From: [redacted]
To: [redacted]
Subject: RE: TRIM: FW: Banning indistinct pourable chlorhexidine [SEC=UNCLASSIFIED]
Date: Monday, 16 October 2017 11:35:55 AM
Attachments: image001.png
[redacted] response.docx

Hi [redacted]

See draft response including updated changes. (Also attached)

Dear [redacted]

Thank you for your recent correspondence regarding the potential safety issues involving the use of pourable chlorhexidine.

Post-market investigation of products by the TGA is an important tool as part of its monitoring and evaluation of the safety and efficacy of therapeutic products in Australia.

With the increased volume of signals of potential safety issues being identified by the TGA, a risk-based process has been developed for the screening and prioritisation of signal investigations. This process provides a solid and consistent rationale for allocation of resources towards significant issues and ensures that the TGA can respond appropriately, and in a timely manner, to emerging safety issues. Signals are prioritised based on frequency and/or severity of the adverse event, plausibility of a causal association (medicine), the detectability of the event if the situation recurred, whether any regulatory action could be taken to help manage the risk as well as the likely public health impact of any regulatory action. Investigation focus is normally on unusual problems, potentially serious problems, or problems that have high levels of incidences.

Chlorhexidine falls into the category of a ‘device-medicine’ boundary product and the intended purpose of the product will determine its status on the Australian Register of Therapeutic Goods. Chlorhexidine intended for use as an antiseptic, skin disinfectant, antiseptic wipe or swab is regulated as a medicine. If the intended purpose of the chlorhexidine is as a disinfectant for use on hard surfaces only, then it is considered an Other Therapeutic Good.

The TGA is aware of the possible safety risks associated with pourable chlorhexidine. However, the TGA’s adverse event database contains only two reports linked to the use of these products. The identified risk associated with chlorhexidine use in hospitals was referred to the Advisory Committee on Medical Devices (ACMD) for advice. The ACMD advice is being utilised to address any issues with current entries on the ARTG and an investigation is ongoing.

The investigation is focussed on the intended purpose, the solution strengths and the presentation, particularly the colour of the solution for both hard surface disinfectants and skin antiseptics. The potential for misuse of hard surface disinfectant as a skin antiseptic is also being assessed. Appropriate regulatory action may be considered by the TGA for entries that do not meet requirements for safety and performance, or where the potential for misuse is of concern.

The TGA is approaching the issue from the regulatory perspective with suppliers and, by extension, manufacturers. As you can appreciate, the safe use of chlorhexidine in hospitals

depends significantly also on users adopting good clinical practice, including following the product's instructions for use, robust clinical guidelines and policies to reduce or eliminate preventable recurrences.

The TGA is responsible for the regulation of manufacturers and suppliers of therapeutic goods in Australia. However, the therapeutic goods legislation does not extend to medical practices of health practitioners who are, as you are aware, regulated under the individual health practitioner laws of each State and Territory. The TGA cannot require hospitals, health professionals or others to use particular products where there is evidence that the products are safe to use as intended and there is sufficient information available to ensure safe use when these products are used by appropriately trained people.

Health professionals, patients and consumers are encouraged to inform the TGA of any problems they encounter (hazards, adverse events, malfunctions, and non-compliance) with regulated therapeutic products throughout their lifecycles. This information provides valuable guidance to support post-market investigations, and any actions the TGA takes in regard to these products. Information on how to report problems to the TGA can be found at 'Report a problem'.

[redacted]

Devices Vigilance and Monitoring Section
Medical Devices Branch

Phone: [redacted]
Email: [redacted]

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606 Australia
www.tga.gov.au

From: [redacted]
Sent: Monday, 9 October 2017 10:26 AM
To: [redacted]
Cc: [redacted]
Subject: TRIM: FW: Banning indistinct pourable chlorhexidine [SEC=UNCLASSIFIED]

Hi [redacted],

Can you please draft a response to this email. Please answer the questions in the last para of the attachment.

Please send it back to me as I want to use it to draft a web statement or an article for the MDSU. Also please add information on how health professionals can report. Why we can only act on evidence and what evidence means for medical device reports. Some of the information will be on the TGA's website.

Can you get it back to me tomorrow please.

Thanks
[redacted]

[redacted]
Director
Device Vigilance and Monitoring Section
Medical Devices Branch | Therapeutic Goods Administration
Department of Health
[redacted]

136 Narrabundah Lane, Symonston, ACT, 2609
PO Box 100, Woden, ACT, 2606

From: [redacted]
Sent: Friday, 6 October 2017 6:27 PM
To: [redacted]
Cc: [redacted]
Subject: Banning indistinct pourable chlorhexidine [SEC=No Protective Marking]

Hi [redacted],

Thank you for receiving my email.

Indistinct pourable chlorhexidine continues to be accidentally injected into patients throughout the world.

Chlorhexidine to my knowledge has never been accidentally injected when it is obviously coloured pr contained within applicators.

Front line staff recognize the severity of this unnecessary hazard and want it banned from hospitals. The TGA is in a position to do this and in doing so will demonstrate its leadership when it comes to patient safety worldwide.

For more information please see the attached posts:

http://wp.me/p8r3e4-sa

http://wp.me/p8r3e4-t

Please feel free to contact me [redacted]

Please could you let us know where the TGA is up to in banning indistinct pourable chlorhexidine.

Thank you again.

[redacted]

Sent from my iPhone

Dear [redacted]

Thank you for your recent correspondence regarding the potential safety issues involving the use of pourable chlorhexidine.

Post-market investigation of products by the TGA is an important tool as part of its monitoring and evaluation of the safety and efficacy of therapeutic products in Australia.

With the increased volume of signals of potential safety issues being identified by the TGA, a risk-based process has been developed for the screening and prioritisation of signal investigations. This process provides a solid and consistent rationale for allocation of resources towards significant issues and ensures that the TGA can respond appropriately, and in a timely manner, to emerging safety issues. Signals are prioritised based on frequency and/or severity of the adverse event, plausibility of a causal association (medicine), the detectability of the event if the situation recurred, whether any regulatory action could be taken to help manage the risk as well as the likely public health impact of any regulatory action. Investigation focus is normally on unusual problems, potentially serious problems, or problems that have high levels of incidences.

Chlorhexidine falls into the category of a 'device-medicine' boundary product and the intended purpose of the product will determine its status on the Australian Register of Therapeutic Goods. Chlorhexidine intended for use as an antiseptic, skin disinfectant, antiseptic wipe or swab is regulated as a medicine. If the intended purpose of the chlorhexidine is as a disinfectant for use on hard surfaces only, then it is considered an Other Therapeutic Good.

The TGA is aware of the possible safety risks associated with pourable chlorhexidine. However, the TGA's adverse event database contains only two reports linked to the use of these products. The identified risk associated with chlorhexidine use in hospitals was referred to the Advisory Committee on Medical Devices (ACMD) for advice. The ACMD advice is being utilised to address any issues with current entries on the ARTG and an investigation is ongoing.

The investigation is focussed on the intended purpose, the solution strengths and the presentation, particularly the colour of the solution for both hard surface disinfectants and skin antiseptics. The potential for misuse of hard surface disinfectant as a skin antiseptic is also being assessed. Appropriate regulatory action may be considered by the TGA for entries that do not meet requirements for safety and performance, or where the potential for misuse is of concern.

The TGA is approaching the issue from the regulatory perspective with suppliers and, by extension, manufacturers. As you can appreciate, the safe use of chlorhexidine in hospitals depends significantly also on users adopting good clinical practice, including following the product's instructions for use, robust clinical guidelines and policies to reduce or eliminate preventable recurrences.

The TGA is responsible for the regulation of manufacturers and suppliers of therapeutic goods in Australia. However, the therapeutic goods legislation does not extend to medical

practices of health practitioners who are, as you are aware, regulated under the individual health practitioner laws of each State and Territory. The TGA cannot require hospitals, health professionals or others to use particular products where there is evidence that the products are safe to use as intended and there is sufficient information available to ensure safe use when these products are used by appropriately trained people.

Health professionals, patients and consumers are encouraged to inform the TGA of any problems they encounter (hazards, adverse events, malfunctions, and non-compliance) with regulated therapeutic products throughout their lifecycles. This information provides valuable guidance to support post-market investigations, and any actions the TGA takes in regard to these products. Information on how to report problems to the TGA can be found at 'Report a problem'.