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To:
General Practitioners
NHS Medical Directors
Cancer and Plastic Surgeons

Dear Colleague

PIP SILICONE GEL BREAST IMPLANTS

Further to my letter of 23 December 2011, I am writing to update you following the publication of the report from the Expert Advisory Group reviewing the above matter.

This is a difficult area because of the lack of hard data, and women's natural concerns. The expert group, which includes surgeons active in this field, have reported this today and can be viewed and downloaded from <http://www.dh.gov.uk>. In summary, this group reviewed the available data and concluded 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, but that the available evidence is subject to considerable uncertainty. They are recommending collection of additional data. The group has concluded that the advice given by the MHRA still stands and that there is not enough evidence to recommend routine explantation of these breast implants. The group also agree there is no link with cancer.

When counselling your patients who have had implants from this manufacturer, I believe that it is useful for patients to be aware of the following:

1. All breast implants carry a risk of rupture increasing over time, and many require removal within 10 years. Please refer to the Expert Advisory Group report which provides data from the FDA on implant removal rate, and the eight and 10 year rupture rate which has been found in two studies of other makes of implant.
2. It is important that patients are aware of all the risks of surgery when considering whether to have their implants removed. This is a major procedure, and like all operations carries associated risks, including anaesthetic risk and the risk of infection. The Royal College of Anaesthetists has published

the risk of death from anaesthesia is approximately 1:100 000. There are clearly other less severe risks, please refer to the Royal College of Anaesthetists Risk Information Leaflets (<http://www.rcoa.ac.uk/index.asp?PageID=1209>).

I also attach a copy of the guidance produced by MHRA, detailing information for women considering breast implants, a version of which should have been provided to your patients prior to consenting to the procedure. I feel that it may be beneficial for you to have sight of this information.

This is a worrying time for patients who have had breast implants, both those who know they have had a PIP implant and those that could be worried their implant might be a PIP.

What this means for NHS Patients

In any situation like this, doctors have a duty of care for their patients and the NHS has a duty of care to NHS patients. As such, the NHS needs to ensure that they receive the support they can expect from the NHS. That support should include the following model of care:

- All women who have received a PIP implant from the NHS will be contacted to inform them that they have a PIP implant and to provide relevant information and advice. If in the meantime NHS patients seek information about the make of their implant then this will be provided free of charge
- Women who wish to will be able to seek a consultation with their GP, or with the surgical team who carried out the original implant, to seek clinical advice on the best way forward;
- If the woman chooses, this could include a non-urgent examination by imaging to see if there is any evidence that the implant has ruptured;
- The NHS will support removal of PIP implants if, informed by an assessment of clinical need, risk or the impact of unresolved concerns, a woman with her doctor decides that it is right to do so. The NHS will replace the implants if the original operation was done by the NHS.

The Department is working with the private sector so they offer the same service to their patients as the NHS is offering. If a clinic that implanted PIP implants no longer exists or refuses to care for their patient - where that patient is entitled to NHS services, they can of course expect to access NHS services in the usual way based on clinical need. Any NHS service in that respect would not include the replacement of private cosmetic implants.

The Expert Advisory Group have also advised of the signs and symptoms of problems with PIP implants for which a specialist referral for assessment may be required. This information can be found in Annex E of the Expert Advisory Group report (please refer to link above).

Sir David Nicholson has written to Chief Executives of all Strategic Health Authority Clusters, Primary Care Trust Clusters, NHS Trusts and NHS Foundation Trusts. A copy of Sir David's letter can be viewed and downloaded at: <http://www.dh.gov.uk>

I hope this information helps you to guide your patients, so that each one can take the best decision for them personally.

I remain concerned, as Chief Medical Officer, at the high level of cosmetic implants in young people. In particular, the apparent lack of real understanding by recipients of the associated risks.

A handwritten signature in black ink that reads 'Sally C Davies'.

**PROFESSOR DAME SALLY C DAVIES
CHIEF MEDICAL OFFICER
CHIEF SCIENTIFIC ADVISER**