http://dx.doi.org/10.5272/jimab.2015211.709

Journal of IMAB
ISSN: 1312-773X
http://www.journal-imab-bg.org

OPEN ACCESS

Journal of IMAB - *Annual Proceeding (Scientific Papers)* 2015, vol. 21, issue 1

BORDERLINE AND CLASSIFICATION IN THE COMMUNITY REGULATORY FRAMEWORK FOR MEDICAL DEVICES – BRIEF REVIEW ON SOME DENTISTRY PRODUCTS

Maya Lyapina[1], Mariela Yaneva -Deliverska[2], Jordan Deliversky[3], Angelina Kisselova[4]

1) Department of Hygiene, Medical Ecology and Nutrition, Medical University, Medical Faculty, Sofia, Bulgaria
2) Legal Department, Military Medical Academy, Sofia, Bulgaria
3) Department of National Security, State University of Library Studies and Information Technologies, Sofia, Bulgaria
4) Department of Oral and Image Diagnostic, Faculty of Dental Medicine, Medical University - Sofia, Bulgaria

ABSTRACT

Defining a given product as a medical device and interpretation of the application of the classification rules fall within the competence of the competent authorities of the Member States where the product is on the market. Different interpretations of Community legislation occur, and, can put public health at risk and distort the internal market. Borderline cases are considered to be those cases where it is not clear from the outset whether a given product is a medical device, an in vitro diagnostic medical device, an active implantable medical device or not. Classification cases can be described as those cases where there exists a difficulty in the uniform application of the classification rules as laid down in the Medical Devices Directive (MDD), or where for a given device, depending on interpretation of the rules, different classifications can occur. The aim of the present work is to make a brief review on discussion on classification in the community regulatory framework for medical devices of some dentistry products.

Key words: medical devices, borderline cases, classification cases, EU, dentistry products

Defining a given product as a medical device and interpretation of the application of the classification rules fall within the competence of the competent authorities of the Member States where the product is on the market. Different interpretations of Community legislation occur, and, can put public health at risk and distort the internal market. The Commission found it important to facilitate a dialogue among regulators and industry where diverse interpretations exist.

The **definitions** of medical device and medicinal product, are:

• Medical device definition (Article 1(2) of Directive 93/42/EEC, as amended) [1, 2]:

(a) 'medical device' means 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

• Medicinal product definition (Article 1(2) of Directive 2001/83/EC, as amended) [3]:

(a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or

(b) 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 24 by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

• Cosmetic product definition (**Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products)** [4]:

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.

• Biocidal product means definition (REGULATION (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products) [5]:

- any substance or mixture, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, with the intention of destroy-

ing, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action,

— any substance or mixture, generated from substances or mixtures which do not themselves fall under the first indent, to be used with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action.

Borderline cases are considered to be those cases where it is not clear from the outset whether a given product is a medical device, an in vitro diagnostic medical device, an active implantable medical device or not.

Or alternatively, borderline cases are those cases where the product falls within the definition of a medical device but is excluded from the Directives by their scope. Where a given product does not fall within the definition of medical device or is excluded by the scope of the Directives, other Community and/or national legislation may be applicable [5].

Classification cases can be described as those cases where there exists a difficulty in the uniform application of the classification rules as laid down in the Medical Devices Directive (MDD), or where for a given device, depending on interpretation of the rules, different classifications can occur.

There may be cases where 'claims' of a medical nature are made for certain products, where those claims cannot be substantiated by technical, clinical and scientific data.

If there is insufficient clinical, technical and scientific data to support the claims made, the product would not meet the requirements of the medical device directives and therefore may not be CE marked as a medical device. For such products no medical claim can be made [6].

The **aim** of the present work is to make a brief review on discussion on classification in the community regulatory framework for medical devices of some dentistry products.

- Dental disclosing products are intended to 'disclose' plaque, *i.e.* to highlight the areas around the teeth where the plaque is in order to aid its removal. There may be claims to 'aid oral hygiene', to 'aid correct brushing regimes' or simply to identify the plaque for its removal. Dental disclosing products may be in the form of solutions, tablets or an applicator containing the solution and may be intended for use by dentists or by individuals at home.

The question is to whether these products should be qualified as medical devices, or whether they are simply intended for oral hygiene and therefore shall not be considered as medical devices. Although in severe cases, in addition with other contributory factors, plaque may lead to dental decay or gum disease, plaque is not considered to be a disease in its own right. Therefore dental disclosing products, intended to disclose plaque in order to help its removal, cannot be qualified as medical devices.

Tooth whitening or bleaching products are borderline medical device –cosmetic products. Dental cosmetic products are intended to clean the teeth and/or to bleach discolored teeth in order to remove the plaque and other residues and/or remove discoloration of the teeth. There may be various claims, such as prevention of odour from the oral cavity or even of some kind of dental caries. Dental cosmetic products may be in the form of solutions, pastes or other forms and are typically intended for use by individuals at home, but also for use in a professional medical environment e.g. by dentists. The question is to whether tooth whitening products may be qualified as medical devices, or whether they are simply intended for aesthetic purposes / toiletry purpose and therefore **cannot be considered as medical devices**.

In some cases, in addition to other contributory factors, discoloration of teeth may be caused by a disease. Nevertheless discoloration of teeth is not considered to be a disease in itself. Besides, application of tooth-whitening products is not intended to treat the underlying disease; it only may mask a sign of an underlying disease. In the definition medical device is clearly established a link between prevention or treatment and disease. Describing the colour of the teeth after treatment does not give an indication about the effectiveness to treat an underlying disease or to prevent a disease. Therefore tooth-whitening products, intended to bleach the teeth, **cannot be qualified as medical devices**.

It should be mentioned that, according to the definition of a cosmetic product as laid down in EU Regulation 1223/2009 [7], tooth whitening or bleaching products belong to the category of cosmetic products. This has been confirmed by the amendment which sets, for these products, maximum concentrations of hydrogen peroxide, present or released, use instructions and labelling warnings.

The dental curing lights are intended for curing of dental filling substances in situ. A number of dental filling materials need for hardening (a kind of polymerization) after application to the tooth to be treated with light. During this application of light, the energy transmitted with this light is absorbed by the filling material as well by the surrounding parts of the body (surface of the tooth, other neighbored fillings and crowns, internal part of the tooth surrounding the filling which is warming up, gum if the filling is close to the gum). It is not possible to avoid the surroundings of the filling to be treated together with the filling; this is an undesired but unavoidable and accepted side effect. Because of the considerable changes in the design of the lights, it is questioned **whether a reclassification would be needed**.

It is confirmed that **no reclassification is needed** and that these products shall be considered as Class I medical devices.

Antimicrobial Photodynamic Therapy (APDT) systems. Photodynamic laser-based disinfection systems, activated by a topical photosensitizer, are intended for the decolonization of potentially-pathogenic bacteria, including methicillinresistant S. aureus (MRSA), from the oral cavity or anterior nasal passages. The topically applied photosensitizer, such as methylene blue or toluidine blue, stains bacteria by binding with microbial cell wall components. Light, at a specifically defined wavelength, is absorbed by the topically applied photosensitiser molecules in the presence of oxygen. This causes the photosensitizer molecules to undergo excitation and electronic state transitions, converting the sensitizer to its photoactive triple state. The excited photosensitizer immediately transfers energy to surrounding mo-

lecular oxygen, thereby producing reactive oxygen species (ROS) which are responsible for lethally disrupting the microbial cell wall. These ROS products are very short-lived, and the ROS-production process ceases immediately upon deactivation of the laser.

Photosensitiser solutions used in APDT systems, such as those containing methylene blue or toluidine blue, for disinfection for a medical purpose do not qualify as medical devices. This decision is based on the following:

- their primary action is not physical,
- their activation to provide an anti-bacterial function is not achieved via physical means,
- their composition, Lasers used in APDT systems for disinfection for a medical purpose do qualify as medical devices. Such lasers are classified as active therapeutic devices under Rule 9 and are Class IIa, unless energy is transferred in a hazardous manner, in which case they are Class IIb. The laser (i.e. laser generator) and photosensitiser system, when used for a medical purpose, is not considered to be an integral product at the time of use and, therefore, **cannot qualify as a Class III medical device**.

Dental abutments. Three parts make up an "artificial" tooth: the crown or cap, the dental abutment, and the implant. This entry refers to final dental abutments which are usually called dental implant abutments or prosthetic abutments for dental implant and does not cover healing abutments which are placed during a variable time before a final abutment. Dental abutments are connecting elements between the dental implant and the crown. The implant is inserted directly into the bone of the jaw. The abutment is fixed to the implant and is in contact with the gum, in the surgical cavity. In the final stage of getting the dental implant, the crown is built above the gum around the other part of the abutment. The question arises as to whether dental abutments should be classified as Class IIa or Iib medical devices.

Rule 8, first hyphen, of Annex IX to Directive 93/42/EEC states that examples of medical devices to be placed in the teeth such as bridges and crowns, dental filling materials and pins and dental alloys ceramics and polymers are to be classified as Class IIa medical devices. Since they are directly placed in the gum, dental abutments should be considered as implantable devices, as well as dental implants. According to rule 8 of Annex IX to Directive 93/42/EEC**, dental abutments should be classified as Class IIb medical devices** [8].

Dentistry products with aluminum chloride are used in haemostasia and are discussed as borderline **medical device – medicinal product**. These products contain aluminum chloride in various concentrations. Liquids and gels contain from 20% to 25% aluminum chloride, while impregnated retraction cords contain from 5% to 10%

The products formulated as liquid and gel are intended to staunching perigingival bleeding that results from decay cavities preparation. The aluminum chloride provides a local astringent effect. The action of these products is based on precipitation of albumins which in turn block the vessels (capillaries). These products are used on the mucous membranes or injured skin creating a protective layer and contracting gums. It is claimed that bleeding stops after several minutes enabling single day treatment without need for temporary dressing. The impregnated retraction cord is used for retraction of the gingival tissues around the teeth for improving the results of dental impressions and haemostasis of the gingival margin. The aluminum chloride reduces the liquid in gingival pocket and closes the smal blood vessels. The effective retraction when the cord is correctly placed would take few minutes. Some product types additionally contain lidocainum.

As that the mode of action of aluminum chloride is other than pharmacological, immunological or metabolic, these **products should be qualified as medical devices**.

E**xamination gloves coated with polyhexamethylene biguanide (PHMB)** which is a broad spectrum bactericide. This substance is also used as an ingredient in various products (contact lens solutions and surgical scrubs and swimming pools). The intended use is to reduce bacterial transfer between the healthcare professional and the patient. The gloves would be single use.

Examination gloves are usually considered to be Class I medical devices, however • Issues guidance documents (MEDDEV 2.1/3) [9] in section A.5 states that 'wound dressings, surgical or barrier drapes (including tulle dressings) with antimicrobial agent' are considered to be devices incorporating medicinal substances and therefore Class III devices. Antimicrobial agents on surgical or barrier drapes intended to come in to contact with the patient have no 'ancillary' effect on the patient and neither would an antimicrobial coating on an examination glove, however the MEDDEV implies that these examination gloves with a PHMB coating should be considered as Class III medical devices. Medical devices may incorporate substances as an integral part which, if used separately, may be considered to be a medicinal product. This is specifically addressed in article 1(4) MDD which makes it clear that such products are devices, provided that the action of the medicinal substance is ancillary to that of the device, as reflected in the product claim and as supported by the scientific data provided by the manufacturer of the devices. Rule 13 places these devices in Class III.

In essence two issues need to be considered: a) is the substance (PHMB), if used separately a medicinal product; b) is the substance liable to act on the human body with action ancillary to that of the devices?

a) Taking into account the published literature, it can be concluded that the PHMB is a substance which could be administered topically to human beings in view to restore or modify physiological functions by mainly means of pharmacological action (e.g. treatment of Acanthamoeba keratitis). As such it could be regarded as a medicinal product in accordance with Article 1(2) of Directive 2001/83/EC as amended [3].

b) The risk that the PHMB acts on the patient highly depends on the intended use of these gloves. For example, an examination of a wound or a mucous membrane will lead to a considerably increased risk of action of PHMB on the patient. On the basis of the above and taking into account the Rule 13, the classification of these gloves **as Class III would appear the most appropriate**.

Multipurpose disinfectants. Disinfectants cover a wide area of uses and, while some are specifically intended

for the disinfection of medical devices, others are of a multipurpose use covering the disinfection of various surfaces including floors, walls, sanitary facilities and sometimes also medical devices.

While usually disinfectant products are regulated within the biocides legal framework, those that are specifically intended for disinfecting medical devices fall within the scope of the MDD.

"Products with a multiple purpose which may be used occasionally in a medical environment are normally not medical devices" (MEDDEV 2. 1/1 paragraph 1.1) [10].

" Examples of accessories of medical devices

- Disinfectants specifically intended for use with medical devices (e.g. endoscopes),

Note: Multipurpose disinfectants or sterilisation agents are not covered by MDD; they are covered by the directive on biocides." (MEDDEV 2. 1/3 rev 3, paragraph A.2.1.4) [9].

General disinfectants fall under the Directive 98/8/EC on the placing of Biocidal products on the market [11]. This directive was repealed and replaced by the Regulation (EU) No 528/2012 applicable 1 September 2013 [5].

Dental Water Line Disinfectants are covered by the definition of accessories to **medical devices** in Article 1 (2) b of Directive 93/42/EEC. These products should be classified according to Rule 15 of Annex IX of Directive 93/42/EEC that has been further developed in MEDDEV 2.4/1, according to which this rule covers substances used principally in a medical environment to **disinfect medical devices** [12].

Hand disinfectants do not appear to be qualified as an accessory to a medical device. These products are for disinfecting the hands and not devices. Such products are likely to be covered by other legislation, for example the Biocides Directive.

REFERENCES:

1. Council Directive 93/42/ EEC of 14 June 1993 concerning medical devices. Official Journal of the European Communities. L 169, vol. 36:1–43 (12 July 1993).
2. Revision of the medical device directives, 2013, Retrieved 15 June 2014, http://ec.europa.eu/health/medical-devices/documents/revision/index_en.htm
3. Directive 2001/83/EC, Regulation (EC) No 726/2004. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:136:0001:0033:en:PDF
4. Cosmetics Regulation (EC) No 1223/2009, 2013, http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32009R1223
5. Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products L167, vol. 55. (27 Jun 2012)
6. Manual on borderline and classification in the Community regulatory framework for Medical devices, version 1.16 (07-2014). http://ec.europa.eu/health/medical-devices/files/wg_minutes_member_lists/borderline_manual_ol_en.pdf
7. Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (Text with EEA relevance). Official Journal of the European Union. L 342/59 (22 Dec 2009).
8. Council of the European Communities: Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. Official Journal of the European Communities L 169, 1–43 (1993); Directive 2001/83/EC, Regulation (EC) No 726/2004 - http://ec.europa.eu/health/human-use/legal-framework/index_en.htm
9. MEDDEV 2. 1/3 rev 3. MEDICAL DEVICES: Guidance document - Borderline products, drug-delivery products and medical devices incorporating, as an integral part, an ancillary medicinal substance or an ancillary human blood derivative. http://ec.europa.eu/health/medical-devices/files/meddev/2_1_3_rev_3-12_2009_en.pdf
10. MEDDEV 2. 1/1. MEDICAL DEVICES: Guidance document. http://ec.europa.eu/health/medical-devices/files/meddev/2_1-1___04-1994_en.pdf
11. Directive 98/8/EC concerning the placing of biocidal products on the market. Official Journal of the European Union. L 247, vol. 50 (21 Sep 2007)
12. http://ec.europa.eu/health/medical-devices/files/meddev/2_2_4-1part1_07-2001_en.pdf

Please cite this article as: Lyapina M, Yaneva-Deliverska M, Deliversky J, Kisselova A. BORDERLINE AND CLASSIFICATION IN THE COMMUNITY REGULATORY FRAMEWORK FOR MEDICAL DEVICES – BRIEF REVIEW ON SOME DENTISTRY PRODUCTS. *J of IMAB.* 2015 Jan-Mar;21(1):709-712.
DOI: http://dx.doi.org/10.5272/jimab.2015211.709

Received: 05/12/2014; Published online: 13/02/2015

Address for correspondence:
Dr Maya Lyapina,
Department of Hygiene, medical ecology and nutrition, Medical Faculty, Medical University, Sofia,
15, Acad. Ivan Geshov blvd., 1431 Sofia, Bulgaria
Mob.: +359/887 161 768
e-mail: saly_grigory@abv.bg