UPDATE ON PIP BREAST IMPLANTS

New evidence has emerged which shows that around 7,000 more women in the UK may be victims of the PiP scandal caused by a French breast implant manufacturer, Health Secretary Andrew Lansley announced today. These women will be eligible for the same NHS care as announced in January.

French authorities had previously advised that only PiP breast implants that were used after 2001 may have been made with unauthorised silicone gel. Following an investigation by the UK regulator, the Medicines and Healthcare products Regulatory Agency (MHRA), the French authorities have this week reported that PiP implants made before 2001 may also contain unauthorised silicone gel.

This means an extra 7,000 women, who had PiP implants before 2001, could be affected. About one in five breast implants need replacing within ten years, whatever the make, so it is unlikely that all these 7,000 women still have the same PiP implants.

The independent expert group – led by the NHS Medical Director Professor Sir Bruce Keogh – continues to advise that there is not enough evidence to recommend routine removal of PiP breast implants given that this would mean many women having to have surgery.

However, we have always recommended that if women are concerned they should speak to their surgeon or GP. The NHS will support removal of PiP implants if, after this consultation, the patient still has concerns and with her doctor she decides that it is right to do so. The NHS will replace the implants if the original operation was done by the NHS.

We expect the private sector to do the same for their patients. We believe that private providers have a duty to take steps to provide appropriate after-care to patients they have treated. 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, the NHS will support the removal of PiP implants where clinically necessary.

All women should be offered the same care, whether they had their implants before or after 2001.

Health Secretary Andrew Lansley said:

“The French regulator has confirmed this week that more women may be affected by the criminal activity of the French breast implant manufacturer PiP. These women are the victims of a fraudulent company and I know this situation is causing a huge amount of anxiety.

“I want to reassure those affected by the news today that they will be provided with all the help they need from the NHS.”
“We are still working to get private clinics to live up to their responsibilities and look after their patients. Our commitment is to ensure support for all women from the NHS if needed; we will continue to press for the same standard of care or redress from private providers.”

Professor Dame Sally Davies, the Chief Medical Officer said:

“The expert group advises that there is no evidence to suggest that every woman with a PiP implant should have them removed. But we know this is a worrying time for them and want them to be able to see a GP or specialist to get reassurance and have them removed if necessary.

“All women who had the implants put in on the NHS will be able to have them removed and replaced by the NHS. We expect private clinics to offer their patients the same care. If they refuse, the NHS will provide advice, a scan and, if necessary, remove the implants. Private patients will not, however, be able to have their implants replaced on the NHS unless this is clinically necessary.

“We will be placing adverts in the weekend papers again to inform all women with PiP implants about the advice from the experts and how they can get help if they are concerned. I have also written to GPs today to remind them that we want them to help women with PiP implants.”

The Department of Health is advising women with PiP implants to take three steps to reassure themselves. The steps are to:

- **Find out** if they have PiP implants by checking their medical notes. This information can be accessed for free from clinics or through GPs. Most women who had PiP implants on the NHS should already have received a letter – anyone who received an implant between 1997 and 2000 will be contacted in the near future.

- **Speak** to their GP or surgeon. Women who had PiP implants on the NHS should speak to their specialist or GP and women who had them done privately should speak to their clinic.

- **Agree what’s best for you.** Women should get advice on whether or not they need a scan then discuss appropriate action with their doctor.

For those who decide with their doctor that they want their implants replaced, the NHS will do it for free if the original operation was done on the NHS. However, if the original operation was performed in a private clinic the patient will need to speak to their clinic to see if they will replace them for free.

Further information is available at [http://www.nhs.uk/Conditions/Breast-implants/Pages/PIP](http://www.nhs.uk/Conditions/Breast-implants/Pages/PIP).
The Chief Medical Officer has written again to all GPs to set out what they should do if a private patient with PiP implants asks for their help and to inform them about the change in advice from the French authorities. The letter is available on the NHS Choices website at www.nhs.uk.

Notes to Editors

1. For media enquiries call the Department of Health Newsdesk on 020 7210 5221.

2. Two reviews have been set up to investigate what happened with PiP implants and to look at whether the cosmetic surgery industry needs to be better regulated. The press notice announcing the reviews can be found at: http://mediacentre.dh.gov.uk/2012/01/24/department-of-health-sets-out-scope-of-pip-implant-and-cosmetic-surgery-reviews/

3. The first report by the expert group can be found at: https://www.wp.dh.gov.uk/mediacentre/files/2012/01/PIP-Breast-Implants_interim-report.pdf

4. The expert group is continuing to collect evidence on rates of rupture, gel bleed and other adverse events, for PiP and for other kinds of implant. Once the new data is analysed the group will meet to review its interim guidance and a further announcement will be made at that time.