

April 1<sup>st</sup> 2010

## Press release

### **Silicone filled breast implants manufactured by POLY IMPLANT PROSTHESE (PIP)**

Afssaps has registered over the last three years an increase in reported incidents concerning silicone filled breast implants manufactured by POLY IMPLANT PROSTHESE (PIP). These incidents are mainly rupture of breast implants with following local complications. These incidents often require reoperation.

Further to these vigilance reports, Afssaps carried out an inspection at PIP implants manufacturing plant.

The elements collected during this inspection showed that most of the breast implants manufactured since 2001 have been filled with a silicone gel different from the one described in the CE marking file and in the batch manufacturing files. Thus, these breast implants do not conform to the 93/42/CEE directive.

Considering these elements, Afssaps decided on March 29<sup>th</sup>, to recall, withdraw from the market, and cease distribution, export as well as the use of the silicone filled breast implants manufactured by PIP company.

Surgeons have been informed of this decision; they have been asked to stop the implantation of these breast implants and to notify their patients of a necessary clinical examination. If needed, they will prescribe an ultrasound scan within 6 months.

Samples have been gathered during the inspection in order to perform several controls.

These controls are currently performed by Afssaps and independent laboratories.

When available, the results of these controls will be published promptly.

PIP company went into receivership on March 30<sup>th</sup>.