Australian Government

Department of Health
Therapeutic Goods Administration

Australian Medical Device
Incident Report Investigation Scheme

File Reference: 2012/011679

Dr William Pouw
Cosmetic Plastic Surgeon
[redacted]

Dear Dr Pouw,

DEVICE INCIDENT REPORT DIR 26634 - PIP Breast Implant

An investigation into the incident you reported to the Therapeutic Goods Administration concerning the above device is now complete.

A copy of the Incident Report Investigation Scheme (IRIS) database entry, including the investigation summary is attached for your information.

Thank you for your support of the Medical Device Incident Report Investigation Scheme. Should you have any questions regarding this report please contact me on [redacted]

Yours sincerely

[redacted]

[redacted]

Incident Report and Investigation Scheme
Device Vigilance and Monitoring
Office of Product Review
Therapeutic Goods Administration

27 November 2013

PO Box 100 Woden ACT 2609 ABN 40 939 406 804
Phone: 02 6232 8695 Fax: 02 6203 1713 Email:

TGA Health Safety Regulation

DIR 26634 - PIP Breast Implant

Reporter Reference #:

Date of Adverse Event:

Date of Report:
23/04/2012

ARTG #:
114902

Brand Name:
PIP Breast Implant

Device Class:
Class III

Model #:

Serial #:
185 (l) & 1467 (r)

Software Version:

Batch #:

Lot #:
53705 (l) & 35105 (r)

Manufacturer:
Poly Implant Protheses (Pip) SA

Sponsor:
Medical Vision Australia Pty Ltd
99 King William Street
KENT TOWN SA 5067

Contact Name:
[redacted]

Phone:
(08) 8132 0300

Reporter:
Dr William Pouw
Cosmetic Plastic Surgeon

Confidential: No

Phone: [redacted]
Fax [redacted]

[redacted]

Email:
drpouw[redacted]

Date of Implant:
04/04/2007

Date of Explant:
04/04/2012

Clinical Event Information:
Ruptured implants right breast implant only (MRI).

Patient had PIP ruptured implant.

Patient Outcome/Consequences:

Investigation Summary:

The information provided in your report has been used to assist the broader TGA investigation of PIP breast implants. As you will understand, the issues associated with the investigation of PIP implants have been complicated by the non-availability of data from the French manufacturer. This has meant that regulatory agencies such as the TGA and its equivalent in the United Kingdom the MHRA, have been required to undertake extensive testing to assess the quality of these implants.

The results of this testing, and that conducted overseas, have not found evidence that the risks involved with the use of PIP breast implants are any greater than those for any other brand of silicone gel-filled breast implants. For your information a copy of the TGA test results summary and the most up to date TGA web statement on PIP implants have been attached to this letter. Additional detail on PIP implants can be found in the Department of Health, Chief Medical Officer Report into PIP implants. This document can be found at http://www.health.gov.au/internet/publications/publishing.nsf/Content/PIP-breast-implants-report-CMO-toc.

TGA will continue to monitor developments with PIP implants and provide updates via the PIP breast implant section of the TGA website (http://www.tga.gov.au/safety/alerts-device-breast-implants-pip.htm) if new information emerges.

Date Completed:
27 November 2013

***** End of DIR 26634 *****