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Medical devices: European Commission asks for further scientific study and draws first lessons from the recent fraud on breast implants

Brussels, 2 February 2012 – Following today's publication of the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) on the safety of silicone products manufactured by the Poly Implant Prothèse (PIP) Company, the European Commission requested to conduct further in-depth study on the potential health impact of faulty breast implants.

The Commission will also discuss with the Member States how surveillance of the medical devices can already be reinforced immediately within the existing legislative framework. In parallel a "stress test" of the legislation on medical devices is under way in order to identify how best the questions raised by this issue can be addressed in the revision of this framework already foreseen for 2012..

Health and Consumers Commissioner, John Dalli said: *"In the current situation, patients' health remains the priority. The opinion published today sums up the current scientific knowledge on this case".* To add : *"Furthermore, the Commission will discuss with the Member States a series of immediate measures to strengthen the existing surveillance and safety controls on medical devices already on the market. The capacity to detect and minimize the risk of fraud must be increased".* To conclude : *"We had already been working on a revision of the Medical Devices Directive, envisaged for adoption this spring. We will now also take into account the lessons learnt from this case and take them on board in redrafting our legislation, in particular with regard to market surveillance, vigilance and functioning of notified bodies."*

Scientists concluded that data available today was insufficient to lead to firm conclusions regarding the health risk for women with PIP silicone breast implants.

The SCENIHR report (requested by the Commission in early January) stresses that, based on the limited data currently available, there is some concern regarding the possibility of inflammation induced by ruptured PIP silicone implants. The report concludes that each case needs to be assessed individually, so the **advice remains that women who are worried should contact their surgeon**.

Scientists also recommend that **further work be undertaken** as a priority to establish with greater certainty any health risks associated with PIP silicone breast implants, in order to ensure that potential risks are properly established, quantified and managed.

With regard to the question of whether the breast implants manufactured by PIP are more prone to failure than those of other manufacturers, SCENIHR said that **PIP implants have been found to vary considerably in composition** and as a result are likely to vary substantially in performance characteristics.

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SCENIHR concluded on the basis of available data, that many PIP implants were manufactured from non-medical grade silicone. This type of silicone may contain some components that can weaken the implant shell and diffuse into the body tissues.

Next steps

First, the European Commission will ask the Scientific Committee to pursue a more in-depth investigation based on data from investigations by Member States.

Second, the Commission will discuss with the Member States how surveillance of the medical devices can be reinforced immediately within the existing legislative framework. These issues could include **further recourse to unannounced inspections, enhanced controls of notified bodies and additional sample testing** on products already on the market.

Third, the Commission is also conducting a stress test in order to identify how best the questions raised by this issue can be addressed in the upcoming revision of the legislation on medical devices which was already underway. The Commission still envisages adopting a proposal on the **revision of the Medical Devices legislation in the course of this semester**.

National health authorities in the **Health Security Committee** convene by audio conference today to discuss the follow up to the Opinion.

Background

Breast implants fall under the European legislation on medical devices[1]. This legislation requires that, before placing such devices on the market, the manufacturers must carry out an assessment to ensure that their devices fulfil the relevant legal requirements, and in particular that their devices will not compromise patient safety. For high risk devices, such as breast implants, a third party conformity assessment body, so-called notified body, is involved in the conformity assessment procedure.

In the present case, an investigation triggered by an unusually high short-term breast implant rupture rate has shown that a manufacturer (Poly Implant Prothèse Company) fraudulently made use of industrial silicone instead of the approved medical grade silicone. The product was withdrawn from the EU market in 2010.

On the basis of available data, it is estimated that around **400 000 PIP silicone breast implants were sold worldwide**. These implants were available in nearly all European Union Member States - in particular they were widely used in the United-Kingdom, France, Spain and Germany, where respectively around 40.000, 30.000, 10.000 and 7.500 women were implanted with PIP silicone breast implants.

Work of the SCENIHR

SCENIHR is an independent advisory body established by the Commission. Its members are chosen on the basis of scientific excellence and they advise the Commission on issues associated with new and emerging health risks.

The current rapid opinion drew on top international scientists' expertise in fields of plastic surgery, polymer science, senology and medical epidemiology.

[1] OJ L 169, 12.7.1993, p. 1

To see the full scientific opinion on the safety of PIP breast implants, see http://ec.europa.eu/health/scientific_committees/emerging/index_en.htm

Link to Medical Devices Directive:
http://ec.europa.eu/health/medical-devices/regulatory-framework/index_en.htm