year on page 49 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.

Library

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

Leases

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

STATEMENT OF INCOME AND EXPENDITURE

For the year ended 31 December 2006

	Note	2006	2005
		€	€
Fee Income	2	15,965,921	13,179,912
Other Income	3	4,154,510	4,208,819
		20,120,431	17,388,731
Salaries and Wages	4	11,985,846	10,129,036
Other Operating Costs	5	5,399,854	4,080,480
Depreciation	1	1,086,383	1,253,489
		18,472,083	15,463,005
Surplus for the year before write back of Superannuation contributions		1,648,348	1,925,726
Staff Superannuation Contributions		594,450	319,701
Surplus for the year		2,242,798	2,245,427
Balance brought forward		8,035,597	5,790,170
Balance carried forward		10,278,395	8,035,597

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

Chairman

Board Member

The accounting policies on page 48 and the notes on pages 53 to 58 form part of the financial statements.

STATEMENT OF TOTAL RECOGNISED GAINS AND LOSSES

For the year ended 31 December 2006

	2006	2005
	€	€
Retained Surplus For The Year	**2,242,798**	2,245,427
Unrealised Gains For The Year	**-**	-
Total Recognised Gains	**2,242,798**	2,245,427

The accounting policies on page 48 and the notes on pages 53 to 58 form part of the financial statements.

BALANCE SHEET

As at 31 December 2006

	Note	2006	2005
		€	€
Tangible Assets	1	**22,530,128**	22,173,082
Current Assets			
Debtors and Prepayments	6	**1,386,328**	1,281,172
Stock of Stationery		**5,040**	4,449
Cash at Bank and in Hand	12	**593,457**	2,826,070
Short Term Deposits		**3,263,387**	325,057
		5,248,212	4,436,748
Creditors – Amounts falling due within one year			
Creditors and Accruals	7	**4,579,945**	3,264,233
Mortgage	13	**340,000**	340,000
		4,919,945	3,604,233
Net Current Assets		**328,267**	832,515
Long Term Liabilities			
Mortgage	13	**12,580,000**	14,970,000
TOTAL NET ASSETS		**10,278,395**	8,035,597
Financed by			
Income and Expenditure Reserve	11	**10,278,395**	8,035,597
		10,278,395	8,035,597

Chairman

Board Member

The accounting policies on page 48 and the notes on pages 53 to 58 form part of the financial statements.

CASH FLOW STATEMENT

For the Year Ended 31 December 2006

	Note	2006	2005
		€	€
Reconciliation of surplus to net cash inflow from operating activities			
Surplus for Year		**2,242,798**	2,245,427
Depreciation Charge		**1,086,383**	1,253,489
(Increase)/Decrease in Debtors		**(105,156)**	834,720
(Increase)/Decrease in Stocks		**(591)**	1,162
Increase/(Decrease) in Creditors – amounts falling due within one year		**1,315,712**	(792,382)
Deposit Interest		**(35,580)**	(52,513)
Bank Interest and Charges		**572,430**	634,045
Loss/(Gain) on Disposal of Fixed Assets		**32,898**	(975)
Net Cash Inflow from Operating Activities		**5,108,894**	4,122,973
Cash Flow Statement			
Net Cash Inflow from Operating Activities		**5,108,894**	4,122,973
Return on Investments and Servicing of Finance	8	**(536,850)**	(581,532)
Capital Expenditure	8	**(1,476,327)**	(1,831,103)
Management of Liquid Resources	8	**(2,938,330)**	3,446,182
Financing	8	**(2,390,000)**	(5,090,000)
Increase/(Decrease) in Cash		**(2,232,613)**	66,520
Reconciliation of net cash flow to movement in net debt			
Increase/(Decrease) In Cash		**(2,232,613)**	66,520
Increase/(Decrease) In Short Term Deposits		**2,938,330**	(3,446,182)
(Increase)/Decrease In Long Term Finance		**2,390,000**	5,090,000
Change In Net Debt		**3,095,717**	1,710,338
Net Debt at start of year		**(12,158,873)**	(13,869,211)
Net Debt at end of year	9	**(9,063,156)**	(12,158,873)

The accounting policies on page 48 and the notes on pages 53 to 58 form part of the financial statements.

NOTES TO THE FINANCIAL STATEMENTS

For the Year Ended 31 December 2006

1	Tangible Assets	Fixtures and Fittings	Computer Equipment	Leasehold Improve-ments	Improve-ments To Premises	Premises	Total
		€	€	€	€	€	€
	Cost						
	Balance as at 1 January 2006	1,102,947	5,001,842	489,884	257,078	20,383,000	27,234,751
	Additions for the year	50,050	886,995	12,561	361,035	166,166	1,476,807
	Disposals for the year	(464,433)	(1,406)	-	-	-	(465,839)
	As at 31 December 2006	688,564	5,887,431	502,445	618,113	20,549,166	28,245,719
	Depreciation						
	Balance as at 1 January 2006	867,718	4,119,255	48,988	25,708	-	5,061,669
	Charge for the year	102,261	872,066	50,245	61,811	-	1,086,383
	Disposals for the year	(431,055)	(1,406)	-	-	-	(432,461)
	As at 31 December 2006	538,924	4,989,915	99,233	87,519	0	5,715,591
	Net Book value at 31 December 2006	149,640	897,516	403,212	530,594	20,549,166	22,530,128
	Net Book value at 1 January 2006	235,229	882,587	440,896	231,370	20,383,000	22,173,082

2	Income	2006 €	2005 €
	Fee Income		
	Clinical Trials	**114,326**	114,286
	Human Medicine – National Fees	**6,818,243**	6,092,233
	Human Medicine – European Fees	**4,601,466**	3,780,287
	Veterinary Medicine – National Fees	**1,128,342**	931,709
	Veterinary Medicine – European Fees	**478,963**	330,468
	Compliance Department	**2,703,422**	1,827,633
	Medical Devices	**121,159**	103,296
		15,965,921	13,179,912
	Other Income (Note 3)	**4,154,510**	4,208,819
	Total Income	**20,120,431**	17,388,731

Certain fees, totalling €10,481,225, are required by law to be disposed of in accordance with the directions of the Minister for Finance.

NOTES TO THE FINANCIAL STATEMENTS

For the Year Ended 31 December 2006 (continued)

		2006	2005
		€	€
3	**Other Income**		
	Dept Of Health & Children Funding	**4,025,000**	3,914,690
	IT Income	**13,000**	13,000
	ISOP Conference Income	**-**	15,272
	Conference Fee Income	**98,828**	84,090
	Deposit Interest	**35,580**	52,513
	(Loss)/Gain on Disposal of Fixed Assets	**(32,898)**	975
	Miscellaneous	**15,000**	128,279
		4,154,510	4,208,819

4	**Salaries and Wages**		
	Salaries and Wages	**10,991,736**	9,304,983
	Social Welfare Costs	**994,110**	824,053
		11,985,846	10,129,036

The average number of staff employed during the year was 218 (2005 – 192).

Staff employed at 31 December 2006 can be analysed across the following departments:

	2006	2005
Medical Technical	**15**	16
Pharmaceutical Technical	**25**	26
Veterinary Technical	**10**	7
Compliance Technical	**13**	15
Medical Devices Technical	**10**	7
Enforcement Technical	**8**	6
Scientific Technical	**1**	2
Blood Directive Technical	**5**	1
Controlled Drugs Technical	**1**	1
Administrative and Operational Staff	**129**	111
Pensioners	**8**	7
	225	199

NOTES TO THE FINANCIAL STATEMENTS

For the Year Ended 31 December 2006 (continued)

		2006	2005
		€	€
5	**Operating Costs**		
	Accommodation Costs	**1,005,524**	762,823
	Travel, Representation and Training	**871,051**	765,657
	Bank Charges and Interest	**572,430**	634,045
	Legal & Professional Fees	**1,072,026**	189,184
	Stationery, Publications and Postage	**306,771**	291,160
	Other Operating Costs	**1,572,052**	1,437,611
		5,399,854	4,080,480
6	**Debtors (all due within one year)**		
	Trade Debtors	**1,131,677**	1,018,254
	Prepayments	**160,313**	179,055
	Other Debtors	**94,338**	83,863
		1,386,328	1,281,172
7	**Creditors (amounts falling due within one year)**		
	Trade Creditors	**555,876**	400,192
	Accruals	**3,675,890**	2,573,384
	Revenue	**348,179**	290,657
		4,579,945	3,264,233
8	**Gross Cash Flows**		
	Returns on Investment and Servicing of Finance:		
	Deposit Interest	**35,580**	52,513
	Bank Interest and Charges	**(572,430)**	(634,045)
		(536,850)	(581,532)
	Capital Expenditure		
	Payments to acquire Tangible Fixed Assets	**(1,476,807)**	(1,832,078)
	Receipts from sales of Tangible Fixed Assets	**480**	975
		(1,476,327)	(1,831,103)
	Management of Liquid Resources		
	(Increase)/Decrease in Short Term Deposits	**(2,938,330)**	3,446,182
		(2,938,330)	3,446,182
	Financing		
	Increase/(Decrease) in Long Term Finance	**(2,390,000)**	(5,090,000)
		(2,390,000)	(5,090,000)

NOTES TO THE FINANCIAL STATEMENTS

For the Year Ended 31 December 2006 (continued)

9 Analysis of Changes in Net Debt	As At 01/01/2006	Cashflow	As At 31/12/2006
Cash at Bank and in Hand	2,826,070	(2,232,613)	593,457
Short Term Deposits	325,057	2,938,330	3,263,387
Debt Due Within One Year	(340,000)	-	(340,000)
Debt Due After One Year	(14,970,000)	2,390,000	(12,580,000)
	(12,158,873)	3,095,717	(9,063,156)

	2006 €	2005 €
10 Administration Expenses		
Surplus for the year was calculated having charged:		
Auditor's Remuneration	**15,800**	15,300
11 Income and Expenditure Reserves		
The Income and Expenditure Reserve disclosed in the Balance Sheet on page 51 comprises the following:		
Retained Reserves	**7,612,098**	5,963,749
Staff Superannuation Contributions	**2,666,297**	2,071,848
	10,278,395	8,035,597
12 Cash and Bank Balances		
Current Account Balances	**91,281**	531,604
Deposit Account Balances	**500,000**	2,293,654
Cash on Hand	**2,176**	812
	593,457	2,826,070

13 Long-Term Liabilities

Mortgage

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

The Irish Medicines Board is committed to making the following capital repayments on its mortgage:		
- within one year	**340,000**	340,000
- between one and five years	**1,360,000**	1,360,000
- after five years	**11,220,000**	13,610,000
	12,920,000	15,310,000

NOTES TO THE FINANCIAL STATEMENTS

For the Year Ended 31 December 2006 (continued)

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 2007 it is estimated that the net borrowings for which an interest rate exposure may arise is €0.

	2006	2005
	€	€
15 Financial Commitments		
Operating Leases		
Amounts payable during the next twelve months in respect of leases which expire		
- within one year	-	-
- between one and five years	-	-
- 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 22 December 2004, which is why no further lease obligations exist in respect of that premises.

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

	2006	2005
	€	€
16 Capital Commitments		
Contracted For (Contract Signed)	**280,000**	360,400
Not Contracted For	**200,000**	442,000
	480,000	802,400

17 Board Remuneration		
Chairman's Salary	**25,822**	24,951
Board Members' Travel Expenses	**9,788**	11,976
	35,610	36,927

18 Staff Remuneration		
Chief Executive's Remuneration (Stated net of Superannuation Contributions)	**152,415**	134,050
	152,415	134,050

NOTES TO THE FINANCIAL STATEMENTS

For the Year Ended 31 December 2006 (continued)

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:
2006 €1 = STG £0.6715
2005 €1 = STG £0.670118

22 Approval of Financial Statements

The financial statements were approved by the Board on 14 June 2007.

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 IT 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. Ide 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. Ide 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

ACMD:	Advisory Committee for Medical Devices
AIMD:	Active Implantable Medical Device
APHA:	Animal and Plant Health Association
BEMA:	Benchmarking of European Medicines Agency
CPAP:	Continuous positive airway pressure machines
DAF:	Department of Agriculture and Food
DCP:	Decentralised Procedure
DoHC:	Department of Health and Children
EEA:	European Economic Area
EMEA:	European Medicines Agency
FDA:	Food and Drug Administration (USA)
FOI:	Freedom of Information
GCP:	Good Clinical Practice
GDP:	Good Distribution Practice
GMD:	General Medical Device
GMP:	Good Manufacturing Practice
GNDU:	Garda National Drugs Unit
HMA:	Heads of Human Medicines Agency
HSE:	Health Service Executive
IFIS:	Intraoperative floppy iris syndrome
IMB:	Irish Medicines Board
IMDA:	Irish Medical Devices Association
IPAR:	Irish Public Assessment Report
IVD:	In-Vitro Diagnostic
IVMP's:	Immunological Veterinary Medicinal Products
MA:	Marketing Authorisation
MAH:	Marketing Authorisation Holder
MDD:	Medical Devices Directive
MDEG:	Medical Devices Expert Group
MHRA:	Medicines and Healthcare products Regulatory Agency
MR:	Mutual Recognition
MRA:	Mutual Recognition Agreement
MSOG:	Market Surveillance Operations Group
NDAB:	National Drugs Advisory Board
NHO:	National Haemovigilance Office
NSAI:	National Standards Authority of Ireland
NSAID:	Non Steroidal Anti Inflammatory Drug
OMCL:	Official Medicines Control Laboratory
PA:	Product Authorisation
PFIPC:	Permanent Forum on International Pharmaceutical Crime
PhVWP:	Pharmacovigilance Working Party
PIC/S:	Pharmaceutical Inspection Co-Operation Scheme
QMS:	Quality Management System
RIO:	Regulatory Information On-Line
VPA:	Veterinary Product Authorisation
WHO:	World Health Organisation

IRISH MEDICINES BOARD

Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Tel: +353 1 676 4971
Fax: +353 1 676 7836
email: imb@imb.ie
web: www.imb.ie