

BORDERLINE CLASSIFICATION COMMITTEE – TERMS OF REFERENCE

Introduction

The Medicines Authority is entrusted by law to regulate medicinal products for human use to be placed on the Maltese market in accordance with the European Community Pharmaceutical Directives and Maltese legislation (Medicines Act, 2003 and subsidiary legislation). By ensuring quality, efficacy and safety of medicines, it protects public health on behalf of the Malta Licensing Authority.

Directive 2001/83/EEC, as amended, and Medicines Act 2003, as amended, state that a:

“medicinal product” means a substance or combination of substances -

- (a) presented as having properties for treating or preventing disease in human beings; or*
- (b) which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action or to making a medical diagnosis;’*

Most human medicines are clearly identifiable as such and are subject to EC marketing authorisation procedures. However, there are some products where it is not so easy to distinguish a medicinal product from, for example, cosmetics, medical devices or food supplements. These products are temporarily called ‘borderline products’ until classified as medicinal products or not.

Therefore, a Borderline Classification Committee is required within the Medicines Authority so as to determine whether a borderline product is a ‘medicinal product’ and, therefore, subject to Article 20 of the Medicines Act, 2003 as amended and Regulation 4 of the Medicines Marketing Authorisation Regulations.

Terms of Reference

The Borderline Classification Committee’s main task is to advise the Licensing Authority as to whether a “borderline” product is a medicinal product, that is, that it falls within the definition of a medicinal

product and be subject to medicines control. It does so on a case-by-case basis following an assessment of all the available evidence and follows a Standard Operating Procedure:

‘Procedure to determine whether an unlicensed product is a medicinal product’ (B001) and other related guidelines including ‘Guide to what is a medicinal product’ (for applicants).

The remit of the Borderline Classification Committee (BCC), depending on the case, includes:

1. to determine whether a borderline product is a medicinal product - any substance or combination of substances presented for treating or preventing disease in human beings, as well as any substance or combination of substances which may be administered to human beings with a view to making a medical diagnoses or to restoring, correcting or modifying physiological functions in human beings by reviewing the status of a borderline product including:
 - a. the assessment of requests received from companies, from bodies or persons outside the Medicines Authority regarding the classification of a product, as well as any complaints
 - b. the medicinal claims made for the product (as per Appendices 6 and 7 of the SOP),
 - c. the pharmacological properties of the ingredients from European Pharmacopoeia or other Pharmacopoeias.
 - d. whether there are any similar licensed medicinal products on the market
 - e. how it is presented to the public through labelling, packaging, promotional literature and advertisements referring to advertising Regulations, where necessary.
 - f. to collect further information regarding a borderline product which may have a bearing on the issue, in order to classify the product. For example, the manufacturer, importer or distributor of the product may well be required to provide full details of the product’s composition, presentation and purpose, or any other information that is important for the classification.
 - g. to inform the Inspectorate section of all products classified as medicinal, in cases when a medicinal product is left on the market without a marketing authorisation,
 - h. to liase with Inspectorate Directorate on any issues that may require inforcement to consider a recommendation to the Inspectorate and Enforcement Directorate to recall a borderline (medicinal) product in cases of risk to public health in accordance with to the Inspectorate and Enforcement SOP.

- i. To liaise with Malta standards authority when dealing with products bordering with foods, medical devices, cosmetics, biocides and other regulatory regimes that may overlap with medicinal products, for an opinion. They may also be invited to attend specific meetings.
- j. to liaise with other European agencies as required.

Composition

The BCC shall be made up of:

1. The Licensing Director, who shall chair the group
2. Six members representing the Licensing Directorate, the Inspectorate and Enforcement Directorate and the Advertising Committee
3. A member of the HMPC and HMPWP
4. A physician (when necessary)
5. A secretary, to take minutes, list actions taken and to manage the administrative duties of the committee.

The BCC may also seek advice from a quality assessor or from experts on nutrition, legislation, inspection, safety and any other subjects as may be necessary, on a case-by-case basis. For the meeting to be held a quorum of 4 people should attend.

The BCC may also seek advice from experts on nutrition, legislation, inspection, safety implications and on any other subjects as may be necessary, on a case-by-case basis.

All members should make their utmost to reach consensus on the final classification. Where the information in hand is not sufficient to reach a definite conclusion, more information is to be requested from the applicant/importer/wholesale dealer, until the information is considered sufficient.

In cases where a final decision cannot be achieved by consensus, a decision based on the opinion of the majority of members is to be taken. In specific cases, the product may need to be discussed with an expert external to the committee, before coming to a final determination.

The quorum of the BCC should be of 6 members (excluding secretary). All members are to attend the meetings unless they are on vacation leave, sick leave or on duty travel.

The proceedings of the committee will be recorded in minutes, drafted by the secretary and approved by the committee.

The BCC shall meet on a regular basis, if an appropriate amount of requests for determinations are received. An *ad hoc* meeting may be set up in urgent cases such as when there is a possible risk to public health.

The final determinations of the committee are to be made public by publication on the official Medicines Authority website.

The annual report of the BCC is to be presented to the committee before being finalized and submitted for publication.