Briefing for the Public Petitions Committee

Petition Number: PE1378

Main Petitioner: Mairi Johnston

Subject: Silicone Gel Implants – Rupture Awareness

Calls on the Parliament to ask the Scottish Government to raise awareness of the dangers of silicone breast implants and to urge the UK Government to ban the use of such implants and review the 3-year time bar rule for medical injury.

Regulation of Medical Devices

Silicone gel implants were first used in the early 1960s. It is now estimated that over 10,000 people in the UK receive breast implants every year, with approximately 80% opting for silicone gel implants\(^1\).

The regulation of medicinal products, including medical devices such as breast implants, is a matter reserved to Westminster and is undertaken by the Medicines and Healthcare products Regulatory Agency (MHRA) for the whole of the UK.

Medical devices such as breast implants and artificial hips are regulated under the EC Medical Devices Directive (93/42/EEC), which is transposed into UK law by the Medical Devices Regulations 2002 No618 (as amended). This lays down requirements for the safety, quality and performance of the devices that the manufacturer must meet before they place their product on the EU market.

Breast implants fall within the highest risk category and therefore the manufacturer has to undergo the most stringent conformity assessment procedure. For products of this type the manufacturer has to obtain EC Certification from an independent conformity assessment body known as a ‘Notified Body’ which is designated as competent to undertake this function by its respective regulatory authority (i.e. the MHRA in the UK). As such the manufacturer must provide clinical data to support the EC certificate application. This data may be generated from a specifically designed clinical investigation looking at the safety and the performance of the device in question. Alternatively it can be generated from available scientific literature

\(^1\) MHRA [Online]
relating to similar devices provided equivalence with these devices can be demonstrated in all relevant areas e.g. design, materials. Once the manufacturer has such certification they can then sign a declaration of conformity, affix the CE mark of conformity and place the product on the EU market without any further restrictions.

The regulatory authorities in Member States (i.e. the MHRA in the UK), are therefore not directly involved in approving devices before they go on the market and instead they have a mainly post market surveillance and enforcement role.

The MHRA only authorises the use of saline or silicone gel filled breast implants in the UK.

**Risks Associated with Silicone Implants**

The MHRA recognises a number of risks associated with silicone gel implants and highlights that these should be fully explained to patients by their surgeon before surgery. In 2005, the MHRA produced a booklet for people considering breast implants and this outlines the consequences and possible risks of such a procedure\(^2\). These complications include:

- **Capsular contraction** – this is where a wall of scar tissue (fibrous capsule) develops around the implant and then shrinks, causing the implant to deform, harden and cause pain. Evidence suggests that this happens in 1 in 10 breast implant operations (N.B. for all implants, not just silicone implants).

- **Possibility of rupture** – this is the development of a split or hole in the implant shell. The MHRA notes that there is little information on the overall rate of rupture and implant life expectancy is unknown. It also notes that rupture does not always cause medical problems and that the majority of silicone gel filled implants will remain within the fibrous capsule created by the body around the implant. However, it does acknowledge that occasionally the gel can spread outwith the capsule and create lumps known as ‘siliconomas’ which may give rise to local symptoms such as tenderness. In a small number of cases, gel has been found in the breast tissue, the muscles under the breast, the armpit and (rarely) around the nerves to the arms.

- **Loss of sensitivity** – this refers predominantly to the loss of sensation around the nipple which is estimated to affect 1 in 7 of all those having implants

- **Scaring** – while scaring is a normal part of any surgery, up to 1 in 20 receiving breast implants will experience scars that are red or highly coloured, thick, painful and which may take many years to improve.

- **Undesirable Appearance** – the position of the breast may be unsatisfactory and the shape of the breast tissue unpredictable

\(^2\) MHRA (2005) *Breast implants information for women considering breast implants*
In relation to the association with autoimmune diseases and connective tissue diseases like rheumatoid arthritis, the MHRA refers to the latest of 3 evidence reviews which have been conducted in this area. The MHRA highlights that the latest review (from 1998) by the Independent Review Group found “no scientific relationship between silicone gel implants and immune reactions” and “no relationship was shown between silicone gel implants and long term systemic illness, nor with specific connective tissue disease or non-specific systemic illness”. The MHRA assures that it continues to evaluate all new scientific evidence and in the event of any change further advice will be communicated to the public. The MHRA also encourages patients and surgeons to report any adverse events to the ‘Adverse Incident Centre’. This helps the MHRA monitor faults with medical devices.

However, in November 2010, the former president of the British Association of Aesthetic Plastic Surgeons (BAAPS), raised concerns over the regulation of medical devices following the removal from the UK market of a specific type of silicone gel implant (manufactured by Poly Implant Prothése). Dr Nigel Mercer claimed patients are treated like “guinea pigs” because medical devices, unlike medicines, do not need to undergo independent clinical trials before being placed on the market (See above for a description of the procedure).

3 Year Time Bar for Medical Injury

Breaches of criminal law are not normally subject to any time limits. However, in relation to civil justice, the law of limitation of actions in Scotland is set out in Part II of the Prescription and Limitation (Scotland) Act 1973.

Section 17 of the Prescription and Limitation (Scotland) Act 1973 provides that a personal injury action must be commenced either within three years of the injury being sustained or within three years of the pursuer becoming aware that the injury had been sustained. Section 19A of the 1973 Act gives the court some discretion to allow an action to be commenced more than three years after an injury has been sustained where it seems equitable to the court to do so.

The rationale for such time bars is that where there is delay, the quality of justice diminishes, as over time witnesses may have died, memories deteriorated and relevant documents lost or destroyed.

Furthermore, it is a general principle in most legal systems that the legal consequences of past events should be assessed or determined according to the contemporary standards applying at the time of the events. Thus, for example, whether a form of medical treatment given to a patient in the past

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3 Independent Review Group (1998) Silicone gel breast implants: The report of the Independent Review Group. The Independent Review Group was set up by the Chief Medical Officer, at the request of the Minister for Health, following concerns expressed by women in relation to silicone gel implants.

4 BBC News Website (14 November 2010) Cosmetic surgeon concerned over “guinea pig” patients
constituted medical negligence has to be assessed in the light of the state of medical knowledge at the time when the treatment was given and of what was regarded as proper medical practice at that time. If a long time has passed between the giving of the treatment and the making of the claim, it may be difficult to establish the state of knowledge and proper practice applying at the time of treatment.

A further reason for making provision for limitation of actions is that of legal certainty. It is considered appropriate that there should come a point at which businesses, public authorities and insurance companies should be able, in reasonable safety, to "close their files" and dispose of records (Scottish Law Commission, 2006⁵).

In 2007 the Scottish Law Commission produced a report (‘Personal Injury Action: Limitation and Prescribed Cases’⁶) which recommended that the time bar should be raised from 3 years to 5 years. The rationale behind this was that it would recognise the time-consuming nature of preparing a case and gathering evidence.

**Scottish Government Action**

Neither the Scottish Government, nor any of its agencies, has issued information on the risks associated with silicone gel implants. However, as noted above, the MHRA (which works on a UK basis) has produced a booklet for patients considering breast implants. This booklet outlines the recognised risks associated with the procedure.

On 8 December 2009, in response to a PQ (S3W-29780), Fergus Ewing MSP announced the Scottish Government’s intention to consult stakeholders on a number of the Law Commission’s reports, including ‘Personal Injury Action: Limitation and Prescribed Cases’. The consultation is expected to be launched next year⁷.

**UK Government Action**

The risks posed by silicone gel implants have been investigated 3 times at the request of the UK Department of Health (in 1992, 1994 and 1998). None of the reviews has found a link between silicone gel implants and connective tissue diseases or other systemic illnesses.

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**25 November 2010**

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⁷ Personal Communication with the Scottish Government
SPICe research specialists are not able to discuss the content of petition briefings with petitioners or other members of the public. However if you have any comments on any petition briefing you can email us at spice@scottish.parliament.uk

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