IMPORTANT PRODUCT INFORMATION

For the Attention of Pharmacists, Nurses and other Healthcare Professionals

DEFINITIONS: [1].

Products making medical claims, as a general rule, will be regulated either by the *Medical Devices Regulations* or by *Medicines Legislation*.

The revised DEFINITION OF A MEDICINE is:

I. *Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or*

II. *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 also provides that, 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 the Directive shall apply.

The definition of a MEDICAL DEVICE is:

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

BACKGROUND – Historical note:

Over time the classification of particular products has changed in accordance with changes in EC Legislation. Legislation on medicinal products predated the Medical Device Regulations (MDR).

This meant that when the MDR came into force or was subsequently amended, as with the change of definition of a medicinal product in Directive 2004/27/EC (amending Directive 2001/83/EC) which came into force on the 30th October 2005 a number of products were then regulated as Medical Devices.

The MDR have now been in place for over 10 years. However there may still be areas where the regulatory classification is unclear, particularly where products incorporate or are used to administer a medicinal product.

DETERMINATION OF REGULATORY ROUTE

In order to decide whether a product is considered a medical device or a medicinal product, the following points should be considered:

- *the intended purpose of the product taking into account the way the product is presented;*
- *the method by which the principal intended action is achieved.*

In the case of a medical device, the principal intended action is typically fulfilled by physical means (including mechanical action, physical barrier, replacement of, or support to, organs or body functions).

The action of a medicinal product is typically achieved by pharmacological, immunological or metabolic means; a substance administered for

diagnostic purposes, even though it does not act in such ways, is also usually considered to be a medicinal product.

Medical devices may contain medicinal substances which act on the body in a manner ancillary to the device. However, where such substances act in a manner that is more than ancillary, the product is regulated as a medicinal product rather than a medical device.

A **Notified Body**, in the *European Union*, is an organisation that has been accredited by a *Member State* (in the case of the UK this is the MHRA) to assess whether a product meets certain preordained standards. Assessment can include inspection and examination of a product, its design and manufacture. For example, a Notified Body may designate that a *medical device* conforms to the EU *Medical Devices Directive*, which defines the standards for medical devices. With this Declaration of Conformity, the manufacturer can label the product with the *CE Mark*, which is required for distribution and sale in the EU.

Hydro-Caine Gel® has been given this designation and approval by a Notified Body and is cleared for sale and distribution within the EU.

1. http://www.mhra.gov.uk/home/groups/es-era/documents/publication/con007498.pdf

Prosys™

Hydro-Caine®

Lubricating Gel

DESCRIPTION

Hydro-Caine Gel® is a sterile aqueous lubricating gel presented in a sterile package.

A CE mark is applied by CliniSupplies to confirm that the device meets the appropriate regulatory requirement for the intended use in the following:

Hydro-Caine Gel® is a lubricant intended for use prior to urethral and suprapubic catheterisation. Other uses include rectal and colonic procedures, urethral dilatation and other instrumentation of the urethra. Lubricating gels are widely used in gynaecological and hospital procedures.

Hydro-Caine Gel® is Certified to

Annex11 Section 3 of council directive Med/Dev 93/42/EEC concerning Medical Devices certificate 668 110711

Annex11 Section 4 of council directive Med/Dev 93/42/EEC concerning Medical Devices certificate 669 110711

INGREDIENTS

Hydro-Caine Gel® comes in the form of a gel of Hydroxyethylcellulose, Propylene Glycol Lubricants* and purified water.

Each 100 gram gel contains:

- **Chlorhexidine Gluconate Solution** 20% Antiseptic (w/v) **0.250g**
- **Methyl Hydroxybenzoate** (E218) Preservative **0.060g****
- **Propyl Hydroxybenzoate** (E216) Preservative **0.025g****
- **Lidocaine Hydrochloride** Anaesthetic **2.000g**

*may cause allergic reactions (possibly delayed)
**may cause skin irritation

CONTRAINDICATIONS

Hydro-Caine Gel contains lidocaine, chlorhexidine, E216 and E218 (also called parabens). The gel should not be used if you know that you are allergic or hypersensitive to these or any of the other ingredients. The gel should not be used if it is going to be in contact with damaged membranes. Tell the person who is going to use the gel if any of these apply to you.

Not to be used in medical procedures where the primary function is anaesthesia.

SPECIAL CARE

Tell the person who is going to use the gel

- **if you have heart problems**
- **if you have liver problems**
- **or if you are epileptic**

Also tell this person if you are taking any medicines for treating irregular heartbeats.

Version 2

CLINISUPPLIES
Ideas into solutions

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