From: [redacted]
Sent: Tue, 2 Apr 2019 14:09:19 +1100
To: [redacted]
Cc: [redacted]
Subject: BROADCAST NOTICE FOR NATIONAL CHO's [SEC=OFFICIAL:Sensitive, ACCESS=Commercial]
Priority: High
Attachments: TGA Distribution List - RC-2019-RN-00501-1.pdf; TGA Recall Notice - RC-2019-RN-00501-1.pdf; image002.png

Hi [redacted]

Please see attached the Broadcast Notice and the Distribution List which I understand from yesterday's meeting you would like to send to the CHOs in the first instance and after that we will send it to the State and Territory Recall Coordinators.

It's in PDF as per normal.

If you don't mind, please copy me (or BCC) so I know when it's gone out.

I also need a completed s(61)7 form in TRIM which is here - D19-5336496 you just need to enter your position number where the red text is and sign it off electronically in TRIM workflow. I've filled it in for you so it just needs the position number and TRIM Signature then it's done.

Happy to assist further as need be.

Thanks & regards,

[redacted]

Recalls Section
Manufacturing Quality Branch

[redacted]

Therapeutic Goods Administration
PO Box 100
Woden ACT 2606
www.tga.gov.au

This response is general information given to you without prejudice; it is not binding on the TGA and you should get your own independent legal advice to ensure that all of the legislative requirements are met.

From: [redacted]
Sent: Tuesday, 2 April 2019 1:00 PM
To: [redacted]
Cc: [redacted]
Subject: RE: File note - CHO teleconference re: J&J Intraluminal Staplers [SEC=OFFICIAL:Sensitive]

Thanks [redacted].

I also spoke to [redacted] about the outcome and he will distribute any info to his members as well. I will send when TGA advice is available.

I also have an email from Qld on alternate supplies which I will forward on to you [redacted], for distribution to the recall coordinators (tell me if you think that is the most appropriate route).

[redacted]

From: [redacted]
Sent: Tuesday, 2 April 2019 12:03 PM
To: [redacted]
Cc: [redacted]
Subject: RE: File note - CHO teleconference re: J&J Intraluminal Staplers [SEC=OFFICIAL]

Thank you [redacted] – I think we achieved a considered and appropriate outcome for the circumstances.

Cheers
[redacted]

[redacted]
Medical Devices Branch
Medical Devices & Product Quality Division, Health Products Regulation Group
Office: Level 1, B Block, Rm FB07
136 Narrabundah Lane, Symonston, ACT, 2609
[redacted]

Please note I am out of the office from 1.00pm on a Friday

From: [redacted]

Sent: Tuesday, 2 April 2019 11:57 AM
To: [redacted]
Cc: [redacted]
Subject: File note - CHO teleconference re: J&J Intraluminal Staplers [SEC=OFFICIAL]

[redacted]

FYI, for completeness, here's a brief File Note from yesterday's teleconference.

Update – as I just advised [redacted], we're just in the final stages of approving J&J's customer (recall) letter. There's a couple of minor points to clarify on both sides. [redacted] is in a meeting until 12.30pm, so we're looking at early afternoon approval. [redacted] – per below, as soon as this is done, our Recall Notice and accompanying cover email (prepared as a s.61 release) will be sent to you for on-forwarding to the CHOs first. You have s.61 delegation.

NOTE FOR FILE

- Monday, 1 April 2019, 4.00 – 4.45pm

- Teleconference convened with State / Territory CHO's

- Chair – [redacted] (TGA)

- Attendees – [redacted] (TGA) and Chief Health Officers (CHOs) and/or their from representatives from all 8 jurisdictions

- **Issue**

Action required in relation to complaints and the confirmed occurrence of uncut washers and malformed staples with specific Intraluminal Staplers (ILS) supplied by Johnson & Johnson Medical Pty Ltd (J&J).

Background

- [redacted] provided a brief update to the meeting, noting the "Recall Action Early Advice" notice issued by the TGA on Friday, 29 March and his follow up email to all CHOs the same day. [redacted] advised that since then, more information has become available regarding product failure rates, available stock and the importance of this device remaining available to perform specified, urgent cancer surgeries.

Proposed action

- [redacted] advised that having regard to the patient risk-benefit scenario, feedback already received from some jurisdictions and from his further discussions with the President of the ANZ Colorectal Society, the TGA would be taking a decision to initiate a recall action known as a " Product Defect Correction", rather than an actual "recall" (removal) of the device from the market. The corrective action would have the effect of advising customers to use an alternative device if available (preferred option), but if this was not possible, to follow to additional precautionary measures that will be issued in relation to continued use of the J&J device.
- This approach is consistent with the action being taken in other countries, including

Germany, China, Japan and New Zealand.

- In order to prolong the use of available stock (noting that a shortage will occur at some time until production and supply can resume), the recall letter will also advise customers to use the device selectively ie only for those procedures considered to be most urgent.
- The meeting also noted J&J's predominant market share in Australia (circa 75%) with Medtronic advising they hold the remaining 25%. The meeting noted that several other comparable devices are included in the ARTG, but the precise marketing status of these devices was unclear at this time.
- Following further discussion, there was general agreement amongst all participants with the proposed action.

Next steps

- TGA will ask J&J to provide a draft recall letter for review and approval (by COB Monday).
- TGA will aim to have the letter approved by late morning, Tuesday, 2 April.
- Given the 'early advice' already disseminated, TGA will distribute its Recall Broadcast Notice (RBN) on the same day, Tuesday (rather than waiting the usual two working days which is the 'norm' for most BAU recall cases).
- The RBN will be provided to [redacted] to send to all CHOs first and following this, it will be sent to all S/T recall coordinators in line with SOPs.

[redacted]

[redacted]

Recalls Section
Manufacturing Quality Branch

[redacted]

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606 Australia
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