Central Management Committee Decision

PROTECTING PUBLIC HEALTH TOGETHER

CMC Decisions on Classification and Borderline Queries

Ref. number: 1-A

A. Wound irrigation solutions containing antimicrobial agents

Decision of the CMC

The majority of wound irrigation solutions with antimicrobial action are intended primarily as wound irrigation solutions and not as topical disinfectants. They are intended to mechanically rinse the wound whilst also reducing the bacterial load. The antimicrobial effect may be considered as ancillary to the primary mechanical action.

MEDDEV 2.1/3 Rev 3, section A.2.2.2.2 states that topical disinfectants for use on patients are considered to be medicinal products. This refers to products where the main intended purpose is to disinfect. This is confirmed by section A.2.1.2. which 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. Such products therefore, provided they are intended primarily for mechanical rinsing will be qualified as medical devices.

Whilst a non-medicated wound irrigation solution would be accepted as a Class IIb medical device, medical devices containing medicinal substances are considered to be Class III under classification rule 13. Antimicrobial agents are considered to be medicinal substances when intended for a medical purpose therefore a wound irrigation solution containing an antimicrobial will fall within classification rule 13. This will apply irrespective of the amount of the antimicrobial substance where it is liable to act on the body, since the medical device directive does not specify the concentration of the medicinal substance in a device.

Background

Irrigation solutions intended for mechanical rinsing are regarded as being medical devices.

Topical disinfectants for use on patients are not considered to be medical devices but rather medicinal products, since they are intended to disinfect the patient.

A number of irrigation solutions intended for mechanical rinsing contain ingredients such as hypochlorous acid (HOCl), free chlorine (chlorine/chloride ion $Cl2/Cl^-$), hydrogen peroxide, hyprchlorous acid, hydrogen peroxide, chlorine dioxide, sodium hydroxide, sodium chloride and sodium carbonate. Many of these ingredients have a disinfectant / antimicrobial effect on the body in a similar manner to antimicrobial agents such as chlorhexidine, cetrimide and iodine.

A question arose with regard to the qualification of these products as medical devices and their classification.

Date of the Decision: 23rd February 2011

B. System to determine bacterial contamination in blood products

Ref. number: 1-B

Decision of the CMC

These devices are intended to reduce the risk of transfusion reaction due to bacterial contamination. They are intended to provide information to determine the safety of the blood donation with the potential recipient. This system comes within the definition of an in vitro diagnostic medical device because it is intended to be used in vitro for the examination of specimens, including blood and tissue donations derived from the human body for the purposes of providing information to determine the safety and compatibility with potential recipients.

Background

The bacterial contamination of blood components represents the highest infection risk in blood transfusion; the risk is particularly high when it affects platelet concentrates. It is usual to determine the bacterial status near to the time of transfusion through the use of such techniques as gram staining or bacterial culture, often in the form of specific syetems to detect bacteria in blood components.

One such system involves a system for specific labelling of a wide spectrum of common pathogenic bacteria by flourencene. After this a direct count is obtained by cytometry.

The question was raised as to whether this system would come within the remit of the in vitro diagnostic medical device directive.

Date of the Decision: 23rd February 2011

3. Qualification of Gallipots as medical devices

Ref. number: 1-C

Decision of the CMC

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.

Background

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”, *”a* small glazed earthenware jar formerly used by druggists for medicaments”, and a small usually ceramic vessel with a small mouth; especially: one used by apothecaries to hold medicines’.

Date of the Decision: 23rd February 2011