IRISH MEDICINES BOARD

GUIDE TO INFORMATION HELD BY THE IMB

MGT-G0016-1
DECEMBER 2008

This guide does not purport to be an interpretation of the law and/or regulations relating to the authorisation and is for guidance purposes only.

CONTENTS

1. SCOPE

This manual is prepared in accordance with publication requirements set out in sections 15 and 16 of the Freedom of Information Acts, 1997 and 2003. Its purpose is to facilitate access to information held by the Irish Medicines Board (IMB).

Sections 2-10 of this guide provide information in accordance with the requirements of section 15 of the Acts, outlining the structure and functions of the Board; details of the services provided and how they may be availed of; information on the classes of records we hold, and information on how to make a request to the Irish Medicines Board under the Freedom of Information (FOI) Acts.

Sections 11-13 of this guide provide information in accordance with the requirements of section 16 of the Acts, detailing the procedures of the IMB in relation to enactments or schemes to which section 16 of the Acts applies.

2. INTRODUCTION

The Freedom of Information Acts, 1997 and 2003 establish three statutory rights:

- a legal right for each person to access information held by public bodies
- a legal right for each person to have official information relating to him/herself amended where it is incomplete, incorrect or misleading
- a legal right to obtain reasons for decisions affecting oneself

The Acts assert the right of members of the public to obtain access to official information to the greatest extent possible consistent with the public interest and the right to privacy of individuals.

The IMB currently makes information routinely available to the public in relation to its functions, activities and schemes. Such information will continue to be available informally without the need to use the FOI Acts. This guide highlights, in relation to each of the Board's activities, where information of this nature is available.

The FOI Acts are designed to allow public access to information held by public bodies which is not routinely available through other sources. Access to information under the Acts is subject to certain exemptions and involves specific procedures and time limits. This guide provides information on the structure of the Board to assist you in accessing information under the FOI Acts.

3. THE ROLE OF THE IRISH MEDICINES BOARD

3.1 Description of the organisation

The IMB is the competent authority in Ireland for human and veterinary medicines, for medical devices and for blood, tissues and cells. It is a government agency, reporting to the Department of Health and Children, and providing advice to the Department of Agriculture, Fisheries and Food. The agency is funded by fee income and by subvention for certain of its activities from the Department of Health and Children. It employs approximately 250 staff in offices in Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2, and on one floor of Alexandra House, also in the Earlsfort Centre.

3.2 Vision and mission

The vision of the IMB is 'to be recognised as a centre of excellence for both the quality and scientific rigour we bring to the work we do and the efficient manner in which it is completed.'

The IMB's mission statement is 'to protect and enhance public and animal health through the regulation of medicine, medical devices and healthcare products.'

3.3 Functions

The functions of the IMB are set out in the Irish Medicines Board Acts 1995 and 2006 and in the Irish Statutory Instruments which govern its operations. They are summarised below.

3.3.1 Authorisation, registration or certification of:

- medicinal products for human and veterinary use
- clinical trials with medicinal products for human use
- manufacturers of medicinal products for human and veterinary use
- manufacturers of investigational medicinal products for human use
- wholesalers of medicinal products for human use
- export of active substances and medicinal products for human and veterinary use
- contract quality testing laboratories
- controlled drugs (narcotics)
- blood, tissue and cell establishments
- medical devices for human use
- Notified Bodies for medical devices

3.3.2 Inspection of:

- manufacturers of medicinal products for human and veterinary use and of medical devices
- wholesalers of medicinal products for human use

- manufacturers of active substances
- blood, and tissue and cells establishments, and when required, blood banks
- sponsors and investigators carrying out clinical trials on medicinal products for human use
- marketing authorisation holders or firms employed by holders for pharmacovigilance
- contract quality testing laboratories
- controlled drugs licence holders

3.3.3 Investigation and follow-up in relation to:

- adverse reactions to medicinal products for human or veterinary use and adverse incidents relating to medical devices
- quality defects and recalls of medicinal products from the market
- recalls of medical devices from the market
- sampling and analysis of medicinal products, active pharmaceutical ingredients, and medical devices
- compliance with legislation falling within the remit of the IMB

3.3.4 Provision of advice to:

- the Minister for Health and Children, Minister for Agriculture, Fisheries and Food, Minister for the Marine and others concerned, in relation to any matter connected with the functions of the IMB

4. CODE OF CONDUCT

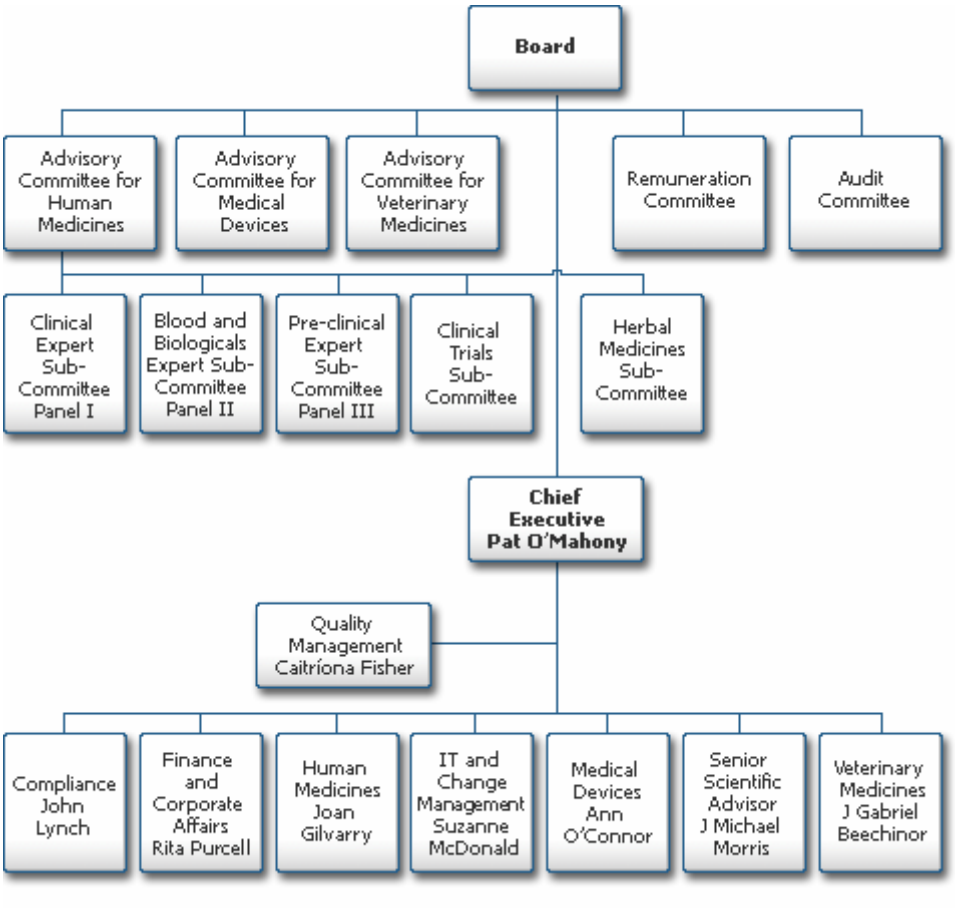
The requirements outlined in the IMB's code of conduct apply to members of the Board, its committees, subcommittees and working parties, and to staff and consulted experts, to whom a copy is given when they become associated with the activities of the IMB.

The IMB's responsibilities and role in the scientific evaluation of medicinal products for human and veterinary use and the regulation of medical devices has a significant impact on the protection and promotion of human and animal health. Integrity and high standards of professional conduct by all involved with the Board (Board members, members of committees, subcommittees and working parties, staff and consulted experts) are crucial for the independence of the IMB and for its public reputation.

In the interests of proper standards of conduct, all persons contributing to the activities of the IMB, where those contributions have a potential to influence decision processes by the Board, must make an annual declaration of any potential conflict of interest at an appropriate early stage and the implications are taken into account in any relevant activities.

5. STRUCTURE AND PROCEDURES

The structure of the IMB's Board, committees and departments is shown below.



Under the Irish Medicines Board Acts 1995 and 2006, the IMB has a Board of nine members appointed by the Minister for Health and Children. The Board is advised by three statutory scientific advisory committees: one for human medicines, one for veterinary medicines and one for medical devices. The members of the Advisory Committee for Human Medicines and the Advisory Committee for Medical Devices are appointed by the Minister for Health and Children, and the members of the Advisory Committee for Veterinary Medicines are appointed by the Minister for Health on the advice of the Minister for Agriculture, Fisheries and Food. The Irish Medicines Board Acts, 1995 and 2006 provide that the advisory committees may establish subcommittees. Ad hoc working groups may be established from time to time to address specific issues. The Board regulates the procedure and business of the IMB. The functions of the advisory committees are described in the legislation. Terms of reference are established for the Board, the advisory committees and any

subcommittees, as well as rules of procedure that govern the proceedings, the participation of members and the decision-making processes.

The Board has devolved the day-to-day management of the IMB to the Chief Executive. The Chief Executive is assisted in this function by the Management Committee, which comprises, in addition to the Chief Executive, the directors of departments and the Senior Scientific Advisor. Department directors are responsible to the Chief Executive and to the Board of the IMB for the activities of their departments.

6. HOW TO ACCESS INFORMATION UNDER THE FOI ACTS

6.1 Applications under the FOI Acts 1997 and 2003

Under the FOI Acts, anyone is entitled to apply for access to information not otherwise publicly available. Each person has a right to:

- access records held by the IMB
- correct personal information relating to oneself held by the IMB where it is inaccurate, incomplete or misleading
- access reasons for decisions made by the IMB directly affecting oneself

The following records come within the scope of the Act:

- all records relating to personal information held by the IMB irrespective of when created
- all other records created from commencement date i.e. 21 April, 1998
- any other records necessary to the understanding of a disclosed record

The IMB is obliged to respond to the request within four weeks.

Applications for information under the FOI Act should be addressed to:
Freedom of Information Officer,
Irish Medicines Board,
Kevin O'Malley House
Earlsfort Centre,
Earlsfort Terrace,
Dublin 2.

Phone: 01 676 4971
Fax: 01 676 7836
E-mail: foi@imb.ie

Applications should be in writing and should indicate that the information is sought under the Freedom of Information Acts. If information is desired in a particular form i.e. photocopy, computer disk, etc., this should also be stated in your application.

Please provide as much detail as possible to enable the staff of the IMB to identify the record. If you have difficulty in identifying the precise records you require, staff will be happy to assist you in preparing your request.

6.2 Amendment of personal information

The FOI Acts confer a right on members of the public to seek amendment of records relating to personal information held by public bodies. The Acts set out the mechanism whereby such a record may be amended if it is incomplete, incorrect or misleading.

The application:

- must be in writing (or such other form as may be determined)
- must specify the record concerned
- must specify the amendment required

It must include appropriate information in support of the application. It is not sufficient for the applicant merely to state that the record in question is incomplete, incorrect or misleading. He or she must provide sufficient evidence to back up the claim e.g. if factual information, such as birth date, is claimed to be incorrect, then evidence of the correct date must be supplied.

The amendment sought must relate to personal information of the individual submitting the application (or a representative properly authorised to act on his or her behalf).

Incomplete - Information may be incomplete if it does not adequately deal with the relevant facts and circumstances.

Incorrect - Information that is wrongly recorded, based on a mistake of fact or without proper regard to the evidence in a particular case may be incorrect.

Misleading - Information can be said to be misleading if it could lead a person reading it to take a mistaken meaning from it. It may also be misleading if the language or terminology used might have particular meaning to a specialist or professional but convey an alternative meaning to the ordinary reader.

6.3 Rights of review and appeal

The Acts set out a series of exemptions to protect sensitive information where its disclosure may damage key interests of the State or of third parties. Where the Irish Medicines Board invokes these provisions to withhold information, the decision may be appealed. Decisions in relation to deferral of access, charges, forms of access, etc. may also be the subject of appeal. Details of the appeals mechanisms are set out below.

6.4 Internal review

You may seek internal review of the initial decision which will be carried out by an official at a higher level if:

- you are dissatisfied with the initial response received i.e. refusal of information, form of access, charges, etc, or
- you have not received a reply within four weeks of your initial application. This is deemed to be a refusal of your request and allows you to proceed to internal review.

Requests for internal review should be submitted in writing to:
Chief Executive,
Irish Medicines Board,
Kevin O'Malley House
Earlsfort Centre,
Earlsfort Terrace,
Dublin 2.

Phone: 01 676 4971
Fax: 01 676 7836
E-mail: foi@imb.ie

Such a request for internal review must be submitted within four weeks of the initial decision. The IMB must complete the review within three weeks. Internal review must normally be completed before an appeal may be made to the Information Commissioner.

6.5 Review by the Information Commissioner

Following completion of internal review and refusal, you may seek independent review of the decision from the Information Commissioner. Also, if you have not received a reply to your application for internal review within three weeks, this is deemed to be a refusal and you may appeal the matter to the Commissioner.

Appeals in writing may be made directly to the Information Commissioner at the following address:
Office of the Information Commissioner,
18 Lower Leeson Street,
Dublin 2.

Phone: 01 678 5222
Fax: 01 661 0570
E-mail: foi@ombudsman.irlgov.ie

7. FEES

In accordance with section 47 of the Freedom of Information Acts, fees may be charged as follows:

Application fees
If your request is for a record containing non-personal information, an application fee of €15 (€10 if you are a medical card holder) must accompany your request. There is no application fee if your request is for personal information.

Search, retrieval and copying fees
Fees also apply in respect of the time spent searching and retrieving records that are released to you on foot of your request and in respect of the copying of any records released. Such fees are unlikely to arise if your request is for personal information. The rates of these fees are as follows:

- €20.95 per hour of search and retrieval
- €0.04 per sheet of a photocopy
- €10.16 for a CD-ROM containing copy documents
- €6.35 for a radiograph (X-ray) containing copy documents

Deposits
A deposit is payable where the estimated cost of search and retrieval of records sought is estimated to exceed €50.79. In such a case, every effort must be made to assist the requester to amend the request so as to reduce or eliminate the amount of the deposit.

Reductions and waivers
A fee in respect of search and retrieval and copying of records will be waived where the cost of collecting and counting for the fee would exceed the amount of the fee itself (a guideline of less than €10 is used in this respect).

A fee in respect of search and retrieval and copy of records or a deposit may be reduced or waived where the information in the record would be of particular assistance to the understanding of an issue of national importance.

A charge applies to most internal and independent reviews (Information Commissioner) concerning access to non-personal records. There is a reduction for medical cardholders. You will be notified of these at the appropriate time by the relevant public body.

8. OPERATIONAL STRUCTURE AND INFORMATION HELD

The following section gives a breakdown of the internal structure and organisation of the IMB. It describes the categories of information held, and the ways in which they

can be accessed, either through existing publications or through the procedures set out in the Act.

8.1 Information common to all departments

8.1.1 Structure of the IMB

The organisation structure of the IMB consists of six departments and the Chief Executive's Office, as shown above. Each department has a director who is responsible for the day-to-day activities of that department. The Chief Executive, the six department directors and the Senior Scientific Advisor comprise the Management Committee.

8.1.2 Delivery of service

As outlined in section 2 above, the IMB is responsible for the authorisation of human and veterinary medicines, of the Notified Body for medical devices, and of manufacturers for human and veterinary medicines or distributors of human medicines.

Other than carrying out its statutory functions the IMB does not routinely provide a service to the general public.

8.1.3 Information available outside the Freedom of Information Acts

The following information is available to the general public and may be accessed without using the FOI Act:

- Annual Reports, including financial statements
- Press releases
- Quarterly newsletters for medicinal products and for medical devices
- Drug safety newsletters
- Lists of authorised human and veterinary medicines, and their summary of product characteristics, package leaflet and public assessment report
- Lists of authorised manufacturers and wholesalers
- Advisory, recall and warning notices
- Anonymised adverse reaction report (ADR) data
- EU and Irish legislation applicable to the IMB's activities
- EU Rules Governing Medicinal Products in the European Union
- Details of authorisation and safety procedures
- Application forms and guidelines for applicants
- Details of fees for applicants
- Licensing minutes (effective from May 2008)

Most of this information can be downloaded from the IMB website, which can be accessed at: www.imb.ie. Online access to anonymised ADR data is not currently available, but is provided on request to pharmacovigilance@imb.ie or in writing to:

Pharmacovigilance Section,
Irish Medicines Board,
Kevin O'Malley House,
Earlsfort Centre,
Earlsfort Terrace,
Dublin 2.

Phone: 01 676 4971
Fax: 01 676 2517

8.2 Compliance Department

Director of Compliance Mr. John Lynch

8.2.1 Structure of the Compliance Department

8.2.2 Functions of the Compliance Department

The Compliance Department has five sections: Inspection, Licensing, Market Compliance, Enforcement and Planning.

The Inspections section comprises the inspectorate which is responsible for GMP inspections of human and veterinary pharmaceutical manufacturing; GDP and controlled drugs inspections of wholesalers of human medicines and of the manufacturing and wholesaling of controlled drugs; GCP and pharmacovigilance inspections of clinical trial sites and pharmacovigilance systems; inspections of blood and tissue establishments; and inspections of contract testing laboratories. Inspections outside the EEA are also performed.

The Licensing section is responsible for all licensing, authorisation and certification of manufacturers of medicinal products for human and veterinary use, wholesalers of medicinal products for human use, laboratories, and blood and tissue establishments. It prepares controlled drugs licences for issue by the Department of Health and Children.

The Market Compliance section is responsible for the evaluation and investigation of reports of quality defects, oversight and monitoring of recalls, management of the sampling and analysis programme, including activities relating to the Official Medicines Control Laboratories network. It is also involved in monitoring the compliance of marketing authorisation holders with the terms of their marketing authorisations.

The Enforcement section is responsible for the prevention, detection, evaluation and investigation of breaches of the legislation relating to the manufacture, wholesale, advertising and marketing of medicinal products and medical devices for human use. (The Department of Agriculture and Food is responsible for enforcement of the animal remedies legislation.)

The Planning section oversees the planning and co-ordination of activities within the department. It maintains oversight of achievement of targets. It also oversees the completion of regular sectional and departmental reports.

8.2.3 Delivery of service

The Compliance Department does not deliver any services directly to the general public.

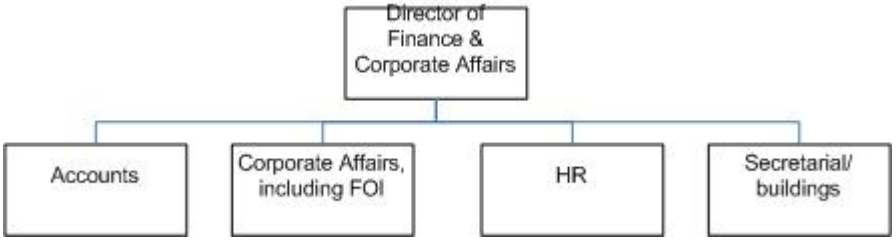
8.2.4 Classes of records held

- Files on each manufacturer, wholesaler, contract laboratory, blood establishment, and tissue and cells establishment
- Site master files
- Files on quality defects and product recalls
- Export certificates
- Enforcement files
- National and EU legislation and guidelines
- Reports of internal meetings
- Documentation from external meetings
- Policies, guidelines, standard operating procedures, work instructions and forms

8.3 Finance & Corporate Affairs Department

Director of Finance & Corporate Affairs Ms Rita Purcell

8.3.1 Structure of the Finance & Corporate Affairs Department



8.3.2 Functions of the Finance & Corporate Affairs Department

The department is responsible for finance, human resources and corporate affairs.

The Accounts section is responsible for processing financial transactions, budgeting, proposing and collecting fees, management accounts, and managing the financial position of the organisation.

The HR section is responsible for resource planning, training and development, recruitment and selection, employee contracts and the policies and procedures for line management of employees.

The department is also responsible for legal issues, secretarial services to the Board and committees, maintenance and refurbishment of the buildings, health and safety, information requests, travel, corporate publications, event management, the archives and the library.

8.3.3 Delivery of service

The Finance & Corporate Affairs Department does not deliver any services directly to the general public other than the service envisaged under the Freedom of Information Acts.

8.3.4 Classes of records held

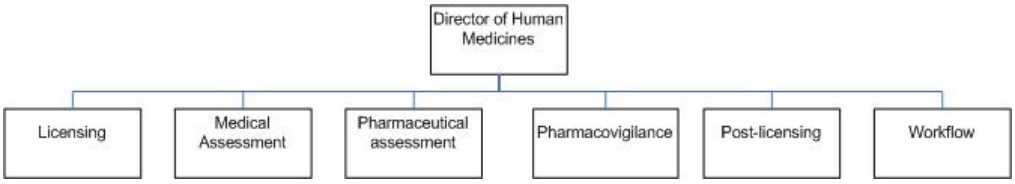
- Finance and accounting records
- Personnel records
- Legal and insurance files
- Budget files
- Buildings and secretarial files
- Board and committee files
- National and EU legislation and guidelines
- Reports from internal meetings
- Documentation from external meetings

- Policies, guidelines, standard operating procedures, work instructions and forms

8.4 Human Medicines Department

Director of Human Medicines Dr. Joan Gilvarry

8.4.1 Structure of the Human Medicines Department



8.4.2 Functions of the Human Medicines Department

The department has six sections: Licensing, Medical Assessment, Pharmaceutical assessment, Pharmacovigilance, Post-licensing, and Workflow.

The Licensing section processes national and EU applications for new authorisations for pharmaceutical, herbal, homeopathic and parallel import products, and applications for clinical trial authorisation or amendment. It also processes applications for scientific advice and manages master files relating to human and veterinary medicines.

The Medical Assessment section is responsible for the assessment of the safety and efficacy data in applications received by the department.

The Pharmaceutical Assessment section is responsible for the assessment of the quality data in applications received by the department.

The Pharmacovigilance section is responsible for the evaluation and follow-up of adverse reactions reports, rapid safety alerts, for conducting product class reviews, and for preparing press releases on safety issues.

The Post-licensing section processes national and EU applications for the variation, renewal, transfer or withdrawal of authorisations for pharmaceutical, herbal, homeopathic and parallel import products, and marketing status notifications.

The Workflow section is responsible for the receipt and validation of applications relating to human and veterinary medicines, for the scheduling, capacity planning and filing of applications for human medicines, and for IMB archiving. It also oversees the completion of regular sectional and departmental reports. A customer query handling service is in development.

8.4.3 Delivery of service

The Human Medicines Department does not deliver any services directly to the general public.

8.4.4 Classes of records held

- Files relating to the medical assessments of products
- Files relating to the pharmaceutical assessment of products
- Clinical trial files
- Adverse drug reaction reports and files (only anonymised ADR data are made available to any enquirer)
- Data submitted in support of applications
- Drug and plasma master files
- National and EU legislation and guidelines
- Reports from internal meetings
- Documentation from external meetings
- Policies, guidelines, standard operating procedures, work instructions and forms

8.5 IT and Change Management Department

Director of IT and Change Management Ms. Suzanne McDonald

8.5.1 Structure of the IT and Change Management Department

8.5.2 Functions of the IT and Change Management Department

The department has four components: change management, projects management, infrastructure management and support services management

The Director is responsible for change management, which is focussed on achieving improvements in performance through changes in business processes, structures and supporting technology.

The Projects Management section is responsible for the business analysis and planning of all IT-related projects, liaising with business users and external

contractors and developers. Upgrades and changes to existing applications and technology are also handled through this section, as are the internal and external websites and also the extranet services to stakeholders.

The Infrastructure Management section is responsible for the management of all hardware, networking and telecommunication at the IMB, and for systems security, risk management and business continuity. Managing systems performance and external user access is also part of this section's remit.

The Support Services Management section is responsible for the 'helpdesk' service to all users on all applications, and training for IMB staff on those applications.

8.5.3 Delivery of service

The IT and Change Management Department does not deliver any services directly to the general public.

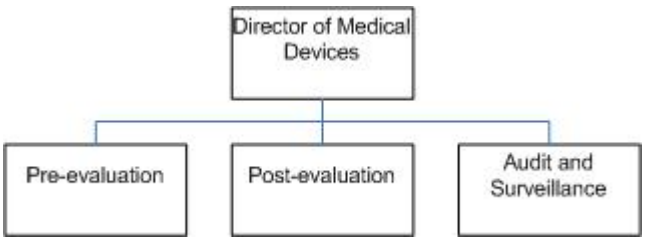
8.5.4 Classes of records held

- Procurement files
- Change Management Structure files
- Budget files
- National and EU legislation and guidelines
- Reports from internal meetings
- Documentation from external meetings
- Policies, guidelines, standard operating procedures, work instructions and forms

8.6 Medical Devices Department

Director of Medical Devices Ms. Ann O'Connor

8.6.1 Structure of the Medical Devices Department



8.6.2 Functions of Medical Devices Department

The Medical Devices Department has three sections: Pre-evaluation, Post-evaluation, and Audit and Surveillance

The Pre-Market Evaluation section is responsible for the designation and monitoring of Notified Bodies in Ireland, the assessment of applications to conduct clinical investigations involving medical devices in Ireland, handling requests for classification of medical devices and maintaining the register of class I, *in-vitro* diagnostic and custom made medical devices.

The Post-Market Evaluation section is responsible for the monitoring, evaluation and follow-up on incident reports, for preparing safety notices, for monitoring recalls and for the issuance of Competent Authority reports. It is also responsible for the prevention, detection, evaluation and investigation of breaches of the legislation relating to medical devices and determines the escalation of compliance issues to enforcement action. The section also carries out reviews of technical documentation. The post-section is also responsible for the issuance of Certificates of free sale for medical device manufacturers.

The Audit section conducts proactive and reactive audits of medical device manufacturers based in Ireland and also audits class I, *in-vitro* diagnostic and custom made medical device manufacturers from the device register.

8.6.3 Delivery of service

The Medical Devices Department does not deliver any services directly to the general public.

8.6.4 Classes of records held

- Files relating to adverse incident reports and investigations
- Records of applications for determination of medical device status
- CEN standards relating to medical devices and diagnostics
- National and EU legislation and guidelines
- Reports from internal meetings
- Documentation from external meetings
- Policies, guidelines, standard operating procedures, work instructions and forms

8.7 Veterinary Medicines Department

Director of Veterinary Medicines Dr. J. G. Beechinor

8.7.1 Structure of the Veterinary Medicines Department

8.7.2 Functions of the Veterinary Medicines Department

The department is responsible for the quality, safety and efficacy assessment of national and EU applications for authorisation, variation, renewal, transfer and withdrawal of veterinary pharmaceuticals, immunologicals, homeopathic and parallel import products. It is also responsible for the scheduling, capacity planning, processing, and filing of these applications. It deals with marketing status notifications and batch-specific requests. It also oversees the completion of regular sectional and departmental reports.

The department assesses applications for clinical trials at the request of the Department of Agriculture and Food. In relation to pharmacovigilance, it is responsible for the evaluation and follow-up of adverse reactions reports, rapid safety alerts, for conducting product class reviews, and for preparing press releases on safety issues.

8.7.3 Delivery of service

The Veterinary Medicines Department does not deliver any services directly to the general public.

8.7.4 Classes of records held

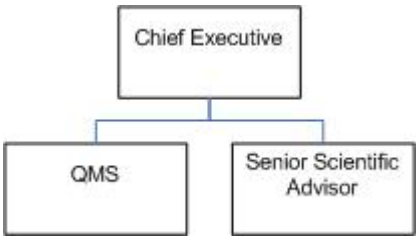
- Files relating to the veterinary assessments of products
- Files relating to the pharmaceutical assessment of products
- Clinical trial files
- Adverse drug reaction reports and files (only anonymised ADR data is made available to any enquirer)
- Data submitted in support of applications
- Records of applications for determination of medicinal status
- Drug and plasma master files
- National and EU legislation and guidelines
- Reports from internal meetings
- Documentation from external meetings

- Policies, guidelines, standard operating procedures, work instructions and forms

8.8 Chief Executive's Office

Senior Scientific Officer	Dr. J. M. Morris
Quality Manager	Dr. C. Fisher

8.8.1 Structure of the Chief Executive's Office



8.8.2 Functions of the Chief Executive's Office

The office comprises the Senior Scientific Advisor and the QMS (quality management system) section

The Senior Scientific Officer provides scientific and regulatory advice to the Board and Chief Executive. He is involved in a number of multidisciplinary initiatives where he works closely with senior staff in other scientific departments – Human Medicines, Veterinary Medicines, Compliance and Medical Devices. Internally he chairs the human medicines Classification Committee and the Human Derived Products Safety Group.

The QMS section is responsible for the quality management system; including internal audits; and liaison with other organisations for external audits, review or benchmarking.

8.8.3 Delivery of service

The Chief Executive's Office does not deliver any services directly to the general public.

8.8.4 Classes of records held

- Records of applications for determination of medicinal status
- National and EU legislation and guidelines
- Reports from internal meetings
- Documentation from external meetings

- Policies, guidelines, standard operating procedures, work instructions and forms

9. TERMINOLOGY MENTIONED IN SECTION 8

Policy
This is information held on the formulation and implementation of government policy, which can evolve from a wide range of sources, including, for example, election commitments or ministerial instructions. It is likely to contain analysis of proposals, from the points of view of cost, impact and practicality. Once a policy has been enacted, information held is likely to relate to measuring its impact, i.e. if grants are providing assistance in the way intended, if the yields from taxation proposals are as expected.

Legislative files
Information kept on this relates to law making, the procedure by which a proposal becomes law through the introduction of an Act of the Oireachtas or by Statutory Instrument. Information kept on legislation files is likely to reflect the various stages of production of legislation and includes material on the following:

- analysis of initial government proposals, setting out the reasons why the Act or Statutory Instrument is required and summarising its main points
- correspondence with and briefing material supplied to the Minister as the Bill proceeds through the Oireachtas
- any further action, i.e. issuing of directions provided for in the Act, further correspondence etc

Information in this category also includes the final copies of legislation, as well as guidelines issued in relation to legislative requirements.

National and EU legislation and guidelines
Much of the work of the public service is now set out in European Union directives and guidelines on particular aspects of policy enacted at EU level. Material held on these would contain information on the directive or guideline in question, and how it is interpreted and operated in this State.

Internal policies, guidelines, standard operating procedures, work instructions and forms
Information in this category includes rules, guidance, instructions and standard forms issued to staff or to external applicants relating to schemes operated by the IMB.

10. DESIGNATIONS OF DECISION MAKERS WITH THE IMB

Human Medicines Department	Director of Human Medicines Pharmaceutical Assessment Manager

	Pharmacovigilance Co-ordinator
Veterinary Department	Senior Veterinary Assessor
Board and Committee Issues	Secretary to the Board
Corporate Affairs, Finance and HR issues	Director of Finance and Corporate Affairs
Compliance Department	Director of Compliance Senior Inspector Enforcement Manager
Medical Devices Department	Medical Devices Director Vigilance Coordinator

11. GENERAL PRACTICES OF THE IMB

11.1 Contracts for services and supplies

The IMB complies fully with the requirements set out in the Department of Finance publication, An Outline of Government Contract Procedures and Public Procurements (1994) which is available from the Government Publications Sales Office, Sun Alliance House, Molesworth Street, Dublin 2.

11.2 Payment of accounts

The IMB complies fully with the requirements of the Prompt Payment of Accounts Act, 1997.

11.3 Standards of service

The IMB will maintain a high standard of service to all its stakeholders and to all those looking to the Board for advice, guidance or support. Our adherence to these standards will be monitored and we will strive to improve these standards over time.

The IMB has published a Service Charter which is available on its website. The charter sets out the standards of service which stakeholders may expect. The Board's offices are open from Monday to Friday, 8:45am to 6:00pm excluding public holidays. We will answer all telephone calls promptly and courteously. If you wish to call outside office hours please leave a message on our answering service and your call will be returned on the following working day.

12. SCHEMES OPERATED BY THE IRISH MEDICINES BOARD

12.1 Assessment of applications for authorisation or registration of medicinal products

Products for which medicinal claims are made or which contain substances likely to have effects on the body are considered as medicines, and will therefore need a marketing authorisation from the IMB. The marketing authorisation is issued with a Product Authorisation (PA) number which is included on the container.

In order to obtain a marketing authorisation, a company must submit information to the IMB which examines the data to make sure that the medicinal product meets standards of quality, safety and efficacy. In determining the safety, quality and efficacy the IMB draws upon the expertise of its staff and its Advisory Committee for Human Medicines (appointed by the Minister for Health and Children). Expert advisory panels also meet as required. The mandate of the Advisory Committee is to assist and advise the Board and the staff in relation to any matters concerning public health or the safety, quality or efficacy of medicinal products for human use which may be referred to it.

Marketing authorisations are valid for five years from the date of first issue. For the authorisation to remain valid, it should be renewed at the end of this five-year period. Following this renewal, the authorisation remains valid for an indefinite period (unless further renewals are deemed necessary by the IMB on drug safety grounds).

After a medicinal product has been authorised, the terms of the marketing authorisation may subsequently be varied. Variation notifications, for example addition of a new manufacturing site or a new indication, are defined in Commission Regulation (EC) 1084/2003 as either ‘minor’ (Type I) variations or ‘major’ (type II) variations.

Companies wishing to market a homeopathic or herbal medicinal product must submit an application to the IMB. The application contains data on the quality and safety of the product. Staff of the IMB, in association with the Board’s committees, subcommittees and individual experts, will review the scientific data and reach a conclusion on the likely benefits versus risks of the medicinal product, before arriving at a decision to grant or refuse a certificate of registration.

12.2 Assessment of applications for clinical trial authorisation

Applications for authorisation of clinical trials in Ireland using medicines for human use are made to the IMB. A Clinical Trials Subcommittee meets to review all applications. This committee is a subcommittee of the Advisory Committee for Human Medicines. The subcommittee meets once a month and applications are submitted two weeks before the meeting. After the meeting and after any queries are

resolved, applications are approved by the Management Committee of the IMB which meets every week.

12.3 Assessment of applications for clinical investigation approval

Individuals who intend to bring a medical device to market, e.g. medical device manufacturers, may be required to sponsor specific clinical investigations involving the device to gather clinical data to demonstrate the safety and performance of the device. These data may be required to demonstrate that the device meets the requirements of the relevant Medical Device Directive.

Applications to conduct certain clinical investigations require notification and review by the Medical Devices Department of the IMB prior to commencement. The IMB reviews the application from regulatory, technical and clinical perspectives.

12.4 Controlled drugs and precursor chemicals

A controlled drug is defined as any substance which, due to its potential for misuse and/or abuse, is listed in the schedule to the Misuse of Drugs Acts 1977 and 1984.

A precursor chemical is a substance that may be used as starting materials for the illicit manufacture of a controlled drug.

Controlled drug licences are required by various sectors of the pharmaceutical-related industry and others including the following:

- Manufactures
- Distributors
- Academic institutions
- Private hospitals
- Cultivators

12.5 Device registration

Class I medical devices, custom-made devices, systems and procedure packs and all *in-vitro* diagnostic medical devices are registered by the IMB.

12.6 Notified body approval

The IMB monitors Notified Body activity in Ireland. Notified Bodies assess data provided by manufacturers to establish if this data demonstrates safety and performance of the device and conformance with the essential requirements. If a Notified Body is satisfied that the device conforms then they award the device a CE mark, which allows the device to be marketed across the European Union.

12.7 Inspection and licensing of manufacturers

With certain exceptions, manufacturers of human and veterinary medicines are required to hold a Manufacturer's Authorisation.

To obtain an authorisation to manufacture medicinal products, compliance with the principles of Good Manufacturing Practice (GMP) must be demonstrated. GMP is defined as "that part of Quality Assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use." To verify that products are manufactured consistently to the required quality, inspectors monitor compliance with the GMP principles through regular on-site inspections.

Third country manufacturers, i.e. those located outside of the European Economic Area (EEA), are also required to meet the equivalent standard of GMP as EEA manufacturers.

12.8 Inspection and licensing of wholesalers

With certain exceptions, distributors of human medicines are required to hold a wholesaler's authorisation. To obtain an authorisation to distribute medicinal products, compliance with the principles of Good Distribution Practice (GDP) must be demonstrated. GDP is defined as "that part of quality assurance which ensures that products are consistently stored, transported and handled under suitable condition as required by the marketing authorisation (MA) or product specification and that traceability is ensured." To verify that the appropriate systems are in place inspectors monitor compliance with the GDP principles through regular on-site inspections.

12.9 Auditing and surveillance of medical device manufacturers

The IMB carries out audits of medical device manufacturer on regular basis. The type of audits that are conducted are as follows:

- Proactive post market surveillance audits
- Reactive post market surveillance audits
- Custom-made medical device audits
- Other audits pertaining to the register of medical devices

The aim of these audits is to ensure that the medical device manufacturer is complying with the essential requirements and schedules of the Medical Device Directives and related Statutory Instruments.

Surveillance audits of the medical device market are used to identify issues and trends in order to highlight priority areas for the medical devices market.

12.10 Safety of medicines

Monitoring the safety of medicines, also known as pharmacovigilance, is carried out in a number of ways, including review and evaluation of suspected adverse reaction reports, published literature, epidemiological studies and additional clinical trial results. The IMB continually assesses new and emerging safety data as they become available and undertakes regulatory action as appropriate.

Reporting of suspected adverse reactions is just one way of identifying a possible new adverse reaction (i.e. a signal), which may also be detected from other sources, such as new clinical trial data, literature reports etc.

Once a signal is identified, further evaluation and additional data are necessary to help determine its significance and which include information between exposed and unexposed patients, to confirm or refute the signal, identify potential risk factors, estimate the incidence etc.

The IMB continually assesses new and emerging safety data as they become available and undertakes regulatory action as appropriate.

12.11 Safety of blood

Haemovigilance is the process of monitoring the safety of blood and blood components from collection of the pre-transfusion sample to completion of the transfusion process.

The IMB is the Competent Authority for medicinal products (including blood-derived medicinal products) and is responsible for the national pharmacovigilance system for collection and evaluation of information relevant to the benefit-risk balance of medicinal products. Suspected adverse reactions associated with blood-derived medicinal products should be notified to the IMB, in addition to NHO reporting requirements.

12.12 Safety of tissues and cells

In accordance with this legislation, the IMB has established a reporting system for the notification of suspected serious adverse reactions and serious adverse events associated with human tissues and cells.

Under the legislation, all tissue establishments are required, through the responsible person (or designee), to notify the IMB and provide a report analysing the cause of and ensuing outcome of:

- Any serious adverse events and reactions which may influence the quality and safety of tissues and cells and which may be attributed to the procurement, testing, processing, storage and distribution of tissues and cells;

- Any serious adverse reaction observed during or after clinical application which may be linked to the quality and safety of tissues and cells

The reporting requirements to the IMB are inclusive of:

- In the case of assisted reproduction, any type of gamete or embryo misidentification or mix-up, which shall be considered a serious adverse event;
- 'Near miss' reports where the event was detected prior to transplantation.

12.13 Vigilance (adverse incident monitoring)

Under the terms of the Irish Medical Devices Regulations, the IMB as the Competent Authority is obliged to institute and coordinate a reporting system for adverse incidents associated with the use of medical devices in Ireland. The system is intended to improve the protection of health and safety of patients, users and others by reducing the likelihood of the same type of adverse incident being repeated in the European Economic area (EEA) and to correct product problems

The vigilance system is the name given to the process of notification and evaluation of adverse incidents associated with Medical Devices. It should also be pointed out that any adverse affects occurring during clinical investigation or performance evaluation should be reported to the Competent Authority.

As required by the directives the following types of incidents and recalls should be reported by the manufacturer to the IMB:-

- Any malfunction of or deterioration in the characteristics and performance of a device as well as any inaccuracies in the instruction leaflet, which might lead to or might have led to the death of a patient or to the deterioration in health.
- Any technical or medical reason due to risk of serious injury or death resulting in the recall of a device from the market by the manufacturer or the issue of an advisory notice.

12.14 Quality defect monitoring

The IMB operates a medicinal product defect reporting and investigation programme.

Product defects, also known as quality defects, may be described as unplanned attributes of a drug product which may affect the quality, safety and/or efficacy of the product and which are not in line with the approved registered file on that product.

The IMB also receives notifications of product defects from the medical professions, patients and consumers, distributors and wholesalers, and from other Competent Authorities.

All quality defects are investigated on a case-by-case basis. Quality defects may result in product recalls, in the issuance of a Caution-in-Use notification to pharmacists and

to the medical professions, or in other actions requested of a company by the IMB. Other Competent Authorities may be informed by the IMB of the quality defect issue.

12.15 Sampling and analysis

The sampling and analysis programme forms part of IMB's market compliance and surveillance activities and operates through the collection of samples of authorised medicinal products, and active pharmaceutical ingredients.

Enforcement samples and other products (for example borderline products and unauthorised products making medicinal claims) are sourced from the marketplace or from the site of manufacture. These products, which are sampled by authorised officers of IMB, are analytically tested and/or assessed internally. A risk-based approach is taken when carrying out sampling and analysis work, and the extent of the work carried out is dependent on the reason for sampling.

12.16 Export certification (free sales certificates)

The IMB is responsible for issuing export certificates for medicinal products and active ingredients or to certify the Good Manufacturing Process compliance of a manufacturing site.

Certificates of free sale for general medical devices, active implantable medical devices and *in-vitro* diagnostic medical devices are also issued by the IMB.

12.17 Further information

For an update on Irish Medicines Board activities, please visit our website at www.imb.ie or, contact:

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13. LEGISLATION AND GUIDELINES

Statutory requirements are laid down in the Irish Medicines Board Acts, 1995 and 2006, and in the regulations relating to the authorisation of medicines, manufacturers, wholesalers and controlled drugs, and the regulations relating to medical devices. These regulations are variously made under the Irish Medicines Board Acts 1995 and 2006, the Animal Remedies Act 1993 and the European Communities Act 1972.

As a Member State of the European Union, Ireland also must transpose or implement as appropriate relevant European Union legislation. The relevant legislation in the pharmaceutical area is found on the website of the EU Commission, for medicines for human use, medicines for veterinary use, primary legislation for medical devices and implementing legislation on medical devices.

A full list of current legislation, EU and national, is available in the appendix.

There are a large number of EU guidelines relating to the functions of the IMB as specified in section 12 above. These can be found on the website of the EU Commission, for medicines for human use (in relation to good manufacturing practice) and medical devices. The website of the European Medicines Agency contains the scientific guidelines on medicines for human use and medicines for veterinary use.

The procedures to be followed in making an application to have a medicinal product authorised are published in a ten-volume series *The Rules Governing Medicinal Products in the European Union*, available on the European Commission's website for medicines for human use and medicines for veterinary use.

APPENDIX NATIONAL AND EU LEGISLATION

Advertising

- Medicinal Products (Control of Advertising) Regulations, 2007, SI No 541 of 2007

Animal remedies

- European Communities (Animal Remedies) (No 2) Regulations 2007, SI 786 of 2007
- Control of Animal Remedies and their Residues (Amendment) Regulations 2004 (SI No 827 of 2004). (Regulation 3 is revoked by SI 734/2005)
- Control of Animal Remedies and their Residues Regulations 1998 (SI 507 of 1998)
- Animal Remedies Act 1993, A 23 of 1993

Blood and blood components

- European Communities (Quality and Safety of Human Blood and Blood Components) Regulations, 2005 (SI No. 360 of 2005)

Clinical trials

- European Communities (Clinical Trials on Medicinal Products for Human Use) (Amendment No. 2) Regulations 2006, SI 374 of 2006
- European Communities (Clinical Trials on Medicinal Products for Human Use) (Amendment) Regulations, 2004, SI 878 of 2004
- European Communities (Clinical Trials on Medicinal Products for Human Use) 2004 (SI No. 190 of 2004)
- European Communities (Good Laboratory Practice) (Amendment) Regulations, 1999 (SI No. 294 of 1999)
- Clinical Trials Act 1990
- Control of Clinical Trials and Drug Act 1987 (Commencement) Order, 1988 (SI No. 321 of 1988)
- Clinical Trials Act 1987

Control of placing on the market

- Medicinal Products (Control of Placing on the Market) Regulations, 2007 SI 540 of 2007
- European Communities (Limitations of Effect of Patent) Regulations, 2006 (SI No. 290 of 2006) amending Section 42 of the Patents Act, 1992 (SI No. 1 of 1992)
- Medicinal Products (Licensing and Sale) (Amendment) Regulations, 2001 (SI No. 512 of 2001)
- Medicinal Products (Licensing and Sale) Regulations, 1998 (SI No. 142 of 1998)

Controlled drugs

- Misuse of Drugs (Amendment) Regulations 2007, SI 200 of 2007

- Misuse of Drugs (Designation) Order, 1998 (SI No. 69 of 1998)
- Misuse of Drugs (Amendment) Order, 1993 (SI No. 342 of 1993)
- Misuse of Drugs (Designation) Order, 1993 (SI No. 340 of 1993)
- Misuse of Drugs (Exemption) (Amendment) Order, 1993 (SI No. 339 of 1993)
- Misuse of Drugs (Scheduled Substances) Regulations, 1993 (SI No. 338 of 1993)
- European Communities (Monitoring of External Trade in Scheduled Substances) Regulations, 1993 (SI 6 of 1993)
- Misuse of Drugs Regulations, 1988 (SI 328 of 1988)
- Misuse of Drugs (Designation) Order, 1988 (SI 327 of 1988)
- Misuse of Drugs (Exemption) Order, 1988 (SI 326 of 1988)
- Misuse of Drugs (Committees of Inquiry) Regulations, 1984 (SI 264 of 1984)
- Misuse of Drugs Act 1984
- Misuse of Drugs (Safe Custody) Regulations 1982 (SI No. 321 of 1982)
- Misuse of Drugs Act 1977 (Controlled Drugs) Declaration Order, 1993 (SI No. 328 of 1993)
- Misuse of Drugs Act 1977 (Controlled Drugs) (Declaration) Order, 1987 (SI No. 251 of 1987)
- Misuse of Drugs Act 1977

Cosmetics

- European Communities (Cosmetic Products) Regulations, 2004 (SI No. 870 of 2004)

Feedingstuffs

- European Communities (Protein Feedingstuffs) Regulations 2007 (SI 711 of 2004)
- European Communities (Additives in Feedingstuffs) Regulations, 1999 (SI No. 398 of 1999)
- European Communities (Feedingstuffs) (Tolerances of Undesirable Substances and Products) (Amendment) Regulations 1994 (SI No. 36 of 2000)
- European Communities (Feedingstuffs) (Tolerances of Undesirable Substances and Products) Regulations, 1998 (SI No. 283 of 1998)
- European Communities (Pesticide residues) (Foodstuffs of animal origin) (Amendment) Regulations 1993 (SI 317 of 1993)
- European Communities (Marketing of Feedingstuffs) (Amendment) Regulations, 1993 (SI No. 261 of 1993)
- European Communities (Control of oestrogenic, androgenic, gestagenic and thyrostatic substances) (Amendment) Regulations 1991 (SI 198 of 1991)
- European Communities (Manufacture of feedingstuffs) (Amendment) Regulations 1988 (SI 249 of 1988)
- Animal and Poultry Compound Feeding Stuffs (Control of Antibiotics) Regulations 1972 (SI 335 of 1972)

Irish Medicines Board

- European Communities (Amendment of the Irish Medicines Board Act 1995) Regulations 2007
- Irish Medicines Board (Miscellaneous Provisions) Act 2006 (Commencement) (No. 2) Order 2007
- Irish Medicines Board (Miscellaneous Provisions) Act 2006 (Commencement) Order 2007
- Irish Medicines Board (Miscellaneous Provisions) Act 2006 (No 21 of 2005)
- Irish Medicines Board (Competent Authority) Order, 1998 (SI No. 143 of 1998)
- Irish Medicines Board Act 1995 (Commencement) Order, 1995 (SI No. 346 of 1995)
- Irish Medicines Board Act 1995 (Establishment) Order, 1995 (SI No. 345 of 1995)
- Irish Medicines Board Act 1995 (Commencement) Order, 1996 (SI No. 40 of 1996)
- Irish Medicines Board Act, 1995 (No. 29 of 1995)

Labelling and package leaflets

- Medicinal Products (Amendment) Regulations, 2004 (SI No. 188 of 1999)
- Medical Preparations (Labelling and Package Leaflets) (Amendment) Regulations, 1999 (SI No. 187 of 1999)
- Medical Preparations (Labelling and Package Leaflets) (Amendment) Regulations, 1994 (SI No. 440 of 1994)
- Medical Preparations (Labelling and Package Leaflets) Regulations, 1993 (SI No. 71 of 1993)

Manufacturers

- Medicinal Products (Control of Manufacture) Regulations, 2007 SI 539 of 2007

Medical devices

- European Communities (Medical Devices) (Reclassification of Breast Implants) (Amendment) Regulations, 2003 (SI No. 358 of 2003)
- European Communities (Medical Devices) (Tissues of Animal Origin) Regulations, 2003 (SI No. 554 of 2003)
- European Communities (Medical Devices) (Amendments) Regulations, 2002 (SI No. 576 of 2002)
- European Communities (Medical Devices) (Amendments) Regulations, 2001 (SI No. 444 of 2001)
- European Communities (In-vitro Diagnostic Medical Devices) Regulations, 2001 (SI No. 304 of 2001)
- European Communities (Active Implantable Medical Devices) Regulations, 1994 (SI No. 253 of 1994)
- European Communities (Medical Devices) Regulations, 1994 (SI No. 252 of 1994)

Pharmacopoeias

- Health Act, 1947 (SI No. 28 of 1947)
- Pharmacopoeia Act, 1931 (SI No. 22 of 1931)

Prescription and control of supply

- Medicinal Products (Prescription and Control of Supply) Regulations, consolidated 2007
- Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2007 SI 201 of 2007
- Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations, 2005 (SI No. 510 of 2005)
- Medicinal Products (Prescription and Control of Supply) Regulations, 2003 (SI No. 540 of 2003)

Tissues and cells

- European Communities (Quality and Safety of Human Tissues and Cells) Regulations, 2006 SI 158 of 2006

Wholesalers

- Medicinal Products (Control of Wholesale Distribution) Regulations, 2007 SI 538 of 2007
- Medical Preparations (Wholesale Licenses) (Amendment) Regulations, 1996 (SI No. 41 of 1996)