Scientific Committee on Emerging and Newly Identified Health Risks

Request for an updated scientific opinion

on the safety of PIP silicone breast implants

1. Background

Following the rapid scientific opinion adopted by SCENIHR on the 1st of February 2012 covering "The Safety of PIP Silicone Breast Implants", it has been recognised that an update of this opinion would be necessary. This was mainly due to the fact that the data available on PIP silicone breast implants was limited at the time of the opinion.

The update of the rapid opinion should be based on additional data to be produced by and collected from the Member States and other international fora, such as the International Laboratory Testing Panel for PIP breast implants[1]. Efforts to produce this data are already ongoing.

The data to be produced and collected should cover:

- the physical and chemical properties of the gel and of the envelope/shell;
- the toxicological properties;
- the incident reports and any other relevant data on the implanted patients follow-up.

In order to accomplish the collection of data on an as complete and broader possible scale, two types of activities are envisaged.

1. The development of an EU questionnaire on implanted patients, to be distributed at national level. The EU questionnaire will be developed based on available models from the Member States and will be used to collect data on implanted patients.

2. The collection of available and forthcoming scientific information on PIP silicone breast implants. If available, besides the data produced by the testing, additional literature data published in the meantime will be taken into account.

[1] Established by the Australian Therapeutics Good Administration, with international participation. http://www.tga.gov.au/safety/alerts-device-breast-implants-pip-120224.htm

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2. Terms of reference

In the light of the above considerations, the Scientific Committee on Emerging and Newly Identified Health Risks is requested to provide an updated scientific opinion on 'The safety of PIP silicone breast implants'.

In particular, the SCENIHR is asked:

1. To contribute to the creation of an EU questionnaire to be used for the collection of data on implanted patients;

2. To provide guidance on the testing undertaken by the member States in terms of tests and studies to be performed, test methodologies, uniform data production;

3. To collect, compile and analyse the data collected;

3. To update its scientific opinion on the safety of the PIP silicone breast implants.

3. Deadline

31 January 2013.