

Saint Denis, 8 December 2011

Letter to healthcare professionals

Medical devices vigilance

New information about a case of breast cancer (adenocarcinoma) in a woman using prefilled, silicone gel PIP breast implants

Dear Sir or Madam,

On 5 December 2011, Afssaps received a report of a case of breast cancer (adenocarcinoma) in a patient who had been using PIP implants for several years.

The FDA recently (June 2011) assessed the occurrence of breast cancer in women with silicone breast implants. After an extensive review of cases in the U.S. and of the literature, it concluded that breast implants were safe and stated that women with this type of implants presented no increased risk of developing breast cancer.

To date, Afssaps has received reports of two cases of breast cancer in women using PIP implants: one concerns a case of anaplastic, large-cell lymphoma (see letter of 29 November 2011), and the other, a case of breast adenocarcinoma.

Given the documented aberrations occurring with PIP implants, which led to their withdrawal from the market in March 2010, this new information justifies upgrading the recommendations issued by Afssaps:

Patients who have PIP implants must systematically be offered a clinical exam and suitable radiological examinations.

Any rupture, suspected rupture or seepage of an implant must result in it being removed, along with the second implant.

The option of a preventive removal of this implant, even without clinical symptoms of its deterioration, must be discussed with all women concerned.

Given these new cases, the Ministry of Health has contacted the competent healthcare agencies and learned societies in order to develop specific recommendations for healthcare professionals, to be released within the month, on methods of diagnosis, removal and monitoring.

Xavier Bertrand, the Minister of Labour, Employment and Health, and Nora Berra, State Secretary for Public Health, have requested that the General Director of Public Health set up a monitoring committee comprised of all stakeholders (health authorities, healthcare professionals, learned societies, patients' associations, etc.).

Allow me to remind you of the obligation to report to the Afssaps Department of Vigilance, by e-mail at: dedim.ugsv@afssaps.sante.fr or by fax at: 01.55.87.37.02, any adverse event observed with these devices, especially any case of lymphoma or breast cancer, and any easily available retrospective data related to complications with, or premature replacement of, breast implants.

All of the documents related to this case, and in particular updated replies to the most frequently asked questions, are available on the Afssaps Web site.

Yours sincerely,

Prof. Dominique Maraninchi
Afssaps General Director