Document 12

Email Message

From:	[redacted]@tga.gov.au]
To:	drpouw [SMTP:drpouw@[redacted]]
Cc:	
Sent:	30/03/2012 at 9:59 AM
Received:	
Subject:	TGA request for additional information [SEC=UNCLASSIFIED]
Attachments:	Dr Pouw (DIR 26187).docx Dr Pouw (DIR 26188).docx

Dear Dr Pouw,

I am writing to request additional information regarding adverse events involving PIP breast implants you reported to the TGA on 26/03/2012. The TGA assigned Device Incident Report (DIR) numbers 26187 and 26188 to this report. All questions asked in the attached questionnaire relate to this adverse event. Some information that was previously reported has been inputted into the attached form for your convenience.

If you could provide the requested information within the next week it would be greatly appreciated.

Please note - It was unclear if the report DIR 26187 related to patient [redacted] (initials) is for ruptured implants or removal due to anxiety only. If these implants were removed intact then the additional form for DR 26187 does not need to be completed.

If you have any questions regarding this request please contact [redacted] on [redacted] or [redacted]@tga.gov.au.

Thank you for your assistance with this matter.

Kind Regards

[redacted]

IRIS Investigator - Device Vigilance & Monitoring
Office of Product Review |Therapeutic Goods Administration

[redacted]@tga.gov.au | url: www.tga.gov.au
Post: PO Box 100, Woden, ACT 2606 | Courier: 136 Narrabundah Lane, Symonston, ACT 2609

Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

Request for additional information – breast implant

The Therapeutic Goods Administration wishes to gather accurate details about reports of problems detected with breast implants. **It would be very helpful to the TGA if, in addition to completing and returning this questionnaire, you would also provide copies of all related reports of investigations (such as ultrasound, MRI, culture of fluids, etc) and copies of any related letters you have sent to any referring doctor. Please retain the same patient identifiers as in the questionnaire but otherwise de-identify the documents before sending to TGA.**

The questions in this column relate to the implant about which you have identified a problem.

Patient identifier

Initials or medical record number	[redacted]
Age OR date of birth	[redacted]
TGA device incident report number	DIR 26188

Site of implant:

Concerning the problem you have reported about an implant in this person:

Site of implantation	Rt ☐ Lt ☐
Date of implantation	14/09/2006
Date of explantation	22/03/2012

Has an implant also been removed from the contralateral breast to that described in the left hand column?

Yes ☐ No ☐

If 'Yes', please answer the questions in this column.

Reasons for removal of the contralateral implant

Was the reason to remove this contralateral implant ***solely*** because of the problems identified with the implant in the other breast?

Yes ☐ No ☐

If NO, please answer the following questions.

Did the patient complain of symptoms or have clinical signs referable to this contralateral implant? Yes ☐ No ☐

If YES, please describe:

The questions in this column relate to the implant about which you have identified a problem.	The questions in this column relate to the other implant.

Brand and model of implant	
Batch number of implant if known	
Serial number	

Investigations:

Was ultrasound reported as indicating rupture?

Yes ☐ No ☐ Not performed ☐

Was MRI reported as indicating rupture?

Yes ☐ No ☐ Not performed ☐

Reasons for removal of the implant

Capsular contraction[1]? I ☐ II ☐ III ☐ IV ☐

Device rupture	☐	Device migration	☐
Device malposition	☐	Haematoma	☐
Seroma	☐		

Silicone extravasation (gel bleed):

intra-capsule	☐	extra-capsule	☐
distant	☐		

On examination:

Was there evidence of capsular contraction?

If YES, please indicate Grade[1]:

I ☐ II ☐ III ☐ IV ☐

Investigations:

Was ultrasound of this contralateral implant reported as indicating rupture?

Yes ☐ No ☐ Not performed ☐

Was MRI of this contralateral implant reported as indicating rupture?

Yes ☐ No ☐ Not performed ☐

[1] Capsular Contraction definitions – "Baker grades" – as in the US FDA Breast Implant Consumer Handbook – 2011

Grade I – breast is normally soft and looks natural

Grade II – breast is a little firm but looks normal

Grade III – breast is firm and looks abnormal

Grade IV – breast is hard, painful and looks abnormal

The questions in this column relate to the implant about which you have identified a problem.	The questions in this column relate to the other implant.

Explanted implant – findings on removal:

At the time of operative removal, was rupture confirmed?

Yes ☐ No☐

If rupture had occurred, was the rupture:

Intracapsular ☐ Extracapsular ☐

If not ruptured at the time of removal, was there any evidence of gel bleed[2] of fluid from the intact implant?: Yes ☐ No☐

If there was evidence of gel bleed, please briefly describe your observations of the state and condition of the removed implant:

Was ultrasound reported as indicating gel bleed or another problem other than rupture? Yes ☐ No☐

If YES, please describe:

Was MRI reported as indicating gel bleed or another problem other than rupture? Yes ☐ No☐

Explanted contralateral implant – findings on removal:

At the time of operative removal, was rupture confirmed? Yes ☐ No☐

If rupture had occurred, was the rupture:

Intracapsular ☐ Extracapsular ☐

At the time of removal, was there any evidence of gel bleed[2] from the intact implant?: Yes ☐ No☐

If there was evidence of gel bleed, please briefly describe your observations of the state and condition of the removed implant:

Was ultrasound reported as indicating gel bleed or another problem other than rupture?

Yes ☐ No☐ Not performed ☐

If YES, please describe:

Was MRI reported as indicating gel bleed or another problem other than rupture? Yes ☐ No☐ Not performed ☐

[2] Gel bleed – a passage of the silicone fluid through the shell of an intact prosthesis, which may or may not have been accompanied by clinical signs or complications, such as pain or lymphadenopathy, and which may or may not have been identified on ultrasound or MRI.

The questions in this column relate to the implant about which you have identified a problem.	The questions in this column relate to the other implant.
If YES, please describe:	If YES, please describe:
Were there any immediately local or more remote apparent clinical consequences to the gel bleed? Yes ☐ No☐	Were there any immediately local or more remote apparent clinical consequences to the gel bleed of this contralateral implant? Yes ☐ No☐
If YES, please describe:	If YES, please describe:
At the time of removal, had the appearance of the implant changed in any way other than as described in the answer to the question about gel bleed? Yes ☐ No☐	At the time of removal, had the appearance of the implant changed in any way other than as described in the answer to the question about gel bleed? Yes ☐ No☐
If YES, please describe the altered appearance:	If YES, please describe the altered appearance:
At the time of removal, were there any immediately local or more remote unusual or abnormal clinical findings other than those described in answer to the question about gel bleed? Yes ☐ No☐	At the time of removal, were there any immediately local or more remote unusual or abnormal clinical findings other than those described in answer to the question about gel bleed? Yes ☐ No☐
If YES, please describe:	If YES, please describe:

The questions in this column relate to the implant about which you have identified a problem.	The questions in this column relate to the other implant.
Was any material sent for laboratory investigation? Yes ☐ No☐ If YES please describe the material, the tests ordered and the name of the laboratory. (If results have been received, please attach a copy).	Was any material from this contralateral implant sent for laboratory investigation? Yes ☐ No☐ If YES, please describe the material, the tests ordered and the name of the laboratory. (If results have been received, please attach a copy).

Name of Reporter		Signature:	
Address of reporter			
Telephone number		Date:	

Please return this form to the Therapeutic Goods Administration

Postal address:

Office of Product Review
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2006

Email: iris@tga.gov.au

Fax: 02 6232 8392

Telephone: 1800 809 361 (freecall within Australia)

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Request for additional information – breast implant

The Therapeutic Goods Administration wishes to gather accurate details about reports of problems detected with breast implants. **It would be very helpful to the TGA if, in addition to completing and returning this questionnaire, you would also provide copies of all related reports of investigations (such as ultrasound, MRI, culture of fluids, etc) and copies of any related letters you have sent to any referring doctor. Please retain the same patient identifiers as in the questionnaire but otherwise de-identify the documents before sending to TGA.**

The questions in this column relate to the implant about which you have identified a problem.

Patient identifier

Initials or medical record number	[redacted]
Age OR date of birth	
TGA device incident report number	DIR 26187

Site of implant:

Concerning the problem you have reported about an implant in this person:

Site of implantation	Rt ☐ Lt ☐
Date of implantation	
Date of explantation	22/03/2012

Has an implant also been removed from the contralateral breast to that described in the left hand column?

Yes ☐ No ☐

If 'Yes', please answer the questions in this column.

Reasons for removal of the contralateral implant

Was the reason to remove this contralateral implant ***solely*** because of the problems identified with the implant in the other breast?

Yes ☐ No ☐

If NO, please answer the following questions.

Did the patient complain of symptoms or have clinical signs referable to this contralateral implant? Yes ☐ No ☐

If YES, please describe:

The questions in this column relate to the implant about which you have identified a problem.	The questions in this column relate to the other implant.

Brand and model of implant	
Batch number of implant if known	
Serial number	

Investigations:

Was ultrasound reported as indicating rupture?

Yes ☐ No ☐ Not performed ☐

Was MRI reported as indicating rupture?

Yes ☐ No ☐ Not performed ☐

Reasons for removal of the implant

Capsular contraction[1]? I ☐ II ☐ III ☐ IV ☐

Device rupture	☐	Device migration	☐
Device malposition	☐	Haematoma	☐
Seroma	☐		

Silicone extravasation (gel bleed):

intra-capsule	☐	extra-capsule	☐
distant	☐		

On examination:

Was there evidence of capsular contraction?

If YES, please indicate Grade[1]:

I ☐ II ☐ III ☐ IV ☐

Investigations:

Was ultrasound of this contralateral implant reported as indicating rupture?

Yes ☐ No ☐ Not performed ☐

Was MRI of this contralateral implant reported as indicating rupture?

Yes ☐ No ☐ Not performed ☐

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The questions in this column relate to the implant about which you have identified a problem.	The questions in this column relate to the other implant.

Explanted implant – findings on removal:

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If rupture had occurred, was the rupture:

Intracapsular ☐ Extracapsular ☐

If not ruptured at the time of removal, was there any evidence of gel bleed[2] of fluid from the intact implant?: Yes ☐ No☐

If there was evidence of gel bleed, please briefly describe your observations of the state and condition of the removed implant:

Was ultrasound reported as indicating gel bleed or another problem other than rupture? Yes ☐ No☐

If YES, please describe:

Was MRI reported as indicating gel bleed or another problem other than rupture? Yes ☐ No☐

Explanted contralateral implant – findings on removal:

At the time of operative removal, was rupture confirmed? Yes ☐ No☐

If rupture had occurred, was the rupture:

Intracapsular ☐ Extracapsular ☐

At the time of removal, was there any evidence of gel bleed[2] from the intact implant?: Yes ☐ No☐

If there was evidence of gel bleed, please briefly describe your observations of the state and condition of the removed implant:

Was ultrasound reported as indicating gel bleed or another problem other than rupture?

Yes ☐ No☐ Not performed ☐

If YES, please describe:

Was MRI reported as indicating gel bleed or another problem other than rupture? Yes ☐ No☐ Not performed ☐

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The questions in this column relate to the implant about which you have identified a problem.	The questions in this column relate to the other implant.
If YES, please describe:	If YES, please describe:
Were there any immediately local or more remote apparent clinical consequences to the gel bleed? Yes ☐ No☐	Were there any immediately local or more remote apparent clinical consequences to the gel bleed of this contralateral implant? Yes ☐ No☐
If YES, please describe:	If YES, please describe:
At the time of removal, had the appearance of the implant changed in any way other than as described in the answer to the question about gel bleed? Yes ☐ No☐	At the time of removal, had the appearance of the implant changed in any way other than as described in the answer to the question about gel bleed? Yes ☐ No☐
If YES, please describe the altered appearance:	If YES, please describe the altered appearance:
At the time of removal, were there any immediately local or more remote unusual or abnormal clinical findings other than those described in answer to the question about gel bleed? Yes ☐ No☐	At the time of removal, were there any immediately local or more remote unusual or abnormal clinical findings other than those described in answer to the question about gel bleed? Yes ☐ No☐
If YES, please describe:	If YES, please describe:

The questions in this column relate to the implant about which you have identified a problem.	The questions in this column relate to the other implant.
Was any material sent for laboratory investigation? Yes ☐ No☐ If YES please describe the material, the tests ordered and the name of the laboratory. (If results have been received, please attach a copy).	Was any material from this contralateral implant sent for laboratory investigation? Yes ☐ No☐ If YES, please describe the material, the tests ordered and the name of the laboratory. (If results have been received, please attach a copy).

Name of Reporter		Signature:	
Address of reporter			
Telephone number		Date:	

Please return this form to the Therapeutic Goods Administration

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WODEN ACT 2006

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