



IRISH MEDICINES BOARD
SERVICE CHARTER

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

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1. INTRODUCTION

This charter sets out the standards of service that stakeholders can expect when dealing with the Irish Medicines Board (IMB). The IMB aims to provide a timely, professional and quality service to its stakeholders and is committed to continuous improvement. We will work co-operatively with our stakeholders to ensure effective quality service. Those subject to the IMB's activities will have opportunity for consultation on matters related to them.

2. THE ROLE OF THE IRISH MEDICINES BOARD

Our mission is to protect and enhance public and animal health through the regulation of medicines, medical devices and healthcare products.

3. OUR STAKEHOLDERS

Our stakeholders include the following:

- The public who consume medicines or use medical devices or healthcare products.
- Animal keepers and owners who use and administer veterinary medicines.
- Healthcare professionals, who prescribe, supply and administer medicines, medical devices, and healthcare products.
- Persons responsible for sponsoring clinical trials and clinical investigations in patients and volunteers.
- Applicants and holders of licences for medicines, controlled drugs, manufacturers, wholesalers, blood establishments and tissue establishments.
- Industry associations of companies involved in medicines, medical devices and healthcare products.
- Environmental protection authorities with whom the IMB consults in relation to environmental matters pertinent to the use and disposal of medicines and medical devices.
- The Minister for Health and Children, who confers functions on the IMB and who is advised by the IMB on matters relating to medicines, medical devices, and healthcare products.
- The Minister for Agriculture, Fisheries and Food and the Minister for the Marine who are advised by the IMB on matters relating to animal remedies and the safety of foodstuffs from treated animals.

- Our partners in the European medicines and medical device regulatory systems.
- Irish government agencies involved in the regulatory process for medicinal products, medical devices and health care products.
- Members of An Garda Síochána and the Revenue and Customs Service and other State agencies involved in the enforcement of legislation for medicinal products, medical devices and healthcare products.
- The US FDA, WHO, and other international medicines, medical devices and healthcare products regulatory bodies.
- Members of the Board, advisory committees and subcommittees and other experts and staff of the IMB.

4. EXPECTATIONS OF OUR STAKEHOLDERS

- The public are entitled to expect that, while accepting that use of any medicine, medical device or healthcare product carries a risk, the risk can be reasonably considered acceptable in the context of the condition being treated and of the likely benefit. Patients and animal owners are entitled to timely access to important innovative therapies. Animal keepers and owners who use and administer veterinary medicines are entitled to be assured that they are safe for the user and the consumer of foodstuffs from treated animals, as well as for the environment.
- Healthcare professionals can expect that the claims made for medicines have been independently reviewed and that, based on existing medical and scientific knowledge, the package leaflet and summary of product characteristics for medicines can be used to form judgements concerning the properties and appropriateness of the product. The IMB provides an information resource for healthcare professionals.
- Environmental protection organisations and local authorities can expect that the claims made for the use and disposal of part-used or out-of-date medicines and medical devices are in accordance with good scientific practice and national requirements.
- Applicants for and holders of licences can expect to be dealt with in an impartial, confidential and efficient fashion. Information disclosed to the IMB will be treated in confidence, consistent always with the IMB's overriding concern for public health. Applicants are entitled to information regarding the status of their application.
- The Minister for Health and Children will be furnished with any information and advice requested or which the IMB in its opinion considers should be reported to the Minister.

- Likewise, the Minister for Agriculture and Food, the Minister for the Marine and other Ministers of government departments will be furnished with information and advice on request and will be kept informed of relevant matters in the area of animal remedies.
- The IMB is committed to playing its full part in the processes of medicines and medical device regulation in the European Community and internationally including meeting the timescales required under the various Directives and Regulations.
- An Garda Síochána, Revenue and Customs Service and other State agencies involved in the enforcement of legislation under the IMB's remit can expect that their request will be treated in a confidential and efficient manner.
- All those who work in or give guidance or advice to the IMB are encouraged to contribute fully to its activities and staff members are supported in training and career development.

5. COMMITMENT TO SERVICE

In our dealings with our stakeholders, we make the following commitments to:

- Provide a high quality service.
- Treat all stakeholders in a positive, helpful and courteous manner at all times.
- Process queries efficiently and within agreed timeframes.
- Listen to stakeholders' views on how we can improve our services further.
- Respect privacy and confidentiality.
- Provide clear and accurate information in guidelines.

6. STANDARDS OF SERVICE

- Hours of business are from 9am to 5pm Monday to Friday, with reception cover from 8:45am to 6:00pm. We currently provide information by phone, letter, e-mail, fax, text and via the web through plain English and text messaging.

Our Access Officer will, on request and with sufficient notice, provide information in other accessible formats such as large print, Braille, audio tape, audio induction loops, Irish language, Irish sign language and easy to read.

Our general contact details are given at the end of this charter.

- We regularly consult with experts to advise us in relation to making all our services accessible.
- If you contact us by telephone, we will answer all calls promptly and always identify ourselves to you by name. We aim where possible to respond to routine enquiries within two days. For non-routine or assessment-related queries we will inform the enquirer when to expect a full reply.
- If voicemail is in operation, we will return your calls as soon as possible. We will update our voicemail messages to inform you if staff are out of the office for more than one working day.
- If you contact us with a query by letter, e-mail or fax, we aim where possible to respond to routine queries within two days of receipt of the query. For non-routine queries we will inform you when you may expect a full reply and identify who will respond. In our response letters, e-mails or faxes to you we will identify ourselves with full contact details. Correspondence on assessment-related matters is more complex and will require longer timeframes appropriate to the issues involved.
- We will use e-mail out-of-office auto-responses when not in the office and provide an alternative contact if out of the office for more than one working day.
- If your query is more appropriate to an external agency or other public body, we will inform you of this and tell you how to contact them.
- If you visit our offices by appointment, reception facilities will be provided. We will keep waiting times to a minimum and direct you to the meeting room as quickly as possible.
- We will provide a broad range of information on our website and ensure that it is up-to-date, accurate and understandable. Our website will contain current contact information and organisation charts.

7. YOUR ROLE

Our website provides a broad range of guidance and information that will prove a useful starting point for any query.

When contacting the IMB you can help us by providing information e.g. contact details and where appropriate, reference numbers, in a timely and accurate manner.

You can also assist us by providing feedback and suggestions about this charter and our service. This will help us in our commitment to continuously monitor and improve our service standards. We will regularly review this charter and stakeholder comments will play an important role in this.

8. INFORMATION

IMB publications including newsletters, general guides for applications, and application forms are available on our website at www.imb.ie. To access these publications, go to the website and click on the publications link.

9. FREEDOM OF INFORMATION

The IMB fully supports access to information on its activities as provided in the Freedom of Information Acts 1997 and 2003 where this does not conflict with the rights of an individual to confidentiality in medical matters or with the rights of the owner of proprietary or commercially sensitive information.

The IMB has prepared a guide in accordance with publication requirements set out in section 15 and section 16 of the Freedom of Information Act, 1997. Frequently asked questions can be found on the FAQ section of our website. For further information, you may contact the Freedom of Information officer either by telephone or by email foi@imb.ie.

10. PERFORMANCE TARGETS AND EFFICIENCIES

The IMB collects information on the conduct of its activities. This permits targets to be set and information on performance gathered. The IMB has a commitment to continuous improvement of its services.

IMB structures reflect an intention to provide an efficient service within the constraints of available resources. There is a commitment to control finances to ensure value for money.

11. COMPLAINTS

The IMB is committed to providing a high quality of service in all activities. In the event that any stakeholder is dissatisfied with the quality of service provided, formal procedures are in place for managing complaints. The IMB will investigate complaints in a confidential, objective and timely manner and will provide a response to the matters raised. We promise that making a complaint will have no implication for your dealings and contacts with the IMB. Where appropriate, corrective actions will be implemented with a view to improving performance.

Complaints must be submitted in writing to the head of the relevant Section or Department. If you are not satisfied with the response, you may submit a complaint in writing to the Complaints Officer of the IMB. Details of the complaint should include the date of occurrence, details of what you are dissatisfied with, the name of the

official with whom you dealt with, your contact details and any other details or documentation related to your complaint.

Complaints should be sent by fax or post to the Complaints Officer at the address below.

12. HOW TO CONTACT US

The IMB would be delighted to answer any question that you may have. Please use the contact details below with any general queries you may have. Refer to our website for the further contact details. Out of hours emergency contact numbers are detailed on our telephone answering service and on our website.

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