Fw: Hospital level TGA Hazard Alert Notice - SMR L2 Metal Back Glenoid Component [SEC=UNCLASSIFIED]

Recalls to: 31/10/2012 12:47 PM
Sent by: [redacted]

To whom it may concern

The TGA Recall Notice below has been resent as the TGA has now published additional information on the TGA Website.

For further information, please see
http://www.tga.gov.au/safety/alerts-device-shoulder-smr-121030.htm

Kind Regards

TGA Recalls unit
----- Forwarded by [redacted] TGA/Health on 31/10/2012 12:47 PM -----

From: Recalls
To: #Recalls Devices Group, [redacted] National Joint Replacement Registry/0882234075@fax.tga.gov.au
Date: 10/08/2012 10:58 AM
Subject: Hospital level TGA Hazard Alert Notice - SMR L2 Metal Back Glenoid Component [SEC=UNCLASSIFIED]
Sent by: [redacted]

Please find attached a copy of TGA Hazard Alert Notice.

RC-2012-RN-00804-3 TGA Recall Notice.pdf

The sponsor of the product is contacting the following customers. **Please do not pass on customer information to third parties**

RC-2012-RN-00804-3 TGA Distribution List.pdf

This action is a Hazard Alert. **Individual units of the device are not being recalled as they have all been implanted.**

In accordance with the URPTG definition, a 'Hazard Alert' means the issuing of precautionary information about an implanted device where it has been proven that there is no stock to be recalled and all affected devices are already implanted (this category only relates to implantable medical devices).

The attached information is being made available to you in accordance with section 61(7) of the *Therapeutic Goods Act 1989* for the purpose of alerting you to recall and other market actions conducted under the *Uniform Recall Procedure for Therapeutic Goods.* As the information may contain personal and commercially sensitive and confidential information, please safeguard the information and do not distribute this email to third parties.

Other Information:

In a situation where liner dissociation has occurred, patient may present with pain, limited range of motion and they may complain of a 'squeaking', 'clicking', or 'grinding' sensation. Diagnostic images will show a reduction in the joint space between the humeral head and the glenoid compared to the immediate post-operative diagnostic images. Lima has discontinued supply of SMR L2 version of the product and now only the previous L1 version is available. Lima is contacting all implanting surgeons and advising them on how to manage patients implanted with the L2 component.