From: [redacted]
To: [redacted]
Subject: FW: REF: 456471 - Accidental injection of pink-tinted chlorhexidine [SEC=UNCLASSIFIED]
Date: Friday, 21 April 2017 5:28:44 PM
Attachments: Accidential injection of pink-tinted chlorhexidine.pdf

FYI

From: [redacted]
Sent: Friday, 21 April 2017 5:18 PM
To: [redacted]
Cc: [redacted]
Subject: REF: 456471 - Accidental injection of pink-tinted chlorhexidine [SEC=UNCLASSIFIED]

Good afternoon [redacted]

Please find attached a response from Dr Larry Kelly acting Deputy Secretary for HPRG.

Kind regards

[redacted]
Health Products Regulation Group
Australian Government Department of Health
T: [redacted] | E: [redacted]
Location: Symonston G.G.08
PO Box 100, Woden ACT 2606, Australia

Australian Government

Department of Health

DEPUTY SECRETARY

21 April 2017

[redacted]
Chief Executive Officer
Australian Commission on Safety and Quality in Health Care
GPO Box 5480
Sydney NSW 2001

Dear [redacted]

Accidental injection of pink-tinted chlorhexidine

Thank you for advice dated 30 March about the Commission's initiative to approach the Australian and New Zealand College of Anaesthetists to propose a joint hospital communique about the use of chlorhexidine. Since our initial correspondence with the Commission last year, the TGA has sought expert clinical advice from its Advisory Committee on Medical Devices. The ACMD considered the use of these products and the issue of colour tinting. The advice is attached. These products have been listed on the Australian Register of Therapeutic Goods (ARTG) as both medical devices and medicines. Therefore, the TGA is communicating with a wide range of sponsors (suppliers) to encourage safe use.

The sponsors of products listed as medical devices are expected to ensure that the labelling and intended purpose is aligned to the regulatory pathway they have chosen. Medical device listing means that these products are intended to be used as hard surface disinfectants. If the evidence indicates that the sponsor is not complying with the regulatory requirements the TGA will take appropriate regulatory action. Actions may include cancellation of the ARTG entry or applying conditions of inclusion that clearly outline the expected supply in accordance with the products intended purpose.

We will also investigate this issue as it pertains to medicines. This will take into account any reports received by the TGA and involve liaison with the sponsors of these products. We will keep the commission informed of any regulatory action.

Information about the use of these products will be published on the TGA's website following confirmation from sponsors that the products fully comply with the regulatory pathway they have chosen.

Yours sincerely

[redacted]

Dr Larry Kelly
A/g Deputy Secretary
Health Products Regulation Group

Attachment 1

ACMD advice – Pink Tinted Chlorhexidine

The following is the ratified committee advice regarding the labelling of pink-tinted chlorhexidine surface disinfectants:

The committee believes:

1. use on skin is not necessarily implied through the instruction not to use on broken skin; however, it is well known that all of these products are used for skin prep; therefore, the labelling should clearly and prominently state that a product is not to be used as a skin disinfectant if it has not been assessed for this use.
2. additional advice should be provided to users through a web statement and/or medical device safety update that the use of hard surface disinfectants as skin disinfectants is outside their intended purpose and they have not been assessed, and are not approved, by the TGA for this use.

In addition the committee believes that pink tint may be acceptable for use in dispensers for hand sanitising but poses unnecessary risk for surgical prep; and red tint should be used for this purpose.