Scientific Committee on Emerging and Newly Identified Health Risks

Request for a rapid scientific opinion

on the safety of PIP breast implants

1. Background

According to the findings of the French Health Authorities, a French manufacturer (Poly Implant Prothese) fraudulently made use of low-quality material (industrial silicone) different from the one it had declared in the documents submitted for conformity assessment (medical grade silicone).

The products were withdrawn from the EU market in March 2010.

More detailed and regularly updated information can be found on the French authority's websites[1].

The French Health Authorities published recommendations on Friday 23 December 2011.The French Health Authorities have recommended in particular:

- that any woman implanted with PIP breast implants consult her surgeon;

- the explantation (removal) of the PIP breast implants in case of implant rupture, or suspicion of rupture or oozing.

- that, as a preventive measure, but not as an emergency, the explantation of PIP breast implants is proposed, even in the absence of any clinical sign of implant deterioration. For women who refuse explantation, a close medical follow up is recommended;

There is today no common approach in terms of risk management in the different Member States and some Member States have not advised to explant PIP breast implants preventively but to closely monitor women who have received these implants.

2. Terms of reference

In the light of the above considerations and on the basis of the available scientific evidence, the Scientific Committee on Emerging and Newly Identified Health Risks is

[1] http://www.afssaps.fr/ and http://www.sante.gouv.fr

requested to provide a rapid scientific opinion on 'The safety of PIP breast implants' according to the provisions of Article 2.3 of Decision 721/2008/EC.

In particular, the SCENIHR is asked:

1. To determine whether implanted PIP breast implants could give reasons for concern from the health point of view when compared with state of the art implants, taking into account their structure, composition and detected defects (*e.g.* low quality silicon, single envelop instead of double envelop) and the risk of rupture and oozing they may present;
2. In case reasons for concern related to implanted PIP breast implants are identified, to make a risk/benefit analysis of explantation.

In its assessment the SCENIHR is invited to take into account in particular:

- the global reported incident rate associated with PIP breast implants;

- the comparison of this global reported incident rate compared with other breast implants;

- the percentage of this global reported incident rate associated with rupture of PIP breast implants;

- the percentage of this global reported incident rate associated with other type of problems (*e.g.* inflammatory reactions);

- any evidence suggesting that PIP breast implants are more difficult to explant, before or after rupture, in comparison with other breast implants;

- any increased report of lymph node complications associated with the PIP breast implants.

3. Deadline

31 January 2012 at the latest provided data becomes available by 13 January 2012