HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Guide to
Information held by the HPRA

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

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1 SCOPE

This guide is intended to identify the classes of records held by the Health Products Regulatory Authority (HPRA) and to facilitate appropriate access to this information. The HPRA routinely makes information available to the public through information leaflets, publications and in response to enquiries. The Freedom of Information Act 2014 provides an additional method of facilitating access to records not made routinely available.

This guide provides information on the Freedom of Information Act 2014 and on how to make a request under the Act to the HPRA. It outlines the structure and functions of the HPRA, with details of the services provided and how they may be availed of, including information on the classes of records we hold.

Sections 11-13 of this guide give details of the procedures of the HPRA in relation to general practices and schemes operated by the HPRA and legislation and guidelines under which the HPRA operates.

2 INTRODUCTION

The Freedom of Information Act 2014 provides that every person has the following legal rights:
- the right to access official records held by government departments and all public bodies that conform to the provisions of Section 6 of the Act;
- the right to have personal information held on them corrected or updated where such information is incomplete, incorrect or misleading; and
- the right to be given reasons for decisions taken by public bodies that affect them.

These rights mean that from a certain date (21 April 1998 in respect of the HPRA) people may seek access to personal information held that relates to themselves, no matter when the information was created, and to other records created after 21 April 1998.

3 THE ROLE OF THE HEALTH PRODUCTS REGULATORY AUTHORITY

3.1 Mission and vision

The HPRA's mission is to regulate medicines and devices for the benefit of people and animals. Our vision is excellence in health product regulation through science, collaboration and innovation.

3.2 Description of the organisation

We are a state agency that puts the health of people and animals at the core of everything we do. We use our scientific and clinical expertise to review and monitor health products available in Ireland or exported abroad. Our aim is to make sure that the health products we regulate are as safe as possible and do what they are intended to do.

Formerly known as the Irish Medicines Board (IMB), we became the HPRA in July 2014. Our name reflects our broad remit and regulatory functions which have expanded over a number of years to include:

- Human medicines
- Veterinary medicines
- Clinical trials
- Medical devices
- Controlled drugs
- Blood and blood components
- Tissues and cells
- Cosmetic products
- The protection of animals used for scientific purposes
- Organs intended for transplantation

3.3 Functions

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

The HPRA functions matrix on our website outlines all our key functions for each of the products/areas we regulate.

4 CODE OF CONDUCT AND DECLARATIONS OF INTEREST

The requirements outlined in the HPRA's code of conduct apply to members of the Authority, 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 HPRA.

The HPRA's responsibilities and role in the scientific evaluation of medicinal products for human and veterinary use and the regulation of medical devices have 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 HPRA are crucial for the independence of the HPRA and for its public reputation.

The HPRA adheres stringently to the Ethics in Public Office Acts, 1995 and 2011. In addition, the Irish Medicines Board Acts 1995 and 2006 have specific provisions which require an annual disclosure of interests by HPRA members, employees and members of committees.

These provisions are administered by the HPRA in line with best Irish and international practice. They provide assurance to the HPRA, patients and the public we serve that potential conflicts of interest do not occur in relation to carrying out our regulatory functions whilst also allowing the HPRA to have access to the best available scientific experts. Annual disclosures extend not only to interests held by these individuals but also by members of their households.

Staff of the HPRA are specifically prohibited by the Authority from having any interest in any matter under consideration. The HPRA also proactively requires its advisory committee members (who are not staff of the HPRA but provide advice based on their scientific experience and expertise) to make an annual declaration of interest. The disclosure of any potential conflict of interest is a standing item on the agenda of every committee meeting and each member is asked to confirm that they have no conflict of interest with matters under discussion.

5 STRUCTURE AND PROCEDURES

The structure of the HPRA's Authority, committees and departments is shown below.

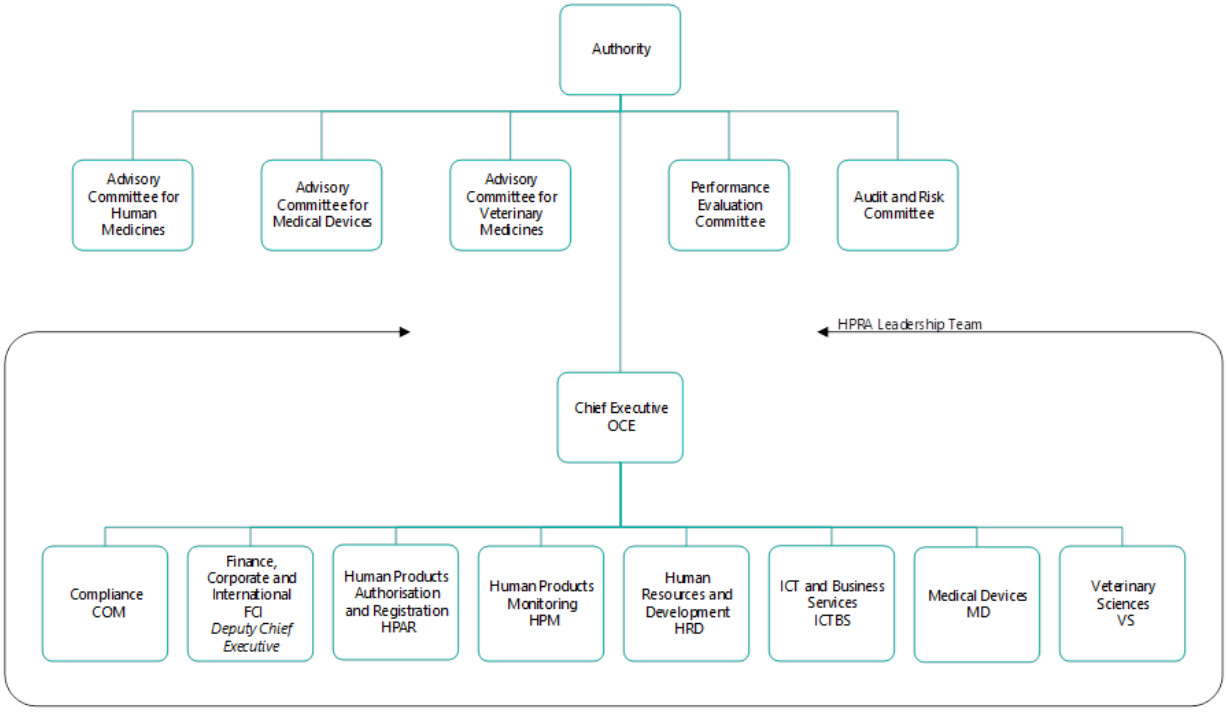

Figure 1: Organisation chart

Under the Irish Medicines Board Acts 1995 and 2006, the HPRA has an Authority of nine members appointed by the Minister for Health. The Authority 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 the members of the Advisory Committee for Veterinary Medicines are appointed by the Minister for Health on the advice of the Minister for Agriculture, Food and the Marine. The Irish Medicines Board Acts, 1995 and 2006 provide that the advisory committees may establish subcommittees. Ad hoc working groups may also be established from time to time to address specific issues. The Authority regulates the procedure and business of the HPRA. The functions of the advisory committees are described in the legislation. Terms of reference are established for the Authority, 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 Authority has devolved the day-to-day management of the HPRA to the Chief Executive. The Chief Executive is assisted in this function by the HPRA Leadership Team, which comprises, in addition to the Chief Executive, the directors of departments. Department directors are responsible to the Chief Executive and to the Authority of the HPRA for the activities of their departments. Further information on the structure of the HPRA is available on the HPRA website at www.hpra.ie.

6 HOW TO ACCESS INFORMATION UNDER THE FOI ACT

6.1 Applications under the FOI Act 2014

Under the FOI Act, anyone is entitled to apply for access to information not otherwise publicly available. Each person has a right to:
- access records held by the HPRA;
- correct personal information relating to oneself held by the HPRA where it is inaccurate, incomplete or misleading;
- access reasons for decisions made by the HPRA directly affecting oneself.

The following records come within the scope of the Act:
- all records relating to personal information held by the HPRA 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 HPRA 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,
Health Products Regulatory Authority,
Kevin O'Malley House,

Earlsfort Centre,
Earlsfort Terrace,
Dublin 2,
D02 XP77

Phone: 01 676 4971
Email: foi@hpra.ie

Applications should be made in writing and should specify that they are being made under the Freedom of Information Act. The form in which the records are sought, e.g. photocopies or electronic copy, should be stated in the request. As much detail as possible should be provided to enable the staff of the HPRA to identify relevant records. HPRA staff will also assist with preparation of requests if needed, for example, if there is a problem in identifying the precise records required. Further information is available from the page on Freedom of Information on the HPRA website.

6.2 Amendment of personal information

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

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

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. Sufficient evidence must be provided 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 their behalf).

6.3 Rights of review and appeal

The Act sets 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 HPRA 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

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

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

Requests for internal review should be submitted in writing to:
Chief Executive,
Health Products Regulatory Authority,
Kevin O'Malley House,
Earlsfort Centre,
Earlsfort Terrace,
Dublin 2
D02 XP77

Phone: 01 676 4971
Email: foi@hpra.ie

Such a request for internal review must be submitted within four weeks of the initial decision. The HPRA 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, an independent review of the decision may be sought from the Information Commissioner. Also, if a reply to an application for internal review is not provided within three weeks, this is deemed to be a refusal and may also be appealed to the Commissioner.

Appeals in writing may be made directly to the Information Commissioner at the following address:
The Information Commissioner,
Earlsfort Terrace,

Saint Kevin's,
Dublin 2,
D02 W773

Phone: 01 639 5689
Fax: 01 639 5674
Email: info@oic.ie

A fee of €50 (€15 for medical card holders) may apply for such an application. There is no fee for appeals to the Office of the Information Commissioner concerning only personal information relating to oneself or in relation to a decision to impose a fee or deposit.

7 FEES

In accordance with section 27 of the Freedom of Information Act, fees may be charged as follows:

Application fees
There is no charge for submitting a request.

Search, retrieval and copying fees
In respect of non-personal requests, charges may be applied for the time spent finding records and for any reproduction costs incurred by the HPRA in providing the material requested (search, retrieval and copying charges).

- Where the cost of search, retrieval and copying is less than €101, no fee is charged.
- Where the cost of search, retrieval and copying is greater than €500 but less than €700, a maximum charge of €500 applies.
- Where the cost of search, retrieval and copying is greater than €700, the HPRA can refuse to process the request.

Details of actual charges relating to the request will be notified in writing. Payment should be made by way of bank draft, money order, postal order or personal cheque made payable to the HPRA. The FOI Officer will provide bank details to facilitate payment by electronic means. A list of relevant fees is set out below:

List of fees
- There is no charge for submitting a request.
- Search and retrieval - €20 per hour (for requests that exceed the €101 minimum), subject to the ceilings mentioned above.
- €0.04 per sheet of a photocopy.
- Internal review fee €30 (€10 for medical card holders) for non-personal records.

Notes:
1 There is no charge if the records concerned contain only personal information relating to the applicant, unless there is a significant number of records.
2 For claimants wishing to avail of a reduced application fee, the request must be accompanied by a Medical Card registration number, issuing Health Board name and consent to allow verification of these details with that Health Board.

8 OPERATIONAL STRUCTURE AND INFORMATION HELD

The following section gives a breakdown of the internal structure and organisation of the HPRA. It describes the categories of information held, and the ways in which they can be accessed, either through existing publications, generation of information, e.g. anonymised summary listing of adverse reaction reports, or through the procedures set out in the Act.

8.1 Information common to all departments

8.1.1 Structure of the HPRA

The organisational structure of the HPRA consists of eight departments and the Chief Executive's Office. Each department has a director who is responsible for the day-to-day activities of that department. The Chief Executive and the eight department directors comprise the HPRA Leadership Team.

8.1.2 Information available outside the Freedom of Information Act

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 summary listings of adverse reaction report/event data
- EU and Irish legislation applicable to the HPRA'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 HPRA website. Online access to anonymised adverse reaction report data is not currently available, but is provided on request to medsafety@hpra.ie or in writing to:

Pharmacovigilance Section,
Health Products Regulatory Authority,
Kevin O'Malley House,
Earlsfort Centre,
Earlsfort Terrace,
Dublin 2,
DO2 XP77

Phone: 01 676 4971

8.2 Compliance Department

8.2.1 Functions of the Compliance Department

Within the Compliance department, the Health Products Distribution section comprises the inspectorate responsible for inspections of wholesalers of human medicines; inspections of manufacturers, wholesalers and other sites holding controlled drugs or precursor chemicals. Inspections are carried out in sites in Ireland.

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 organ procurement and transplantation centres; and inspections of contract testing laboratories. Inspections are carried out in sites in Ireland and routinely performed outside the EEA; occasional inspections in other EEA countries 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.

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

The Medicines Shortages and Borderline Classification section is responsible for classification of products on the 'borderline' between health products and non-health products; the co-ordination and management of human medicines shortage notifications, their evaluation and onward communication; the regulatory system for cosmetics and the co-ordination of activities relating to exempt medicinal products.

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.

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, blood, tissues and cells and organs for transplantation, while the HPRA works with the HSE in relation to enforcement of cosmetics legislation and with the Department of Agriculture, Food and the Marine for enforcement of the animal remedies legislation.

8.2.2 Classes of records held

- Files on each manufacturer, wholesaler, contract laboratory, blood establishment, and tissue and cells establishment
- Data submitted in support of applications
- Site master files
- Files on sampling and analysis, quality defects and product recalls
- Files on advertising reviews
- Files relating to cosmetic regulatory activities
- 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 and International Department

8.3.1 Functions of the Finance, Corporate and International Department

The Finance, Corporate and International department is responsible for processing financial transactions, budgeting, proposing and collecting fees, management accounts, and managing the financial position of the organisation.

The department manages declarations of interest and Ethics in Public Office declarations..

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

8.3.2 Classes of records held

- Finance and accounting records
- Legal and insurance files
- Budget files
- Buildings and secretarial files
- Authority and committee files
- National and EU legislation and guidelines
- Records of applications for classification of borderline products
- Reports from internal meetings
- Documentation from external meetings
- Policies, guidelines, standard operating procedures, work instructions and forms

8.4 Human Products Authorisation and Registration Department

8.4.1 Functions of the Human Products Authorisation and Registration Department

The Human Products Authorisation and Registration department has the following sections: Business Process Co-ordination, Centralised and Clinical Trials Licensing, National Licensing, Receipts and Validation.

The Business Process Co-ordination section processes all national and EU marketing authorisation applications for medicinal products for human use, as well as applications for scientific advice on medicinal products, applications for clinical trials using medicinal products and marketing status notifications.

The Centralised and Clinical Trials Licensing section is responsible for the assessment of the quality (biological), safety and efficacy, nonclinical, pharmacokinetic and statistical data in centralised marketing authorisation applications for medicinal products, except for those data assessed by the Vigilance Assessment section in the Human Products Monitoring department. The Centralised and Clinical Trials Licensing section is also responsible for the assessment of clinical trial applications.

The National Licensing section is responsible for the assessment of the quality and clinical data in marketing authorisation applications for medicinal products received by the department, assessment of quality data (chemical) submitted in clinical trial applications and drug device combinations. The National Licensing section is also responsible for the management of national licensing activities such as national scientific advice, quality defects and batch specific requests.

The Receipts and Validation section is responsible for the receipt and validation of applications relating to human and veterinary medicines, filing of applications for human medicines, and archiving. It also includes responsibility for scheduling and capacity planning.

8.4.2 Classes of records held

- Files relating to the preclinical and clinical assessments of medicinal products
- Files relating to the pharmaceutical assessment of medicinal products
- Clinical trial files (human medicines)
- 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 Human Products Monitoring Department

8.5.1 Functions of the Human Products Monitoring Department

The Human Products Monitoring Department has three sections: Pharmacovigilance, Vigilance Assessment, and Pharmacovigilance Risk Communication and Assessment.

Pharmacovigilance responsibilities include evaluation and follow up of nationally occurring adverse reaction reports related to medicines, reports of serious adverse reactions and events associated with human tissues and cells, and those arising in the context of organ transplantation. The section is also responsible for co-ordination of HPRA pharmacovigilance-related communications, routine and ad-hoc exchange of information with relevant national bodies, the European Medicines Agency (EMA), WHO and national competent authorities in other Member States. In addition, the section is responsible for the co-ordination of haemovigilance activities internally and with the National Haemovigilance Office (NHO).

The Vigilance Assessment section is responsible for the evaluation and regulation of the benefits and risks of medicines both pre- and post-marketing. This includes signal detection and evaluation (including implementation of the outcomes of signal analyses by the Pharmacovigilance and Risk Assessment Committee), assessment of risk minimisation plans, pharmacovigilance plans including post authorisation study protocols, periodic safety update reports, safety-related variations for centrally-authorised products, , and participation in ongoing risk management and major safety reviews of medicinal products at EU level. It also promotes communication and exchange of information with the EMA and EU national competent authorities.

The Pharmacovigilance Risk Communication and Assessment section is responsible for co-ordination of: HPRA pharmacovigilance related communications to healthcare professionals and

the public; the HPRA patient forum and HPM's patient/public engagement; rapid alerts and non-urgent information requests from national competent authorities. It is also responsible for the review and approval of educational materials and communications to healthcare professionals relating to emerging new safety information. It leads the approach to stakeholder engagement on medicines related pharmacovigilance issues.

8.5.2 Classes of records held

- Adverse reaction and event reports (only summary anonymised adverse reaction listings are made available, although additional information or records may be provided if personal to the individual)
- Files on pharmacovigilance assessment procedures
- 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 Human Resources and Development Department

8.6.1 Functions of the Human Resources and Development Department

The Human Resources and Development Department is responsible for resource planning, training and development, recruitment and selection, employee contracts and the policies and procedures for line management of employees.

8.6.2 Classes of records held

- Personnel records
- 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 ICT and Business Services Department

8.7.1 Functions of the ICT and Business Services Department

The Business Services section is responsible for business analysis in respect of new technology requirements, provision of project management support and training, process improvement analysis and support, application development testing and support for implementation and migration, the organisational Project Management Office, application maintenance and external vendor management.

The Applications Development section is responsible for developing new and enhancing existing applications in line with business requirements; facilitating data cleansing, mapping and migration activities; managing external vendors in the delivery of application related services; and providing level 2 application support for HPRA users.

The ICT section is responsible for systems administration, IT security, level 1 and 2 support, ICT standards and policies, networks, infrastructure and telecoms.

8.7.2 Classes of records held

- Procurement files
- Change management 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

8.8 Medical Devices Department

8.8.1 Functions of the Medical Devices Department

The Medical Devices department has the following sections: Assessment and Surveillance, Regulatory and Policy, and Clinical Assessment.

The Assessment and Surveillance section is responsible for the monitoring, evaluation and follow-up of adverse incident reports, for preparing safety notices, for monitoring recalls, for the designation and management of notified bodies in Ireland, for inspection of medical device manufacturers and wholesalers, and for the issuance of competent authority reports.

The Regulatory and Policy section is responsible for the implementation and maintenance of EU Regulations and for contributing as an active member of EU committees and working groups involved in the assessment and development of medical devices regulation on the market.

The Clinical Assessment section is responsible for the clinical assessment of data (including post-marketing data) relating to medical devices and *in-vitro* diagnostic medical devices.

8.8.2 Classes of records held

- Clinical investigation files
- Records of medical device company and product registration
- Records of applications for determination of medical device status
- CEN standards relating to medical devices and diagnostics
- Data submitted in support of applications

- Files on medical device manufacturers and wholesalers
- Export certificates for medical devices
- Adverse reaction and event reports (only summary anonymised adverse reaction listings are made available, although additional information or records may be provided if personal to the individual)
- Files on adverse incident reports and investigations in relation to medical devices
- National and EU legislation and guidelines
- Reports from internal meetings
- Documentation from external meetings
- Policies, guidelines, standard operating procedures, work instructions and forms

8.9 Veterinary Sciences Department

8.9.1 Functions of the Veterinary Sciences Department

The Veterinary Sciences 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 on veterinary medicines that are submitted nationally. 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.

The department assesses applications submitted under scientific animal protection legislation relating to the conduct of research and regulatory studies in animals.

8.9.2 Classes of records held

- Files relating to the assessments of veterinary product applications and applications submitted under Directive 2010/63/EU on scientific animal protection
- Clinical field trial files
- Adverse reaction reports and files (only anonymised adverse reaction data are 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

8.10 Office of the Chief Executive

8.10.1 Functions of the Office of the Chief Executive

The Communications section and the Operational Excellence and Quality sections operate out of the office of the Chief Executive.

The Communications section handles queries related to HPRA publications, media statements, the website, etc.

The Operational Excellence and Quality section is responsible for:
- operational excellence and lean management
- strategic and business planning
- the quality management system
- administration of the system for data protection
- the risk management system
- managing the provision of responses to the Department of Health in relation to parliamentary and government department questions, ministerial representations and briefing requests

8.10.2 Classes of records held

- Strategic and business plans
- 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, e.g. 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 HPRA.

10 DESIGNATIONS OF FOI DECISION MAKERS WITHIN THE HPRA

Area	Designated FOI decision maker
Authority and Committee matters	Chief Executive Secretary to the Authority Secretary to the Committees
Compliance Department	Director of Compliance Enforcement Manager Health Products Distribution Manager Inspections Manager Market Compliance Manager
Finance, Corporate and International Department	Deputy Chief Executive Financial Controller Information Officer Senior Financial Accountant
Human Products Authorisation and Registration Department	Director of Human Products Authorisation and Registration Centralised and Clinical Trials Licensing Manager National Licensing Manager

Area	Designated FOI decision maker
Human Products Monitoring Department	Director of Human Products Monitoring Pharmacovigilance and Risk Communication Assessment Manager Pharmacovigilance Manager Vigilance Assessment Managers
Human Resources and Development Department	Director of Human Resources and Development Human Resources Manager Learning and Development Manager
ICT and Business Services	Director of ICT and Business Services IT Manager
Medical Devices Department	Director of Medical Devices Assessment and Surveillance Managers Clinical Manager Regulatory and Policy Manager
Veterinary Sciences Department	Director of Veterinary Sciences Pharmaceutical Assessment Manager Planning and Authorisations Manager Scientific Animal Protection Manager Veterinary Assessment Manager

11 GENERAL PRACTICES OF THE HPRA

11.1 Contracts for services and supplies

The HPRA complies with the requirements for procurement which are set out on the Office of Government Procurement website: eTenders.gov.ie.

11.2 Payment of accounts

The HPRA complies fully with the requirements of the European Communities (Late Payment in Commercial Transactions) Regulations 2012.

11.3 Standards of service

The HPRA maintains a high standard of service to all its stakeholders and to all those looking to the Authority for advice, guidance or support.

On its website the HPRA has published standards of service which stakeholders may expect. The offices are open from Monday to Friday, 8:45am to 6:00pm, excluding public holidays. We answer all telephone calls promptly and courteously. For those calling outside office hours, a message may be left on our answering service and calls will be returned on the following working day.

Our adherence to these standards is monitored and we strive to improve these standards over time.

12 SCHEMES OPERATED BY THE HEALTH PRODUCTS REGULATORY AUTHORITY

12.1 Medicinal products

Licensing

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

To obtain a marketing authorisation, a company must submit information to the HPRA, 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 HPRA draws upon the expertise of its staff and its Advisory Committee for Human Medicines (appointed by the Minister for Health). Expert advisory panels also meet as required. The mandate of the Advisory Committee is to assist and advise the Authority 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 HPRA on medicinal product safety grounds).

After a medicinal product has been authorised, the terms of the marketing authorisation may subsequently be varied, e.g. by the addition of a new manufacturing site or a new indication for use of the medicine.

Companies wishing to market a homeopathic or herbal medicinal product must submit an application to the HPRA. The application contains data on the quality and safety of the product. Staff of the HPRA, in association with the Authority's committees, subcommittees and individual experts, 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.

Safety

Monitoring the safety of medicines, also known as pharmacovigilance, is carried out in a number of ways, including the review and evaluation of suspected adverse reaction reports, published literature, epidemiological studies and additional clinical trial results.

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. Additional data is reviewed to help compare exposed and unexposed patients, confirm or refute the signal, identify potential risk factors, estimate the incidence, etc.

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

Clinical trials

Applications using medicines for human use are made in Ireland under the Clinical Trial Regulation through Clinical Trials Information System (CTIS). Applications are approved by the HPRA Leadership Team which meets every week.

Manufacturers

With certain exceptions, manufacturers of human medicines are required to hold a manufacturer's authorisation or licence.

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.

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.

Quality defect monitoring

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

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

The HPRA 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 HPRA. Other competent authorities may be informed by the HPRA of the quality defect issue.

Sampling and analysis
The sampling and analysis programme forms part of HPRA'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 the HPRA, 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.

Compliance monitoring
The HPRA operates a number of compliance monitoring programmes in respect of human medicines: general retail sale investigations, regulatory compliance inspections and an advertising compliance programme.

12.2 Medical devices

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

Notified body approval
The HPRA 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

Clinical investigations
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 relevant medical device legislation.

Applications to conduct certain clinical investigations require notification and review by the HPRA prior to commencement. The HPRA reviews the application from regulatory, technical and clinical perspectives.

Safety

Under the terms of the Irish Medical Devices Regulations, the HPRA 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. Any adverse effects 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 HPRA:

- 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.

Auditing and surveillance of medical device manufacturers

The HPRA carries out audits of medical device manufacturers on a regular basis, including:

- 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 medical device manufacturers are complying with the essential requirements and schedules of the EU medical device directives and related statutory instruments.

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

12.3 Blood establishments

Authorisation

The HPRA is responsible for ensuring that blood establishments (which perform collection, testing, processing, storage and distribution of blood and blood components) and hospital based blood banks (which store and cross-match blood for patient use) comply with the

Statutory Instrument No. 360 of 2005 (Quality and Safety of Human Blood and Blood Components) Regulations. These regulations set standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components. Blood establishments in Ireland are authorised by the HPRA following inspection and demonstration of compliance.

Safety
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 National Haemovigilance Office (NHO) is responsible for collection, collation and evaluation of serious adverse events and reactions associated with blood and blood components and for onward reporting to the HPRA in its role as the national competent authority.

The HPRA 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 HPRA, in addition to NHO reporting requirements.

12.4 Tissue establishments

Authorisation
Requirements relating to quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells for human application are regulated under Statutory Instrument No. 158 of 2006 (Quality and Safety of Human Tissues and Cells) Regulations, 2006. These Regulations set standards on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells. Tissue establishments in Ireland are authorised by the HPRA following inspection and demonstration of compliance.

Safety
The HPRA operates a reporting system for the notification of suspected serious adverse reactions and serious adverse events associated with human tissues and cells. Guidance on reporting is available from our website.

12.5 Organs

Authorisation
The HPRA is responsible for the inspection and authorisation of organ procurement and transplant centres and in conjunction with the HSE, for the development of a system for reporting of serious adverse reactions and events under European Union (Quality and Safety of Human Organs intended for Transplantation) Regulations 2012 (S.I. No. 325 of 2012). Organ procurement and transplant centres are required to be authorised by the HPRA following an inspection and demonstration of compliance with the legislative requirements.

Safety
In accordance with the legislation, development of a system to facilitate reporting, evaluation and the management measures applied to serious adverse reactions and events is underway, in collaboration with the HSE and relevant parties. Guidance on reporting is available from our website.

12.6 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 a starting material for the illicit manufacture of a controlled drug.

Controlled drug licences are required by various sectors of the pharmaceutical-related industry and others such as:
- Manufacturers
- Distributors
- Academic institutions
- Private hospitals
- Cultivators

12.7 Export certification (free sales certificates)

The HPRA 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 HPRA.

12.8 Cosmetics

The HPRA is responsible for the regulation of cosmetic products on the Irish market. This function includes processing cosmetic product notifications and generating certificates of free sale. A broad-reaching market surveillance programme is operated in conjunction with the HSE, and safety concerns arising during cosmetic product use are investigated by the HPRA.

12.9 Veterinary Medicines

Licensing
Products for which medicinal claims are made or which contain substances likely to have effects on the animal's body are considered as veterinary medicines, and require a marketing

authorisation from the HPRA. The marketing authorisation is issued with a Veterinary Product Authorisation (VPA) number which is included on the container.

To obtain a marketing authorisation, the company must submit information to the HPRA which examines the data to make sure that the veterinary medicinal product meets standards of quality, safety and efficacy. In determining the safety, quality and efficacy the HPRA draws upon the expertise of its staff and its Advisory Committee for Veterinary Medicines (appointed by the Minister for Health, with the consent of the Minister for Agriculture, Food and the Marine). The mandate of the Advisory Committee is to assist and advise the Authority and the staff in relation to any matters concerning public or animal health or the safety, quality or efficacy of veterinary medicinal products 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 HPRA on drug safety grounds).

After a medicinal product has been authorised, the terms of the marketing authorisation may subsequently be varied, e.g. by the addition of a new manufacturing site or a new indication for use of the medicine.

Companies wishing to market a homeopathic veterinary medicinal product must submit an application to the HPRA. The application contains data on the quality and safety of the product. Staff of the HPRA, in association with the Authority's committees and individual experts, 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.

Safety

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

Once a new adverse reaction or a change of incidence of known reactions is identified, further evaluation and additional data are necessary to help determine its significance and causality, to confirm or refute the signal, identify potential risk factors, estimate the incidence, etc.

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

Clinical trials

Applications for authorisation of clinical field trials in Ireland using veterinary medicines are made to the HPRA. The HPRA is obliged to consult with the Department of Agriculture, Food

and the Marine (DAFM) prior to reaching a decision on an application for a trial. The HPRA issues a recommendation to the Department, which then issues the authorisation.

Manufacturers

With certain exceptions, manufacturers of veterinary medicines are required to hold a manufacturer's authorisation or licence.

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.

12.10 Scientific animal protection

Licensing

Since 1 January 2013, the use of animals for scientific purposes is regulated by means of authorisation at three levels:

1. Establishments: Breeders, suppliers and establishments where procedures are performed must be authorised and are subject to HPRA inspections, including unannounced inspections.
2. Projects: Scientific procedures can only be performed on an animal following a detailed submission of the planned study and subsequent approval by the HPRA.
3. Individuals: All individuals performing scientific procedures on animals in an authorised establishment must be adequately trained and hold an individual authorisation.

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 Act 1995 as amended, 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 list of current legislation is available on the website foi.gov.ie.

There are many EU guidelines relating to the functions of the HPRA as specified 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.

14 FURTHER INFORMATION

For an update on HPRA activities, please visit our website at www.hpra.ie or contact:

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