

## **REJECTION OF APPLICATIONS**

Most applications to the IMB will require answers to questions raised during the assessment process. In the majority of cases, these will be resolved by dialogue with the applicant and the provision of additional data. Inevitably however, there will be cases in which there are fundamental defects in the submission which cannot be resolved in the context of that submission and the decision will have to be taken to recommend rejection of the application. The main criteria for this are set out in Article 9 of the Medical Preparations Regulations 1996 (SI No. 43 of 1996) for human medicines and in Regulations 11 and 12 of the Animal Remedies Regulations 1996 (SI No. 179 of 1996) for animal medicines. As required by the Irish Medicines Board Act, 1995, “the Board shall not refuse to grant a licence in respect of a medicinal product on any ground relating to safety, quality or efficacy of a medicinal product unless it has requested the advice of the appropriate committee” (Section 9(8)). These committees are the Advisory Committee on Human Medicines and the Advisory Committee on Veterinary Medicines.

The rejection procedure proceeds as follows:

1. Defects identified during the course of the assessment are relayed to the applicant or in the case of mutual recognition application to the reference member state. Reasonable opportunity is given to the applicant to reply.
2. Where it is not possible to resolve the deficiencies, in the opinion of the assessor (taking into account any consultative expert advice obtained), and a fundamental objection in terms of quality, safety or efficacy remains, the products are scheduled for rejection in consultation with the Head of Department.
3. The applicant is informed by the assessor that it is intended to recommend the application for rejection.

4. The recommendation for rejection is reviewed by the Executive Board.
5. If the Executive Board adopts the recommendation, the applicant is informed by letter that the application will be proposed for rejection to the Advisory Committee. The applicant is given 30 days to submit any comments.
6. Any resulting comments or proposals are reviewed by the Executive Board and the assessor(s). If these do not resolve the reasons for rejection, the proposal to reject will stand.
7. The proposal to reject is scheduled for presentation and review at a meeting of the Advisory Committee.
8. If the Advisory Committee agrees with the proposal, then a recommendation to reject is made to the Board.
9. Recommendations for rejection from the Advisory Committee are normally presented to the next scheduled Board meeting.
10. If the Board agrees to the rejection, then the applicant is notified in writing.
11. An applicant may make subsequent representations to the Board but should be aware that a review of the existing submission will have taken place and that any such request should address that and draw attention to any fresh and relevant material.

## Flow Chart of Rejection Procedure

