27/10/2010 07:21 PM

To "Jenny Hefford" <Jenny.Hefford[redacted]
cc Pamela Carter[redacted]
Subject Fw: breast screening [SEC=UNCLASSIFIED]

Classification: UNCLASSIFIED

As promised.

"TGA - Effective and Timely Regulation of Therapeutic Goods"
Philippa Horner

----- Original Message -----
From: Philippa Horner
Sent: 27/10/2010 07:57 AM ZE10
To: Rohan Hammett
Cc: Larry Kelly
Subject: breast screening [SEC=UNCLASSIFIED]

Rohan

Following up on our conversation last night about Sophia's request for a quick briefing on where breast screening is up to, as I mentioned, I directed her to the Hansard discussion and your description of the TGA ongoing investigation and cancellations etc, and that you would be at the [redacted] function this morning if they wanted some further advice.

Just to fill you in more on my discussion with Pam Carter and Penny about where things are up to:

- the investigation has found 7 devices on the ARTG, one of which [redacted] is not in fact used for screening breast cancer (used for checking temperature of feet in diabetes) - entry of has been cancelled for other reasons
- the other 6 use various techniques, only one (as I understand it) actually uses thermography [redacted]
- 2 of the 6 were cancelled by the sponsor effective 4 June 2010 [redacted] cancelled its registration after receiving a s.42JA letter requesting information about compliance with the essential principles
- proposals to cancel have been issued for another 3 of the 6 [redacted] and [redacted] on the basis of no or insufficient evidence to support intended purpose
- a response to a s.41JA letter is due on 5 November from the remaining device [redacted] contrary to the reports that gave rise to its inclusion in the investigation, it appears that no claims have been made about breast screening - the question is whether it should have been entered on the ARTG as a Class 1 device (which it apparently was) rather than a Class 11A or B device
- the [redacted] and [redacted] have not actually been supplied in Australia
- as you know it is only an offence under the Act to import or supply a medical device that is not on the ARTG
  - it is understood that the [redacted] device is used in 41 clinics
  - [redacted]
- possible future action discussed:
  - re any cancelled entries, consideration will be given to requiring (under the recall provisions) sponsors to write to clinics and informing them of the basis on which cancellation has occurred - any recall action must be published in the Gazette
  - TGA should also write to known users about why entries were cancelled (s.61 allows publication of information about decisions) so that clinics cannot say to the ACCC they were not aware of the outcome of TGA investigations if claims continue to be made

- recall of devices (whether voluntary or mandatory) may not been practical or feasible in the circumstances
- information about reasons for cancellations to be included on TGA website and inform ACCC
- re registration of devices in future, Pam's area has a process in place the manual flagging the use of particular words (eg thermograph, breast screening etc) used in the electronic entries which will result in an audit (the electronic flags only work for Class 1 and these devices are Class 11A or B)
- propose to talk further about possible next steps.

In addition, the colleges and professional bodies will be written to about the use of these devices (Larry's area?).

Philippa

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Your Notes	