Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

International Laboratory Testing Panel for PIP breast implants (ITPP)

Meeting Record

Teleconference
Thursday 8 March 2012
9.00pm Australian EST

1. Members present and apologies

Please note that it was not completely clear exactly who was at the teleconference from each country. I apologise if we have not got all the names included in the list below.

Australia

- Dr Peter Bird - Head of the Office of Laboratories and Scientific Services (OLSS), TGA. [Coordinator and Chair]
- Dr Bill Sherwin - Director, Chemistry Section, OLSS
- Dr Lisa Kerr - Scientific Operations Advisor, OLSS [Secretariat, Record]

European Commission (EC)

- Dr Federica de Gaetano - Scientific officer, Unit B2 - Health Technology and Cosmetics Directorate-General for Health and Consumers
- Isabelle Demade

Germany

- Dr Wolfgang Lauer - Head of Medical Devices Division, Federal Institute for Drugs and Medical Devices (BfArM)
- Rebecca Winterhoffer.
- Dr. Bruno Heinz - Head of non-active-devices section (BfArM)

Ireland

- Joan Gilvarry - Irish Medicines Board

United Kingdom

- Andrew Crosbie
- Khalid Razak

Czech Republic

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Apologies:

European Commission (EC)

- Dr Philippe Martin - Emerging Technologies - Risks - R&D – Nanotechnologies, Directorate-General for Health and Consumers

Netherlands and Belgium did not participate.

2. Record of Last Meeting

The record of the meeting of 9 February 2012 was accepted. Australia indicted that they were establishing a secure ITPP website for this group so that meeting records and other documents can be accessed by members. Members were asked to email Dr Lisa Kerr (lisa.kerr@tga.gov.au) if they wished to have access to this ITPP website.

Action 1: Australia to set up secure website to share information and to provide access to some members. Each country to provide a contact person for access to the ITPP website.

3. Actions Arising from Previous Meeting(s)

3.1 Australia will construct a spreadsheet containing batch numbers, test type and any available results. The spread sheet was emailed to members and updated results are available on the TGA website at http://www.tga.gov.au/safety/alerts-device-breast-implants-pip.htm. **Completed.**

3.2 Germany agreed to approach the notified body and ask if they have samples and test results. **Completed**. The Notified Body doesn't have any materials for testing.

4. Discussion Items

4.1 Mechanical testing

Australia is continuing to do elongation tests on PIP breast implants to increase the number of samples in the test. Viscosity testing is also continuing on the gels.

4.2 Toxicology testing

Intradermal irritation test – Australia has commissioned tests both in Australia and Europe. Results from both laboratories indicate that the samples tested were non-irritant. Study is still to be finalised.

Cytotoxicity testing - Australia is continuing to carry out cytotoxicity testing to increase the number of PIP breast implants tested and to test raw materials used in the manufacture of the PIP breast implants. To date, all results have shown no cytotoxicity.

4.3 Chemical testing

The UK is in the process of finalising the contract for chemical testing.

The AFSSAPs report indicated that the unauthorised PIP gel contained high levels of cyclosiloxanes. Australia is working on quantifying low molecular weight siloxanes in the gels. Results using GCMS are showing that D4 is less than 300 ppm, which appears to be consistent with findings from AFSSAPS and the manufacturers of the raw materials.

Australia is using thermogravimetric analysis to determine physico-chemical differences in gels and it appears that there are differences between the unauthorised gels and gels that have been manufactured using a Nusil brand. This is consistent with reports from the AFSSAPS. This investigation is on-going and will be supported by gel permeation chromatography.

4.4 Explants

Australia has received 9 explants to date. Ruptures appear to be associated with a milky fluid. Chemical analysis shows the fluid is silicone and water. Generally, the actual gel is quite firm, although the TGA has noted gels that are broken up and lumpy. It was suggested that, apart from differing formulas, the curing process may also contribute to differences in the consistency of the gel.

Another observation is that the intensity of discolouration is not necessarily correlated with ruptures.

Germany reported on preliminary analysis of reports received from explanting surgeons.

5. Items for Noting

Nil

6. Other Business

Nil

Next meeting

Further teleconferences would be arranged via email as necessary.