

Directorate General of Health  
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PRESS RELEASE

### First meeting of the Monitoring Committee Women with breast implants PIP

At the request of the Minister of Labour, Employment and Health, a Monitoring Committee Women with breast implants PIP, chaired by the Director General of the Health, held its first meeting December 14, 2011.

It is composed of the French Agency for Safety of Health Products (AFSSAPS) Institute of Health Surveillance (InVS), the National Cancer Institute (INCA), the Fund National Health Insurance (CNAM), representatives of the French Society of Senology and Breast Pathology (SFSPM), the French Cancer Society (SFC) of the French Society of Oncology Private (PCF), the French Society Hematology (SFH), the French Society of Surgical Oncology (SFCO), the French Society of Plastic Reconstructive and Aesthetic Surgery (SOFCPRE), the National Union of Plastic Reconstructive and Aesthetic Surgery (SNCPRE), the National Council of the Medical Association, Association of human carriers of Brand implants P.I.P. (PPP), the Movement for the Defense of Women with implants and prostheses (MDFPIP) and the National League of fight against cancer ..

During this first meeting, Afssaps reported the reports of adverse serious adverse events observed in women with implants with PIP in particular, today, 8 cases of cancer reported that to date no accountability has been established between these cancers and the port of PIP breast implants (1 case of lymphoma Anaplastic large cell, 5 cases of mammary adenocarcinoma, 1 case of lymphoma amygdala and a case of acute myelogenous leukemia). These monitoring data will be updated two times a month and made available on the Afssaps website.

The committee then reviewed the steps taken since the recall of these prostheses March 2010, in terms of terms of diagnosis, and possible explanation monitoring of women with implants PIP.

Thus, it is currently indicated:

- The women with these implants, the need to consult their surgeon or physician:
  - They must have a systematic examination and testing radiological appropriate.
  - Any rupture, suspicion of rupture or oozing of a prosthesis should lead to its explantation, as well as that of the second prosthesis.
  - A preventive explantation of the prosthesis without clinical signs of deterioration of the implant should be discussed with the women concerned.
- To health professionals to contact all their patients bearing implants PIP to conduct these reviews. They must also notify the AFSSAPS explantation of PIP breast implants, defective or not;
- The patient groups, to inform their members with updates recommendations

of the AFSSAPS. They must also notify the AFSSAPS explanation of PIP breast implants, defective or not.

These recommendations for health professionals and women with PIP implants, will be adapted according to the bi-monthly assessments of Afssaps and results of the collective expertise entrusted by the Minister to the CNIB and the expected end of December.

The terms of medical management of women with implants PIP health insurance were also recalled. Thus, all women with PIP implant will be reimbursed for expenses related to medical and surgical explantation (ultrasound, analysis, removal of the implant, postoperative examinations). Women who are part of a reconstruction after breast cancer surgery will also be reimbursed for the installation of a new prosthesis. In addition, it will ask the Council of the Order of Physicians to educate practitioners so that there is match between the repayment terms and fees.

Beyond the ongoing legal proceedings, the harm suffered by women with PIP prostheses may be a claim before the Compensation Board of victims of crime (CIVI), or for women with had breast reconstruction after mastectomy for cancer before the Commission Regional conciliation and compensation (RCCI) under the ONIAM.

A further meeting of the Monitoring Committee will be held next month.

Finally, it is recalled that a toll-free number 0800 636 636, was established to meet the questions on this topic.

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