

## Poly Implant Protheses (PIP): Government Clarity or Confusion?

**The Government has sought to clarify their position in respect of the PIP implants by publishing advertisements in national newspapers. The Government has said there is no need for routine removal of the PIP implants, but that women should be able to have the implants taken out by private clinics or the NHS if they are anxious.**

The chief medical officer, Professor Dame Sally Davies, said the government had already been issuing the advice through a number of sources.

"What we're doing... this weekend (14 January) is making sure the clarity of the information, with the advice from an expert group involving plastic surgeons, is out there for the whole population to see."

The Government has raised the temperature of the debate, with the Health Secretary Andrew Lansley accusing private clinics which inserted potentially faulty PIP breast implants of "not stepping up to their responsibilities" in removing them. Mr Lansley said he would be examining the clinics' "ability to meet their liabilities towards their patients".

This advice is unlikely to calm patients' nerves, until investigations have determined the risks, if any, associated with the industrial gel used in the French implants. Indeed, it is somewhat premature for the Health Secretary to make accusations against private clinics, simply because they inserted the implants. One assumes the clinics will say they relied on health agencies to ensure the implants were not harmful to health. In that respect it will be interesting to see how the Medicines and Healthcare products Regulatory Agency ("MHRA") respond.

Patient concern is recognised by those in Europe, in that the PIP breast implant scandal "reinforces" the need to reform Europe-wide regulation, according to the European Commission. Such reform is unlikely to be limited to breast implants, but all implants, such as pacemakers and buttock implants. The British Association of Aesthetic Plastic Surgeons also calls for the European health and safety standard (CE) to be tightened up.

These statements follow the Government review of early January, cognisant that the implants may have been used in over 40,000 women in Britain. This review was carried out notwithstanding the opinion of the UK watchdog, the Medicines and Healthcare products Regulatory Agency, that the risk of a PIP implant rupturing is just 1%.

Sir Bruce Keogh, NHS Medical Director has delivered an interim report upon the health risks from PIP implants, involving an expert group. The main conclusions of the interim report are that there is no clear evidence at present that patients with a PIP implant are at greater risk of harm than those with other implants. Consequently, the group agree with the MHRA advice that there is no specific safety concern identified which requires a recommendation of routine removal of PIP implants.

The experts have considered the available evidence, which is not determinative, and therefore recommend additional information be collated and a further report be produced, so that a more informed view can be taken.

The overriding concern of the group is the safety and compassionate treatment of women with PIP breast implants. Therefore, it further recommends that where women have received a PIP implant as part of NHS treatment, they should be contacted to inform them that they have a PIP implant. Secondly, those patients should be provided with relevant information and advice. They should be

offered further procedures subject to clinical need and taking full account of the wishes and concerns of the patient. The group make recommendations that the private sector take similar action.

This interim report will do little to address the fears of patients following the concerns expressed in France, when surgeons noticed the breast implants ruptured more easily than others.

In a police interview in 2010, PIP's owner Jean-Claude Mas admitted the company had deceived European safety inspectors "without a problem" for 13 years by ordering employees to hide the unauthorised silicone when they visited its factory. The company used industrial grade silicone rather than medical grade material, which has passed safety tests for use in a human body.

As a result of the investigation PIP was shut down in 2011 by the French Government. Notwithstanding the concerns of the French, Germany, Czech Republic and Venezuela Governments, the British administration is less anxious. There is not a consensus across the political spectrum.

Companies that sell cosmetic surgery are duty-bound to help women who have had faulty breast implants, a Labour MP has said.

Such firms should honour their responsibilities and offer help to their patients who have had the surgery, according to shadow health secretary Andy Burnham.

Mr Burnham said the companies which provided the surgery should pay for women to have consultations with a doctor to talk about what they can do.

Health Secretary Andrew Lansley, speaking to BBC Radio 4's Today programme, agreed. He said: "The industry should meet that cost (of GP consultations).

"You get the distinct impression here we are dealing with an industry that's good at the sales pitch and taking the money up front but less good at the after-care and facing up to responsibilities when things go wrong."

Mr Lansley said the cosmetic surgery companies are "evading responsibilities", adding: "I would ensure that people who have had a problem, where there has been evidence of rupture, that they get immediate corrective surgery paid for by the private cosmetic surgery industry. It's just not acceptable to hear they have refused to do that."

This lack of consensus from scientists and politicians will leave patients anxious. Some patients may seek legal redress, perhaps compensation for personal injury, particularly those who have already suffered ruptures. They will have suffered some physical harm, psychological upset and perhaps also undergone secondary procedures to replace those implants, with further implants made by PIP. The outcome of such litigation will be influenced by the further findings of the expert group led by Sir Bruce Keogh and separate investigations in France.

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