Guide to
Refusals and Appeals
1 SCOPE

This guide provides information to applicants on refusals and appeals procedures in respect of applications and on written or oral representations the applicant may wish to make to the Advisory Committees or the Authority.

The guide, and the procedures described in it, do not cover:
- Complaints of an administrative procedure. The handling of such complaints is described on the HPRA website;
- Decisions taken at European level, as in the centralised, decentralised or mutual recognition procedures;
- Urgent suspensions, where the threat to public or animal health is such that there is insufficient time to follow the steps in the procedure on refusals;
- Refusals of Type IA, Type IB or standard Type II variations;
- Restrictions which are required by legislation;
- Applications to make medical devices available in Ireland in the interests of protection of public health under Article 11.13 of 93/42/EEC; or

The procedure for refusals is described in section 2 and the procedure for appeals in section 3. It is only possible to appeal classification decisions, and objections to clinical trials and clinical investigations.

2 REFUSALS PROCEDURE

2.1 Introduction

The HPRA is the Competent Authority for authorisations, licences, and certificates relating to manufacture, distribution and marketing of medicinal products for human or veterinary use and it approves notified bodies for medical devices. Applications are considered in the first place by assessors or inspectors. Where an applicant company does not adequately address issues raised during assessment or inspection, the assessor or inspector may propose:
- Refusing to grant an application for an authorisation, licence, approval or certificate, or a variation
- Granting the application subject to certain conditions
- Imposing a compulsory variation
- Suspending or revoking an existing authorisation, licence, approval or certificate, or
- Refusing to designate a certification organisation as a notified body, or limiting the scope of that designation

For convenience, all of these actions are termed ‘refusals’.
2.2 Procedure

The Irish Medicines Board Acts 1995 and 2006 require that the advice of the relevant Advisory Committee is sought by the Board before refusing certain licences or authorisations.

Section 9(8) states that:
"(8) The Board shall not refuse to grant a licence or authorisation in respect of—
(a) a medicinal product or class of medicinal products,
or
(b) the manufacture or wholesale of a medicinal product or class of medicinal products,
on any ground relating to the safety, quality or efficacy of the medicinal product or class of medicinal products, as the case may be, unless the Board has requested the advice of the appropriate committee in relation thereto and considered the advice given pursuant to the request."

There are three statutory Advisory Committees:
- Advisory Committee for Human Medicines
- Advisory Committee for Medical Devices
- Advisory Committee for Veterinary Medicines
These committees meet approximately three to four times annually and offer independent, expert scientific advice to the HPRA.

The refusals procedure is designed to comply with the requirements above and with the principles of proportionality, fairness, consistency and transparency. At each stage, separate and independent decisions are taken with regard to the proposal to refuse. You will be kept informed at all stages and given copies of all documents presented to the committees or Authority. You will also be given the opportunity to make written or oral representations.
The detailed procedure for refusals is shown below.

When notified of an intention to refuse, you will wish to consider your response. You will be given the opportunity to make a written representation to the Management Committee; if you choose to do so, the response must be received within 30 days. Alternatively, you may decide to withdraw your application and notify us of this decision, which will end the refusals procedure. If you do not respond to the notification letter, the Management Committee’s proposal to refusal will be sent to the relevant Advisory Committee for their consideration and advice.

When the proposal to refuse is sent to the relevant Advisory Committee, you will be invited to make a written or oral submission for consideration at the meeting. Should you wish to make a submission, you must notify the Secretary to the Authority at least 14 days before the date of the meeting. The Advisory Committee will consider the proposal to refuse and decide to advise the Authority to accept or reject it, ensuring that the decision is based on adequate scientific grounds and that it is proportionate in relation to the risk to public health. You will be notified of the committee’s decision within seven days of the meeting.

The Management Committee’s proposal and the advice of the Advisory Committee are sent to the Authority of the HPRA. You will be notified of the Authority meeting date and given the opportunity to make representations. The Authority will consider all information regarding the proposal and make a decision to refuse the application or not. In coming to its decision,
the Authority ensures that due process has been carried out and that its decision is fair, unbiased and based on the best available information and data. You will be notified of the decision within seven days of the meeting.

3 APPEALS

3.1 Introduction

The HPRA is the Competent Authority for clinical trials on medicinal products and clinical investigations of medical devices. Where assessment of the application results in a letter of non-acceptance (for a clinical trial) or a letter of objection (for a clinical investigation) from the Management Committee, the sponsor may submit an appeal to the relevant Advisory Committee within 28 days of the notification. The ‘Guide to Fees’ gives details of the fee that must accompany an appeal; please see the ‘Publications and Forms’ section of www.hpra.ie.

The HPRA also issues decisions on the classification of products as medicines or medical devices and applicants may appeal these decisions to the Management Committee.

3.2 Procedure

The appeals procedure is designed to comply with the principles of proportionality, fairness, consistency and transparency. At each stage, separate and independent decisions are taken with regard to the appeal. You will be kept informed at all stages and given copies of documents presented to the committees or Authority. You will also be given the opportunity to make written or oral representations.

The appeals procedure begins with the appeal received from the company to a decision regarding clinical trials, clinical investigations or classification. For appeals to the Management Committee’s non-acceptance of a clinical trial or objections to a clinical investigation, you should submit the appeal to the relevant Advisory Committee. For appeals to classification decisions, which are taken by an assessor or the Classification Committee, you should submit the appeal to the Management Committee.
The detailed procedure for appeals is shown below.

The appeal notification should be accompanied by detailed grounds explaining why you believe the original decision should be overturned. You will then be notified of the date of the meeting at which it will be considered.

Before the meeting of the relevant Advisory Committee, you will be invited to make a written or oral submission for consideration at the meeting. Should you wish to do this, you must notify the Secretary to the Authority at least 14 days before the date of the meeting. The Advisory Committee will consider the appeal and decide to advise the Authority to either accept or reject it, ensuring that the decision is based on adequate scientific grounds and that it is proportionate in relation to the risk to public health. You will be notified of the committee’s decision within seven days of the meeting.
The Management Committee’s recommendation (for classification decisions) and the advice of the relevant Advisory Committee are sent to the Authority of the HPRA. You will be notified of the Authority meeting date and given the opportunity to make representations. The Authority will consider all information regarding the proposal and make the decision to accept the appeal or not. The Authority ensures that due process has been carried out and that its decision is fair, unbiased and based on the best available information and data. You will be notified of the decision within seven days of the meeting.

4 SUBMISSION OF WRITTEN INFORMATION

Where written information is supplied at any stage of the refusals or appeal procedures, you should make sure that the submission addresses the issues raised. Written material should be supplied in both hard copy and electronic format (unless otherwise agreed with the Secretary to the Authority), by the date specified.

Written submissions will be reviewed by the assessor or inspector who was dealing with the case. They will provide a summary of the information and an assessment of it for the committee meeting; you will be provided with copies of these documents before the meeting.

5 ORAL HEARINGS

If you wish to make an oral representation, you must submit any presentation and all supporting documentation no later than one month before the date of the advisory committee meeting. The documents should be submitted on CD-ROM and in hard copy (approximately 20 copies, the number to be confirmed with the Secretary to the Authority).

No later than one week before the committee meeting, you should inform the Secretary to the Authority of the number of company representatives who will attend (usually not more than five) and the name of the chief spokesperson.

The committee members will have been sent all the material available on the matter (internal assessment reports and procedural documentation, and company data) before the meeting, and will be familiar with the data and the procedure thus far.

After a preliminary discussion among the committee members, you will be invited into the boardroom. Your presentation should take not more than 15 minutes and should specifically and directly address the scientific issues relating to the refusal or appeal. After your presentation, the committee members or HPRA staff members may ask questions relating to issues raised in your presentation or supporting data or may raise questions of clarification. Your company representatives should have the technical expertise to address these questions and the managerial authority to take decisions on behalf of your company. They should also be fluent in English.
Following the presentation and questions, you will be asked to leave the boardroom. The committee will consider the evidence provided and agree the advice it will give to the Authority. You will be notified of the committee's advice within seven days of the meeting.

6 CONTACT POINT FOR PROCEDURES

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