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To:
General Practitioners
NHS Medical Directors
Cancer and Plastic Surgeons

Dear Colleagues

PIP SILICONE GEL BREAST IMPLANTS

I wrote to you on 6 January, and again on 27 January, about the advice from Sir Bruce Keogh's expert advisory group and about the support which the NHS should give to women with PIP silicone gel breast implants.

Recent developments

2. When the problems with PIP breast implants first came to light in March 2010, we understood – based on information from the French regulator AFSSAPS – that the fraudulent use of non-medical silicone gel began in or after 2001. The French regulator has now informed us that they cannot be certain when the fraud started. It is therefore possible that some women who received PIP implants before 2001 may also be affected. From sales data we understand that some 7,000 women in the UK may have received PIP implants prior to 2001, although some of these implants may already have been explanted or exchanged.

3. We are asking all NHS Trusts to check their records and identify any additional patients who received PIP implants as a result of NHS treatment during this period. This extends the exercise which was originally launched following Sir David Nicholson's letter to the service of 6 January 2012.

4. In every other respect our guidance remains the same. On the evidence at present available, we do not consider that routine explantation of PIP implants, as a precautionary measure, is necessary. We will however support women who, in agreement with their doctor and based on clinical need, decide that they would like the implants removed.

Care of NHS patients

5. The NHS is therefore asked to support the following model of care as set out in my earlier letters:

- 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 general practitioner, 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.

NHS care for private patients

6. We are encouraging all private providers to support the same model of care, and many have agreed to do so. However, we are aware that a number of large private providers are falling short in a number of ways, for instance by failing to provide scans free of charge or (in some cases) refusing even to remove PIP implants in the absence of clear evidence of rupture or bleeding. We are also aware that some private providers have ceased trading.

7. I would be grateful therefore if you could provide all necessary reassurance and support for patients of private clinics who, for whatever reason, come to the NHS for help. The patient should be encouraged to go back to the original provider if possible. However, if the original provider is unable or unwilling to help, or has gone out of business, NHS GPs should carry out a clinical examination and refer onwards to NHS specialist services as appropriate. They should make clear that the NHS will pay for removal of the implants, if this is the decision taken by the woman following clinical examination and discussion with an NHS GP or specialist. The NHS will not replace the implants unless this is clinically necessary.

Further work of the expert group

8. The expert group is continuing to collect evidence on the rates of rupture, gel bleed and other adverse effects on explantation of PIP and other makes of implant; and has commissioned a programme of further chemical and toxicology tests on a wider sample of PIP implants. The group will meet again in the near future to consider any further evidence, and further guidance will be issued then as needed.

Yours sincerely

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

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