

Eucomed position paper on the classification of Dental Bleaching Agents

Scope

This paper summarises the status of the discussion on the classification of Dental Bleaching Agents (DBAs), which has been recently debated by the Medical Devices Expert Group, and introduces new elements to the discussion in a move to contribute to the timely resolution of this issue acceptable to all stakeholders. Its' aim is to demonstrate that the classification of DBAs as medical devices may be legally justified and is in full compliance of the provisions of the Medical Devices Directive ("MDD"). This paper applies irrespectively and independently of any possible adaptation of, or amendment to, the Cosmetics Directive (CD).

This document has been elaborated in consultation with Eucomed members who manufacture DBAs and other non-member manufacturers.

Background

There has been much debate at European level about the classification of DBAs as cosmetics or as medical devices. The CD covers "oral hygiene products", without providing a definition of these products. During the debate, DBAs have been assimilated into this category although no legal justification has been provided. The MDD defines medical devices as

any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,*
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,*
- investigation, replacement or modification of the anatomy or of a physiological process,*
- control of conception,*

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

From this definition it is clear that the classification of a product as a medical device depends on the intended purpose assigned to it by its manufacturer. It is probably worth mentioning that the Global Medical Devices Nomenclature system covers DBAs by defining them as a "dental liquid solution or a paste used to whiten teeth for therapeutic or cosmetic purposes" (38785). On the basis of the above, some Notified Bodies (from different Member States [MS]) have agreed on the classification of DBAs as class IIa medical devices. This has allowed manufacturers to place these products on the market with a CE marking of conformity to the MDD. However, this classification has been challenged by some MS, resulting in conflicting Court Decisions in the UK and Germany. The issue was brought before the MDEG, which was asked to advise on whether "tooth bleaching products" (no definition given) have to be considered as medical devices. The MDEG provided its opinion pursuant to which *Tooth whitening products placed on the market for the principal purpose of lightening discoloured teeth, whether or not they contain peroxide and regardless of concentration cannot be considered as medical devices since they do not meet the definition of "medical device" contained in directive 93/42/EEC.*

The above opinion has been circulated among MS. This has led some MS to order the withdrawal of all tooth bleaching products (“TBP”) which contain hydrogen peroxide in excess of 0.1%, which is the maximum permitted concentration in oral hygiene products under the CD.

Intended purpose determines classification

- Pursuant to Article 1.5 (d) of the *MDD*, the MDD does not apply to cosmetic products covered by the *CD* (see also, fifth Recital of the *CD*). This means that the MDD and the CD are mutually exclusive and do not legally establish a preference between them. Consequently, if an *individual* product falls within the scope of the definition of a medical device in Article 1.2 MDD *owing to the specifics of its intended use*, it cannot *at the same time be* considered as a cosmetic product under the CD. An individual product may, however, be subject at one time to the CD, and at another time to the MDD, depending on the different specifics of its intended use.
- It is the “intended purpose” of a DBA (as defined by the manufacturer) that determines its classification as a medical device under the MDD or as a cosmetic product under the CD (see, definition of “intended purpose” in Article 1.2 (g) MDD; see also Article 3 MDD).
- The category of DBA is comprised of a wide range of indications and strengths which are intended for a variety of different uses including both medical and cosmetic purposes. Debate has often focussed erroneously on whether DBAs as an entire category fits the definition of “cosmetic product”. Eucomed believes that this misses the real point which is that it is the “intended purpose” of the product in question which dictates the legal classification. Each individual DBA must be examined on its own merits taking into account its specific intended use.
- If a DBA is indicated for the treatment of a severe intrinsic tooth discolouration, due to e.g. fluorosis or the result of the use of certain antibiotics, its intended purpose is medical (i.e. treatment of a disease) and it must be classified as a medical device. Conversely, if a DBA is indicated merely for improvement of appearance without regard to any underlying pathological, physiological or degenerative condition, it must be classified as a cosmetic product.
- Some MS courts (such as the Administrative Court of North Rhine-Westphalia and the Superior Administrative Court of North Rhine-Westphalia [Germany]) have correctly adopted this approach and have classified DBAs with an intended medical purpose as medical devices as defined by the MDD, to the exclusion of the CD. However, the criterion of “intended use” has not always been consistently applied by other MS’ Courts (such as the House of Lords in the UK). This has caused regulatory uncertainty.

Respecting the principles of free movement of goods and of mutual recognition

- Pursuant to Article 4.1 MDD:

Member States shall not create any obstacle to the placing on the market or the putting into service within their territory of devices bearing the CE marking provided for in Article 17 which indicate that they have been the subject of an assessment of their conformity in accordance with the provisions of Article 11.

The basic principle of free movement of goods within the EU and mutual recognition thus underpins the MDD.

In the framework of the conformity assessment under Article 11 MDD, the notified body examines whether the product fits the definition of medical device and whether the essential requirements of the MDD, which apply to the product, are met.

As stated above, several DBAs have been classified as medical devices by notified bodies in different MS, including Germany and France, taking into account the intended purpose of these products as defined by their respective manufacturers.

A way forward

Eucomed believes that there is a need to find ways to allow DBAs, to which the manufacturer has assigned a principal intended purpose that fits the definition of medical device, to fall within the scope of the MDD.

In the context of the MDD review, which is currently ongoing, and in order to contribute to a pragmatic solution for the issue at stake, which is going to be acceptable to all stakeholders, Eucomed suggests that art 1.5.d of the MDD 93/42/EEC is amended as follows:

Cosmetic products covered by Directive 76/768/EEC.

In deciding whether a product falls under that Directive or the present Directive, particular account shall be taken of the principal intended purpose of the product.