From: s22(1)
To: [redacted]
Subject: FW: Chlorhexidine [SEC=UNCLASSIFIED]
Date: Monday, 16 October 2017 11:18:02 AM
Attachments: image003.png

[redacted],

I thought that you might be interested in this. There might be the occasional word or two that you could use in the web statement. The link to the anaesthetist statement would be good.
Thanks

[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: Thursday, 12 October 2017 10:02 PM
To: [redacted]
Subject: FW: Chlorhexidine [SEC=UNCLASSIFIED]

[redacted] continually thinks of me - the letter he thinks TGA should release and he refers to is below and if you go to his link it has a photograph showing different syringes:

Protected: Chlorhexidine and the TGA

on October 11, 2017

This is a letter I wish and hope the TGA will write. One can only imagine the number of lives it will save.

The TGA has made the decision to ban indistinct pourable chlorhexidine solutions.

This decision is in keeping with recommendations from the root cause analysis (RCA) performed after the accidental epidural injection of chlorhexidine at St George Hospital in 2010. The RCA stated 'all chlorhexidine solutions should be coloured in a way which clearly distinguishes them from any fluid for injection'.

We acknowledge correspondence from the Australian Commission on Safety and Quality in Healthcare that we work with suppliers to ensure no chlorhexidine is of pale colour. We acknowledge alerts from the Australian and New Zealand College of Anaesthetists in response to a more recent accidental chlorhexidine injection that 'only highly tinted skin preparations should be used'.

The St George Hospital incident is not an isolated event. We are aware of many other accidental administration and near miss events which have occurred within Australia and worldwide.

We acknowledge there was a profound near miss event in the weeks leading up to the St George incident. Despite being managed at the highest level the hazard of indistinct chlorhexidine unfortunately was not removed. We extend our sincerest apologies to the patient, family and healthcare staff who suffered as a result.

To our knowledge accidental administration of chlorhexidine has only been reported in the presence of indistinct solutions.

The TGA's approach to therapeutic product vigilance is to continually monitor and

evaluate the safety and efficacy (performance) profile of therapeutic products and to manage any risks associated with individual products. The requirement for specific vigilance activities is for the purpose of protecting the health and safety of Australians and will in no way result in the reduction in a product's requisite efficacy (performance) and safety.

The TGA takes a risk-based approach to regulation.

There is no benefit in having pourable indistinct chlorhexidine in healthcare institutions and while they exist they represent a serious unnecessary risk to patient safety.

We recognise the complexity of healthcare environments. This highlighted by some institutions which had previously replaced indistinct chlorhexidine with vivid solutions having gone back to ordering indistinct chlorhexidine. This for no other reason than staff ordering chlorhexidine being unaware of cases of accidental administration.

We accept, given our position of protecting the health and safety of Australians, that the most effective way to remove this unnecessary hazard is to ban it from healthcare institutions. Further we will contact our counterparts elsewhere in the world – FDA, MHRA, others and inform them of our decision and encourage them to do the same for the safety of patients worldwide.

We acknowledge the excessive time lag between the St George Hospital incident and our decision.

We acknowledge a serious deficiency with error reporting both in Australia and worldwide. Each state and each individual private hospital have their own siloed reporting systems which lack transparency. There is minimal communication between these error reporting systems. Many of these reporting systems need to be updated to allow a 'search' function allowing better capture of clustered recurring events.

We acknowledge there is minimal awareness by front line healthcare staff of our own reporting system 'IRIS' and that there needs to be direct communication with our IRIS reporting system and all other healthcare error reporting systems in Australia.

Further we acknowledge the need for a transparent hazard reporting system. Many frontline staff recognised the risk of indistinct chlorhexidine before the St George incident yet without a system to report this hazard little could be done by them to remove it.

We accept it is unsatisfactory that 500 healthcare staff have felt the need to resort to a petition to remove an unnecessary hazard from the front line.

We recognise the indistinct chlorhexidine issue reveals massive inefficiencies with existing safety improvement systems.

We accept we will see a huge improvement in error and hazard reporting when we have efficient, transparent systems in place which allow front line staff to observe effective interventions being delivered in response to their reports.

We will ensure it is clear to everyone how and when our healthcare hazard and error reporting systems are being improved.

Australia has a healthcare system which is renowned worldwide. We believe in acknowledging and rectifying these issues we position Australia as world leader in healthcare safety.

Please feel free to contact us directly on [redacted] if you have any questions regarding this matter.

Thank you.

From: [redacted]
Sent: Thursday, 12 October 2017 9:48 PM
To: [redacted]
Subject: Chlorhexidine [SEC=No Protective Marking]

Hi [redacted],

I hope you are well. I have attached a letter which I hope the TGA would write - one can only imagine the lives it will save.

Please do feel free to contact me at any time to discuss on [redacted].

The letter is in the format of a password protected post with links in red.

The password is Chlorhexidine

http://wp.me/p8r3e4-sX

Thanks you as always for your valuable time - I realise you have an extremely difficult job and would like to offer you all the support you need.

[redacted]