afssaps
Agence française de sécurité sanitaire des produits de santé

**Silicone gel breast implants from Poly Implant Prothèse Company - Information**
15/07/2010

**On March 23. 2010, Afssaps suspended the marketing and use of breast implants pre-filled with silicone gel manufactured by Poly Implant Prothèse (PIP). This decision followed the report in 2009, within the scope of medical devices vigilance, of an increasing number of shell ruptures of these breast implants and the conclusions of the inspection which Afssaps carried out, then, on the premises of the company. This inspection revealed Poly Implant Prothèse used a silicone gel different from the one it declared in the implants' design and manufacture dossier.**

After the suspension decision was made, it was necessary to assess the risk involved for women with these implants, though a risk of rupture exists with any breast implant and, as far as data stands, Afssaps had not pinpointed at the time of the decision any complications different from those usually encountered with other breast implants pre-filled with silicone gel.

A series of analyses on implant specimens collected on the premises of the company PIP had to be carried out to determine the reality and the extent of an over-risk. These analyses could only start during the month of June because of difficulties encountered to get the seized products which had been sealed in the course of an opened preliminary inquiry. They are performed jointly with legal authorities.

These analyses correspond to those PIP should have performed within the framework of the dossier to characterize the silicone gel and to get the EC label.

They have several objectives:

- identify raw materials used in PIP prosthesis,
- evaluate prosthesis and silicone gel properties to characterize the resistance of implants and in particular the shell ,
- perform compatibility with biological tissues tests.

Considering the variable duration of the analyses to be performed, the results of some tests won't be available before the end of August 2010. Afssaps needs the results of all of these tests in order to formulate a reliable evaluation on the impact of the substitution of the silicone gel.

With these results, which are due by mid September, Afssaps will be in a position to eventually adjust its recommendations to women with PIP implants.

Furthermore, Afssaps reminds women with these breasts implants they ought to contact their surgeon so that he/she can prescribe the annual ultrasound or an appropriate examination if necessary.