MANUAL ON BORDERLINE AND CLASSIFICATION IN THE COMMUNITY REGULATORY FRAMEWORK FOR MEDICAL DEVICES

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PLEASE NOTE: THE VIEWS EXPRESSED IN THIS MANUAL ARE NOT LEGALLY BINDING; ONLY THE EUROPEAN COURT OF JUSTICE ("COURT") CAN GIVE AN AUTHORITATIVE INTERPRETATION OF COMMUNITY LAW.

MOREOVER, THIS MANUAL SHALL ONLY SERVE AS "TOOL" FOR THE CASE-BY-CASE APPLICATION OF COMMUNITY-LEGISLATION BY THE MEMBER-STATES. IT IS FOR THE NATIONAL COMPETENT AUTHORITIES AND NATIONAL COURTS TO ASSESS ON A CASE-BY-CASE BASIS.

THE CONTENT OF THIS MANUAL AND ALL UPDATES ARE PRESENTED TO THE WORKING GROUP ON BORDERLINE AND CLASSIFICATION FOR CONSULTATION. THIS GROUP IS CHAIRED BY THE COMMISSION AND IS COMPOSED OF REPRESENTATIVES OF ALL MEMBER STATES OF EU, EFTA AND OTHER STAKEHOLDERS

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INTRODUCTION

1. **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.**

2. **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 MDD (or where for a given device, depending on interpretation of the rules, different classifications can occur).**

3. **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.**

4. **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.**

5. **Different interpretations of Community legislation occur, and, can put public health at risk and distort the internal market. Both issues are of great concern to Member States and the Commission. Therefore, the Commission finds it important to facilitate a dialogue among regulators and industry where diverse interpretations exist.**

6. **To this end, the working party on borderline and classification comprised of Commission services, experts of Member States and other stakeholders meet on a regular basis to discuss borderline and classification cases in order to ensure a uniform approach. The borderline and classification meeting's primary aim is to provide for a forum to exchange opinions, and, possibly reach consensus.**

7. **This manual represents the views agreed by the regulators in this group, after a broad consultation with stakeholders, on products, or categories of products, which have raised doubts. The Commission, Member States and other stakeholders concluded that guidance is needed which goes beyond abstract rules and addresses their actual application.**

8. **However, please note that the views expressed in this manual are not legally binding, since only the European Court of Justice ("the Court") can give an authoritative interpretation of Community law.**

9. **This manual does not relieve national competent authorities from their obligation to render decisions in these areas for any individual product, on a case-by-case basis. National authorities, acting under the supervision of the courts, must proceed on a case-by-case basis, taking account of all the characteristics of the product.**

10. **Therefore, this manual shall not "prescribe" which regulatory framework applies or how the classification rules must be applied by national authorities. Rather, it shall serve as one out of many elements supporting the national competent authorities in their case-by-case decision on individual products.**

11. **In particular, this manual does not prevent a national authority from consulting with colleagues from other regulated sectors concerned in order to reach a complete view on all aspects related to a given product.**

12. **This manual will be updated in the light of the outcomes of the discussions of the working party on borderline and classification issues.**

1. MEDICAL DEVICE/IN VITRO DIAGNOSTIC MEDICAL DEVICE – MEDICAL INTENDED PURPOSE

Introduction

According to article 1 (2)a MDD "'*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;"

According to article 1 (2)b IVDD *"'in vitro diagnostic medical device' means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment, or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information:*
— concerning a physiological or pathological state, or
— concerning a congenital abnormality, or
— to determine the safety and compatibility with potential recipients,
or
— to monitor therapeutic measures."

From this definition it follows that in order to fall within the definition of an in vitro diagnostic medical device, the product must also meet the definition of a medical device.

It is suggested to consult MEDDEV 2.1/1 for more detailed guidance on the interpretation of the definition of "medical device" and MEDDEV 2.14/1 for more detailed guidance on the interpretation of the definition of "in vitro diagnostic medical device".

1.1. Light box indicated to treat seasonal affective disorder (S.A.D)

- Background

The product in question is a light box that emits bright light and the manufacturer states that light therapy is 'a convenient and effective way of compensating for the lack of light without resorting to medication'. The manufacturer also states: 'in autumn and winter, the seasons with the least sunlight because the days are shorter, increased symptoms resulting from light depravation may be experienced. Even standard artificial lighting in buildings cannot compensate for a shortage of natural light. The consequences of this may be depression, lack of drive, interrupted sleep and melancholia – the typical autumn winter blues'.

- Outcome

These statements are effectively claims for treatment of seasonal affective disorder (S.A.D.), which is a generally recognised medical condition, and therefore this product is considered a medical device.

For the classification of this product see paragraph 8.1.

1.2. AB0 and Rhesus (D) blood grouping intended for diet purposes

- Background

These products are tests for AB0 and Rhesus (D) Blood Grouping, which is sold through the internet and which is used by lay persons in the home environment.

The manufacturer states the following: HOME-KIT, For in Vitro Diagnostic Use, Not for Bed-Side Testing; and currently in the text, which describes interpretation of the result, the manufacturer states NOT FOR CLINICAL USE. The manufacturer has stated that the main reason and purpose of the tests is educational. It is indicated that the product enables the user to ascertain their blood group in order to determine whether a specific (food) diet should be followed. This decision was *not* related to following a specific diet for medical purposes.

- Outcome

According to the information given by the manufacturer, it is concluded that even though it can be argued that this product fits some parts of the definition of an in vitro diagnostic medical device, it does not meet the definition of a medical device. As the definition on in vitro diagnostic medical device (Article 1 (2) b IVDD) reads "*'in vitro diagnostic medical device' means any medical device*, the product must also meet the definition of medical device.

It can be concluded that as the intended purpose of this product cannot be qualified as a medical purpose as described in definition of a medical device (Article 1 (2) a MDD), this product is not an in vitro diagnostic medical device. The product in question is not a blood typing test for a medical purpose.

This conclusion is reached in the light of the information provided by the manufacturer. It would be necessary to check if these statements are correct, and, consequently do not contain a deceptive and misleading labelling. Therefore, no reference to in vitro diagnostic medical device (e.g. 'for in vitro diagnostic use') can be made. Also, as the product is intended to be used by lay persons, there is a need for a strong and clear disclaimer which is understandable for lay users; i.e. a statement that the test results cannot be used for transfusion purposes or for blood group determination for medical purposes. It has to be noted that only a statement that the product is not a medical device can not constitute a reason to escape from the Directive and to avoid the CE marking if the criteria of the definition of a medical device are satisfied.

1.3. Pharmacy compounders

- Background

Pharmacy compounders may be used in a hospital pharmacy or in an industrial environment. They are products that are intended for the production of fluids for administration to a patient, usually as intravenous fluids (IV fluids) for administration parentally. They are intended to be used by clinical nutritionist specialists and pharmacists. They mix a number of ingredients that are subsequently administered to the patient. These fluids may be nutritional solutions or pharmaceuticals. They may also be used for compounding formulas for cardioplegia, hydration, fluid drugs and renal replacement therapy.

The issue is whether pharmacy compounders are medical devices, particularly if the compounder is specifically intended to be used by clinical nutritionist specialists and pharmacists to correctly prescribe nutritional solutions for Total Parenteral Nutrition.

- Outcome

Pharmacy compounders are regarded as processing equipment and should not be qualified as medical devices. The compounder is only used for mixing the solution to be administered to patients, but it does not administer itself anything to a patient. It should therefore not be qualified as a medical device.

1.4. Dental disclosing products

- Background

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.

- Outcome

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.

1.5. Mixer

- Background

The product is a Thermomixer (mixer) intended to control the temperature of (and mix) liquids in closed micro test tubes and micro test plates. The manufacturer claims that this mixer is specifically intended for the preparation and processing of samples from the human body within the scope of *in-vitro* diagnostic applications, in order to allow the *in-vitro* diagnostic medical device to be used as intended. Therefore the manufacturer considers this Thermomixer, being an *in-vitro* diagnostic accessory, to fall within the scope of Directive 98/79/EC.

- Outcome

MEDDEV 2.14/1 rev.1, states that "*if, however, the product does not in fact possess specific characteristics that make it suitable for one or more* ***identified*** *in vitro diagnostic examination procedures, then the manufacturer is not free to bring it within the scope of the IVDD merely by affixing the CE marking to it. In other words, a manufacturer is not able to bring within the scope of the IVDD a product that, in reality, is a piece of general laboratory equipment simply by affixing the CE mark to it".*

For example, the point 4 of MEDDEV 2.14/rev.1 mentions that laboratory centrifuges are not usually considered to fall within the scope of the IVD directive.

According MEDDEV 2.14/1 rev.1, the fact that this mixer is intended by the manufacturer to be used especially for *in vitro* diagnostic procedures is not sufficient to qualify it as an IVD medical device, if this mixer does not possess specific characteristics that make it suitable for one or more identified *in vitro* examination procedures.

If this mixer possesses such specific characteristics, the manufacturer will have to demonstrate these specific characteristics and the link with one or more identified *in vitro* examination procedures.

This case is similar to the cases of pipettes or glass slides, considered as products for general laboratory use, already published in the manual.

On the basis of the above this mixer could not be considered as an *in vitro* diagnostic medical device.

1.6. Non-corrective contact lenses with a medical purpose

- Background

In general, non-corrective contact lenses (commonly known as ‘plano’ lenses) are not considered to be medical devices as they have no corrective function.

Some non-corrective contact lenses, coloured or not, however may have a medical purpose. They serve to treat a number of congenital or traumatic conditions. They are often used in clinical practice or post-surgical setting as a medical prosthesis.

Examples of non-corrective contact lenses with medical purpose are:

- UV blocking contact lenses that help protect against transmission of harmful UV radiation to the cornea and into the eye so as to alleviate photophobia as seen in albinism.

- Contact lenses for therapeutic use as a bandage lens for the following acute and chronic ocular conditions:

    - For corneal protection in lid and corneal abnormalities such as entropion, trichiasis, tarsal scars and recurrent corneal erosion. In addition they are indicated for protection where sutures or ocular structure malformation, degeneration or paralysis may result in the need to protect the cornea from exposure or repeated irritation;

    - For corneal pain relief in conditions such as bullous keratopathy, epithelial erosion and abrasion, filamentary keratitis, and postkeratoplasty,

    - For use as a barrier during the healing process of epithelial defects such as chronic epithelial defects, corneal ulcer, neurotrophic and neuroparalytic keratitis, and chemical burns;

    - For post-surgical conditions where bandage lens use is indicated such as post refractive surgery, lamellar grafts, corneal flaps, and additional ocular surgical conditions;

    - For structural stability and protection in piggy back lens fitting where the cornea and associated surfaces are too irregular to allow for corneal rigid gas permeable (RGP) lenses to be fitted. In addition the use of the lens can prevent irritation and abrasions in conditions where there are elevation differences in the host/graph junction or scar tissue.

- Outcome

All of the above are recognised medical conditions and therefore non-corrective lenses, coloured or not, which have the above mentioned functions are considered to be medical devices on the basis that they prevent, monitor, treat or alleviate disease.

Manufacturers of such products must, however, clearly indicate the specific intended medical purposes for these non-corrective contact lenses both on the packaging / labelling and in the instructions for use. Non corrective contact lenses without specific claims (such as those listed above) would be regarded as having no medical purpose and therefore not medical devices.

1.7. Biofunctional clothes

- Background

Bio functional clothes or "therapeutic clothes" consist of clothes (e.g. socks, leggings, pyjamas, undershirts…) impregnated with silver and brown algae extract. These clothes are presented as having anti-bacterial, anti-microbial, breathable, thermal regulating and anti-odour properties. According to the manufacturer, the silver ions (positively charged) integrated into the fiber

reduce the microbial growth in the fabric and inhibit microbial growth on the skin, and the brown algae extract protects against rash act by neutralization of neuromediators and vasodilator agents responsible for flushing. The intended use of these clothes is to prevent inflammatory crisis of atopic dermatitis.

The main mode of action described by the manufacturer is the creation of a physical barrier that prevents the contact of sensitive skin with the outside and other tissues potentially sensitizing, creating an environment helping to the attenuation of skin conditions. The actions of silver and algae extract were presented as an ancillary action. The product was presented as a Class I medical device.

- Outcome

The clothing in itself cannot be considered as a medical device unless it achieves a specific medical purpose. Silver is a medicinal substance, presented as having anti-microbial properties. The combination of clothes with a medicinal substance might not be qualified as a medical device.

In addition, the intended use described by the manufacturer, prevention of inflammatory crisis of atopic dermatitis, is likely to be achieved by pharmacological or immunologic means and linked to the presence of silver and algae extract. Therefore the clothes would not be considered as a medical device, based on the determination of the principal mode of action.

In case the clothes would have in themselves a medical purpose and the principal mode of action would not be achieved by metabolic, pharmacologic or immunologic means, the product might be seen as a medical device. However in that case, the medical device would fall in Class III under rule 13, due to the combination with a medicinal substance.

1.8. System for the determination of bacterial contamination in blood products

- Background

The bacterial contamination of blood components represents a high infectious risk in blood transfusion, particularly for platelets concentrate. In order to estimate the bacterial contamination, manufacturers have developed some bacterial detection systems near the time of blood collection. A new system has been developed based on the detection and identification of a wide spectrum of common pathogenic bacteria. Following the identification, a direct count is obtained by cytometry.

- Outcome

These devices are intended to reduce the risk of transfusion reaction due to the bacterial contamination. The system is providing information regarding the safety of blood donation and therefore should be qualified as an in vitro diagnostic medical device.

1.9. Independent *in-vivo* dosimeters

- Background

In vivo dosimetry systems are used in radiotherapy to monitor the radiation dose received by the patient during a radiotherapy treatment. The device consists in a semi-conductor detector placed on the patient's skin and an electrometer placed in the control room where the physicians control the radiotherapy equipment. When performed early in treatment as an additional measure, the in vivo measurements of the radiation dose are an additional safeguard against setup, calculation or transcription errors. If the dose delivered to the patient is higher than the calculated dose, the system, independently of the radiotherapy equipment, can alert the physician, allowing him to act on the treatment.

- Outcome

Even if the in-vivo dosimeter is independent of the radiotherapy equipment, it can be considered that it is used to control the performance of the radiotherapy device. Therefore the in-vivo dosimeter should be qualified as a medical device. The in vivo dosimeter controls the performance of an active device intended to emit ionizing radiation and therefore should be classified as Class IIb, according to rule 10.

1.10. Gallipots

Gallipots are containers usually made from metal or plastic. They may be sterile or non-sterile and may be disposable. They are intended to be used to contain various items including medicinal products or disinfectants for antiseptic fluids to scrub the incision area prior to surgery. They are defined variously as "a small glazed pot used by apothecaries for medicines, confections, or the like[1]", as "a small glazed earthenware jar formerly used by druggists for medicaments[2]", and as "a small usually ceramic vessel with a small mouth; especially: one used by apothecaries to hold medicines[3]".

- Outcome

Gallipots do not meet the definition of a medical device: They do not diagnose, prevent, monitor, treat or alleviate disease, diagnose, monitor, treat or alleviate or compensate for injury or handicap or investigate, replace or modify the anatomy or physiological process. Nor do they fit the definition of an accessory to a medical device. Therefore Gallipots are not considered to be medical devices or accessories to medical devices.

1.11. Shoe covers

- Background

On the EU market there are shoe covers sold at hospitals used for different purposes :

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[1] Source: Dictionary.com Unabridged (v 1.1)
[2] Source: The American Heritage® Dictionary of the English Language, Fourth Edition
[3] Source: Merriam-Webster's Medical Dictionary

• Shoe covers which are intended by their manufacturer to be worn by the nursing staff to limit cross contamination in operating theatre and care units.

• Shoe covers for visitors which are intended to be worn by visitors to prevent patient's contamination when they visit a patient.

- Outcome

According to the section 3.3 of Meddev 2.1/4, the labelling of the product is crucial for its classification under the directive 93/42/EEC. "As a general rule, the principal intended purpose can be established as being the one of a medical device if the product is intended to be used in a medical context with the aim to provide protection of health and safety for the patient, regardless of whether the product aims simultaneously to protect also the user. Where a product is mainly intended to protect the person using it, irrespectively whether in a medical environment or not, it falls under Directive 89/686/EEC."

Consequently, shoe covers which are specifically intended by their manufacturer to be used in operating rooms, intensive care units or immunodepressed patients to protect the patient from potential contamination are medical devices. In application of rule 1, they are in class I.

In this case, shoe covers are considered as being similar to surgeons' gowns and hats.

On the other hand, shoe covers for visitors even in a hospital are products of control of environment.

1.12. Urine Diverter / Funnel Element for Mid-Stream Urine Collection

- Background

There are a number of mid-stream urine collection kits on the EU market. In general, these products consist of a specimen receptacle and a urine diverter / funnel element. They are usually packaged together in a 'kit' and in general the funnel part is not attached to the specimen receptacle in the kit. The user puts the two parts together, produces the sample, then removes the 'funnel' and closes the specimen receptacle.

The specimen receptacle is an IVD medical device as it is intended for the primary containment and transport of the urine sample.

The question arose as to the qualification of the urine diverter or 'funnel' and whether it is a general medical device (Class I) or an IVD medical device.

Some of these 'funnels' are intended to be held away from the body, whilst others are intended to be applied to the body. Some of these have been specifically designed for female use and this can be seen in their shape and form. In the majority of these cases the intention is for the 'funnel' to be held against the body whilst the urine specimen is collected.

- Outcome

The funnel / diverter itself does not fit the definition of an IVD medical device: it does not directly diagnose or provide information. It has no diagnostic function in itself. It therefore cannot be an IVD medical device in its own right, but is regarded as an accessory to the specimen receptacle.

Directive 98/79/EC states in Article 1.2 (c) that for the purposes of the definition of an accessory, invasive devices or those which are 'directly applied to the human body' are not considered to be accessories to IVD devices, therefore the 'funnel' / diverter cannot be considered to be an accessory to the specimen receptacle.

MEDDEV 2.14/1 states that specimen receptacles which come into contact with the patient fall within the MDD and not the IVDD. It also reiterates Article 1.2 (c) of the Directive and states that devices which are made available with IVD devices and which are directly applied to the human body for the purpose of obtaining a specimen within the meaning of Directive 93/42/EEC are not considered to be accessories to IVDs and come within the scope of Directive 93/42/EEC.

Therefore, where the funnel / urine diverter is intended to be directly applied to the human body for the purpose of obtaining a specimen (within the meaning of Directive 93/42/EEC) it shall not be an accessory to an *in vitro* diagnostic medical device but it will be a Class I medical device. The intended direct application to the female/male body for obtaining the specimen is demonstrated by the instructions for use, the labelling and/or other information provided by the manufacturer.

1.13. Air purifiers / Air decontamination units / Mobile air decontamination units

- Background

There are various types of air purifiers and air decontamination products on the market. There are two main types:

- 'Stand alone' / mobile units which are intended to purify or decontaminate the air in individual rooms or areas, which may be moved from room to room in accordance with the perceived need to purify or decontaminate the air in the room. They stand in the room and function independently. They are not connected to individual patients directly (e.g. via the use of a mask). These may or may not include filters.

- Units which are installed into the fabric of the healthcare institution, supplying purified / decontaminated air through pipe works that are part of the fabric of the building, into specific rooms /areas. Filters may also be used within the systems.

The claims for these products vary from 'purifying' the air to 'decontaminating' the air; however in general they are intended to remove allergens (dust, pollen etc.) and / or to remove bacteria from the air in a specific room or area.

Some of these systems contain filters in order to remove particulates in the air whilst others claim to destroy airborne micro-organisms.

In both cases the purified air is supplied into rooms and not directly connected to individual patients (e.g. via a mask) nor to breathing machines (which are directly connected to a patient).

In hospitals, these systems for air decontamination are used to reduce infection risks in intensive care units and operating theatres. They include Burnt units or systems comprising a mobile air decontamination unit and a mobile deployable room put directly above the patient with the intent to protect burnt patients or immuno-compromised patients from air contamination.

The question has arisen as to whether such products are considered to be medical devices, since it is claimed that they reduce infection risks to patients or protect patients from airborne contaminants.

- Outcome

These products are intended to 'control the environment' by removing allergens or microbial contamination from the air. They do not act directly on an individual patient and there is no direct contact with an individual patient. In order for a product to be a medical device, the device must have a direct association with the individual patient.

Although maintaining clean air may contribute to keeping a patient in an appropriate environment, this is not considered to be a 'medical purpose'. Air is part of the environment of the patient and its cleanness is necessary in a similar way as for surfaces, walls, floors and other objects which also need to be cleaned and disinfected.

Since these products do not fulfil the definition of a medical device, they are not considered to be medical devices, but are rather products for the general environment.

1.14. Wigs and head scarves

- Background

Both wigs and head scarves are routinely used by people for aesthetic reasons. They may also be used by patients undergoing chemotherapy or suffering from alopecia (hair-loss) from other causes.

The question arose whether wigs and head scarves intended for such patients would be regarded as medical devices on the basis that they may protect the head, reduce physical or emotional effects of hair loss and so on.

- Outcome

Wigs and head scarves are primarily intended for a cosmetic purpose, i.e. to improve or change the appearance of the wearer.

They do not treat or alleviate any specific medical conditions and do not fit the definition of a medical device. They are therefore not qualified as medical devices.

1.15. Blood irradiation indicators

- Background

Lymphocytes contained in the blood components can bring to Transfusion Associated Graft-versus-Host Disease (TA-GvHD) in specific cases. Lymphocytes may be deprived of the possibility of multiplication through the use of irradiation. Therefore, for example red cells for intrauterine transfusion and whole blood for exchange transfusion in neonates should be irradiated prior transfusion.

Blood irradiation indicators provide information as to whether the blood products have been irradiated and protect from repeated irradiation of those products.

According to instruction for use, indicators only indicate that irradiation has occurred, while they do not measure the dose from an irradiator.

The manufacturer of the above mentioned indicators has placed these products on the market as class I medical devices.

- Outcome

The blood irradiation indicators simply show that blood product has been irradiated. They do not affect the irradiation process and only provide additional information to the user.

In this connection, blood irradiation indicators do not fulfil the definition of a medical device laid down in Article 1(2)(a) of Directive 93/42/EEC; therefore they are not considered to be medical devices.

Blood irradiation indicators cannot be considered to be accessory to a medical device because they are not intended specifically by its manufacturer to be used together with a device to enable it to be used in accordance with the use of the device intended by the manufacturer of the device.

1.16. Odour neutralizers

- Background

Odour neutralizers, which may be presented in a spray form or as oil, are products used for the control of odours generated by the ostomy devices. The spray is intended to neutralize odours in room where in use ostomy equipment is present, while the oil is intended to be instilled in ostomy pouches.

These products are intended to improve the quality of life of people holding ostomy pouches by controlling the odours.

- Outcome

It is considered that these products have no medical purpose and therefore cannot be qualified as medical devices.

The sprays are not considered to be medical devices – they are intended to be used in a room and do not fit the definition of a medical device.

The oils meet the definition of an accessory to a medical device only when these articles are intended specifically by their manufacturer to enable the pouches to be used in accordance with their intended purpose, as specified by their manufacturer, according to the definition of accessory in Article 1 par. 2(b) of Directive 93/42/EEC.

1.17. Bedwetting alarm

- Background

A bedwetting alarm is a device intended to be used as a treatment of nocturnal enuresis. Each device has a moisture sensor component and an alarm component. A moisture sensor snaps onto underwear. The alarm sounds at the first sign of moisture, and interrupts the wetting process. The bedwetting alarm conditions the user to timely recognize bladder fullness, and awaken before wetting occurs.

- Outcome

When such devices are intended for treatment of nocturnal enuresis, which is generally recognized as medical condition, they should be qualified as a medical device. Such bedwetting alarm devices should be classified as Class I under rule 12 of Annex IX of the Directive 93/42/EEC.

1.18. Sweat generation and diagnostic system – status of sweat card

- Background

The product is a sweat card which is part of a system intended to measure chloride ions in sweat for the diagnosis of cystic fibrosis. The system runs the sweat test in two stages: iontophoresis sweat stimulation done by delivering pilocarpine through the skin to stimulate sweating (by exciting the sweat glands) and measurement of the chloride concentration in sweat sample. It includes three components namely:

a) sweat cards: contains pilocarpine for delivery via iontophoresis and a gel component that collects the resultant sweat;
b) remote module: sweat card is inserted into a unit, which is placed in direct contact with skin and is held in place via a strap; this battery powered module stimulates

delivery of pilocarpine and resultant production of sweat is collected, analysed and sent to a receiver base;

c) terminal or receiver base: this contains a unit for calculation and display of results.

The manufacturer considered that the sweat card element of the system would be either a class IIa medical device or an IVD medical device. He did not consider the sweat card to be a class III rule 13 medical device on the basis that the main purpose of the sweat sensor card is not to elicit a response via a pharmacological action but to diagnose cystic fibrosis by measuring sweat chloride. They considered that the pilocarpine iontophoresis is used for stimulation of sweat as a first step and hence the pilocarpine iontophoresis is an ancillary process to collect sweat.

- Outcome

The primary purpose of the sweat card is sweat collection; the pilocarpine is acting in an ancillary manner by stimulating glands to ensure collection of sweat is more effective.

The sweat card is directly applied to the human body for the purposes of obtaining a sample and therefore is not considered to be an IVD Medical Device as per MEDDEV Guideline 2.14/1 but rather a medical device according to Directive 93/42/EEC.

This device incorporates, as an integral part, pilocarpine which, if used separately, can be considered to be a medicinal product, as defined in Article 1 of Directive 2001/83/EC, and that is liable to act on the human body with action ancillary to that of the device. Therefore, the sweat cards should be qualified as medical devices and regarded as class III medical devices in accordance to rule 13 in Annex IX of the Medical Devices Directive 93/42/EEC.

1.19. Products intended to reduce the effect of alcohol

- Background:

The product is formulated as a suspension to ingest before drinking alcohol. This kind of suspension is intended to help reduce the absorption of ethylic alcohol in the intestinal lumen after ingestion. The main component of the product is a mineral salt (zeolite).

The product is used before the consumption of alcohol with the intention to reduce the blood content of alcohol. Consequently, the product is claimed to reduce the caloric intake, behavioural effects of alcohol and also the production of substances liable to be toxic linked to the metabolism of alcohol.

According to the manufacturer, the product is a medical device because it prevents and reduces the risk of developing some diseases as hepatic cirrhosis, arterial hypertension, ischemic/haemorrhagic ictus.

- Outcome:

The reduction of the absorption of ethylic alcohol, without any medical purpose, in order to reduce the blood content in alcohol cannot be considered as a medical purpose.

In the case of alcoholism (addictive illness) this product would not have a medical purpose, because it would not help the control of the behaviour (compulsive inability to stop drinking), nor of the dependence.

The product does not fall within the scope of the definition of medical device set out in Article 1.2 of Directive 93/42/EEC, concerning medical devices and should not be qualified as such.

1.20. Radiation shields

- Background:

Radiation shields are used to protect against unintended exposure to radiation, for example when using X-ray machines, during radiotherapy and long term surgery such as cardiology interventional procedures (occupational exposure).

Some radiation shields may be worn by an individual healthcare worker, however other radiation shields may be wall mounted, mounted on X-ray machinery, ceiling mounted or may be free-standing.

Products that are worn by an individual healthcare worker are regulated under the regulations covering personal protective equipment; however, these regulations do not cover products which are not worn by an individual. Products intended to protect the patient would be regarded as medical devices.

The question is whether radiation shields that are not worn by an individual may be qualified as medical devices.

- Outcome:

The shields are intended to protect persons in the vicinity of the equipment when it is in use (e.g. healthcare professionals) against exposure to radiation – they are not intended to protect the patient.

Although the shields will protect against over-exposure to radiation, radiation is not a disease although it may cause disease.

The purpose of these shields is similar to that of filters used for general protection of the persons in the building.

Therefore these types of radiation shields should not be qualified as medical devices.

1.21. Rugby helmet 

- Background:

A helmet that is intended to be worn by any person participating in rugby can protect the skull from non-penetrating direct impacts that could lead to brain injury and other clinical complications.

- Outcome:

A helmet worn during rugby can prevent brain tissue damage or other trauma by providing mechanical protection against a hazard e.g. impact to the head. The helmet does not prevent, treat or alleviate a disease nor does it treat or alleviate an injury. Therefore the helmet does not meet the definition of a medical device and should not be qualified as such.

1.22. Autopsy saw

- Background:

The product under discussion is a saw with extractor unit intended for use only in the mortuary for autopsy. The question has arisen as to whether such a product can be considered to be a medical device, since it is claimed by the manufacturer that it is intended for diagnosis of disease, diagnosis of an injury or handicap or investigation of the anatomy or of a physiological process.

- Outcome:

This product should not be qualified as a medical device because it is not intended for use on living human beings.

1.23. UV flow germicidal lamp

- Background:

UV flow germicidal lamps are intended to decrease the level of microbiological load in hospitals (operating rooms, treatment rooms, patient rooms, emergency room, isolation room and the refuse disposal site). These lamps are able to destroy bacteria, viruses, fungi, and other microorganisms. Contaminated air is drawn by a fan, through a filter that retains dust and other particles, into the disinfection chamber.

- Outcome:

Although maintaining clean air may contribute to keeping a patient in an appropriate environment, this is not considered to be a 'medical purpose'. Also, these devices are not intended to be used for disinfecting medical devices but only for disinfecting air. Since these products do not fulfil the definition of a medical device or definition of accessory of medical device, they should not be qualified as such.

1.24. Water filter

- Background:

The product is a water filter with a fibre membrane for removing microorganisms from the water without changing its chemical composition. The manufacturer claims that filtered water is specifically intended for washing wounds and rinsing invasive medical equipment (e.g. endoscopic material) and that the filter should be classified as a medical device of class llb according to rule 4 or 15 (both apply according to the manufacturer).

The question has arisen as to whether such a product meets the definition of medical device or accessory of medical device.

- Outcome:

The water filter does not come into contact with injured skin and it does not disinfect medical devices, so neither rule is applicable. Water filtration systems that use mechanical barriers such as a fibre membrane for removing microorganisms should be regarded as general hospital equipment and should not be qualified as a medical device or accessory of medical device.

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2. BORDERLINE IN VITRO DIAGNOSTIC MEDICAL DEVICE

Introduction

The definition of in vitro diagnostic medical devices reads as follows:

Article 1 (2) b of the IVD Directive 98/79/EC *"'in vitro diagnostic medical device' means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment, or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information:*
— concerning a physiological or pathological state, or
— concerning a congenital abnormality, or
— to determine the safety and compatibility with potential recipients,
or
— to monitor therapeutic measures."

From this definition it follows that in order to fall within the definition of an in vitro diagnostic medical device, the product must also meet the definition of a medical device.

Article 1 (2)a of the MD Directive 93/42/EEC *"'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;"

Other relevant provisions are:

Article 1 (2) b IVDD "*Specimen receptacles are considered to be in vitro diagnostic medical devices. 'Specimen receptacles' are those devices, whether vacuum-type or not, specifically*

intended by their manufacturers for the primary containment and preservation of specimens derived from the human body for the purpose of in vitro diagnostic examination."

Article 1 (2)b IVDD "*Products for general laboratory use are not in vitro diagnostic medical devices unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for in vitro diagnostic examination;"*

It is suggested to consult MEDDEV 2.14/1 for more detailed guidance concerning in vitro diagnostic medical devices.

2.1. Sample receptacles and sampling devices which are intended to be used for the collection by the lay user of samples, which are subsequently examined by third persons.

- Background

The products in question are IVD kits which are being supplied to the public for a variety of medical conditions including tests for food allergies and infections such as Chlamydia. These tests are being supplied by post to members of the public in the following manner:

The patient orders the kit from the company concerned and the kit is despatched to him. The kit contains the required equipment to take a sample. The patient is instructed to take the sample (for example, usually a urine sample or blood sample – either via a lancet, or they are advised to take their kit to their doctor for a blood sample to be taken). The sample is then placed in some type of storage container. Once the sample is obtained, the patient is instructed to send it back to the company supplying the kit. The patient is then supplied with the result of the test, indicating whether or not they have a positive result. None of these activities involve healthcare professionals.

- Outcome

These kits are in vitro diagnostic medical devices by means of applying article 1 (2) b IVDD which states that: *"Specimen receptacles are considered to be in vitro diagnostic medical devices. 'Specimen receptacles' are those devices, whether vacuum-type or not, specifically intended by their manufacturers for the primary containment and preservation of specimens derived from the human body for the purpose of in vitro diagnostic examination."*

The question arises whether these specimen receptacles could be considered as a 'device for self-testing' in accordance with article 1 (2)d IVDD according to which '*device for self-testing' means any device intended by the manufacturer to be able to be used by lay persons in a home environment;*

In this determination, the notion 'used' is essential. Firstly, it is necessary to examine the instructions for use. Where the instructions for use require an action to be taken by the end-user of the device in question, the notion 'used' is fulfilled. In addition, the definition of 'self-testing' provides guidance on the action to be taken i.e. "testing".

Thus where a specimen receptacle is simply used by the patient to contain a specimen it remains a specimen receptacle. To become a 'device for self-testing', either the filling of the receptacle with a specimen should result directly in a result being given or the patient should

need to do something directly to the specimen prior to its despatch in order to fulfil the concept of ‘used’.

2.2. CE labelled microscope slides

This product is a microscope slide which is made of a thin sheet of glass used to hold objects for examination under a microscope. Unless the manufacturer’s intended purpose falls within the definition of an in vitro diagnostic medical device, it must be regarded as a general laboratory product. The latter are excluded from the IVDD by article 1 (2) b IVDD.

In addition, MEDDEV 2.14/1 rev.1 states in this context:

"*if, however, the product does not in fact possess specific characteristics that make it suitable for one or more **identified** in vitro diagnostic examination procedures, then the manufacturer is not free to bring it within the scope of the IVDD merely by affixing the CE marking to it. In other words, a manufacturer is not able to bring within the scope of the IVDD a product that, in reality, is a piece of general laboratory equipment simply by affixing the CE mark to it".*

2.3. Single or multiple channel pipettes

The single or multiple channel pipettes are used for aspirating and dispensing specific volumes in the microlitre scale. The volume is set by rotating the thumbwheel or the push-button. These pipettes have various laboratory purposes.

Unless the manufacturer’s intended purpose falls within the definition of an in vitro diagnostic medical device, these pipettes must be regarded as a general laboratory product. The latter is excluded from the IVDD by article 1 (2) b IVDD.

In addition, MEDDEV 2.14/1 rev.1 states in this context:

"*if, however, the product does not in fact possess specific characteristics that make it suitable for one or more **identified** in vitro diagnostic examination procedures, then the manufacturer is not free to bring it within the scope of the IVDD merely by affixing the CE marking to it. In other words, a manufacturer is not able to bring within the scope of the IVDD a product that, in reality, is a piece of general laboratory equipment simply by affixing the CE mark to it".*

Moreover, the MEDDEV 2.14/1 rev. 1 specifically refers to pipette. Under point 4 *“Products for general laboratory use”,* it is mentioned that pipettes are laboratory products that are not usually considered to fall within the scope of the IVD directive.

2.4. Qualification of fluid collection bowl

- Background

The product is a single-use plastic device consisting of a round container, a cover, a drainer and a liquid-absorbent inner layer. The absorbent material would receive the waste fluid from syringes, therefore avoiding spillage.

This product is intended to facilitate the safe disposal of fluids during a medical procedure (e.g. in operating theatres), avoiding any spills or splashes.

- Outcome

The product's intended purpose is the safe disposal of body fluids collected during a medical procedure and therefore this product is not intended to be used so as to achieve a medical purpose.

This bowl is similar to containers for used syringes, needles and other bio-hazardous materials or waste, which are not qualified as medical devices. They could also be compared to gallipots, which, as stated in the entry 1.10. of the Manual on Borderline and Classification, should not be qualified as medical devices.

Therefore, this product should not be qualified as a medical device.

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3. BORDERLINE ACTIVE IMPLANTABLE MEDICAL DEVICE – MEDICAL DEVICE

3.1. Bone anchored hearing aids

- Background

Bone anchored hearing aids consist of a titanium implant (that is screwed into the patients cranium), an abutment to transfer vibrations and a sound processor (hearing aid). The sound processor collects sound, amplified the vibrations and passes them on to the implant (*via* the abutment). The vibrations find their way to the inner ear without the help from any other devices and make it possible for the patients to hear. The sound processor relies on an electrical power source, while both the abutment and the implantable titanium piece are passive.

It must be noted that bone anchored hearing aids are different from cochlear implants which are intended to stimulate the hearing nerve directly via an electrode array inserted into the cochlea (inner ear). According to MEDDEV 2. 1/2 rev 2, cochlear implants activated by an external power transmitter are regarded as active implantable medical devices as the implanted component clearly depends on a power source for its function and its purpose is to convert the power it receives into electrical signals which trigger appropriate sensory channels in the brain.

The question is whether bone anchored hearing aids fall under the Directive 93/42/EEC on medical devices or under the Directive 90/385/EEC on active implantable medical devices.

- Outcome

Guidance MEDDEV 2. 1/2 rev 2 states that a product falls under the definition of an active implantable medical device if it is at the same time both active and implantable. Under its point 2.1.2 the MEDDEV 2.1/2 rev.2 excludes that a device is active if the function of the device is only a mere transmission of vibration. With the bone anchored hearing aid the

implantable component is not an active medical device – it is a titanium 'rod'. The sound processor, which is the active component, is not implanted.

On the basis of the above, bone anchored hearing aids fall under Directive 93/42/EEC on medical devices. The sound processor shall be classified as class IIa medical device according to classification rule 9 while the implant is regarded as class IIb medical device according to classification rule 8 of Annex IX of Directive 93/42/EEC. Where the two elements are supplied as one system, the higher classification applies to the overall product and the system is therefore classified as class IIb medical device.

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4. BORDERLINE MEDICAL DEVICE – MEDICINAL PRODUCT

Introduction

It is suggested to consult MEDDEV 2.1/3 rev 3 for more detailed guidance on the borderline issues concerning medical devices and pharmaceuticals.

The definitions of medical device and medicinal product, as well as the Article 2(2) of Directive 2001/83/EC are reproduced here for reference.

- **Medical device definition (Article 1(2)a of Directive 93/42/EEC, as amended):**

(*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):**

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

- **Article 2(2) of Directive 2001/83/EC, as amended:**

In cases of doubt, where, taking into account all its characteristics, a product may fall within the definition of a "medicinal product" and within the definition of a product covered by other Community legislation the provisions of this Directive shall apply.

Note: It must be noted that for the purposes of determining whether a product falls within the definition of a medicinal product by function, the national authorities must decide on a case-by- case basis, taking account of all the characteristics of the product, in particular its composition, its pharmacological properties to the extent to which they can be established in the present state of scientific knowledge, the manner in which it is used, the extent of its distribution, its familiarity to consumers and the risks which its use may entail.

4.1. Product for testing patient reflex cough

- Background

The product may be used, following initial diagnosis, by health care professionals as a part of a neurological evaluation to assess the patient's laryngeal cough reflex (LCR), neurological airway protection and the vagal (cranial nerve X) component of reflex cough. The test uses 1-3 inhalations of a nebulized 20% solution of L-(+)-tartaric acid in a medicinal non-ventilatory nebulizer. Tartaric acid acts as a mild irritant to the mucosa of the larynx.

The resultant involuntary reflex response, i.e., cough, is indicative of whether the upper airway is neurologically protected. The expected result of a normal test is an immediate series of a forceful coughs, which are primarily expiratory "airway cleaning" in character. The expected result of an abnormal test is represented by an absence of coughing, or a diminished (weak) coughing, or coughing not immediately after administration of the test stimulus. The testing is terminated when the subject either elicited a cough or failed to cough after three valid inhalations.

According to the manufacturer's statements the test functions like many other devices which assess neurological pathways, including the reflex hammer, nerve conduction stimulators, and the fiberoptic endoscopic evaluation of the swallowing with sensory testing, where a physical stimulus (either electrical or physical) challenges a neurological pathway to elicit a response.

The manufacturer regards 20% tartaric acid (TA) solution used to induce cough as a physical stimulus, although it cannot be denied that it induces chemical changes to the sensory nerves and that there may be "pharmacological" agents involved. Another consideration given by the manufacturer is that TA in the dose used will have no measurable effect on general body metabolism, and it should therefore not be considered to have a "metabolic" action. Finally the manufacturer stresses that the purpose of the TA test is not diagnostic. As with the use of

other physical stimuli, the patient's diagnosis will already have been established (e.g. stroke) and the test will be used to determine appropriate treatment for the individual patient.

The manufacturer will market 20% L-(+)-tartaric acid in normal saline as a sterile, pure solution. The item will be used with a commercially available disposable jet nebulizer for single-patient use (the nebulizer is not pre-filled with the solution). Continuous flow will deliver the agent through the inspiratory cycle, and will allow re-charge of the agent during the exhalation phase. According to the manufacturer's statements the use of the solution is deemed ancillary to the nebulizer, as the solution cannot be administered without nebulization.

- Outcome

The tartaric acid is intended to be used for neurologically impaired patients to test the functioning of their laryngeal cough reflex in order to determine appropriate treatment. A pharmacological action on the patient cannot be excluded.The tartaric acid is used as an irritant to produce a cough reflex and is a substance administered for in-vivo diagnostic purposes. The administration of this substance could be considered as a component of the general medical diagnosis since it consents to improve definition of the extent of neurological damage.

On the basis of the above, the product does not meet the definition of a medical device.

4.2. Elastoviscous fluids

- Background

This product is a sterile, non-pyrogenic, elastoviscous fluid containing hylans (derivatives of hyaluronan-sodium salt of hyaluronic acid that consists of repeating disaccharide units of N-acetylglucosamine and sodium glucoronate). It is biologically similar to hyaluronan which is a component of synovial fluid which is responsible for its viscoelasticity. The product achieves its therapeutic effect through viscosupplementation, a process whereby the physiological and rheological states of the arthritic joint tissues are restored. Viscosupplementation is a treatment to decrease pain and discomfort, allowing more extensive movement of the joint. The product has to be injected in the affected joint to achieve its effect. Hylans are degraded in the body by the same pathway as hyaluronan.

- Outcome

The data presented does not allow issuing a general statement for the qualification of the elastoviscous fluids.

Viscoelastic materials with intended use for mechanical/physical purposes such as protection of tissues during and after surgery and separation of tissues are considered to be medical devices. Such materials are also used as synovial fluid replacements where viscosupplementation provides support and lubrication. Additional pharmacological benefits claimed which are ancillary to the mechanical action do not alter the medical device status. However, certain of these materials such as some hyaluranon based products, where the

predominant claims are of a pharmacological nature and not primarily related to any viscoelastic characteristics, are classed as medicinal products.

Therefore it is appropriate to follow a case by case approach, taking into account all product characteristics and in particular:

- The intended purpose of the product and the claims of the manufacturer, taking into account the way the product is presented;

- The nature of the principal intended action. For example, is there any pharmacological or metabolic action (e.g. anti-inflammatory effect, stimulation of in vivo hyaluronic acid synthesis etc.) not ancillary to the mechanical/physical action of the product?

4.3. In-Vitro Fertilisation (IVF) and Assisted Reproductive Technologies (ART) products

- Background

The In-Vitro Fertilisation (IVF) and Assisted Reproductive Technologies (ART) products cover a large spectrum of products.

For some of these products the principle intended action is clearly a pure physical or mechanical action. On the other hand, a number of products that fall within this category contain substances that act by pharmacological, immunological or metabolic action. In the latter cases, it is of utmost importance to assess whether such a pharmacological, immunological or metabolic action represents an ancillary or primary action. It is concluded that this analysis should be done on a case by case basis.

- Outcome

IVF/ART products may be qualified and regulated as medical devices provided that they meet the definition of a medical device as laid out in Directive 93/42/EEC, taking into consideration the principal intended action and intended purpose of the product. The concept of 'used for human beings' is interpreted in the broadest sense. The whole IVF/ART procedure and related products would be seen as (indirectly) *"(…) used for human beings for the purpose of (…) replacement or modification of (…) a physiological process"* by promulgating pregnancy. Therefore, the definition of medical devices can include IVF/ART products.

Examples of products which could be qualified as medical devices (classification is only indicative and must be assessed on a case by case basis taking into account all product characteristics):

- Devices that act in a physical or mechanical way intended to be used for IVF/ART (such as pipettes or syringes) should be classified according to the rules set out in Annex IX of Directive 93/42/EEC, depending mainly on their intended use;

- Devices, such as washing, separating, sperm immobilizing, cryoprotecting solutions, which are liable to act with close contact on the inner or outer cells during the IVF/ART are likely to be considered as Class IIb medical devices, in particular by analogy of rule 3.[4]

- Devices manufactured utilizing animal tissues or derivatives rendered non-viable are considered as Class III medical devices according to rule 17;

- Devices incorporating, as an integral part,

(i) a human blood derivative or

(ii) a substance which, if used separately, can be considered to be a medicinal product, as defined in Article 1 of Directive 2001/83/EC, and which is liable to act on the human body with action ancillary to that of the devices,

are considered as Class III medical devices according to rule 13. The assessment of the ancillary nature of the pharmacological, immunological or metabolic action of any medicinal product contained in IVF/ART products should be done on a case by case basis, taking also into account the purpose of the inclusion of this substance into the product. Although case by case analysis should always be performed, media intended for use in the IVF process to support the growth / storage of the embryo may generally be considered to be Class III medical devices.

In case of doubt where taking into account all product characteristics, and provided that the concerned product meets both definitions of a medicinal product and of a medical device, Article 2(2) of Directive 2001/83/EC could apply.

4.4. Peritoneal dialysis solutions

- **Background**

Solutions for peritoneal dialysis are preparations for intraperitoneal use which contain electrolytes in a similar concentration to that in plasma, and also contain glucose or another suitable osmotic agent.
Peritoneal dialysis solutions always contain sodium, chloride, and hydrogen carbonate or a precursor. They may also contain calcium, magnesium, and potassium.

In peritoneal dialysis, the solution is infused into the peritoneal cavity, where exchange of electrolytes takes place by diffusion and convection, and excess fluid is removed by osmosis, using the peritoneal membrane as an osmotic membrane. Such exchange of electrolytes induces a metabolic effect.

- **Outcome**

Peritoneal dialysis solutions are used for specific and restricted medical conditions to be administered parenterally to patients with an identified medically diagnosed condition and

4 These products are considered to present the same level of risk as non-invasive devices intended for modifying the biological or chemical composition of blood, other body liquids or other liquids intended for infusion into the body

have a metabolic mode of action. Therefore such solutions cannot be qualified as medical devices.

4.5. Agents for transport, nutrition and storage of organs intended for transplantation[5]

- Background

Historically, solutions for the transport and storage / preservation / nutrition of organs for transplant have been regarded as medicinal products.

However these products are not currently regulated in all Member States as medicinal products since some authorities do not consider that they fit the definition of a medicinal product.

There is a direct parallel between IVF media and these solutions for the preservation, storage, nutrition and transport of organs, cells or body parts. The solutions are intended to store and / or maintain the viability of the organs / cells until such time as they are reintroduced to the human body.

- Outcome

Some agents for transport, nutrition and storage of organs intended for transplantation may be qualified and regulated as medical devices provided that they meet the definition of a medical device as laid out in Directive 93/42/EEC, taking into consideration the principal intended action and intended purpose of the product. In this case, the transplantation procedure would be seen as *used* (indirectly) f*or human beings for the purpose of replacement or modification of the anatomy*.

1) The physical containers for the transport of organs are regulated as medical devices and are given as an example in MEDDEV 2.4/1 under classification rule 2, second indent 'devices intended for temporary storage and transport of organs for transplantation' and 'devices intended for the long term storage of biological substances and tissues such as corneas, sperm, human embryos, etc.'

2) Agents for transport, nutrition and storage of organs intended for transplantation usually act through pharmacologic, immunologic or metabolic means. Therefore the assessment of the ancillary nature or not of the pharmacological, immunological or metabolic action of the product is a crucial element for the qualification of the product.

According to Article 1 (2)a of Directive 93/42/EEC, medical devices do not achieve their principal intended action in or on the human body by pharmacological, immunological or metabolic means but may be assisted in its function by such means.

Provided that they meet the definition of a medical device as laid out in Directive 93/42/EEC:

[5] Corresponding section in MEDDEV 2.1/3 rev.2 is currently under revision

- Devices manufactured utilizing animal tissues or derivatives rendered non-viable are considered as Class III medical devices according to rule 17;

- Devices incorporating, as an integral part,

  (i) a human blood derivative or

  (ii) a substance which, if used separately, can be considered to be a medicinal product, as defined in Article 1 of Directive 2001/83/EC, and which is liable to act on the human body with action ancillary to that of the devices,

are considered as Class III medical devices according to rule 13.

The assessment of the ancillary nature of the pharmacological, immunological or metabolic action of any medicinal product contained in agents for transport, nutrition and storage of organs intended for transplantation should be done on a case by case basis, taking also into account the purpose of the inclusion of this substance into the product.

In accordance with Article 2(2) of Directive 2001/83/EC, in case of doubt where taking into account all product characteristics, and provided that the concerned product meets both definitions of a medicinal product and of a medical device, the provisions of Directive 2001/83/EC shall apply.

4.6. Zinc oxide containing creams

- **Background**

Products containing zinc oxide are available as creams for local administration.

Some zinc oxide containing products, depending on their claims and intended use, might be covered by Directive 76/768/EEC on cosmetic products.

The discussion below only concerns zinc oxide containing products used to treat or prevent minor skin irritations (*e.g.* burns, cuts, nappy rash, eczema etc.).

- **Outcome**

A medical device should not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but may be assisted in its function by such means.

For zinc oxide containing products, according to the literature, a pharmacological and metabolic action is demonstrated, *e.g.* may play a role in enzymatic processes, support of wound granulation.

The pharmacological action may, however, be ancillary when the product concerned is primarily a barrier cream.

In such cases the qualification of zinc-oxide containing products is defined taking into account the claims, the intended purpose and the relevant primary mode of action. Some

products that act primarily as a barrier may therefore be acceptable as Class III medical devices in accordance with rule 13 of Annex IX of Directive 93/42/EEC.

In accordance with Article 2(2) of Directive 2001/83/EC, in case of doubt where taking into account all product characteristics, and provided that the concerned product meets both definitions of a medicinal product and of a medical device, the provisions of Directive 2001/83/EC shall apply.

4.7. Eye drops intended for related to the alleviation of 'soreness' , 'discomfort' or 'irritation' caused by environmental factors (such as dust, heat, smoke, etc.)

- Background

On the EU market there are many different types of eye drops used for different purposes.

1) Eye drops regulated as medicinal products:

Eye drops used in or administered to human beings with a view to making a medical diagnosis are regulated as medicinal products in accordance with article 1(2) of Directive 2001/83/EC.

Eye drops with pharmacological, immunological or metabolic principal mode of action will fall under the definition of a medicinal product if they may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions.

2) Eye drops regulated as medical devices:

Products specifically intended to be used for disinfecting, cleaning, rinsing or, when appropriate, hydrating contact lenses are medical devices.

Eye drops with a physical mode of action that are clearly indicated for a medical purpose are acceptable as medical devices (*e.g.* for the treatment of hay fever).

Therefore, the discussion below only concerns products for which no 'medical' claims are made, nor any claims associated with the use of contact lenses. Commonly the only claims made relate to the alleviation of 'soreness' , 'discomfort' or 'irritation' caused by environmental factors (such as dust, heat, smoke, etc.) or simply 'for tired eyes'.

- Outcome

The qualification of a particular eye drop products shall depend upon the intended purpose and mode of action of the product, and must be assessed on a case by case basis.

Some products may claim indications such as 'treatment' of a physiological response to external factors (*i.e.* dust, smoke, dry heat, air conditioning) and are used to create a humidification of the eyes or to treat minor irritations of the eyes. As such, they are designed to complement physiological functions provided by normal tears to help meet an increased demand for humidification / lubrication of the eyes.

These products do not need to stimulate physiological functions of the natural tears. The intended effect may be achieved by physical means only, *i.e.* by washing the eye surface (effect of dust, smoke), or supplement the aqueous layer of natural tear film with additional water under conditions of significantly increased evaporation (dry heat, air conditioning). By decreasing the exposure to irritants they may be helpful in treatment of 'minor irritations' of the eye.

Therefore products which claim to treat damage caused by environmental factors may be acceptable as medical devices (or medicinal products, dependant on their mode of action) provided that they clearly claim to treat or alleviate damage to or irritation of the eye (*e.g.* via repairing damage to the tear film caused by environmental conditions).

These products must not claim to be artificial tears, or any kind of replacement of natural tears. Products called 'artificial tears' are usually those that replace or complement natural tear functions when natural tear function has been compromised. The term 'artificial tears' should therefore only be used for products that replace the function of natural tears. Such products may be regulated as either medical devices or medicinal products, depending upon their mode of action.

For the classification of these products see paragraph 8.19.

4.8. Product for use in acute sore throat

- Background

The product is intended to be used, according to the instruction for use, in acute sore throat with irritated mucosa. This product contains Icelandic Moss and benzocaine.

The mechanism of action of Icelandic Moss is a mucilaginous drug which spreads on the oral and pharyngeal mucosa, forming an internal coating on the mucosa, acts by covering the mucosa with a protective layer. The benzocaine helps reducing further sensitivity.

The European Pharmacopoeia contains monographs for "Iceland Moss" and "Benzocaine (benzocainum)".

Icelandic moss may be considered as a medicinal substance and is described as having pharmacological properties including anti-inflammatory, antibacterial and antiviral activities.

Benzocaine is a known medicinal substance with pharmacological action as local anaesthetic and is found in several medicinal products intended for temporary local relief of pain associated with sore throat.

- Outcome

A pharmacological action of Icelandic moss cannot be excluded, as it is described to have pharmacological properties including anti-inflammatory, antibacterial and antiviral activity.

Furthermore, even if the Icelandic moss may be considered as providing a physical barrier, the benzocaine contained in this product could not be considered having an ancillary action.

On the basis of the above, it is concluded that this product achieves its principal intended action by pharmacological means and therefore do not meet the definition of a medical device.

4.9. Plaster with capsaicin

- Background

The products in question are warming plasters (adhesive) containing capsaicin (capsicum oleoresin or capsicum extract). These plasters are intended for heat-treatment, local analgesia and are indicated to treat muscular, rheumatic and neuralgic pains.

The European Pharmacopoeia contains monographs for "Capsici fructus" and "Capsicum Oleoresin". The European Scientific Cooperation on Phytotherapy (ESCOP) has classified "Capsici fructus" as an herbal medicinal product.

According to classification rule 13, devices incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product, and which is liable to act on the human body with action ancillary to that of the device, are in Class III.

- Outcome

The adhesive plaster described appears to be acting as a carrier for the substance (Capsaicin) in order for the substance to be delivered to the body to produce the analgesic effect. It therefore cannot be excluded that this product achieves its principal intended action by pharmacological means. Therefore warming plasters with capsaicin may not be qualified as a medical device.

4.10. Gold implants for treatment of osteoarthrosis

- Background

Various gold salts are available for systemic treatment of painful joint diseases, mainly arthritis and arthrosis. There is increasing evidence that the gold salts exert their effect by a direct intervention with the cellular immune response. It is generally assumed that the active part of the gold salts is the gold ions.

Solid gold implants for local treatment of painful joint diseases in animals have been used by veterinarians in a number of years. Several studies have documented a therapeutic effect of solid gold implants in animals. Research has provided evidence that gold ions are released from the implanted gold and diffuse into the surrounding tissue, where they can be detected in connection with inflammatory cells from the immune system. The researchers concluded that solid gold implants as a local treatment, mimics systemic treatment with a gold-containing drug.

The question is whether gold implants should be qualified as medical devices or not.

- Outcome

In the view of the above mentioned mode of action which mimics systemic treatment with a gold-containing drug, gold implants for treatment of osteoarthrosis exert their effect by a direct intervention with the cellular immune response and therefore cannot be qualified as medical devices.

4.11. Substances for chemical peeling

- Background

Skin exfoliation is widely used to reduce the signs of aging in the skin since it diminishes imperfections by peeling away the skin's top layers (solution to sun-damaged, unevenly pigmented, and finely wrinkled facial areas). It is also used on acneic skin and on acne scars. Skin exfoliation could be obtained by different means such as mechanical peeling (also called dermabrasion which consists of a sand blasting technique with particles), physical peeling (carbon dioxide ultrapulsed laser, erbium:YAG laser) and chemical substances. In this case, the depth of peeling depends of many factors such as the substance used (e.g. alpha hydroxy acids (AHA), beta hydroxyl acids as salicylic acid, trichloroacetic acid (TCA) and phenol), its concentration, the pH of the solution, and the length of the application.

Considering their intended use on acneic skin some manufacturers requested an opinion about placing chemical peeling containing salicylic acid (and glycolic acid) as class I medical device. The question is whether these chemical peeling must have a specific action on treatment of acnea to be considered as a medical device or whether the claim that they are indicated in case of acneic skin could be sufficient to qualified them as medical device.

- Outcome

It is concluded that, depending on their principal mode of action and in the case they have a specific medical purpose (for example treatment of acne), these products might be qualified as medical devices. However the claim that they may be used on acneic skin is not considered sufficient to indicate a medical purpose.

When these products could be qualified as medical devices they shall be classified as class III medical devices according rule 13 if they contain a medicinal substance with ancillary action.

4.12. Mustard packs

- Background

Mustard packs, consisting of mustard seed powder, are usually applied on the chest, abdomen or articulations and the intended use is to alleviate the symptoms of common colds and other respiratory system ailments, and rheumatism. The mechanism of action of the mustard pack remains unclear and the properties which could prove their suitability for the treatment of disease and prophylaxis are still unknown.

The mustard packs work in a manner analogous with Capsaicin plasters (see section 4.9.).

- Outcome

It is considered that the mustard seed powder produce a heating effect by causing capillaries to expand and an analgesic effect by interacting with skin receptors to reduce sensitivity due to the release of allyl isothiocyanate compounds that follows the hydrolyzation of the glucosinolates contained in the seeds.

Therefore, mustards packs principal intended action is achieved by pharmacological means and cannot be qualified as medical devices.

4.13. Washing solutions used for pathogenic microorganisms

- Background

There are washing solutions with antimicrobial properties, destined for the disinfection of healthy skin, being placed on the market as class III medical devices, even though, according to European guidance, topical disinfectants (antiseptics) for use on patients are given as examples of medicinal products.

According to manufacturer information, these washing solutions (which are presented as concentrate solutions, gel, foam and impregnated wipes) are intended for multi-drug resistant organisms decolonization by physical cleansing (inhibiting their spreading and transmission with sustained antimicrobial barrier effect), and may also be used for pre-operative cleansing.

General treatment indications include washing of hair, face, ears, nose, upper body, lower body, perineum, urethra and catheter entry sites, legs, and others such as spectacles, jewellery and prosthesis.

These washing solutions are also presented as oral solutions/mouthwashes for: the disinfection of the oral cavity and pharynx; prevention of plaque formation, caries, periodontitis, gingivitis, and are applicable on impaired mucous membranes, according to manufacturer claims.

- Outcome

Considering that:

- These washing solutions for inhibition of pathogen microorganisms present medical claims such as: multi-drug resistant organisms' decolonization, prevention of plaque formation, caries, periodontitis, and gingivitis;

- Only products intended for disinfecting medical devices or cleaning contact lenses (rule 15 of annex IX of the MMD) are medical devices;

- As indicated on point 5.1 of the Manual on Borderline and Classification: “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.”;

- According to MEDDEV 2.1/3 rev 3, section A.2.2.2.: “Topical disinfectants (antiseptics) for use on patients” are given as examples of medicinal products;

- Mouthwashes are medicinal products when the intended purpose is to treat or prevent oropharynx diseases;

- The solutions presented have a pharmacological main mode of action as antiseptics/disinfectants.

Therefore, washing solutions used for pathogenic microorganisms cannot be considered to be medical devices.

4.14. Mousse for rapid relief from irritation, itching, burning and sensitivity associated with chickenpox

- Background

A product, available as a mousse (foam), designed to relieve the symptoms of chickenpox on large surfaces of the skin and used for rapid relief from irritation, itching, burning and sensitivity associated with chickenpox, was placed on the market as a class I medical device, according to rule 4 of Annex IX of the Directive 93/42/EEC.

According to information provided by the manufacturer, the product is based on a patented complex (that results from the filtration process of the Aloe barbadensis gel) which helps to protect and soothe the irritated skin, this ingredient supports the skin's own natural immune system. Its polysaccharide chains have the unique characteristic of binding to harmful bacteria. This blocks the bacteria, thus protecting the skin cells from being attacked. This patented complex creates a barrier for pathogenic bacteria avoiding the invasion of the hosts' tissue.

- Outcome

Considering that:

- According to expert opinion, this complex acts in a manner similar to that of the body's immunological response;

E.g. There are several receptors for the recognition of pathogenic organisms, some of them are present in the bloodstream, and in tissue fluids as soluble blood serum proteins, and others can be found in cell membranes of macrophages, neutrophils and dendritic cells.

An example of soluble forms that bind to the microbial surface and promote their opsonization is mannose binding lectin and C-reactive protein. These receptors, when connected to the microbial surface, also have the ability of triggering the complement system, turning the invader into a sort of target for the complement-mediated lysis.

- There is an antimicrobial action through the blockage of pathogenic bacteria's receptors;

- There is insufficient data to demonstrate a mere physical action;

- In case of doubt where taking into account all product characteristics, and provided that the concerned product meets both definitions of a medicinal product and of a medical device, Article 2(2) of Directive 2001/83/EC could apply.

On the basis of the above, it is concluded that this product does not meet the definition of a medical device.

4.15. Injectable substance for treatment of localized adiposity

- Background

The product is described by the manufacturer as an injectable aqueous solution with a micro-gelatinous base, which helps to modulate and favour the action of external ultrasound waves (generated by the use of a medical ultrasound generator) for the non-surgical treatment of localized adiposity by means of intralipotherapy. It is placed on the market as a class III medical device.

According to manufacturer information the product is a totally resorbable solution, composed of an aqueous gelatinous micro-containing polymer. The solution is injected into the adipose tissue, during intralipotherapy technique, and produces a swelling in the tissue, and, when followed by the external application of ultrasound to the skin, leads to the generation of micro-cavitation in the area where the solution was injected, increasing the drainage of the fluid present in the treated area.

Also, according to the labelling and instructions for use, this product has as the intended use simply the treatment of localized adiposity, without any relation to a specific pathology, although it bears the instructions that it is intended to be used only by physicians.

The IFU mention the use on the "culotte de cheval" as well as in medicine and aesthetic surgery / dermatology, as the manufacturer intends the product to be used for the treatment and improvement of body imperfections due to small accumulations of adiposity. The indication is limited only to healthy patients.

- Outcome

Considering that the treatment of localized adiposity on healthy patients is not a medical purpose, and that the product does not have any medical claim, it is concluded that the product does not meet the definition of a medical device and cannot be qualified as such.

4.16. Riboflavin solution for treatment of keratoconus

- Background:

The product is a solution containing riboflavin supplied in the form of eye drops and is intended for the treatment of keratoconus (a degenerative disorder of the eye which causes structural changes within the cornea).

The riboflavin solution is administered into the eye and is activated via illumination with UV-A light for approximately 30 minutes. The riboflavin causes new bonds to form across

adjacent collagen strands in the stromal layer of the cornea which increases the tensile strength of the cornea.

The intended purpose of the product is to increase the collagen cross linking by using riboflavin in treatment of keratoconus by causing the collagen fibrils to thicken, stiffen and cross link and reattach to each other making the cornea stronger, more stable and in turn halting the disease progression.

The question is if the mode of action of the riboflavin in this clinical indication is a chemical reaction or a pharmacological, immunological or metabolic action.

- Outcome:

The available information indicates that the riboflavin has a dual function, firstly on the production of oxygen free radicals, and secondly by absorbing the UV-A radiation and preventing damage to deeper ocular structures, such as corneal endothelium, the lens and the retina.

The application of riboflavin results in an alteration of the normal chemical process of cross-linking of collagen. Considering this, as well as the definition of medical device and metabolic action included in MEDDEV 2. 1/3 rev 36 (an action which involves an alteration, including stopping, starting or changing the speed of the normal chemical processes participating in, and available for, normal body function), it can be concluded that this product should not be qualified as a medical device.

4.17. Dentistry products with aluminium chloride used in haemostasia

- Background

Dentistry products with aluminium chloride are used in haemostasia. These products contain aluminium chloride in various concentrations. Liquids and gels contain from 20% to 25% aluminium 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 aluminium 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 aluminium chloride reduces the liquid in gingival pocket and closes the smaller blood vessels. The effective retraction when the cord is correctly placed would take few minutes. Some product types additionally contain lidocainum.

[6] http://ec.europa.eu/health/medical-devices/files/meddev/2_1_3_rev_3-12_2009_en.pdf

- Outcome

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

4.18. Qualification and classification of a wound gel containing soluble beta glucan

- Background

The product is a sterile, non-preserved, amorphous and thixotropic wound filling gel containing water, glycerol, carboxymethylcellulose and soluble beta-glucan (SBG) 2%. It is to be administered to the wound surface as a primary wound dressing, which then would be covered with a conventional secondary dressing.

The question is whether such a product would be qualified as a medical device and classified as a class III medical device with ancillary medicinal action under classification rule 13.

The soluble beta-glucan utilised is an aqueous soluble 1,3/1,6-glucan produced from baker's yeast; it is a polymer containing glucose as the only monomer. A 2% formulation in water presents as an adhesive gel-like solution. SBG has been found to be an inducer of innate immune responses through its action on phagocytic cells at the beta-glucan receptor Dectin-1, which stimulates macrophage migration into wounds. The gel product also contains carboxymethylcellulose (CMC) and glycerol, which are both established components of wound healing dressings presented as gels.

The manufacturer claims that the product has as its primary function, as a hydrogel wound dressing, the moistening and an assisting debriding effect in the wound bed. This is achieved by the functionality of glycerol and CMC being able to bind excessive amounts of water (i.e. having a high viscosity event at 1 to 2% concentration), but also by the soluble beta-glucan polysaccharide component which forms a weak gel at a 2% concentration in water.

The soluble beta-glucan is claimed to have a dual action. The ancillary, or medicinal substance effect, is claimed to stimulate the wound healing process by modulating phagocytic cells in the wound bed, especially macrophage functions. Soluble beta-glucan may also contribute to reducing the risk for secondary wound infection by modulating the functions of cells belonging to the innate immunological system and by recruiting phagocytic cells into the wound area.

- Outcome

For this specific product, the data provided sufficient evidence to indicate that while the principal action is exerted by the moist wound healing effect, the soluble beta-glucan which, if used separately, can be considered to be a medicinal product, as defined in Article 1 of Directive 2001/83/EC, is liable to act on the human body with action ancillary to that of the wound healing process. Therefore this product should be qualified as medical device and regarded as a class III medical device under rule 13. This should not be taken to mean, however, that other products containing soluble beta-glucans or other dual action products should be always qualified as medical devices.

4.19. Glycerin suppositories

- Background:

This product is used to relieve occasional constipation. Glycerin suppositories act as a hyperosmotic laxative by drawing water into the intestine. This effect usually results in a bowel movement. Glycerin suppositories act by increasing the transportation of electrolytes through the bowel membrane (osmotic effect) and by stimulating nerve endings of rectum triggering defecation reflex (stimulant effect).

In this case an osmotic process leads to a metabolic effect while the stimulant effect is considered as a pharmacological mode of action.

- Outcome:

Glycerin suppositories are a product intended to treat and prevent constipation that act via a metabolic and pharmacological mode of action and should not be qualified as a medical device.

4.20. D-mannose for the prevention of urinary tract infections

- Background

D-mannose for the prevention of urinary tract infections (UTIs) was placed on the European market in 2015 as a Class IIa medical device.

UTIs are predominantly caused by *Escherichia coli* (*E. coli*). The first step in infection is the adhesion of *E. coli* to the urothelium, the epithelial cells of the urinary tract. This step is mediated by the binding of FimH – a mannose-binding protein located at the tip of bacterial type 1 fimbriae – to the mannosylated proteins, called uroplakins, coating the urothelium.

In vitro experiments have shown that D-mannose binds to FimH, thereby preventing the binding of *E. coli* to the uroplakins. At a sufficient concentration in urine, D-mannose causes saturation of FimH and prevents *E. coli* from colonizing the urothelium. At the same time, the reduction of bacterial levels in urine by D-mannose has also been confirmed in in vivo animal UTI models.

- Outcome

According to the judgment of the Court of 6 September 2012, case C-308/11, Article 1(2)(b) of Directive 2001/83/EC must be interpreted as meaning that, for a substance to be regarded as exerting a "pharmacological action" within the meaning of that provision, it is not necessary for there to be an interaction between the molecules of which it consists and a cellular constituent of the user's body, as an interaction between that substance and any cellular constituent present within the user's body may be sufficient.

Many peer-reviewed journal publications support the molecular interaction between D-mannose and FimH – a cellular constituent of the fimbria of *E. coli* present within the user's body – resulting in the prevention of the adhesion to and colonization of the urinary tract by *E. coli*.

In the light of the above rationale, D-mannose intended to prevent UTI does not act by a mechanical or physical action, but by a pharmacological mode of action. Consequently D-mannose intended to prevent UTIs does not meet the definition of a medical device and should not be qualified as such.

4.21. Solution of 8-MOP in extracorporeal photochemotherapy

- Background

The 8-methoxypsoralen (8-MOP) solution is intended to be used with a system of extracorporeal photochemotherapy. The 8-MOP solution is placed on the market separately. The intended use of the solution is to treat erythrodermic cutaneous T-cell lymphoma (CTCL). The solution is applied to a sample of the autologous mononuclear cells (MNC) outside of the body and 8-MOP is activated by UV illumination. The treated cells are subsequently re-injected into the patient.

The presence of photo activated 8-MOP results in cellular modifications, including cell membrane damage and antigen modification, irreversible cross-linking between 8-MOP and DNA, as well as the formation of covalent bonds with several cytosolic proteins and fatty acids, leading to apoptosis of the treated cells. The principal intended action of this technique is achieved through the activated substance 8-MOP by pharmacological, immunological and metabolic means.

8-MOP would not be an accessory to any of the medical devices used during the therapy, i.e. the apheresis machine or the UV illumination device, as it is not required for these devices to fulfil their intended function.

- Outcome:

In the described case, the 8-MOP solution is intended to treat a specific pathology of the blood (CTCL) by pharmacological, immunological and metabolic action of 8-MOP on autologous MNC.

Consequently, the 8-MOP solution intended to be used with a system of extracorporeal photochemotherapy in the treatment of erythrodermic cutaneous T-cell lymphoma (CTCL), does not fulfil the definition of a medical device and should therefore not be considered as medical device.

4.22. Bone void fillers containing animal growth factors 

- Background

A bone void filler (BVF) made of a resorbable matrix (β-tricalcium phosphate granules (β-TCP, 46 w-%), polyethylene glycol (PEG, 20 w-%), glycerol (31 w-%), stearic acid (1.8 w-%)) and animal growth factors is indicated for the filling of non-load bearing osseous defects of the extremities and pelvis. The manufacturer claims (i) that the matrix provides an osteoconductive scaffold in the bone void for new bone formation and (ii) that the animal growth factors stimulate bone growth and enhance the resorption of the matrix (osteoinduction).

It has been categorised by its manufacturer as a medical device and attributed to class III according to rule 17 of Annex IX MDD concerning devices manufactured with non-viable products derived from animal tissue. Regulation EU 722/2012 lays down particular requirements in relation to the placing on the market of such medical devices. The TSE risk has thus been assessed according to EN ISO 22442. The pharmacological properties of the growth factors have, however, been ignored in the assessment procedure in spite of the claimed osteoinductive action of the animal growth factors.

- Outcome:

With the assumption that the principal intended action of the resorbable BVF is achieved by the osteoconductive matrix and is only assisted in its function by the osteoinductive action of the animal growth factors, the BVF should be qualified as a medical device and attributed to class III according to rules 8, 13 and 17.

In this case, the assessment procedure includes not only

- the risk management measures in connection with tissues of animal origin (as referred to in Directive 2003/32/EC) applied to reduce the risk of infection, but also

- the consultation procedure for medicinal products (see Section 7.4 of Annex I of MDD, and part C of MEDDEV 2. 1/3 rev 3).

If it cannot be clearly established that the osteoinductive nature of the animal growth factors is merely ancillary to the osteoconductive matrix, the BVF will fall within the definition of a medicinal product (see MEDDEV 2.1/3 rev 3 chapter B.4.1 and MEDDEV 2.1/3 rev 3 chapter B.2.1) and should therefore not be qualified as a medical device.

4.23. Weight management products 

- Background

Following dietary intake of carbohydrates, the digestive enzyme alpha-amylase is released. It catalyses the hydrolysis of the alpha-1,4-glucosidic linkages of the starch molecules and eventually converts them into monosaccharides such as glucose which can be absorbed from the intestine. Any excess carbohydrates will be converted into fat following several metabolic routes (e.g. lipogenesis) and stored. Excessive carbohydrate intake over time may consequently result in weight gain and possibly obesity.

The extract from *Phaseolus vulgaris* contains the active ingredient phaseolamin, a proteinaceous substance (glycoprotein) that has been claimed to reduce the activity of alpha-amylase in digesting dietary carbohydrates. When the product is ingested with a starch-containing meal, the active ingredient mimics the molecular structure of starch, and competes with starch molecules for binding to alpha-amylase. Consequently fewer starch molecules will be processed. The reduced amount of carbohydrate being absorbed by the body will decrease the amount of carbohydrates available for conversion into stored fat.

A product based on extract from *Phaseolus vulgaris* is marketed for general weight management and prevention and treatment of obesity. The mode of action is inhibition of the activity of alpha-amylase and as a consequence facilitation of weight loss or reduction of weight gain.

- Outcome:

The product achieves its principal intended action in the human body by inhibiting an endogenous enzyme, which is an alteration of a metabolic process. Therefore the product does not meet the definition of a medical device and should not be qualified as such.

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5. BORDERLINE MEDICAL DEVICE – BIOCIDES

Introduction

General disinfectants fall under the Biocides Directive[7]. Article 1 (2) of this Directive excludes products that are defined or within the scope of Directive 93/42/EEC on medical devices (MDD) and Directive 90/385/EEC on active implantable medical devices (AIMDD).

A guidance document exists for borderline cases between the Biocides Directive and the Cosmetics Regulation as well as a manual of decisions for implementation of the Biocides Directive.

5.1. Hand disinfectants

- Background

A manufacturer directed a request to the Commission services on the qualification of a range of products. These products are hand disinfectants.

- Outcome

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 Community legislation, for example the Biocides Directive.

5.2. Insect repellent

- Background

The product is an insect repellent packaging in a spray and consisting of lactic acid. According to the manufacturer's claims the product is intended to be applied on the human skin and is intended to prevent diseases by preventing human exposure to diseases transferred by mosquitoes. The manufacturer also claims that the product alleviates injuries on the skin

[7] Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market, OJ L 123, 24.4.1998, p. 1–63.

since the product reduces the amount of skin penetration caused by the bites of mosquitoes. According the manufacturer, the mode of action is that the product acts as a barrier on the skin against mosquitoes and other blood sucking insects, with an effect during four hours. Therefore, the manufacturer intends to put its product on the market as a medical device.

- Outcome

This product is primary intended to repel insects in order to prevent mosquitoes and insects bites. This product is not intended to be used principally for a medical use. According to Annex V of Directive 98/8/EC, repellents and attractants products including those that are used for human or veterinary hygiene either directly or indirectly are considered biocides products. In addition, insect repellents are considered to have a primary effect on the insects and not on the human body.

On the basis of the above this insect repellent cannot be consider as a medical device.

5.3. Multipurpose disinfectants

- Background

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 Directive 93/42/EEC.

“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).

" 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)

- Outcome

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

5.4. Brushes and sponges for washing/cleaning nails, hands and/or harms in hospitals (prior to surgery)

- Background

Single use sterile brushes and sponges with or without disinfectants are used by healthcare professionals for washing and cleaning the nails, hands and/or arms before surgical procedures.

Manufacturers claim that, as these products act to prevent infections in patients undergoing surgical procedures, they are medical devices.

- Outcome

Brushes and sponges, with or without disinfectants, for washing and cleaning the nails, hands and/or arms, used by healthcare professionals, do not qualify as medical devices as they do not meet the definition of a medical device according to Directive 93/42/EEC.

Additionally, it should be noted that only products intended specifically to be used for disinfecting medical devices come into the scope of the MDD.

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6. BORDERLINE MEDICAL DEVICE –COSMETIC PRODUCTS

Introduction

Article 1(5) d MDD states that the MDD does not apply to cosmetic products covered by Directive 76/768/EEC on cosmetic products.[8]

It is suggested to consult MEDDEV 2.1/1 section 1.1. (d) for more detailed guidance on the borderline issues concerning cosmetics.

6.1. Tooth whitening or bleaching products

- Background

Dental cosmetic products are intended to clean the teeth and/or to whiten/bleach discoloured 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 whether tooth whitening/bleaching 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.

[8] Council Directive of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products, OJ L 262, 27.9.1976, p. 169, as last amended.

- Outcome

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/bleaching products is not intended to treat the underlying disease; it only may mask a sign of an underlying disease.

Art. 1 of the Directive 93/42/EEC defines that a medical device is intended to be "used for human beings for the purpose of: - diagnosis, prevention, monitoring, treatment or alleviation of disease [..]". This definition clearly establishes 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.

It should be mentioned that, according to the definition of a cosmetic product as laid down in article 2 of Regulation (EC) No. 1223/2009 on cosmetics products ('Cosmetics Regulation') tooth whitening or bleaching products qualify as cosmetic products. This has been confirmed in Annex III of this Regulation (entry 12 (d) and (e)), which sets maximum concentrations of hydrogen peroxide, present or released, use conditions and labelling warnings[9].

Therefore, tooth whitening/bleaching products whether placed within the tooth cavity or placed on the surface of the teeth should not be qualified as medical devices.

6.2. Alum styptic pencils

- Background:

Styptic or haemostatic pencils are sticks made of powdered crystal from an alum block — aluminium sulfate or potassium aluminium sulfate — and a waxy binder, which are pressed into a pencil shape. They are generally used to seal cuts and minor abrasions, especially from razors. They are applied directly to the bleeding site and will stop the bleeding rapidly. The ingredients have astringent properties and act as vasoconstrictor in order to disable blood flow.

Styptic pencils are presently (2015) put on the European market both as cosmetic products and medical devices.

- Outcome:

Styptic pencils are not considered as cosmetic products, since they are intended to come into contact with injured skin. The aluminium sulfate salts provide a local astringent effect. The action of these salts is based on (1) the precipitation of proteins on the superficial layer of the skin which in turn (2) constricts the tissues, thereby (3) controlling the bleeding. The precipitation is a simple chemical reaction leading to the physical blockage of the damaged

[9] OJ l 283, 29.10.2011, p. 36. At the time, the rules were incorporated into Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products, OJ L 262, 27.9.1976, which is now replaced by the Cosmetics Regulation.

blood vessels. As the mode of action of aluminium sulfate salts is other than pharmacological, immunological or metabolic, styptic pencils should fall under the medical devices regulatory route, namely as Class IIa medical devices according to rule 4, third indent of Annex IX of Directive 93/42/EEC.

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7. ACCESSORY TO A MEDICAL DEVICE OR AN IN-VITRO DIAGNOSTIC MEDICAL DEVICE

Introduction

The definitions of accessory read as follows:

Article 1 MDD (b) *'accessory' means an article which whilst not being a device is intended specifically by its manufacturer to be used together with a device to enable it to be used in accordance with the use of the device intended by the manufacturer of the device;*

Article 1 (2)c IVDD *"'accessory' means an article which, whilst not being an in vitro diagnostic medical device, is intended specifically by its manufacturer to be used together with a device to enable that device to be used in accordance with its intended purpose. For the purposes of this definition, invasive sampling devices or those which are directly applied to the human body for the purpose of obtaining a specimen within the meaning of Directive 93/42/ EEC shall not be considered to be accessories to in vitro diagnostic medical devices;"*

It is suggested to consult MEDDEV 2.14/1 for more detailed guidance concerning in vitro diagnostic medical devices, and MEDDEV 2.1/1 on the definition of accessory for medical devices.

7.1. Haemodialysis water test strips

- Background

The matter at hand concerned the question whether the following two products can be considered as an accessory to a haemodialysis machine which is a medical device. Both products are used together with the haemodialysis machine, one is a residual peroxide reagent strip, which confirms, when used, that the residue of disinfection agents used in the haemodialysis machine have been reduced to safe levels. The other is a reagent strip used to test the water in the haemodialysis machine to ensure that the level of water hardness has been reduced to a level where it is safe to proceed with haemodialysis.

- Outcome

From the information provided by the manufacturer of the strips, they do not enable the haemodialysis machine to be used. The strips are used for testing and are not necessary for the functioning of the machine.

According to Article 1 (2) b of Directive 93/42/EEC and the developed guidance (MEDDEV 2.1/1) the decisive criterion to decide whether a product is an accessory to a medical device is whether or not the product is specifically used together with a medical device to enable it to be used in accordance with the use intended by its manufacturer.

The notion "enabled it to be used" implies that the accessory is necessary for the medical device to function.

Therefore, such strips are not considered to be 'accessories' of a medical device within the meaning of Article 1 (2) (b) MDD.

If a manufacturer can claim, substantiated with a solid reasoning that the strips are necessary for the proper functioning of the machine, then these products might be qualified as 'accessories'.

7.2. Surgical instrument decontamination products

- Background

A manufacturer directed a request to the Commission services on the qualification of a range of products. The products in question are surgical instrument decontamination products.

- Outcome

Surgical instrument decontamination products are covered by the definition of accessories to medical devices in Article 1 (2) b of Directive 93/42/EEC. The respective guidance (MEDDEV 2. 1/1) expressively mentions disinfectants specifically intended for invasive medical devices as one example for accessories.

For the classification of these products see paragraph 8.9

7.3. Dental Water Line Disinfectants

- Background

A manufacturer directed a request to the Commission services on the qualification of a range of products. The products in question are Dental Water Line Disinfectants.

- Outcome

Dental Water Line Disinfectants are covered by the definition of accessories to medical devices in Article 1 (2) b of Directive 93/42/EEC.

For the classification of these products see paragraph 8.10

7.4. Sterilization indicators

- Background

The sterilization procedure is monitored routinely by using chemical and biological indicators to evaluate the sterilizing conditions and indirectly the microbiologic status of the processed items.

- Outcome

Sterilization indicators monitor the performance of the sterilizer. They do not affect the sterilization procedure and only provide additional information to the user.

Sterilization indicators do not fulfil either the definition of a medical device laid down in Article 1(2)a of Directive 93/42/EEC or the definition of an accessory laid down in Article 1(2)b of Directive 93/42/EEC as they are not intended specifically to be used together with a device to enable it to be used in accordance with its stated use.

7.5. Microplate washers

- Background

The product is a microplate washer intended to wash standard flat-bottom 96-well plates or microstrips during the enzyme-linked immunosorbent assay (ELISA) in diagnostic laboratories.

This microplate washer is a fully programmable device ensuring multi-step solution ripening and aspiration.

The manufacturer claims that this microplate washer falls within the scope of the Directive 98/79/EC and meets the definition of in vitro diagnostic medical device because this microplate washer is intended for the performance of the ELISA protocols and therefore specifically intended for the use for in vitro diagnostic examination. However, this microplate washer is not used for direct examination of specimens and calculation of the ELISA results and no specific IVD requires this washer to be used to enable the IVD to perform its intended purpose.

- Outcome

This microplate washer is not intended to be used in vitro for the examination of specimens, solely or principally for the purpose of providing information concerning a physiological or pathological state or concerning a congenital abnormality or to determine the safety and compatibility with potential recipients or to monitor therapeutic measures. No specific ELISA requires this washer to be used for in vitro diagnostic tests.

In addition, MEDDEV 2.14/1 rev.1 states in this context:

"if, however, the product does not in fact possess specific characteristics that make it suitable for one or more identified in vitro diagnostic examination procedures, then the manufacturer is not free to bring it within the scope of the IVDD merely by affixing the CE marking to it. In other words, a manufacturer is not able to bring within the scope of the IVDD a product that, in reality, is a piece of general laboratory equipment simply by affixing the CE mark to it".

If this microplate washer possessed such specific characteristics, the manufacturer would have to demonstrate them and the link with one or more specifically identified in vitro diagnostic tests.

On the basis of the above this microplate washer should be regarded as a general laboratory product. This is excluded from the IVDD by article 1 (2) b IVDD.

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8. CLASSIFICATION

Introduction

It is suggested to consult MEDDEV 2.4/1 rev 9 for more detailed guidance concerning the classification rules for medical devices.

8.1. Light box indicated to treat seasonal affective disorder (S.A.D)

- Background

The product in question is a light box that emits bright light and the manufacturer states that light therapy is 'a convenient and effective way of compensating for the lack of light without resorting to medication'. The manufacturer also states: 'in autumn and winter, the seasons with the least sunlight because the days are shorter, increased symptoms resulting from light depravation may be experienced. Even standard artificial lighting in buildings cannot compensate for a shortage of natural light. These statements are effectively claims for treatment of seasonal affective disorder (S.A.D.), which is a recognised medical condition and therefore this product is considered a medical device.

- Outcome

In the classification of this product, it must be decided whether it performs any active action as defined in Annex IX I - Definition 1.5 'Active therapeutic device'.

That is, does it support, modify, replace, or restore biological functions or structures with a view to treatment or alleviation of a disease? If the device performs an 'active' function, then it is class IIa.

8.2. Oxygen delivery

- Background

These products are intended to deliver oxygen to the patient and are connected to active devices such as ventilators, anesthetic machines etc. and / or to a pressure regulator.These devices may be connected to the different kind of oxygen delivery systems with regulators; via oxygen piping to the oxygen supply/oxygen delivery centre, to oxygen bottles/oxygen cylinders or to oxygen concentrators.

- Outcome

In the classification of this product, Class IIa is appropriate based upon rule 2, 5 or 11 of Annex IX.

8.3. Examination gloves coated with polyhexamethylene biguanide (PHMB)

- Background

The case relates to examination gloves with 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.

- Outcome

Examination gloves are usually considered to be Class I medical devices, however MEDDEV 2.1/3 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.

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.

8.4. Picture Archiving and Communication Systems (PACS)

- Background

Basically, a PACS workstation is specifically designed to be networked with a wide variety of diagnostic imaging systems, e.g. x-ray, nuclear medicine, magnetic resonance imaging (MRI) or ultrasound, as well as laboratory or hospital information systems. It does not contain controls for the direct operation of a diagnostic imaging system and is designed to receive, archive, and transmit data both on-line and off-line. It is typically located at a site remote from imaging systems and is configured to provide limited or extensive capabilities to further process, manipulate and/or view patient images and information collected from diagnostic imaging systems. The manufacturer of the PACS states that the system does not influence the radiation of the diagnostic x-ray machine.[10]

Generally speaking there are various types of PACS:

(a) PACS used for viewing, archiving and transmitting images.

(b) Where the post-processing of the image for diagnostic purposes is such as:

- image processing functions which alter the image data (e.g. filtering, multiplanar reconstruction, 3D reconstruction)

- complex quantitative functions (e.g. arterial stenosis evaluation, ventricular volume calculation, calcium scoring, automatic indication (detection) of potential lesions

(c) With image enhancing by controlling image acquisition

- Outcome

In cases where the PACS falls under the definition of a medical device, *i.e.* is specifically intended by the manufacturer to be used for one or more of the medical purposes set out in the medical device definition, the following situations can be foreseen:

(i) In relation to **PACS (a)** intended by its manufacturer to be used for viewing, archiving and transmitting images, it is considered that applying rule 12 could be appropriate and accordingly this type of PACS are generally classified as Class I medical devices. However, PACS that are only intended for archiving or storage of data may not fall within the definition of a medical device provided that data is not manipulated.

(ii) Those types of **PACS (b)** which drive a device or influence the use of a source device fall automatically in the same class in accordance with implementing rule 2.3, which classifies them as Class IIa or IIb. If this type of PACS does not drive or influence the use of the source device, this type of PACS can be classified under rule 10 if such PACS are intended to allow direct diagnosis, classifying them as Class IIa.

(iii) PACS with image enhancing by controlling image acquisition **(c)** should fall into the same class as the source device. This is based upon, firstly, implementing rule 2.3*"Software,*

[10] GMDN code 40943

which drives a device or influences the use of a device, falls automatically in the same class." and the last paragraph of MEDDEV 2.4/1 - rev. 8, Section 3.2 stating that: "*Standalone software, e.g. software which is used for image enhancement is regarded as driving or influencing the use of a device and so falls automatically into the same class. Other standalone software, which is not regarded as driving or influencing the use of a device, is classified in its own right*". Applying this classification rule and the interpretation of the MEDDEV allows this type of PACS to be classified as Class IIa or IIb medical devices according to the classification of the device itself.

8.5. Blood refrigerators, freezers and defrosters

- Background

The product in question concerns blood product cooling devices/blood bank refrigerators. A blood storage refrigerator and a blood storage freezer are devices intended for medical purposes that are used to preserve blood and blood products by storing them at cold or freezing temperatures. Plasma defrosters are designed for defrosting of blood plasma.

- Outcome

Blood storage refrigerators, freezers and defrosters sold for the specific intended purpose of dealing with blood should be medical devices in their own right.

The cooling device or refrigerator store substances that will be eventually delivered into the body and are Class IIa (rule 2). The plasma defrosters are in Class I (rule 1).

8.6. Warming blankets

- Background

This matter relates to the classification of warming blankets. It concerns a manufacturer who markets warming blankets on the basis of warm air, produced by an extra warming device.

The manufacturer considers the blanket to be an accessory to the active device and as such the manufacturer considered it Class I.

- Outcome

1/ Medical device or not?

The medical purpose has to be clearly identified and substantiated to qualify these products as medical devices

2/ If the blanket and the generator are sold as a single medical device:

Classification rule 9 would classify these products as class IIa or class IIb medical devices depending on the state of the patient (which is inherently linked to different levels of risks). When the product is intended to be used on an unconscious patient (who therefore cannot remove the blanket), *e.g.* in reanimation services, the device is to be classified as class IIb

medical device. If the device is intended to be used on a conscious patient (who therefore can react), the device is to be classified as class IIa medical device.

3/ If the blanket and the generator are sold separately:

The blanket sold separately cannot be considered as an active medical device and is a Class I medical device in accordance with rule 1.

The generator sold alone would be class IIa or class IIb in accordance with classification rule 9. The manufacturer will have to specify the use of such generator.

8.7. Products evaluating the condition of respiratory muscles

- Background

The product assists in evaluating the condition of the respiratory muscles. It is a small battery operated device that performs two tests: the Pmax and the Sniff tests. Both tests measure pressure.

The Pmax test operates through the mouth through a voluntary respiratory manoeuvre. This test requires a maximal respiratory effort by the patient. The test starts by a deep breath filling the full capacity of the lungs and then the patient tries to breathe out into a plastic tube which is closed from all sides except the connection to the mouth. The device measures the maximum pressure that is developed in the tube and sustained for at least one second. This pressure is then compared to normal pressures. This is done for both expiratory and inspiratory pressures. The Sniff test measures the pressure that develops in the nose during a sniff manoeuvre. Both tests are supposed to give similar results.

It gives an indication whether the respiratory muscles are working properly. Bad readings do not necessarily indicate a disease but an indication that further clinical investigation might be appropriate. Neither does it monitor any physiological process since it does not allow air flow through it, so it cannot monitor respiration.

- Outcome

The product measures how fast a person can exhale air. It is one of many tests that measure the function of the airways, which are commonly affected by diseases such as asthma. This product is intended to measure the condition of the respiratory muscles and as such is to be classified as a Class IIa medical device in accordance with classification rule 10 third indent.

8.8. Neutral electrodes for high frequency surgery

- Background

The issue relates to the classification of neutral electrodes which are accessories for High Frequency (HF) surgery. In general there are two types of electrodes used in high frequency surgery: those which are ‘active’ concentrate the energy and convert it into heat and those which are ‘neutral’ and simply transfer the energy between two points.

The MEDDEV does not make this distinction and places both electrodes active and neutral under rule 9, consequently they are both considered to be in Class IIb. This is the result from discussions a few years ago, and that is why the MEDDEV puts both electrodes in the same Class IIb. However, manufacturers do make this distinction.

- Outcome

Current guidance (MEDDEV 2.4/1 under rule 9) indicates that all such electrodes should be considered as Class IIb products, irrespective of their nature (active or neutral) as they may be potentially hazardous. It is concluded that the neutral electrodes are medical devices which involve potentially hazardous exchange of energy and should be Class IIb medical devices.

8.9. Surgical instrument decontamination products

- Background

A manufacturer directed a request to the Commission services on the classification of a range of products. The products in question are surgical instrument decontamination products.

- Outcome

These products should be classified according to Rule 15 of Annex IX of Directive 93/42/EEC. This rule 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.

Examples listed in the MEDDEV 2.4/1 include disinfectants specifically intended for instance for endoscopes or haemodialysis equipment, sterilizers specifically intended to sterilize medical devices in a medical environment and washer disinfectors.

8.10. Dental water line disinfectants

- Background

A manufacturer directed a request to the Commission services on the qualification of a range of products. The products in question are Dental Water Line Disinfectants.

- Outcome

These products should be classified according to Rule 15 of Annex IX of Directive 93/42/EEC. This rule 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.

8.11. Dental curing lights

- Background

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 polymerisation) 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 neighboured 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.

- Outcome

It is confirmed that no reclassification is needed and that these products shall be considered as Class I medical devices in accordance with classification rule 12. Also, the guidance MEDDEV 2.4/1 on classification lists the example of "dental curing light" under classification rule 12.

8.12. Bacterial/viral filter for use on patient undergoing pulmonary function testing

- Background

The product is a bacterial/viral filter indicated for single use on patients undergoing pulmonary function testing and its main function is to avoid secretion and moisture deposition in the equipment, reducing the need of frequent decontamination procedures. The equipment is a spirometer, a class IIa active medical device, according Directive 93/42/EC.

The manufacturer states that the product should be classified as class I, because the product does not interfere at all with the diagnostic function of the test machine, and because the energy used by the active device (spirometer) is not exchanged with the patient. In consequence the manufacturer applies the rule for devices not intended for connection to an active medical device.

- Outcome

The product is an invasive device since it is partially inserted inside a natural body orifice (patient's mouth).

The product is intended for transient use, as the duration of contact seems to be usually less than 60 minutes and is intended for connection to a Class IIa active device (spirometer).

On the basis of the above and taking classification rule 5 into account, this device should be classified as Class IIa medical device.

8.13. Hydrocolloid plaster for blisters

- Background

Blisters are resulting from frictional forces that mechanically separate epidermal cells and dermal cells and the separation fills with a fluid. The epidermal cells will be weakened. The blister management could be done by protecting the blister without puncture it or puncturing the blister with a sterile needle and removing the skin on the blister area before placing the plaster.

Hydrocolloids are more effective than ordinary first aid plasters and claim that they promote rapid healing. Indeed, some of hydrocolloid dressing mentions the principle known as moist wound healing to provide the ideal treatment for blisters. Moisture enhances wound re-epithelization since occlusive dressings that maintain moisture and warmth were optimal for healing.

- Outcome

A blister is injured skin.

Hydrocolloid acts by its proprieties on the microenvironment of the blister and is not placed on a blister to act simply as a mechanical barrier for absorption of exudates.

On the basis of the above and taking classification rule 4 and guidance MEDDEV 2.4/1 – rev 8, part 2 into account, it is considered that hydrocolloid which claims promoting rapid healing should be classified as class IIa medical devices.

8.14. Movement monitor for babies

- Background

The manufacturer claims that this product is recommended for all babies, especially during their most vulnerable first 6 months, to help guard against life-threatening events such as Apnoea and Sudden Infant Death Syndrome (SIDS or Cot Death).

A little vibrating motor is used to stimulate babies in neonatal wards that suffer apnoea episodes and can indicate if they are rhythmic or general movements. If the baby becomes dangerously inactive, this product will provide a small tactile stimulation even before human intervention. If breathing effort stops, slows down too much or becomes too shallow the built-in stimulator will gently stir baby to breathe, failing which a loud alarm will alert the nearest adult and consequently should be help by a doctor. The problem is to know whether this product could be considered as a general product or as a medical device or as an active medical device.

- Outcome

This product is intended to help preventing life-threatening events such as apnoea and Sudden Infant Death Syndrome (SIDS or Cot Death). Taking this medical purpose into account this product fulfils the definition of a medical device.

This product is to be connected with a source of electrical energy and could then be considered as an active medical device. According to classification rule 10, this product should be classified as Class IIb medical device.

8.15. Medical devices containing silver

- Background

There are many medical devices being placed on the market containing silver (*e.g.* wound dressing containing silver, coated catheters or secondary bandage to cover primary dressings…). The claims for these products are usually that the silver is acting as an antimicrobial agent in an ancillary manner.

Silver is well known as an antimicrobial agent and is active at low levels. It is considered to be a medicinal substance in its own right when such claims are made.

The question is whether or not silver containing medical devices should be classified as class III medical devices under classification rule 13 of Annex IX.

- Outcome

In general, medical devices containing or coated with silver, specifically those making antimicrobial claims, should be considered as Class III medical devices under classification rule 13 of Annex IX. This is because in order for the silver to act as an antimicrobial agent, it has to be in an available form and therefore would be liable to act on the body.

The Directive 93/42/EEC states that if a device incorporates as an integral part a medicinal substance and that this substance is liable to act on the body with ancillary action to that of the device then the device should be classified as class III medical device. The Directive does not state that the medicinal substance must be intended to act on the body. The fact that the silver is not intended to reach the body or act on the body does not preclude the silver from being liable to act on the body.

There may be some exceptions to this:

If a device does not come into direct contact with the body (for example a secondary bandage intended to cover primary dressings) then a lower classification might be possible, provided that the manufacturer has clear data to support the claims being made and the fact that the silver is not liable to act upon the human body.

If it is claimed that the silver in the product will not act on the body or that it is intended to maintain specific characteristics of the device and would therefore not have any ancillary action, the manufacturer must demonstrate the claim via clinical and scientific data, using suitably rigorous testing to prove that the silver does not leach out of the device. If there is clear data to support such a claim then a product could potentially be classified in a lower class. In the absence of valid data to support such a claim then the product would remain Class III under rule 13.

8.16. Ethyl chloride spray for local refrigeration anaesthesia

- Background

A manufacturer of a spray for local anaesthesia containing ethyl chloride wants to place this product on the market as a medical device. Several other products with a similar intended use and mode of action are already placed on the market as medical devices but with some discrepancies regarding their classification.

In some countries, ethyl chloride is regulated as a medicinal product because of its toxicity and its narcotic properties.

Ethyl chloride is used as local anaesthetic in minor operative procedures and is used also to alleviate pain associated with bruises, contusions, etc…

The rapid vaporization of ethyl chloride when applied as a spray to the skin produces freezing of superficial tissues to -20°C, which results in insensitivity of peripheral nerve endings and a local anesthesia.

- Outcome

In the present case the principal mode of action of ethyl chloride is not pharmacological, immunological or metabolic and therefore this product could be qualified as a medical device.

As stated in MEDDEV 2.4/1 rev.9, medical devices using pre-stored gases and/or vacuum as a power source are regarded as active devices. Consequently this product could be qualified as an active medical device and, according to rule 9 of Annex IX of Directive 93/42/EEC, could be classified as Class IIa medical device.

8.17. Pathogen inactivation system for platelets

- Background

These specific systems for storing platelets are used to protect patients against transfusion-transmitted disease by inactivating pathogens in platelets. The system is designed to inactivate viruses, bacteria, other pathogens and white blood cells in platelets intended for transfusion. This system is composed of a blood bag, a chemical compound and if necessary an illumination device. The compounds have a high affinity for nucleic acids of viruses, bacteria and others pathogens and prevent the replication of the pathogens by damaging the nucleic acid. The chemical compounds could be psoralen-derivatives, riboflavin, ethylene imines and methylene blue. Psoralen-derivatives and riboflavin require a photo-activation by an illumination device to be active.

After the pathogen inactivation process, the chemical compounds could be removed and the platelets are transferred to the final blood bag where they are stored until transfusion.

The question is on the classification of such devices, the blood bag with chemical compounds and the illumination device,

- Outcome

According to MEDDEV 2.1/3 rev 3, "systems intended for the collection, storage and preservation of blood or blood components and as an ancillary function, the treatment of blood or blood components where this effect is achieved outside the human body, are

classified as devices provided that any residual material is not intended to achieve its intended effect when the blood or cells are reintroduced into the body, *e.g.* systems incorporating chemicals activated by light to reduce the viral load where the quantity of chemical remaining has no intended effect when transfused".

According to MEDDEV 2.4/1 rev 9, blood bags are class IIb except if they " have a function greater than for storing purposes and include systems for preservation other than anti-coagulants the other rules (*e.g*. rule 13) may apply". Therefore, if the compound has an ancillary pharmacological or metabolic action, the blood bag with the compound has to be classified as Class III medical device under rule 13.

In the present case, the compound which inactivates pathogens is used to provide an antimicrobial effect and not for the purpose of the preservation of the solution. This antimicrobial effect is considered to be a pharmacological action and therefore the blood bag with the compound should be classed class III under rule 13.

The illumination device is considered to be an accessory of the device as it enables the action of the blood bag with the chemical compound and therefore could be classified as Class IIa medical device under rule 3, as the illumination process modifies the biological composition of blood and consists on exchange of energy.

8.18. Pre-transfusion confirmatory tests

- Background

Pre-transfusion devices are made of a support on which anti-A and anti-B reagents are applied. Those devices are used by nurses and doctors for the pre-transfusion compatibility testing at the patient's bedside. The purpose is to verify the ABO system compatibility between the recipient and the red blood cell component to be transfused immediately before transfusion to prevent any incidental incompatibility.

The simultaneous comparison of agglutination between the recipient's blood and the blood of the donor's bag allows a last verification of the ABO system compatibility between recipient and donor. These devices are considered as In vitro Diagnostic medical devices. The question is whether these devices are falling under Annex II list A of Directive 98/79/EC, which includes *"Reagents and reagent products, including related calibrators and control materials, for determining the following blood groups: ABO system…".*

- Outcome

Although the Pre-transfusion devices are not specifically used for the determination of the ABO system blood groups, those devices include anti-A and anti-B reagents used for the determination of the ABO system blood groups, which are falling under Annex II list A. Therefore, these devices are falling under Annex II list A of Directive 98/79/EC.

8.19. Eye drops regulated as medical devices

- Background

The ocular surface is a physiological complex fundamental in the maintenance of a good visual function, so its integrity must be properly safeguarded irrespective of the use of contact lenses. The use of substances that increase the retention time of the lubricants, tend to increase the contact time between the lubricant and the ocular surface.
According to point 3.1.2.2 of MEDDEV 2.4/1 rev.9 on the Concept of continuous use, if it cannot be demonstrated that components of the device are totally eliminated in the interval between uses, this is also considered as an immediate replacement.
The continued use in situations where there is no lasting relief of symptoms as well as the continuation of aggressive conditions (environmental or not / or due to a number of medical conditions) can lead to the permanent and / or high frequency use (with products whose rate of elimination is unknown), setting the conditions for the continued use of these lubricants.
Considering eye lubricants as examples of medical devices (in which there is no demonstration of their total elimination between applications) destined for continuous use.

- Outcome

According to rule 15 of Annex IX of Directive 93/42/EEC, all devices intended specifically to be used for disinfecting, cleaning, rinsing or, when appropriate, hydrating contact lenses are in Class IIb, and in MEDDEV 2.4/1 rev.9, comfort solutions are given as an example to rule 15.

When qualified as medical devices, eye drops intended for the lubrication of the eyes, should be classified on a case-by-case basis, and would be class IIa or class IIb, in accordance with classification rule 5 of Annex IX of Directive 93/42/EEC, depending on if they are intended for short or long-term use.

8.20. Wound irrigation solutions containing antimicrobial agents

- Background

Irrigation solutions intended for mechanical rinsing are regarded as being medical devices. Topical disinfectants for use on humans are not considered to be medical devices but rather medicinal products. A number of irrigation solutions intended for mechanical rinsing contain ingredients such as chlorhexidine, cetrimide, iodine, hypochlorous acid (HOCl), free chlorine (chlorine/chloride ion Cl2/Cl-), hydrogen peroxide, hypochlorous acid, hydrogen peroxide, chlorine dioxide, sodium hydroxide, sodium chloride and sodium carbonate. Many of these ingredients have an antimicrobial effect on the body. A question arose with regard to the qualification of these products as medical devices and their classification.

- Outcome

MEDDEV 2.1/3 rev.3 states that irrigation solutions for mechanical rinsing are considered to be medical devices unless the principle intended purpose is to provide a local antimicrobial effect. The majority of wound irrigation solutions with antimicrobial action are intended primarily as wound irrigation solutions to mechanically rinse the wound whilst also reducing the bacterial load. The antimicrobial effect may be considered as an ancillary action.

Antimicrobial agents or substances are generally considered to be medicinal substances when intended for a medical purpose. Therefore a wound irrigation solution containing an antimicrobial agent, irrespective of the amount of the antimicrobial substance liable to act on the body, will be considered to be Class III according to classification rule 13.

8.21. Contact lenses

- Background

There are three main types of contact lenses:

- Daily disposable (single use) contact lenses: these single use devices are worn only during the waking period of one day and then disposed of;

- Contact lenses for daily wear (planned replacement): these contact lenses are reusable devices. They are worn only during waking periods; taken out overnight for cleaning, disinfected during the sleeping period, and put back in the eye the following day;

- Contact lenses for extended or continuous wear: these lenses are worn continuously during successive waking and sleeping periods.

- Outcome

The overnight period when lenses are cleaned and disinfected is considered as a discontinuation of the device use. For the determination of the duration of use, only the specified time period of uninterrupted wear of the lens (e.g. 16 hours) needs to be taken into account.

On the basis of the above, contact lenses are classified as follows**:**

- Daily disposable (single use) contact lenses are classified as class IIa medical devices according to classification rule 5, 2nd indent;

- Contact lenses for daily wear with discontinuation of use overnight are classified as class IIa medical devices according to classification rule 5, 2nd indent;

- Contact lenses for overnight wear with discontinuation of use during the day are classified as class IIa medical devices according to classification rule 5, 2nd indent;

- Contact lenses for continuous wear for up to 30 days are classified as class IIa medical devices according to classification rule 5, 2nd indent;

- Contact lenses for continuous wear for more than 30 days as classified as class IIb medical devices according to classification rule 5, 3rd indent.

8.22. Paraffin oil for IVF/ART procedure

- Background

Paraffin oil is placed over the culture media containing the human embryos during an ART or IVF procedure. The paraffin oil overlay is intended to protect the culture medium from evaporation in the incubator, to reduce gas, temperature and pH fluctuation in the medium surrounding the embryos. Besides, the paraffin oil eases the examination of embryos during culture under the microscope.

- Outcome

The paraffin oil protects the medium and embryo from environmental conditions by creating a physical barrier like containers for organs or body tissues and is intended to be used for IVF/ART procedure. When intended to be used for IVF/ART procedure, the paraffin oil should be qualified as a medical device.

Besides, it has been established that the paraffin oil by its relative close contact between the oil and the embryo could interfere on the embryo development.

Thus, by similarly with containers for organs or body tissues, the paraffin oil should be classified as a Class IIa medical device in accordance with classification rule 2 second indent.

8.23. Dental abutments

- Background

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.

- Outcome

MEDDEV 2.4/1 rev. 9 relating to the 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.

8.24. Autologous Platelet Preparation System

- Background

This product is a system which is used in the preparation of autologous platelet rich plasma (PRP) for injection/application in/on the skin surface or wound and is claimed to promote accelerated healing and rejuvenation. The system comprises several devices such as preparation tubes and filters, syringes, hypodermic needles and blunt needles. Each of these devices is CE marked.

The patient's blood is drawn into the preparation tube which contains a gel and an anti-coagulant solution (ACD). The preparation tube is then centrifuged to separate the patient's blood sample into two phases: red blood cells (erythrocytes) and plasma, which contains the platelets. The gel, which has a specific gravity between that of the plasma and red blood cells, acts as a barrier to prevent the two phases reconstituting.

The plasma phase consists of two 'layers': a top layer of Platelet Poor Plasma (PPP) and a bottom layer of Platelet Rich Plasma (PRP). The PPP is removed by inserting a blunt needle syringe into the plasma and then discarded. The remaining PRP is extracted through a filter sleeve, which is placed within the preparation tube, using the blunt needle syringe. The blunt needle is removed from the syringe and replaced with a hypodermic needle which is then used to inject the PRP into the patient.

The manufacturer has classified and CE marked the preparation tube, containing the gel and anti-coagulant solution (ACD), as a Class IIa medical device under Rule 3 as he means the tube to be a non-invasive device modifying the composition of blood (with the aid of centrifugation) and intended for infusion into the body.

Anti-coagulant solution (ACD) is considered to be a medicinal product as defined in Article 1 of Directive 2001/83/EC and according to Rule 13 of Annex IX of Directive 93/42/EEC 'all devices incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product as defined in Article 1 of the Directive 2001/83/EC, and which is liable to act on the human body with action ancillary to that of the devices, are in Class III'.

However, as per MEDDEV 2.4/1 Rev. 9, this rule does not cover those devices incorporating substances which under other circumstances may be considered as medicinal substances, but which are incorporated into the device exclusively for the purpose at maintaining certain characteristics of the device and which are not liable to act on the body.

The appropriate classification of the preparation tube, containing the gel and anti-coagulant solution (ACD) was queried, specifically the appropriateness of Rules 3 and 13. The appropriate classification of the filter sleeve was also queried.

- Outcome

Anti-coagulant solutions (ACD) and preservative solutions for human blood have a European Pharmacopeia monograph of 0209 and would be considered to be a medicinal product as defined in Article 1 of the Directive 2001/83/EC.

Considering the anti-coagulant solution (ACD) is mixed with the blood during manipulation of the patient sample, the anti-coagulant solution (ACD) is liable to act on the human body when PRP is introduced in or used on the human body.

Therefore, the platelet preparation tubes, containing the anti-coagulant solution (ACD), may be classified as a Class III medical device under Rule 13 in the case where either the PRP

infusion that the patient receives contains medicinal substances or in circumstances where the manufacturer cannot appropriately demonstrate that such medicinal substances have been completely removed from the PRP infusion. In the case where this can be demonstrated, the second indent of Rule 3 of Annex IX to Directive 93/42/EEC may apply due to the treatment process consisting of a centrifugation step.

Analogy to Rule 18 of the above mentioned Annex which classifies blood bags, including those containing or coated with an anticoagulant, as Class IIb medical devices was made. This rule, however, is a special derogation rule which is exclusively applied to blood bags and cannot be extended to other product which may contain an anti-coagulant solution.

Sleeve filters should be classified as a Class IIa medical device under Rule 3 of Annex IX of Directive 93/42/EEC according to which all non-invasive devices intended for modifying the biological or chemical composition of blood, other body liquids or other liquids intended for infusion into the body are in Class IIb, unless the treatment consists of filtration, centrifugation or exchange of gas or heat, in which case they are in Class IIa.

In the scenario where the system is placed on the market containing one or more medical devices not bearing valid CE marking the system shall be treated as a device in its own right. In the same manner, where the manufacturer of the system changes or modifies the IFU for the medical devices included in the system, or creates a new IFU in order to claim the production of PRP, the system shall be treated as a device in its own right. The applicable conformity assessment procedure shall be determined by the medical device component with the highest classification i.e. the platelet preparation tubes containing the anti-coagulant solution (ACD). Therefore, the entire system would be classified as a Class III medical device under Rule 13 where either the PRP infusion that the patient receives contains medicinal substances or in circumstances where the manufacturer cannot appropriately demonstrate that such medicinal substances have been completely removed from the PRP infusion.

8.25. Antimicrobial Photodynamic Therapy (APDT) systems

- Background

Photodynamic laser-based disinfection systems, activated by a topical photosensitiser, are intended for the decolonization of potentially-pathogenic bacteria, including methicillin-resistant 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 photosensitiser immediately transfers energy to surrounding molecular 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.

- Outcome

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,
- they are typically sold separately from the laser.

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, are not considered to be an integral product at the time of use and, therefore, cannot qualify as a Class III medical device under Rule 13.

8.26. Tissue expanders used in the breast

- Background

The product is intended by the manufacturer to be introduced under the skin in the breast area, during a breast reconstruction or breast augmentation when there is not enough skin to accommodate a permanent implant.

The tissue expander consists of an expansion envelope with fill tube and an inflation valve. The device is filled every week or fortnight with saline solution causing the skin to stretch and grow until the achievement of the required volume. Once the skin has expanded sufficiently (generally in 6 to 9 months), the device is removed and a permanent breast implant is placed.

The directive 2003/12/EC required that the breast implants should be classified as class III medical devices.

The question under consideration is since the breast expanders are introduced in the breast area should these devices be covered by Directive 2003/12/EC.

- Outcome

The breast expander is implanted into the body by surgical intervention and is intended to remain in place after the procedure for at least 30 days, the tissue expander is an implantable device.

Considering that this implantable device is placed in the breast tissue, it should be considered that a breast tissue expander is a breast implant.

Thus, by application of the Directive 2003/12/EC, the breast tissue expander should be classified as a class III medical device.

8.27. Dura guard for use with a craniotome

- Background:

The cranial dura mater is the outermost layer of the meninges which cover the brain. It lines the interior of the skull. The outer surface of the cranial dura mater adheres closely to the inner surface of the cranial bone.

The dura guard device is intended to be attached to the craniotome during a craniotomy procedure to prevent the drill of the craniotome from damaging the dura mater.

- Outcome:

The dura guard device is for use with a craniotome and is a device in its own right which is specifically intended by its manufacturer to protect dura mater during a craniotomy procedure.

To achieve its protective function, the device will come in contact with the inner surface of the cranial bone. The outer surface of the cranial dura mater is in contact with the inner surface of the cranial bone.

As the dura guard will get into contact with the inner surface of the cranial bone it will also come in direct contact with the cranial dural mater.

The contact with dura mater cannot be considered as accidental. Therefore, in normal conditions of use, the dura guard device is specifically for use in direct contact with the central nervous system (dura mater) and should be classified as a class III medical device in accordance with rule 6 of annex IX of Medical Devices Directive.

8.28. Heart bypass cannulae

- Background

Open heart surgery is performed with the use of the heart-lung machine, also called cardiopulmonary bypass machine that can interrupt the circulation by taking over the functions of the heart and lung while the heart is stopped. The blood is shunted thanks to different catheter/cannulae in contact with the heart or the central circulatory system. The surgery is performed for a duration of under 6 hours.

The aortic cannula is inserted in the aorta and is intended to carry oxygenated blood from the haemofilter to the heart. The venous cannula is inserted in the vena cava and/or the right atrium and is intended to drain non-oxygenated blood from the heart to the reservoir.

- Outcome

The aortic cannula and the venous cannula are specifically intended to be used in cardiopulmonary bypass surgery, in a context of a defect of the heart (stopped heart).

They are intended to channel the blood from the heart or the central circulatory system and back into the central circulatory system in order to replace heart function.

In order to establish circulation, a cardiopulmonary bypass circuit is created and the venous and aortic cannulae are parts of the essential elements of the circuit.

It is considered that maintenance of blood circulation using a circuit whose parts are in direct contact with the central circulatory system and/or the heart constitutes control of a heart defect.

Besides, the Meddev 2.4/1 rev.9 quotes "thoracic catheters intended to drain the heart" as examples of class III medical devices per rule 7.

On the basis of above, aortic perfusion cannulae and venous drainage cannulae should be classified as class III devices per rule 7 of Annex IX of Directive 93/42/EEC.

8.29. Liquid nitrogen for cryopreservation of cells and tissues of human origin for medical purpose

- Background

Liquid nitrogen, packaged in closed pressurized containers available in different sizes or in fixed closed pressurized tanks connected by a vacuum pipe to cryogenic containers, is used for preservation of cells and tissues of human origin, intended to be re-implanted or re-used in the human body. Liquid nitrogen has a medical purpose, even if direct contact with biological material does not occur.

- Outcome

Liquid nitrogen for cryopreservation of tissues and cells of human origin, intended to be re-implanted or re-used in the human body, should be regulated as medical device although there is no direct contact with tissues and cells.

For this intended use liquid nitrogen should be classified in class IIa based on rule 2.

8.30. Whole body and partial body cryotherapy chambers 

- Background

Cryotherapy chambers deliver intense cold (around –110°C) to the body for short periods of time (around 3 minutes). The whole body could be exposed (Whole Body Cryotherapy - WBC) or the body with the exception of the head (Partial Body Cryotherapy - PBC).

Cryotherapy chambers which are medical devices are intended by their manufacturers to be used for pain relief, limitation of oedema post-surgery, treatment of rheumatologic pathologies and muscular injuries, and/or for reduction of inflammation.

- Outcome

WBC and PBC devices generate a temperature around -110°C. The site of action of the WBC and PBC devices is the whole body, including the extremities such as feet, hands and, for whole body cryotherapy, the head, which are particularly sensitive to the cold. According to

contraindications given by the manufacturers, use of such devices may affect the vital physiological functions of the patient. Their use entails potential hazards: asphyxiation, hypoxia or oxygen deficiency, as well as frostbite, burns and eye injury.

As these devices exchange energy with respect to the human body in a potentially hazardous way, they should be classified as active therapeutic devices class IIb according to rule 9.

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9. SOFTWARE AND MOBILE APPLICATIONS

Introduction

Software and mobile applications that fall under the definition of a medical device or an *in-vitro* diagnostic medical device are regulated by the respective Directives 93/42/EEC[11] or 98/79/EC[12].

In the context borderline cases, the MEDDEV Guidance 2.1/6, entitled "Guidelines on the qualification and classification of stand-alone software used in healthcare within the Regulatory Framework of Medical Devices" and released by the Commission services in January 2012, is the most relevant document which provides practical advice to manufacturers, organisations and public authorities on how to determine when a software falls under the definition of a medical device or of an *in-vitro* diagnostic medical device. Such criteria apply also to mobile applications.

9.1. A mobile application for processing ECGs

- Background

This application -or app- (software program) allows clinicians to review a patient's ECG history during routine check-ups and see a full presentation generated by the analysis algorithms. ECG-related and supplementary data can be received wirelessly, for example from the hospital ECG management system.

The app's intended use is to allow for more timely and accurate diagnosis and treatment of the patient.

- Outcome

This app, which is not incorporated to a medical device, uses signal data from an external source and processes it to an ECG waveform thereby performing an action on data other than just storage, for the medical benefit of individual patients.

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[11] OJ L 169, 12.7.1993, p.1.

[12] OJ L 331, 7.12.1998, p.1.

In accordance with the guidance document MEDDEV 2.1/6 rev. 1[13], such a mobile app for viewing ECGs should be qualified as standalone class IIa medical device, according to Rule 10 of Annex IX to Directive 93/42/EEC.

9.2. A mobile application for the communication between patient and caregivers while giving birth

- Background

This app allows storing data on each moment of contraction during delivery, after a healthcare professional established that a woman is in the process of giving birth. Users can make notes and take pictures for the purpose of exporting them to an external website also providing documentation for a later stage.

The app's intended use is to improve the quality of communication between the patient and caregivers.

- Outcome

This app, which is not incorporated in a medical device, performs an action on data limited to storage and simple search.

In accordance with the guidance document MEDDEV 2.1/6 rev.1, a mobile app for the communication between patients and caregivers while giving birth should not be qualified as a medical device.

9.3. A mobile medical application for viewing the anatomy of the human body

- Background

This app allows users to view illustrations of the anatomy of the human body. In addition, it introduces the reader to anatomical terminology, positioning and medical imaging.

- Outcome

Although the app is not only performing simple data search it is not used directly for the medical benefit of the individual patients. In light of this, this app should not be qualified as a medical device.

9.4. Qualification of software for interpretation of a guideline

- Background

The product in question consists of a software application which allows for faster consulting/reading of an international guideline regarding the Classification of Malignant Tumours (TNM) issued by the UICC (International Union Against Cancer), in the view of classification of cancer by anatomic disease extent.

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[13] http://ec.europa.eu/health/medical-devices/documents/guidelines/index_en.htm.

Three variables are introduced into the system:

- the size of the primary tumour and whether it has invaded nearby tissue (described as T0, T1, T2, etc.);
- regional lymph nodes that are involved (indicated as N0, N1, N2, etc.);
- metastasis (M0 or M1).

According to the selection of these 3 categories/variables, the application indicates the disease's stage of development (cancer extent), according to the above mentioned guideline.

According to the manufacturer this information software simply facilitates the search and use of an international guideline which physicians usually consult via electronic file, or in paper format.

- Outcome

The software does not perform an action on data other than simple search function, as per in MEDDEV Guidance 2.1/6.

The product does not therefore fulfil the definition of medical device, according to Directive 93/42/EEC, and should not be qualified as such.

9.5. Qualification and classification of software for delivery and management of cognitive remediation and rehabilitation programs

- Background

This software is designed to deliver and manage cognitive remediation and rehabilitation programs and is intended to be used for the treatment of a variety of neurotrauma, neurodegenerative and neuropsychiatric conditions.

The software contains different programs designed for targeted stimulation of cognitive functions, by using interactive games and exercises. Such cognitive functions include executive functions (reasoning and strategy), verbal memory, visual memory, spatial memory, auditory memory, processing speed. This software also allows the clinician to plan, monitor and assess the patient's progress throughout the treatment plan.

- Outcome

Based on the intended purposes, namely the treatment of disease, injury or handicap, this software should be qualified as a medical device. When such software qualifies as a medical device it shall be classified as class I medical device according to rule 12 of Directive 93/42/EEC.

9.6. Classification of software for information management and patient monitoring

- Background

The product in question is a software-based system that includes an informatics management and patient monitoring platform. The informatics management component of the software is intended to route and store medical device data and device diagnostic information from supported bedside devices to the electronic medical record and clinical information system. The patient monitoring platform is intended to allow health care professionals remotely consult a patient's status and remotely review other standard or critical near real-time patient data, waveforms and alarms in order to utilize this information to support clinical decisions and deliver patient care in a timely manner.

The patient monitoring platform has the following functions:

1. view collated patient information and track changes in patient history;

2. generate audible alerts when an alarm is coming through the system;

3. generate trend graphs which include red-shading when an alarm is sounding;

4. set patient specific "filtering rules" based on alarm severity and alarm type. These alarm rules support the ability to suppress specific alarms, delay specific alarms and separate rules for visual, audio, and paging of alarms;

5. send SMS and e-mails and filter alarm forwarding to 3rd party annunciation systems.

- **Outcome**

This system is intended to be used in intensive care wards with ventilators, pulse oximeters and other devices used for monitoring patients, although similar systems could be used with devices for monitoring non-vital physiological processes. Per MEDDEV 2.12/6 clinical information systems are not qualified as medical devices. The patient monitoring platform contains a number of different functions, each of which must be assessed when determining whether the software meets the definition of a medical device using the criteria described in MEDDEV 2.1/6.

Per MEDDEV 2.1/6 "if the software does not perform an action on data, or performs an action limited to storage, archival, communication, "simple search" or lossless compression (i.e. using a compression procedure that allows the exact reconstruction of the original data) it is not a medical device". This is applicable for the listed functions performed by the patient monitoring platform with the exception of the alarm filtering function.

The software is not considered to be "generating" an alarm as it is the bedside device that generates the alarm based on its analysis of patient physiological data. The bedside device also assigns a severity to that alarm. While this software does not generate the original patient alarm, it applies user-defined filtering rules to each alarm category (e.g. severity) received by the software. This filter function is considered to be performing a search of the nearly "live" data received from the bedside device that results in a specific action being taken on that alarm i.e. alarm is delayed. The action of the filter function is not considered a "simple search" of archived data. The delay to the alarm that results from the filter function is considered to lead to the generation of new or additional information that contributes to the monitoring and follow-up of the patient connected to the bedside device. If an alarm is noted on the system the users are instructed to interact with the bedside device, which would be considered to be influencing the use of the bedside device.

Therefore this software, having one of its functions qualified as medical device, complies with the definition of a medical device and should be qualified as such. When classifying this device implementing rule 2.3 of Annex IX applies.

9.7. Mobile application for managing pictures of moles

- Background

This app allows users to take pictures of moles on the skin and subsequently store them for the purpose of managing these picture and showing them to a doctor when it is suspected that visible characteristics of the mole change over time.

- Outcome

This app, which is not incorporated in a medical device, does not perform an action on data other than just storage. In accordance with the guidance document MEDDEV 2.1/6 rev. 1, this mobile app should not be qualified as standalone medical device software.

9.8. Mobile application for the assessment of moles

- Background

This app allows users to take pictures of moles on the skin and subsequently store and compare them. Based on image processing algorithms, the app provides detailed assessment of the scanned moles. Additionally, the app assesses the probability that the scanned mole is a melanoma in order to support early diagnose of skin cancer.

- Outcome

This app, which is not incorporated in a medical device, uses computer image processing technology to make assessments of the moles, whereby performing an action on data other than just storage, for the medical benefit of individual patients. In accordance with the guidance document MEDDEV 2.1/6 rev. 1, a mobile app for the assessment of moles should be qualified as standalone class I medical device, according to Rule 12 of Annex IX to Directive 93/42/EEC.

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10. APPENDIX

Below are listed the examples mentioned in the MEDDEV 2.1/3 rev **2** that have not been included in the MEDDEV 2.1/3 rev **3**.

These examples will be subject to further discussion in the future and will be added to the relevant sections of this Manual.

However at present these products are regulated as per MEDDEV 2.1/3 rev 2.

Therefore, in order to avoid any gap in the guidance for manufacturers and notified bodies, information on their current qualification according to MEDDEV 2.1/3 rev 2 can be found below:

10.1. Products currently qualified as medical devices according to MEDDEV 2.1/3 rev 2

- Products containing collagen where adhesion of platelets to the surface triggers platelet adhesion and aggregation

10.2. Products qualified as accessory to medical devices according to MEDDEV 2.1/3 rev 2

- Challenge tests specifically intended to assess the tolerance to a given medical device, or its constituents (*e.g.* injectable collagen).

10.3. Products currently qualified as medicinal products according to MEDDEV 2.1/3 rev 2

- Haemofiltration substitution solutions,

10.4. Products qualified as medical devices incorporating a medicinal substance with ancillary action according to MEDDEV 2.1/3 rev 2

- Blood bags containing anticoagulant or preservation agents

- Haemostatic devices enhanced by the incorporation of collagen, where the primary action of the device is mechanical even though there may be ancillary action due to the presence of collagen having demonstrable action with platelet receptors resulting in platelet adhesion through a pharmacological process

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