MALTA
MEDICINES
AUTHORITY

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BORDERLINE CLASSIFICATION COMMITTEE – TERMS OF REFERENCE

Introduction

The Malta 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 Union 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 Licensing Authority.

Directive 2001/83/EC and Medicines Act 2003 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 marketing authorisation procedures before they can be marketed. However, there are some instances where it is not so easy to distinguish medicinal products from, for example, cosmetics, medical devices or food supplements. These products are called 'borderline products' until classified as medicinal products or not. Until classified under the correct category, a product should not be placed on the market. If in doubt, the Borderline Classification Committee is there to help companies decide whether a product is medicinal or non-medicinal.

Therefore, the Borderline Classification Committee (BCC) within the Malta Medicines Authority determines whether a borderline product *is* a 'medicinal product' and, therefore, subject to Article 20 of the Medicines Act, 2003 and Regulation 4 of the Medicines Marketing Authorisation Regulations (i.e., requires a marketing authorisation to be placed on the market in Malta).

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. This is done following an assessment of all the available evidence in line with the relevant standard operating procedures and guidelines.

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

1. to determine whether a borderline product is a medicinal product in accordance with the definition of a medicinal product given in the legislation – requests are received from companies, from bodies or persons outside the Malta Medicines Authority regarding the classification of a product, as well as any complaints.

2. to liaise with Inspectorate Directorate on any issues that may require enforcement 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 Standard Operating Procedures

3. liaise with the directorate responsible for medicinal devices, when dealing with products bordering with medical devices.

4. to liaise with the Malta Consumer Competition Affairs Authority (MCCAA) when dealing with products bordering with foods, cosmetics, biocides and other regulatory regimes that may overlap with medicinal products, for an opinion. They may also be invited to attend specific meetings

5. to liaise with other European agencies as required.

<u>Factors taken into consideration by the BCC when making its determination include</u>:

a) the medicinal claims made for the product

b) the intended use of the product

c) its mode of action

d) the pharmacological properties of all the ingredients and if the pharmacological action is significant

e) whether there are any similar licensed medicinal products on the market

f) how the product is presented to the public through labelling, packaging, promotional literature and advertisements referring to advertising Regulations, where necessary

g) 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 be required to provide full details of the product's composition, presentation and purpose, or any other information that is important for the classification, such as its classification in other countries, especially in the European Union.

The BCC may also seek advice from experts on subjects related to the product being classified and may include nutrition, legislation, inspection, safety and any other subjects as may be necessary, on a case-by-case basis. The legal advisor could also be consulted.

The BCC shall meet on a regular basis, if an appropriate number 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 where products are classified as medicinal products are to be made public by publication on the Malta Medicines Authority website.