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RÉPUBLIQUE FRANÇAISE

MINISTÈRE DU TRAVAIL,
DE L'EMPLOI
ET DE LA SANTÉ

SECRÉTARIAT D'ÉTAT
CHARGÉ DE LA SANTÉ

PRESS RELEASE

Paris, 23 December 2011

Update of Recommendations for Women with Silicone filled Poly Implant Prosthesis (PIP)
Breast Implants

Xavier Bertrand, Minister for Labour, Employment and Health, and Nora Berra, State Secretary for Public Health, are updating the healthcare recommendations for women with PIP implants.

As a preventive measure, but not as an emergency, they suggest that the explantation of the implants, even without any clinical signs of deterioration of the implant, should be proposed to women with PIP implants. This procedure should be discussed during a visit to their surgeon, already recommended as a preliminary step.

On December the 7th, the ministry officials responsible for public health asked government health oversight agencies (the National Cancer Institute, the Public Health Monitoring Institute and Afssaps) to obtain their expert input, along with professional societies, on reports of adverse effects in women with PIP implants.

The opinion issued on 22 December indicates that to date there is no increased risk of cancer in women who have PIP implants compared to other implants. However, the well-documented risks associated with these implants are ruptures and the gel's capacity to cause irritation that may lead to inflammatory reactions, thus making removal difficult.

The ministry officials responsible for public health have therefore decided:

1. To reinforce the recommendations made by Afssaps:

   - Women with breast implants shall check the brand of their implant on the implant card they were given. If they have no such card, they shall contact their surgeon or the institution where the implantation was done.
   - Patients with PIP implants shall consult their surgeon. At that time, they will be proposed a preventive explantation, even if there is no clinical sign of deterioration of the implant. If they do not wish to have their implant removed, they shall receive a follow up by ultrasound scan every 6 months, targeting breast and axillaries lymph node areas;
   - Any rupture, suspected rupture or oozing of an implant shall result in its explantation, as well as the second breast implant.
   - Prior to any removal, whatever the reason is, a recent imaging (including a mammography and a breast and axillary ultrasound scan) shall be available.

2. To ensure that any woman who wishes to undertake preventive explantation can do so, the ministry officials have requested that all Regional Public Health Agencies (ARS) set up, as of early January, a hotline for women with PIP breast implants who might have difficulties reaching a healthcare professional to propose them a list of institutions able to treat them.

3. To initiate a prospective epidemiological study on ruptured breast implants.

The involved healthcare institutions and healthcare professionals are likewise being informed of this decision and these new recommendations.

Any costs associated with eventual explantation, including hospitalisation, will be covered by the national health plan. In the case of women who have had reconstructive surgery following a breast cancer, the implantation of a new prosthesis will also be covered by the health plan. Ministry officials remind that independent plastic surgeons are requested not to charge off-schedule fees for these procedures, as recommended by the French Medical Association.

The monitoring committee, which will meet at the Ministry of Health on January the 5th 2012, will provide another progress report on the situation and will closely examine the procedures and measures for applying this decision in order to best respond to the concerns of the women involved, and to enhance the management of all requests for explantation.

For any additional information, a free hotline : 0800 636 636, is available nationwide, from Monday through Saturday: 9:00 a.m. – 7:00 p.m.

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Important new information about a case of breast anaplastic large cell lymphoma in a woman who has had breast implants prefilled with silicone gel PIP (French company Poly Implants Prothèses)

Breast anaplastic large cell lymphoma with breast implants.

This is a malignant tumour of the lymphatic system developed at the expense of particular T lymphocytes and not of epithelial tissue of the breast. Several cases of this type of lymphoma have been described in the literature, which led the FDA to publish in January 2011 a review of this new risk potentially associated with breast implants.

In the United States,
The FDA has identified in January 2011, 60 cases associated with a breast prosthesis and reported worldwide, including 34 located in the breast and documented (17 in USA.). This particular type of lymphoma is very rare among all lymphomas: as recorded by American cancer registers (SEER), it is estimated that one woman out of 500,000 suffers from this type of lymphoma each year in the United States. The location in breast of this form of lymphoma is even more rare. The projection in the United States is of 3 cases per year over 100 million women.
Considering that nearly 4 million women have been implanted with breast implants in the United States between 1998 and 2009, the FDA believes that in the United States, the incidence of anaplastic large cell lymphoma is higher in women with breast implants compared with the epidemiological data observed for the general population.

About anaplastic large cell lymphoma, the FDA concluded in January 2011:
1. to a "possible" association of this type of lymphoma with prosthesis, reinforced by the fact that the cases described occurred preferentially in areas at the near proximity of the prosthesis;
2. to be today unable to connect reliably this serious event to a type of prosthesis;
3. that the physiopathological cause of this serious event is not established today;
4. that, given the extremely low frequency of this type of lymphoma and given evidence collected today on breast implants, the safety of these products is not in question.

In France,
A fatal case has been reported to Afssaps on November 25th, 2011. The concerned patient, carrier of PIP prostheses, presented a breast anaplastic large cell lymphoma.
This case reported in France is in itself a factor to be considered epidemiologically as occurring in a woman among the 30 000 carriers of PIP prosthesis which have been removed from the market.

PIP prostheses removed from French market on March 29th, 2010.

The first abnormalities clinically observed and reported within the medical device vigilance system, showed at the end of 2009, an increase of rupture for the PIP breast implants, leading to a rupture rate higher than the rate observed with implants from other manufacturers.
Abnormal oozing phenomenon (also called perspiration or transudation) of the gel was also observed.

Inspections and controls performed by Afssaps have documented several nonconformities justifying the suspension of PIP prostheses from the market on March 29th, 2010.

These failures were :

- On the nature of the silicone gel inside the prosthesis: the gel did not have the degree of quality of a silicone gel for breast implants;
- On the mechanical strength of the prosthesis: the tear elongation test was not in compliance. This result showed a weakness of PIP gel-filled envelopes and corroborates the observations of retrospective surveys conducted by Afssaps with many user establishments of these prostheses. They revealed a rupture rate higher than the average;
- On the "irritant behaviour" of the silicone gel used for PIP prostheses which is neither found with silicone gels of other prostheses nor with the gel described in the technical documentation for the placing on the market. This can lead to inflammatory reactions in some patients,
- On the lack of genotoxicity of the gel used, which does not exclude that the oozing of the gel in contact with the capsule may have contributed to the development of anaplastic large cell lymphoma: in fact, abnormal oozing of a particularly irritating gel could be a factor of risk of occurrence of this rare tumour.

Follow-up of recommendations

These recent events in France led Afssaps to update its recommendations sent to the whole medical profession in April 2011 to enable it to respond to each individual situation:

- Patients should routinely receive a clinical examination and an ultrasound scan every 6 months, targeting for each of these examinations, breast and axillaries lymph node areas;
- Any rupture, suspected rupture or oozing of a prosthesis should lead to its explantation, as well as that of the second prosthesis.

Afssaps recommends that patients contact their surgeon to discuss the possibility of explantation even without clinical signs of deterioration of the prosthesis. **The concerned women will consider the most appropriate attitude according to their personal situation, their feelings, the age of their prostheses and their expectations at the aesthetic level.** This choice will take place after evaluation with the surgeon of the individual risk / benefit ratio.

Conditions for medical expenses within health insurance in France are :

- All women with PIP breast implants will be reimbursed for their medical and surgical expenses related to explantation (ultrasound, analysis, implant removal, examination post-operative).
- Women who are recovering from a reconstruction after breast cancer surgery will also be reimbursed for the implantation of a new prosthesis.

Necessary information is available on the website of the French Health Insurance:
http://www.ameli.fr/assures/soins-et-remboursements/combien-serez-vous-rembourse/implantsmammaires.php

Safeguarding public health

MHRA

Press Statement

Date: Friday 23 December 2011
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PIP breast implants – UK medical devices regulator says no evidence to support routine removal

Following the announcement in France today, the Medicines and Healthcare products Regulatory Agency (MHRA) is not recommending routine removal of PIP silicone gel breast implants in the UK.

We recognise the concern that some women who have these implants may be feeling but we currently have no evidence of any increase in incidents of cancer associated with these implants and no evidence of any disproportionate rupture rates other than in France.

We therefore do not believe that the associated risks of surgery from breast implant removal can be justified without further evidence.

We will continue liaising with the French medicines and medical devices regulator and we are awaiting the evidence to support the decision made in France. This will be evaluated as a matter of priority by our clinical and toxicological experts and we will issue further advice if necessary.

In the absence of strong clear evidence to the contrary, we see no reason to alter our current advice that there is no need to routinely remove these PIP breast implants.

In the meantime we would recommend that all patients who have questions about their PIP breast implants should seek advice from their implanting surgeon.

We had discussions on 21 December 2011 with other health or regulatory experts from France, the Netherlands, Portugal, Italy, Ireland, Hungary, Austria, Denmark and Malta. They all agreed that there was no evidence of any increase in incidents of cancer associated with PIP breast implants and no evidence of any disproportionate rupture rates other than in France. Information obtained from the Australian Regulatory Authority (TGA) is consistent with the figures from all the above European countries other than France in terms of rupture. They have no reported cases of lymphoma.

We have continually monitored the safety of these breast implants. In March 2010 we advised clinicians not to implant these devices and at the same time advised patients who were concerned about their PIP implants to consult their implanting surgeon. MHRA commissioned toxicity testing on the unapproved silicone gel used to fill PIP breast implants, including genotoxicity and chemical toxicity. The results of these tests have been discussed with relevant experts and we have concluded that there is no safety issue related to this filler material. Similar testing carried out by the French medicines and medical devices regulator confirmed these conclusions.

Ends

Notes to Editor

1. Please see the MHRA's medical device alert issued on 31 March 2010:

http://www.mhra.gov.uk/Publications/Safetywarnings/MedicalDeviceAlerts/CON076499

2. Please see the MHRA's previous press releases about the testing of the unapproved silicone gel used to fill PIP breast implants:

http://www.mhra.gov.uk/NewsCentre/Pressreleases/CON076513

http://www.mhra.gov.uk/NewsCentre/Pressreleases/CON093706

http://www.mhra.gov.uk/NewsCentre/Pressreleases/CON094170

http://www.mhra.gov.uk/NewsCentre/Pressreleases/CON114614

3. The MHRA is aware of the US Food and Drug Administration's (FDA) January 2011 Medical Device Safety Communication entitled 'FDA Medical Device Safety Communication: Reports of Anaplastic Large Cell Lymphoma in Women with Breast Implants'.

4. The MHRA informed UK healthcare professionals about the FDA's communication via a medical device alert issued in February 2011.

http://www.mhra.gov.uk/Publications/Safetywarnings/MedicalDeviceAlerts/CON108774

   The MHRA also continued to review available evidence for association of cancers of women with breast implants in consultation with the relevant UK professional bodies for breast surgery and surgical oncology and has concluded that there is no evidence to indicate an association with cancer. Additionally the MHRA worked with the Cancer Registry and could find no evidence for an association. The MHRA has not received any reports of women with breast implants of any type in the UK with a diagnosis of anaplastic large cell lymphoma (ALCL).

   Also, the MHRA consulted with experts to discuss whether there was any danger to babies having been breast fed by mothers with these implants. It was concluded that there were no safety issues.

5. Based on reports to the MHRA from our Adverse Incident Centre (AIC) approximately 1% of women in the UK with PIP breast implants have suffered implant failure, including rupture. This contrasts with information from the French medical device regulatory authority, AFSSAPS, which suggests a failure rate, including rupture, of around 5% in France.

6. 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

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