28.11.2014

NOTICE TO MEMBERS

Subject: Petition No 1529/2013 by M.T.C. (Spanish) on replacing a PIP breast implant

1. Summary of petition

The petition concerns a type of PIP breast implant which has been inserted into thousands of women in Spain. The petitioner wishes to have the implants removed, but cannot afford do, nor can she afford to pay a lawyer.

2. Admissibility

Declared admissible on 19 May 2014. Information requested from Commission under Rule 216(6).

3. **Commission reply**, received on 28 November 2014

The safety of medical devices, including breast implants, is of highest priority for the European Commission. This importance was strongly reiterated to all EU Health Ministers on the occasion of the EPSCO Council[1] that took place on 20 June 2014.

Following the discovery of the PIP fraud, the Commission immediately launched a number of initiatives aiming at reinforcing the controls on medical devices under the current legal framework. A document outlining these initiatives and their results is available on the

[1] Employment, Social Policy, Health and Consumer Affairs Council

European Commission's website[1]. In addition, and in a longer term perspective, the Commission adopted on 26 September 2012, two proposals to revise the regulatory framework governing medical devices[2]. These proposals aim at considerably reinforcing the rules applicable to medical devices.

Also as an immediate reaction to the scandal, the Commission asked the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) for an assessment of the potential health impact of faulty PIP silicone breast implants. The opinion was published on 1 February 2012[3].

The Commission subsequently requested from the SCENIHR a more in-depth assessment based on additional data and on investigations carried out by Member States. In its opinion of 15 May 2014[4] SCENIHR concluded that: "*There is currently no convincing medical, toxicological or other data to justify routine removal of intact PIP implants*."

Conclusion

With regard to the requests put forward in the petition, it needs to be underlined that Article 168 of the Treaty on the Functioning of the European Union lays down limitations to the competence of the European Union in the field of health. In particular, it requires that the Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care. As a consequence, the issue of compensation is decided by each Member State. According to the information received from the Spanish National Competent Authority, certain costs relating to explantation and re-implantation could, under certain conditions, be covered for patients treated within the National Healthcare System. Therefore the requests of the petitioner should be addressed to the Spanish National Competent Authorities[5].

[1] Staff Working Document "Implementation of the Joint Plan for Immediate Actions under the existing Medical Devices legislation" SWD (2014) 195 final http://ec.europa.eu/health/medical-devices/files/swd_pip_14_en.pdf
[2] COM(2012) 541 final and COM(2012) 542 final http://ec.europa.eu/health/medical-devices/documents/revision/index_en.htm
[3] http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_034.pdf
[4] http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_043.pdf
[5] http://ec.europa.eu/health/medical-devices/links/contact_points_en.htm