

Ref no: 201120716  
From: Commercial  
Date: 13/07/16  
Subject: RCS/MHRA

## REQUEST

A 2% chlorhexidine in 70% IPA is currently supplied through NHS Supply Chain as a biocide.

Please would you indicate the exact number of bottles of the following products that your hospital trust ordered in the last 12 months:

- 2% chlorhexidine in 70% IPA (Ecolab) in 500ml bulk bottles with the manufacturer product code 3059670 and EAN code 4028163058733, and catalogue code MRB 613
- 2% chlorhexidine in 70% IPA (Ecolab) in 200ml bottles with the manufacturer product code 3059650, the EAN code 4028163058757 and catalogue code MRB 620

Approximately a year ago the Royal College of Surgeons and the Medicines and Healthcare products Regulatory Agency issued a joint statement:

“Joint RCS/MHRA Statement on the use of Topical Chlorhexidine for Skin Preparation Prior to Surgery”

This document can still be found on the Royal College of Surgeons website <https://www.rcseng.ac.uk/government-relations-and-consultation/joint-rcs-mhra-statement-on-use-of-topical-chlorhexidine-for-skin-preparation-prior-to-surgery>

The Royal College of Surgeons and the MHRA recommend the use of licensed medicines to prepare the skin prior to surgery. The MHRA explained that chlorhexidine is classified differently for different presentations. These are:

- Medical Use: Topical disinfectant for clinical use (e.g. pre-operatively)

- Medical Device: Disinfectant for medical equipment
- Biocide: General use as disinfectant (e.g. washing hands)

They further recommend that where an authorised product exists this should be used in preference to another product as only it will be fully supported by risk-benefit analyses as to its use for that specific purpose.

The MHRA highlights that there are health risks associated with using chlorhexidine. Using the appropriately authorised product for its specific intended use, in accordance with the manufacturer's instructions for use, is the best way of minimising harm.

The MHRA updated their guidance note 8 – what is a medicinal product – in March 2016. This guidance offers the following advice:

## RESPONSE

- MRB613 – 2056 bottles ordered in the last 12 months.
- MRB620 – No bottles ordered.