**Scientific Committee on Health Environmental and Emerging Risks**

Request for a call for data and a literature review on the safety of PIP silicone breast implants and on a possible association between breast implants and anaplastic large cell lymphoma

1. **BACKGROUND**

   A. The safety of the PIP silicone breast implants

   Over many years PIP manufacturer fraudulently made use of industrial silicone instead of the approved medical grade silicone in many of the breast implants produced. Investigations were triggered by an unusually high short-term breast implant rupture. The product was thereafter withdrawn from the EU market.

   Following this fraud SCHENIR was requested to provide two scientific opinions on the safety of the PIP silicone breast implants. The first one, a rapid scientific opinion, was adopted by SCENIHR on 1 February 2012\(^1\). This opinion was updated by a second one, adopted on 12 May 2014\(^2\).

   Given the importance of the matter, DG GROW is committed to monitor the publication of possible new and valid scientific information and allow for the update of the previous opinion on the PIP silicone breast implants in the light of such new scientific data.

   Besides its regular consultation of the National Competent Authorities, DG GROW recognises the need of a formal scientific evaluation of the availability of the said information.

   This need is also highlighted in the remarks of the European Ombudsman’s Decision in case 174/2015/FOR on the Commission's alleged failure to investigate conflicts of interests relating to the adoption of a report on the safety of removing PIP breast implants.

   “The Commission should continue to evaluate new scientific data relating to the safety of PIP implants.”\(^3\)

   The investigation into the availability of new scientific data that would warrant an eventual update of the May 2014 Opinion on the safety of the PIP breast implants should take into account all the necessary fields and especially those covered by the previous

---

\(^1\) http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_034.pdf
\(^2\) http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_043.pdf
\(^3\) http://www.ombudsman.europa.eu/cases/decision.faces/en/61195/html.bookmark
opinion such as the physiochemical properties of PIP implants, their toxicology, the clinical impact and recommendations.

B. Possible association between breast implants in general and anaplastic large cell lymphoma

Anaplastic large cell lymphoma (ALCL) is a very rare type of lymphoma. ALCL is not a cancer of the breast tissue and the prognostic of the disease is generally favourable. A possible association between breast implants and ALCL is under scrutiny in the EU and at international level by regulators and scientists.

According to one estimation\(^4\) there are between 100-250 known cases of ALCL in women with breast implants out of an estimated number of 5 to 10 million women who have received breast implants worldwide.

The information to date suggests that women with breast implants may have a very low but increased risk of developing ALCL while the rarity of the disease makes it difficult to establish a definite causal relationship.

Given that this suspected association between breast implants and ALCL appears to be an emerging risk, SCHEER should investigate if there is enough scientific information available to allow for a full risk assessment of the matter. The existence of information on a specific association with PIP silicone breast should also be investigated.

2. MEANS OF ACHIEVING THE GOALS

In order to accomplish the collection of data on the two issues described above on an as complete and broad possible scale, two types of activities are envisaged:

1) A public call for data open to all stakeholders, of a duration sufficient to ensure that any information pertaining to the two abovementioned topics may be submitted.

2) A review of the published scientific literature and of any other source of relevant data available on the two topics.

The relevant scientific information should be retained and, based on this, SCHEER will reply to the questions described in the terms of reference. Any rejection of acquired information should be justified. The Committee will decide if both topics may be addressed by one call for data and one scientific literature review at the same time or if separate processes need to be organised.

3. TERMS OF REFERENCE

Following the assessment of the availability of the scientific information SCHEER should:

1) Indicate if there is sufficient new scientific information to warrant for an update of the May 2014 Opinion on the safety of the PIP breast implants.

\(^4\) http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm239995.htm
2) Provide an advice on the state of scientific knowledge regarding a possible connection between breast implants and anaplastic large cell lymphoma.

4. **DEADLINE**