

CTPA Guide on Classification of Toothpaste Claims

Borderline issues between Cosmetics and Medicinal Products or medical devices Common Understanding

Objective of this Guidance

The objective of this guidance is to set a common understanding on the types of claims made for toothpastes, and what this means in terms of the regulations that will apply to individual products in light of those claims.

This guidance was created in collaboration with the Medicines and Healthcare products Regulatory Agency (MHRA).

Introduction

A toothpaste can potentially be classified as a cosmetic, a medicinal product or medical device depending on its composition, mode of action, and how the product is presented. The MHRA reaches a determination on whether a product is a medicinal product or a medical device on a case by case basis, and in the light of:

- the definition of a medicinal product;
- the definition of a medical device;
- an assessment of all the available evidence;
- relevant ECJ and domestic Court precedents.

The Cosmetics Regulation (EC) N° 1223/2009 allows the use of fluoride compounds in oral care products with a maximum concentration of 0.15% calculated as fluoride. Therefore, the determination of how a fluoride toothpaste within this limit will be regulated will be assessed principally on the overall product presentation. The MHRA will be mindful of the broader public health purpose of certain cosmetics, including toothpastes, when considering whether individual products fall within the definition of a medicinal product or a medical device. Given their public health role, it is important that there is provision of accurate and complete information to consumers on a toothpaste's benefits to ensure that they can choose a product appropriate for their specific needs.

Sections 4 and 12 of the '[MHRA Guidance Note 8 – A guide to what is a medicinal product](#)' give respectively the definition of a medicine and a cosmetic product. In addition to the definition, the guide stresses that the **context** is very important for assessment of borderline cases. The overall presentation of the product (pack design, claims, advertisements, etc.), as well as the understanding of the average consumer, should be considered on a case-by-case basis by the MHRA to establish the product classification. Jurisprudence and the Consumer Protection from Unfair Trading Regulations 2008 describes the average consumer as someone who is "*reasonably well-informed and reasonably observant and circumspect*". The relevance of this point arises when trying to ascertain what the average consumer might understand by a specific claim. The company can expect the consumer to be reasonably well-informed, observant and circumspect and can assume the consumer understands both the indicated benefits claimed by the product, assuming the language and meaning is reasonably clear, and the context in which it is presented, including the medium through which the presentation is made. Daily use products, such as toothpastes, are part of everyone's normal grooming routine and the MHRA recognises that they are not, intuitively, regarded as medicines by the consumer. However, a presumptive classification of toothpastes as cosmetics, which may facilitate

easy consumer access and affordability, innovation, and market entry does not apply where the purpose of the toothpaste goes beyond that envisaged by the definition of a cosmetic product.

Appendix 1 of the 'MHRA Guidance Note 8 – A guide to what is a medicinal product' lists a (non-exhaustive) list of words and phrases that could be associated with a medicinal product. However, the intended and implied meaning of such words and phrases has to be considered in context. As noted above, the MHRA considers the overall presentation of the product when coming to decisions about the regulation of a product as a medicinal product and this must be borne in mind when using specific statements or phrases. A few examples or words relevant to cosmetic toothpaste, which may be used in the context of keeping in good condition, but which may be medical claims if not used in this way, are 'fights', 'protects' and 'prevents'. It is important to stress that the use of such words should not determine the classification of a product, as their meaning must be taken into context of the particular claim and the overall presentation of the product. For example, claims such as 'fight against plaque formation', 'protect against tartar' or 'prevent bad breath' would generally not be regarded as medicinal claims. The use of the word 'problem(s)' would typically be regarded to be in the context of a medicinal claim and, while there are exceptions and wording such as 'bad breath problems' that may not be regarded to be a medical claim, MHRA's preference would be for the wording to be 'freshens breath' which is more in line with the cosmetic function.

Common Understanding on Toothpaste Claims

Cosmetics Definition

Article 2(1)(a) of the Cosmetics Regulation (EC) 1223/2009 as amended defines a **‘Cosmetic Product’** as: *“any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours;”*.

Section 12 of the ‘MHRA Guidance Note 8 – A guide to what is a medicinal product’, also stresses that the definition envisages that a cosmetic product may have a secondary preventative (but not curative) purpose. When deciding whether a product on the borderline between cosmetics and medicines is a medicinal product, the MHRA will apply the tests set out in Directive 2001/83/EC. If a product falls within the definition of a cosmetic and within the definition of a medicinal product, it will be classified as a medicinal product (Delattre 1991, C369/88). The regulatory status of products in other Member States will also be taken into account as well as ECJ court cases.

Therefore, a toothpaste that is marketed with the purpose of cleaning (e.g. helping remove and preventing plaque), perfuming (e.g. fresh breath), protecting (e.g. helps protects against tooth decay) and keeping teeth and the oral cavity in good conditions (e.g. maintain healthy teeth and gums) fulfils the cosmetics definition.

Medical claims

Article 1 of Directive 2001/83/EC as amended defines a **‘medicinal product’** as: *“Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; [the first/presentational limb] Any substance or combination of substances 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” [the second/functional limb]*

Medicinal products may well fall under both limbs of the definition, but the European Court of Justice (ECJ) has confirmed that falling under either limb is sufficient to classify a product as a medicinal product.

Under Directive 93/42/EEC on **medical devices**, medical device means *“any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and 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.”

A product which claims to treat or prevent a disease falls within the first limb of the definition of a medicinal product or medical device. Claims to relieve symptoms, or to cure, or to provide a remedy or heal a specific disease or adverse condition of body or mind will also be regarded as medicinal claims. The MHRA view is that claims to 'maintain' or 'help to maintain' or 'support' health or a healthy lifestyle can be approved under food law and thus would not normally regard such claims to be medicinal. Likewise, if such claims are clearly made in relation to healthy bodily functions. In general, the MHRA is only likely to consider 'health maintenance' claims as medicinal if they suggest or imply that a product may prevent a disease or, where targeted on a vulnerable section of the population, may restore, or help to restore, a specific bodily function or organ to a normal healthy state. For toothpastes, once a product is recognised as a medical product, either under Limb 1 of the definition of a medicinal product or in respect of the definition of a medical device, the mode of action may also be considered to decide whether a product should be regulated as a medical device or as a medicinal product. The MHRA, as the UK Competent Authority, will make a final decision on the classification of the product.

When looking at the intended purpose of a product, both individual statements and the overall perception of the product to the consumer should be considered.

Keeping teeth and gums in good condition by protecting them

Cosmetic toothpastes clean teeth and the oral cavity, freshen the breath and maintain a good oral hygiene as part of a daily oral care routine. They are generally formulated with cleaning agents and abrasive particles that mechanically remove plaque and surface-bound stains, with fluoride to protect against cavities, and may contain anti-microbial agents that are effective against plaque bacteria. The addition of fluoride to toothpastes is an effective means of ensuring the tooth enamel retains adequate minerals to resist acid erosion and decay. By removing plaque, toothpaste reduces the likelihood of developing teeth and gum problems, and ultimately cavities and gum disease, therefore keeping teeth and gums in good condition. **It is therefore important to recognise that whilst toothpastes are most often classified and regulated as cosmetics, by virtue of keeping tooth and gums and tooth in good condition, they have a clear role in helping prevent tooth decay, acid erosion and gum disease in the general population.** Claims made in the context of helping to protect teeth from cavities and gums from gum disease by keeping teeth and gums in good condition are in line with the cosmetics definition and acceptable for a cosmetic toothpaste. Such claims are important to ensure consumer awareness of the protection benefits of keeping teeth and gums healthy by using fluoride toothpastes, and the importance to use such products daily as a part of an effective oral care regime.

Tooth decay, tooth wear and gum disease

Tooth decay (or cavities), tooth wear and gum disease are considered adverse conditions, therefore products intended to 'repair' teeth / gums / enamel damaged by an adverse condition, or 'fight' against cavities already formed, will be considered medicines or medical devices depending on their mode of action.

By reducing the amount of plaque on teeth and by promoting the re-mineralisation process and making enamel harder, toothpastes protect teeth against certain conditions that can arise if an oral care routine is not followed (e.g. plaque and tartar development, tooth decay, cavity formation, tooth wear, teeth and gums problems), as described below.

Tooth decay and tooth wear

When it comes to tooth decay prevention, the rationale for claim classification are made by the MHRA in line with the established framework for the classification of borderline products. Oral care products in general, and toothpastes in particular, pose a challenge to classification, because daily hygienic practices using appropriate oral care products are crucial for maintaining good oral health. Moreover, the overwhelming majority of toothpastes are formulated with fluoride which plays a key role in the health of teeth and it is classified as anti-caries and oral care agent. As noted above, the Cosmetics Regulation allows a maximum concentration of 0.15% calculated as fluoride.

Cavities form when plaque acids cause progressively more serious conditions in the tooth. The initial stage is reversible partial demineralisation of enamel surfaces occurs in still-healthy enamel (see section B below). This can progress to the next stage of caries (characterised by subsurface demineralisation), which if left unchecked can lead to an irreversible stage of collapse of the enamel surface with formation of a cavity.

While such stages may not be regarded to be adverse medical conditions by dental practitioners, the averagely well-informed consumer would not, necessarily, be able to differentiate and it is incumbent on the manufacturer to ensure that this is made clear.

It is important to stress that fluoridated toothpastes promote the natural remineralisation process: the new enamel that is formed is harder and more resistant to acids produced by plaque bacteria that demineralise tooth enamel. This is because fluoride replaces some of the hydroxyl groups in the hydroxyapatite crystals forming enamel; the presence of fluoride ions instead of hydroxyl ones tightens up the crystals structure, making it more stable and resistant to the acidic dissolution caused by plaque bacteria. In this way, fluoride toothpaste slows down the daily enamel erosion, strengthening teeth and therefore helping to protect teeth from cavities and keep teeth in good conditions. Similar protective effects are acceptable for other types of cosmetics, such as sun protection products which help protect against sunburn.

Gum problems

Gingivitis is a reversible condition in which bacteria in plaque on teeth, in particular around the gumline, cause an inflammatory response in the gums characterised by reddening, swelling and occasional bleeding of the gums. Before the full onset of gingivitis there exists an early stage of still healthy gingiva, in which there is no clinical evidence of gingivitis and yet the state of the gums is less than pristine. The fact that this early stage gum 'problem' is widely considered as a state of gingival health is supported by recently published definitions of gum health by the consensus report of Chapple et al and by Trombelli et al. as well as gum health classification from FDI (World Dental Federation). While dental practitioners may regard gums as healthy even in the early stages of gingivitis, the averagely well-informed consumer would not, necessarily, be able to differentiate between completely healthy gums and early gingivitis and it is thus incumbent on the toothpaste manufacturer to ensure that this is made clear.

By reducing the amount of plaque and tartar on teeth and by promoting the re-mineralisation process and making enamel harder, toothpastes protect teeth against certain conditions that can arise if an oral care routine is not followed (e.g. plaque and tartar development, tooth decay, cavity formation, teeth and gums problems). Anti-bacterial agents, which assist in combating bacteria which produce plaque, are also commonly used and also perform a cosmetic function.

Repairing daily damage

The Natural Cycle of Enamel Remineralisation and Demineralisation

There is a natural cycle of dissolution and re-mineralisation of tooth surfaces that happens every day, and it can over time progress to the point that teeth are damaged. It is only when the dissolution process outstrips the repair process over an extended period that cavities or tooth wear occur.

Tooth wear occurs when dietary acids cause progressively more serious conditions in the tooth. The initial stage is reversible partial demineralisation of enamel surfaces occurs, leading to the next stage of surface softening of still-healthy enamel (Lussi et al. 2011). At no time in this situation is the enamel 'unhealthy' or 'diseased': it is merely undergoing normal remineralisation-demineralisation cycles. While such wear and tear may not be regarded to be adverse conditions by dental practitioners, the averagely well-informed consumer would not, necessarily, be able to differentiate between the normal cycle and cavities caused by an advanced disease state; it is thus incumbent on the toothpaste manufacturer to ensure that this is made clear.

Repairing enamel

A fluoridated toothpaste is understood to facilitate maintenance of this status quo: fluoride is remarkable in that, in the presence of saliva, it both promotes remineralisation and inhibits demineralisation of enamel. Fluoride toothpaste can therefore repair the damage caused by the natural cycle, by promoting the remineralisation process and fill in the gaps on tooth enamel. The new enamel that forms is harder and more resistant to acids produced by plaque bacteria, making teeth more stable and resistant to the acidic dissolution caused by plaque bacteria or dietary acid. This action contributes to keeping teeth healthy and in good conditions, in line with the cosmetics definition and therefore, in this context appropriate claims can be made. Use of claims such as 'repair enamel' and 're-mineralise' may imply a medical function when they claim to reverse a disease state and if they are being used in the context described above, it must be sufficiently clear to the averagely well-informed consumer that this is in the context of a cosmetic and not a medical purpose and it is incumbent on the manufacturer to ensure that this is made clear.

The Natural Action of Plaque Bacteria and Effect of Antibacterial agents

The actions of plaque bacteria that cause gingivitis, first create an early stage where the gingiva is still healthy, yet the state of the gums is less than pristine. This stage is fully reversible. Anti-bacterial agents, which assist in combating bacteria which produce plaque are commonly used to reduce the action of plaque bacteria that cause gingivitis, thereby also performing a cosmetic function.

While such stages may not be regarded to be adverse conditions by dental practitioners, the averagely well-informed consumer would not, necessarily, be able to differentiate them and it is incumbent on the manufacturer to ensure that this is made clear.

Sensitivity and pain

A reference to treating or preventing pain will be considered a medical claim. Please refer to section 10 of the 'MHRA Guidance Note 8 – A guide to what is a medicinal product' for more details on claims about sensitive teeth. References to 'sensitive formula' or '(also) suitable for sensitive teeth' are acceptable for cosmetics. Chemical compounds can be incorporated into toothpaste formulations which reduce sensitivity, these are well established, documented and beneficial to public health.

Educational statements

The oral care category of the cosmetic industry has the possibility to promote oral hygiene by educating consumers on a daily oral care routine and its benefits. It is important for consumers to understand how to maintain healthy teeth and gum by brushing their teeth with a fluoride toothpaste twice daily. Educational statements appearing on pack or any other materials should not imply a medicinal claim, and could include general information on the benefits associated to the regular brushing and use of fluoridated toothpaste in the long term for the purpose of promoting good oral hygiene.

For internet sale and information available on website, please consult Appendix 8 of MHRA Guidance Note 8.