The Association for Perioperative Practice (AfPP)

Guidance on the Use of Unlicensed Products in Pre-Operative Skin Preparation

Introduction

This guidance document is intended for National Health Service (NHS) and Independent Hospital staff in surgical theatres across the UK regarding the use of unlicensed products for skin antisepsis prior to surgery. In particular, it relates to the use of unlicensed biocides or products classed as medical devices. It is concerned with the use of these products beyond their license for pre-operative skin antisepsis in surgical theatres.[i]

Prescribing Unlicensed Products: A Summary of Current Guidelines

The MHRA outlines in 2020 guidance that in normal circumstances, products that are to be used for skin antisepsis should be regulated by, and have received market authorisation from, the Human Medicines, Regulation 2012.[ii] A statement released by the Royal College of Surgeons and the MHRA also outlines that:

"While NICE recommends either chlorhexidine or povidone-iodine for pre-operative antisepsis, operating theatres should be using the medicinally licensed product over those which are classed as a general disinfectant."[iii]

However, the MHRA also outlines that products may be used outside of license by the Human Medicines Regulation 2012 in two particular circumstances.

- **When a licensed product cannot meet an individual patient's clinical needs**. This could include, for example, intolerance or allergy to a particular ingredient. This should not extend to reasons of cost or convenience.
- **When there is a shortage of licensed products**. Temporary supply issues may necessitate the use of unlicensed alternatives.[iv]

In the instance that an unlicensed product is used to meet the clinical needs of an individual patient, the MHRA "expects that documentary evidence of this special need should be obtained by manufacturers, importers or distributors."[v]

The Responsibility of Prescribers when using Unlicensed Products

The General Medical Council (GMC) also provides additional information in its 2021 Good Practice in Prescribing and Managing Medicines and Devices on the responsibilities of prescribers when administering an unlicensed product.[vi] These principles include:

- Notifying clinical staff when an unlicensed product is being used.
- Being aware and paying attention to any risks associated with the use of an unlicenced product.
- Being satisfied that there is sufficient evidence or experience of using the unlicensed product medicine to demonstrate safety and efficacy.
- Taking responsibility for the use of the unlicensed product and for overseeing the patients care, monitoring and any follow up treatment, or ensuring arrangements are in place for another suitable doctor to do so.
- Make a clear, accurate and legible record of all unlicensed products used and your reasons for doing so.

Information for Clinical Staff

The above GMC guidance builds on 2014 MHRA guidance which makes a number of recommendations to clinical staff who are involved in the treatment of a patient with an unlicensed product. This guidance also outlines several areas of best practice when communicating the use of an unlicensed product to patients. These recommendations outline that clinical staff should:

- Give patients, or those authorising treatment on their behalf, sufficient information about the proposed treatment, including known serious or common adverse reactions, to enable them to make an informed decision.
- Where current practice supports the use of a medicine outside the terms of its licence, it may not be necessary to draw attention to the licence when seeking consent. However, it is good practice to give as much information as patients or carers require or which they may see as relevant.
- Explain the reasons for prescribing a medicine off-label or prescribing an unlicensed medicine where there is little evidence to support its use, or where the use of a medicine is innovative.[vii]

Clinical staff should also inquire whether there is a local policy or protocol in place within their organisation prior to using an unlicensed product on a patient. This is to ensure that best practice and patient safety is adhered to in the use of unlicensed products.

A number of NHS Trusts in England, Health and Social Care Trusts in Northern Ireland and Health Boards in Wales, Scotland also provide protocols for staff on the use of unlicensed products. These protocols are referenced here as examples and can provide details on local policies and clinician responsibilities when using an unlicensed product and the policies and procedures that a particular Trust has in place prior to the use of an unlicensed product.[viii]

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References -
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