Safeguarding public health

Press Release

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PIP breast implants – UK test results

The Medicines and Healthcare products Regulatory Agency (MHRA) has received encouraging results of UK testing on the silicone gel breast implants manufactured by the French company Poly Implant Prosthese (PIP).

The tests found no evidence of genotoxicity (potential for cancer) or chemical toxicity of the filler material in the implants.

The tests are not as extensive as those being carried out in France, but they have provided initial information as to whether there is a safety issue with the filler material.

MHRA Director of Devices Clinical, Dr Susanne Ludgate said, “It’s reassuring that our test results have shown no evidence of any associated risks with the filler material.

“We are however waiting for the results of the French tests which are more extensive and include mechanical testing of the implant shell because there maybe a suggestion of an increased rupture rate compared with other breast implants. We will update clinicians and women once these test results are available and provide further advice on patient management as necessary.

“If women have any concerns, they should speak to their implanting surgeon.

“Implanting surgeons should report any clinical and radiological problems associated with these implants to the MHRA Adverse Incident Centre.

“Further advice and information can be obtained from the Association of Breast Surgery and the British Association of Plastic, Reconstructive and Aesthetic Surgeons (BAPRAS).”

Ends

Notes to Editor

1. As these products have been widely used in the UK, the MHRA was keen to identify as early as possible any potential toxicity associated with the implant filler. It therefore commissioned independent UK testing.

2. The previous press release about this issue can be seen at: http://www.mhra.gov.uk/NewsCentre/Pressreleases/CON076513

3. Further advice and information can be obtained from the following websites:

    - Association of Breast Surgery (www.associationofbreastsurgery.org.uk);
    - British Association of Plastic, Reconstructive and Aesthetic Surgeons (www.bapras.org.uk)

4. In general, a medical device cannot be marketed in the UK without carrying a CE Mark of Conformity. A CE mark is applied by the manufacturer to denote that the device meets the relevant regulatory requirements and performs as intended. For all but the very lowest risk devices, such as unmedicated bandages, an EC Certificate of Conformity must be obtained from an independent certification organisation, called a Notified Body, before the CE marking can be affixed. The MHRA is responsible for designating UK Notified Bodies and regularly audits them to ensure that they continue to perform to the required standards.

5. For further general information about breast implants, see link to MHRA website: http://www.mhra.gov.uk/Safetyinformation/Generalsafetyinformationandadvice/Product-specificinformationandadvice/Breastimplants/index.htm

6. Adverse incidents relating to medical devices can be reported at the MHRA website: www.mhra.gov.uk. Information and printed incident report forms are available from: the MHRA Adverse Incident Centre on 020 7084 3080 or e-mail: aic@mhra.gsi.gov.uk

7. The MHRA is the government agency responsible for ensuring that medicines and medical devices work, and are acceptably safe. No product is risk-free. Underpinning all our work lie robust and fact-based judgements to ensure that the benefits to patients and the public justify the risks. We keep watch over medicines and devices, and take any necessary action to protect the public promptly if there is a problem. We encourage everyone – the public and healthcare professionals as well as the industry – to tell us about any problems with a medicine or medical device, so that we can investigate and take any necessary action. www.mhra.gov.uk