European Alliance for
Access to Safe Medicines

→ WHEN IS A MEDICINE NOT A MEDICINE?

UNLICENSED PRODUCT USE IN PRE-OPERATIVE SETTINGS

Unlicensed products made and intended for use as general disinfectants and cleansers, are used for pre-operative skin disinfection. →

Unclear and ambiguous product labelling that allows unlicensed product to circumvent a regulatory intention measure clouds this issue. There are clear reasons why it is totally unacceptable to put patients at risk at their time of greatest vulnerability – on the operating table.

During treatments and procedural techniques, professionals, having a duty to ensure the delivery of safe and therapeutic care, are required to act in the best interests of their patients and to minimise risk at all times. Intentional or not, the use of unlicensed products as medicines can put patients at avoidable risk.

1→ Why is this a Patient Safety Risk?

Using unlicensed, unsuitable products for pre-operative skin disinfection, unwittingly or otherwise, could cause damage to the patient's body and be less than effective in preventing surgical site infections.

Additionally, without the knowledge or consent of the patient, and often the surgeon, this malpractice destroys the vital bond of trust between clinician and patient. When a patient signs a pre-operative release form he or she implicitly trusts that the treatment will be the very best available. Patients assume that equipment, medicines or other substances used prior to, during or following surgery, are appropriately licensed.

EU and Member State regulations seem to support that view but, as the EAASM has discovered, even here, a 'medicine' is not always a medicine.

2→ Medical and Licensing Background to this Dangerous Regulatory Loophole

There are three main substances used for patient pre-operative skin preparation:

- Traditional Idophors
- Alcohol
- Chlorhexidine
- (and combinations of the above)

Chlorhexidine is highly recommended by at least 17 organisations and initiatives, with 11 specifically advocating a 2% formulation.[1] The only such preparation holding a UK marketing authorisation is ChloraPrep®.

A study published in the *New England Journal of Medicine* states that pre-operative skin cleansing with ChloraPrep® is superior to cleansing with povidone iodine for preventing surgical-site infection after clean-contaminated surgery.[2]

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By law, before a medicine is placed on the market, it must be given a marketing authorisation (product licence) by a medicines regulator (the MHRA in the UK). The MHRA also inspects the factory where the medicine is to be made, to make sure that supplies will be of a uniformly and consistently high standard. These checks are not one-offs but continue throughout the existence of the site.

The licensing system is designed to:

- Guarantee that all those involved are answerable for their actions
- Ensure that processes, supplies and quality can be thoroughly monitored
- Enable swift corrective action to be taken when needed

The MHRA has also stated that: "The consequences of using even simple medical devices outside their intended purpose can be serious."[3]

An update to MHRA guidance published on 18 June 2008 is quite clear on which products require marketing authorisation: "wipes/swabs containing antiseptics/antimicrobials such as chlorhexidine, iodine, cetrimide and similar will remain as medicinal products and therefore will continue to require a marketing authorisation."[4]

The licensing requirement appears to be clear. However, a loophole exists which seriously compromises patient safety as it is enabling unlicensed products to be used for pre-operative skin disinfection.

Products used for the disinfection of humans may be regulated as biocides or medicinal products, depending upon their **intended** purpose. According to the MHRA, those considered to be medicinal products will require a marketing authorisation.

- Disinfectant products intended for use by the general public or by healthcare professionals for hand cleansing are usually considered to be biocides and do not require a marketing authorisation
- Products specifically intended as surgical scrubs for use prior to operative procedures are usually considered as medicinal products and do require a marketing authorisation
- Disinfectant products intended for use on patients are considered to be medicinal products, including swabs, solutions to disinfect wounds, and topical antiseptics and do require a marketing authorisation

Products that are intended for use as multi-purpose hard surface disinfectants, cleansers and or general environmental disinfectants should come within the regulations covering biocides.

Poor labelling of products, regarding what they should or should not be used for, can and does lead to the wrong product being sourced and used on patients pre-operatively, putting them and those charged with their care at avoidable risk.

1 → http://www.chloraprep.co.uk/evidenceBasedGuidelines.html

2 → Darouiche RO, Wall MJ, Itani KMF et al: Chlorhexidine-Alcohol versus Povidone-Iodine for Surgical-Site Antisepsis. N Engl J Med 2010; 362: 18-26

3 → MHRA Medical Device Alert: MDA/2004/006 Issued: 2 February 2004

4 → Medicated and alcohol based wipes and swabs. Medicines and Healthcare products Regulatory Agency; www.mhra.gov.uk/Howweregulate/Medicines/Medicinesregulatorynews/CON020666 Last accessed 30.03.11