47,000 British Women
Victims of Health Fraud

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TO: **MHRA Medical Devices**

Date: 10 June 2016

From: PiP Action Campaign

Response to request for information by MHRA in relation to recently published report by Dutch authorities.

We have ignored the "synopsis" on page 5 of the Surveillance Study as it only serves to undermine concerns raised by the study in relation to non-compliance and patient safety.

The aims, as well as the findings, of the study are quite clearly set out:

> **Aim**
> The aim of this report is to investigate the quality of SBIs available on the Dutch market. In order to do this, we have addressed the following questions:
> 1. Do the technical files provide adequate proof of conformity with the requirements of the Medical Devices Directive (MDD) [11]? For a manufacturer to legally place a medical device on the EU market, these requirements have to be met.
> 2. Are key physicochemical characteristics of the products, such as the silicone materials used, in line with the information in the technical documentation?
> 3. Are the physicochemical characteristics in line with the state-of-the art? SBI have been in use for more than fifty years and product design has evolved ever since.
> 4. Is the silicone material present in the products biocompatible?
> 5. In case of shortcomings, do these lead to a concern for patient safety?

Findings

1 The requirements of the Medical Devices directive are not being met therefore non-compliant implants are illegally on the EU market.

> **2.12 Conclusions assessment technical files**
> All SBI files showed shortcomings in one or more of the submitted file items. These shortcomings were most frequently found in the IFU and label, risk analysis, biocompatibility testing, mechanical testing, clinical evaluation and PMS activities. The only item that frequently scored 'good' or 'moderate' was the device description.

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> ...
>
> **Identified shortcomings in the technical files could impact patient safety.**

2. In two cases, and in PIP health fraud, the silicone materials used were not in line with the information contained in the technical documentation.

> **3.1 Type of silicone gel** In two cases (manufacturers SBI06, SBI08 in Table 3.1), the experimentally determined type of gel does not match with the data submitted in the technical file.
>
> **3.2 Impurities in the silicone gel. The** starting material for silicone gel is produced from cyclosiloxanes [22]. Therefore, residues of these cyclosiloxanes are found in silicone gels. **For a medical grade silicone gel, cyclosiloxanes are actively removed because of possible toxicity [23] ...For breast implants the use of medical grade silicone gel is required.** In one implant, order number A072238, from manufacturer SBI08, various cyclosiloxanes were detected (Figure 3.4). The presence of the cyclosiloxanes in order number A072238 was verified by gas chromatography hyphened to a mass spectrometer (GC- MS). From this analysis, D4, D5 and D6 appeared to be present, as well as the larger cyclosiloxanes D7, D8 and D9 (Figure 3.5).Quantitation of the signals in order number A072238 showed that it contains 8 ppm D4, 156 ppm D5 and 918 ppm D6 (based on extrapolation of the signal of the D5 reference standard). **These values are comparable to those found in PIP2 SBI [20].**

3. Women have been complaining of and dying from silicone related illness for 50 years. See Medical Literature and:

> **2.4 Biocompatibility...**a literature review is considered to be essential as a first step to determine biocompatibility issues, evaluate any existing data on these issues, and subsequently decide on the need for further biocompatibility testing. **In five files, such a literature review was not found.** In all cases, however, a comprehensive set of biocompatibility tests were always conducted and the applicable standards for these tests were used. **Overall, only two files were assessed as 'good' and one was moderate.**

Historical concerns over the safety of breast implants have resulted in 6yr ban by French and 14yr ban by FDA in the USA.

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4. A detailed product description from Nusil published in 2009 regarding **MED3-6300** clearly states ***"About Product Safety… NuSil Technology has completed no testing to establish safety of use in any medical application."*** Evidence of safety and testing of Nusil Med3-6300 is now urgently required.

> **Table 3.1:** Comparison between the type of silicone gel as documented in the technical file and as determined experimentally

This shows at least 6 manufacturers using MED3-6300

5. Concerns over the safety of implants are raised by the study and must, under NO CIRCUMSTANCES be ignored. Safety concerns have also been raised by health professionals, chemists, toxicologists, regulatory specialists, European Parliament, European Commission and patients. The seriousness of the risks to patients of non-compliant class III medical devices in general and of PIP implants in particular requires immediate and urgent action. These concerns include:

- Links to breast cancer
- Links to BIA-ALCL Cancer
- Implants and mammograms
- Breast feeding with implants
- Biofilm Infections and capsular contracture
- Brain Cancer
- Suicide
- Symptoms associated with implants including auto-immune illness
- Implications of inflammatory reactions and post operative complications
- Re-operation
- Lymphadenopathies, Lymphadema, BIA-ALCL
- Repro-toxicity & repeated dose toxicity, target organs of contaminants
- Effects on Pregnancy, miscarriage, still birth
- Endocrine Disruptor Chemicals - effects on developing embryos and breast feeding infants
- Estrogenic effect of chemical contaminants on estrogen-receptive breast cancers
- Effects on off-spring of DEHP and other known EDCs contained in plastics, silicone and vinyls

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Women are constantly drawn into the semantics of failures in medical devices regulations as well as the lack of accountability. "Shortcomings" in this instance is taken to mean *non-compliant and potentially dangerous*. **Non-compliant, high risk, surgically implanted medical devices, including breast implants present unacceptable risks to patients and users.**

> **2.12 Conclusions assessment technical files**
> ...the regulatory system of medical devices depends to a large extent on the quality of the submitted technical file to demonstrate compliance to the applicable requirements. Shortcomings in that documentation could imply that product safety and safe use of the device are insufficiently guaranteed.
>
> **Identified shortcomings in the technical files could impact patient safety.**
>
> **2.11 Impact of findings on patient safety**
> Shortcomings in the technical documentation could imply that product safety and safe use of the device are insufficiently guaranteed, which could in turn have impact on patient safety.

Further to this study and in light of the extraordinary failings of the MHRA to act according to its obligations and duties in the case of PIP affecting more than 45,000 UK women, we now make a request for the MHRA to take a leading role to protect the health and welfare of women in the UK and in Europe, to take the necessary **Safeguarding Action.**

93/42/EEC Article 8

> **Safeguard clause**
> 1. Where a Member State ascertains that the devices referred to in
> Article 4 (1) and (2) second indent, when correctly installed, maintained
> and used for their intended purpose, may compromise the health and/or
> safety of patients, users or, where applicable, other persons, it **shall take all appropriate interim measures to withdraw such devices from the market or prohibit or restrict their being placed on the market or put into service.** The Member State shall immediately inform the Commission of any such measures, indicating the reasons for

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its decision and, in particular, whether non-compliance with this Directive is due to:
(a) failure to meet the essential requirements referred to in Article 3;
(b) incorrect application of the standards referred to in Article 5, in so
far as it is claimed that the standards have been applied;
(c) shortcomings in the standards themselves.

Urgent help and support for PIP Health Fraud Victims

Victims of the PIP health fraud in the UK should now expect a policy review and immediate information, help and support to preventatively remove all PIP implants AND to establish appropriate diagnostics, care and monitoring of all PIP exposed women and children.

Victims of the PIP health fraud will expect MHRA to take part in the PIP review announced by the European Commission.

Scientific Committee on Health Environmental and Emerging Risks Request for a call for data and a literature review on the safety of PIP silicone breast implants and on a possible association between breast implants and anaplastic large cell lymphoma
http://ec.europa.eu/health/scientific_committees/scheer/docs/scheer_q_003.pdf

A copy of this document will be made publicly available on PIP Action Campaign's social network.

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