AWTORITÀ DWAR IL-MEDIĊINI

GUIDE TO WHAT IS A MEDICINAL PRODUCT

1. INTRODUCTION

The Medicines Authority

To protect public health, and on behalf of the Licensing Authority, the Medicines Authority regulates medicinal products for human use in accordance with the European Union and Maltese pharmaceutical legislation. As part of this, the Medicines Authority may be called on to determine whether a product ***is*** a "medicinal product". Any product classified as a medicinal product is subject to Article 20 of the Medicines Act, 2003.

Any person or company marketing a product has a legal duty to do so in accordance with the law. The Medicines Act and Regulations provide that, a medicinal product may not be placed on the Maltese market unless it has an authorisation granted by either the European Medicines Agency (EMA), or the Licensing Authority in Malta. A marketing authorisation is only granted for a product that meets statutory standards of safety, quality and efficacy.

In practice, the status of many products on the "borderline" between medicinal products and, respectively, food supplements, cosmetic products, biocides and medical devices can be difficult to determine. This Guidance has been developed to explain how, and on what basis, the Borderline Classification Committee on behalf of the Medicines Authority decides whether a particular product is a medicine or not.

When, following its assessment of the status of any product, the Medicines Authority gives a final determination that the product ***is*** a medicinal product, the Licensing Authority will require compliance with the law, that is, that an unlicensed product already on the market is withdrawn, or that it is not placed on the market until a Marketing Authorisation is issued. Where compliance is not achieved, the Medicines Authority, on behalf of the Licensing Authority, will consider and instigate whatever enforcement action is appropriate. The Medicines Act provides enforcement options, which include fines and prosecution in the criminal courts.

2. MEDICINAL PRODUCTS

2.1 Definition of what *is* a medicinal product.

Directive 2004/27/EC provides a definition of the term "*medicinal product"*. This definition is transposed into the Medicines Act, 2003:

A "medicinal product" means a substance or combination of substances -

(a) presented as having properties for treating or preventing disease in human beings; **['presentation']**

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;'* **['intended or actual function']**

The European Court of Justice ("ECJ") has said clearly that a product which comes within *either* definition *is* therefore a medicinal product. **Therefore, a product is medicinal if it falls within either of those definitions (or both).**

2.2 The **Medicines Authority policy and practice**

As national competent Authority, the Medicines Authority applies the definitions of a medicinal product to products within its borders. Accordingly in Malta, the above definitions, supported by relevant ECJ judgements, are the legal basis on which the Medicines Authority, on behalf of the Licensing Authority, determines whether a product is a medicinal product. This is done on a case-by-case basis following an assessment of all the available evidence, and liaison with other competent authorities and bodies where relevant.

Products may be brought to the attention of the Medicines Authority via applications from local and foreign companies wishing to start marketing the product/s in Malta, referrals from other authorities or departments (e.g. Malta Competition and Consumer Affairs Authority (MCCAA), Customs or Port Health) or through complaints by third parties. In some cases, the initial application, referral or complaint may contain insufficient information to determine whether the product concerned is a medicinal product. If this is the case, the Medicines Authority will request further information, which may have a bearing on the issue. For example, the manufacturer, importer or distributor of the product may be required to provide full details of the product composition (qualitative and quantitative), presentation and purpose. A sample of the carton (box)/leaflet (if available) is also requested. The application form should therefore be correctly filled in and all requested documentation submitted. A guideline on how to fill in the application form is also available.

When considering the evidence and determining whether a product falls within the definitions of a medicinal product, no single factor or combination of factors will *necessarily* be conclusive, or more or less significant than others. However, in relation to a particular product, a single factor or combination of factors may be more important than others, and may even be conclusive.

2.2.1 Explanation of the first definition – 'Presentation' as a medicinal product.

In assessing whether a product is a medicinal product in terms of the first definition, that is whether it is *"presented for treating or preventing disease"*, the Medicines authority takes note of any claims (implicit as well as explicit uses) which are made for it, and considers its presentation. A product may be determined by the Medicines Authority to be a medicinal product because it satisfies the first "presentation" definition, even when it does not satisfy the second "function" definition as well.

a. Claims to treat or prevent disease

A product for which claims are made to treat or prevent disease will clearly come within the first definition of a medicinal product. The Medicines Act, 2003 defines disease as follows: *'"Disease" includes any injury, ailment or adverse condition*

whether of body or mind'. Claims of "*relief*" from symptoms, or to *cure, remedy or heal* a specific "disease" (including *any adverse condition of body or mind*) may also be regarded as medicinal. In context, *stress, anxiety,* and *nervous tension* may be regarded as adverse conditions of the mind. Again in context, (and particularly in the case of products on the borderline between food and medicines), claims to *"protect"* or *"avoid"* may well be regarded as having much the same meaning for consumers as *"prevent"*. For example, a product in pharmaceutical form presented to "protect" consumers against a specific disease or adverse condition in such a way that consumers would believe the product *could* "prevent" it.

b. Claims to "maintain" or "support" health

The Medicines Authority does not, as a rule, consider that claims to *"maintain"* or *"help to maintain* or *"support"* health or a healthy lifestyle are, in themselves, medicinal claims. Nor does it do so if these claims are made in relation to *healthy bodily functions* or *organs*. In general terms, the Medicines Authority is only likely to consider such claims as being medicinal, if, in context, they suggest or imply that the product in question may be used to *restore,* or *help to restore* a specific bodily function to a healthy condition: for example, where the product is targeted on people with existing problems.

Factors particularly relevant to deciding whether a product is a medicinal product in terms of the first definition include:

i. *All claims made for the product,* both explicit and implicit, including any made on linked "help lines", websites or publications. "Implicit" claims may include the product's name. The Medicines Authority is committed to considering each product on its merits, and it is not possible to produce more than an indicative list of claims that the Medicines Authority may regard as presenting the product for treating or preventing disease. In context, and used in relation to disease, illness or specific adverse condition, claims which include certain words, which still need to be determined, may be regarded by Medicines Authority as indicating that the purpose of the product is to treat or prevent disease, that is, a medicinal purpose;

ii. the *context* of the claims, and the *overall presentation*;

iii. *how consumers,* or *those on whom it is targeted,* will perceive the product;

iv. the *labelling* and *packaging/package inserts* including any *graphics or reference to websites on which medicinal claims about the product are made*;

v. the *promotional literature*, including *testimonials* and any *literature issued by a third party on behalf of the supplier*;

vi. *advertisements*, including those appearing in *"advertorials"*, on *television,* and in/on *other media including the internet*;

vii. the *product* form, (capsule, tablet, etc), and the *way it is to be* used;

viii. *any particular target* of the *marketing information/advertising material*, for example, population groups with, or particularly vulnerable to, specific diseases or adverse conditions;

ix. *if an essentially or very similar product is on the market in Malta*, is/was it classified as a medicinal product or has a marketing authorisation.

The Medicines Authority may determine that a product is a medicine *solely* because it falls within the first (*presentation*) definition. This is to protect vulnerable consumers from products that could not deliver the medicinal results claimed for them.

In practice, however, in cases where it is presentational factors alone which make the product a medicinal product, the Medicines Authority will advise the promoter which presentational factors are unacceptable.

2.2.2 The second definition - "Function"

The second definition is concerned with the *function* and *intended use of the product*, that is, whether the product *"may be used in or administered to human beings with a view to…"* achieving a medicinal purpose (Directive 2001/83/EC). If, for example, a food supplement also contains an active ingredient that has an established use as (or in) a medicine, the Medicines Authority may still determine that the product is a medicinal product because it satisfies the second definition. When there is doubt or dispute whether the recommended dosage of the active medicinal ingredient(s) is "therapeutic" or not, the Medicines Authority will rely on the expert advice of its medical and pharmaceutical assessors or external experts if required.

It is important to remember that, whether the product is presented as a medicine or not, the Medicines Authority may determine that a product is a medicinal product *solely* because it contains substances with properties that indicate that it *"may be administered with a view to…"*, that is, under the second definition.

Factors particularly relevant to deciding whether a product is a medicine under the second definition include"

i. the *pharmacological properties of the active ingredient(s)*and any significant effect(s) they have on physiological functions in human beings, in particular the mode of action;

ii. the *product promotional literature*, including testimonials, supportive clinical trial or research papers, and any literature issued by a third party on behalf of the product`s supplier;

iii. the *product form*, (capsule, tablet etc.) and the *way it is to be used*;

iv. the *presence of essentially similar licensed medicines* on the Malta market;

v. *if the product is imported from another Member State*, how it is classified there.

3. COMMUNICATIONS

Advice

The Medicines Authority may discuss and give general advice, (and in cases of urgency, offer a provisional opinion), on the status of products by telephone, e-mail and letter.

In exceptional circumstances, the Medicines Authority will, without further investigation, issue a final determination that a product is a medicinal product and require immediate compliance with the law. Examples of such exceptional circumstances are where:

i. there is an identifiable risk to public health and/or patient safety
ii. the product is a copy, or is identical in all material respects to, another medicinal product that the Medicines Authority has already classified as a medicinal product.

As a rule, authoritative advice and statutory determinations will only be issued in writing. When a product is classified as a medicinal product, the determination letter will include detailed reasons for it and set a deadline for assurances about compliance. If further written representations or evidence are received within 20 days, the product's status will be reconsidered. Following any review, the final determination letter will be issued, again giving detailed reasons for the determination.

If compliance is not achieved by correspondence, the case will be referred for consideration of enforcement action to the Inspectorate and Enforcement Directorate.

Appeals

If applicants for any reason disagree with the decision taken by the Borderline Classification Committee (BCC) they may appeal within 20 days from the date of the determination letter by writing to the Borderline Appeals Board, composed of members external to the BCC. The case will be presented to the Borderline Appeals Board by a member of the BCC. Following this the Board will review the product and relevant literature and will issue a recommendation regarding the classification of the product.

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