

Defective silicone gel breast implants made by French company PIP

European Parliament resolution of 14 June 2012 on defective silicone gel breast implants made by French company PIP (2012/2621(RSP))

The European Parliament,

- having regard to Article 184 of the Treaty on the Functioning of the European Union,
- having regard to the Council conclusions on innovation in the medical device sector¹,
- having regard to Council Directive 93/42/EEC of 14 June 1993 concerning medical devices²,
- having regard to Council Directive 90/385/EEC of 20 June 1990 on the approximation of laws of the Member States relating to active implantable medical devices³,
- having regard to European Parliament and Council Directive 98/79/EC of 27 October 1998 on in vitro diagnostic medical devices⁴,
- having regard to Directive 2000/70/EC of the European Parliament and of the Council of 16 November 2000 amending Council Directive 93/42/EEC as regards medical devices incorporating stable derivatives of human blood or human plasma⁵,
- having regard to the opinion 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’ published on 1 February 2012⁶,
- having regard to the conclusions⁷ of the High Level Health Conference on innovation in medical technology held in Brussels on 22 March 2011,
- having regard to its resolution of 13 June 2001 on the petitions declared admissible concerning silicone implants (Petitions 0470/1998 and 0771/1998)⁸,
- having regard to its resolution of 2 February 2012 on ‘Towards a Coherent European Approach to Collective Redress’⁹,
- having regard to Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws

¹ OJ C 202, 8.7.2011, p. 7.

² OJ L 169, 12.7.1993, p. 1.

³ OJ L 189, 20.7.1990, p. 17.

⁴ OJ L 331, 7.12.1998, p. 1.

⁵ OJ L 313, 13.12.2000, p. 22.

⁶ http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_034.pdf

⁷ http://ec.europa.eu/consumers/sectors/medical-devices/files/exploratory_process/hlc_en.pdf

⁸ OJ C 53 E, 28.2.2002, p. 231.

⁹ Texts adopted, P7_TA(2012)0021.

of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market¹,

- having regard to the question of 18 April 2012 to the Commission on defective silicone gel breast implants made by French company PIP (O-000101/2012 – B7-0118/2012),
 - having regard to Rules 115(5) and 110(2) of its Rules of Procedure,
- A. whereas according to the findings of the French health authorities, a French manufacturer (Poly Implant Prothèse) is under investigation for the fraudulent use of low-quality material (industrial silicone) different from the material indicated in the documents submitted for conformity assessment (approved medical-grade silicone);
 - B. whereas there is a lack of both clinical and epidemiological data on the potential risks of PIP breast implants;
 - C. whereas for third-generation implants there is a rate of rupture within ten years of implantation of 10-15 %;
 - D. whereas tests conducted by the French authorities on the physical integrity of a sample of PIP silicone breast implants indicated weaknesses in PIP shells not found in other commercially available implants;
 - E. whereas the SCENIHR report requested by the Commission in early January 2012 stresses that there is some concern regarding the possibility of inflammation induced by ruptured or leaking PIP silicone implants;
 - F. whereas the lack of EU-wide registration of breast implants means that the overall number of women who have received implants is unknown; whereas, however, it is estimated on the basis of the available data provided by the European Commission that around 400 000 PIP silicone breast implants have been sold worldwide; whereas many women in the United Kingdom (40 000), France (30 000), Spain (10 000), Germany (7 500) and Portugal (2 000) have received PIP silicone breast implants;
 - G. whereas patients need to know that implants are not permanent and may need to be replaced or removed; whereas patients also need to be informed about the quality of implants and the potential risks associated with them;
 - H. whereas the transposition of EU legislation on medical devices into national legislation has not prevented this health fraud, which has had, and will continue to have, a serious negative impact on health worldwide;
 - I. whereas this health fraud has brought to light a malfunction at the European and national levels, notably as regards the lack of cooperation between Member States and the international community in terms of information sharing and notification of adverse effects, and lack of traceability of raw material used for medical devices;
 - J. whereas the case of PIP implants, like the case of hip implants, illustrates the failure of the

¹ OJ L 247, 21.9.2007, p. 21.

current system of certification of compliance with essential health and safety requirements and of the control and surveillance of notified bodies by national competent authorities pursuant to the Medical Device Directive (2007/47/EC);

- K. whereas the desire to provide swift access to new medical devices for patients must never take precedence over the need to ensure patient safety;
- L. whereas the Medical Device Directive (2007/47/EC) will be reviewed in 2012; whereas it is essential that lessons be learned from the fraudulent marketing of PIP implants such that surveillance and safety controls and requirements for placing products on the market are strengthened at national and at European level;
- M. whereas the available data indicate that many PIP implants have been manufactured from non-medical-grade silicone containing components that can weaken the implant shell and diffuse into body tissues;
1. Notes that several Member States have advised patients to consult their surgeon, or have recommended patients to have breast implants made by PIP removed as a precaution;
 2. Notes, however, that inequalities exist between Member States as some have given their citizens conflicting advice as to what action to take, causing confusion among patients;
 3. Calls on the Commission and the Member States to strengthen their cooperation within the existing legal framework, in particular in the fields of market surveillance, vigilance and inspection, and to tighten controls, in order to provide a better guarantee of safety of patients, especially those exposed to high-risk medical devices;
 4. Stresses that after carrying out an assessment, Member States must immediately inform the Commission and the other Member States of measures that have been taken, or are being contemplated, to minimise the recurrence of such incidents;
 5. Calls on the Commission to develop an appropriate legal framework to guarantee the safety of breast implants and of medical technology in general;
 6. Calls for the introduction and implementation of essential and immediate specific measures on the basis of the current legislation on medical devices, in particular designed to:
 - strengthen the controls on medical devices already on the market, including those using samples;
 - ensure that, in the context of the conformity assessments, all notified bodies make full use of their powers to conduct frequent (at least once per year) unannounced inspections of the whole supply chain and of the operations of certain suppliers, notably suppliers of medical devices associated with the greatest risks and those in relation to which users' reports indicate that the number of incidents is growing;
 - strengthen the criteria for accreditation and assessment of notified bodies – with particular emphasis on the demonstrated competence of full-time staff, the use of contract resources, and transparency with regard to their functioning and tasks – and set up an EU-wide qualification management system for notified bodies, their staff, auditors and experts;

- reinforce market surveillance by, and information sharing between, national authorities to monitor the adverse effects of medical devices and the withdrawal of such devices from the market, in order to guarantee better traceability of medical devices and better follow-up of measures to control their marketing;
 - improve supervision by national authorities of notified bodies and ensure consistency across Member States;
 - encourage innovation in medical technology, as innovation is crucial to efforts to overcome the health challenges of today and tomorrow;
 - require manufacturers of medical devices to communicate immediately to their national competent authority any ban, restriction or legal action under way in one or more Member States;
 - improve the functioning of the vigilance system for medical devices, for example by facilitating and actively encouraging patients, patients' associations, patient groups and healthcare professionals to report all adverse events and harmful effects to the competent authorities, without their being hampered by excessive red tape, by giving notified bodies systematic access to reports of adverse events and by setting up a centralised procedure for gathering and treating notifications on adverse effects and on the withdrawal of devices from the market;
 - establish tools that, while providing data protection, ensure traceability of medical devices and long-term monitoring of their safety and performance, such as a 'Unique Device Identification' system, an implant register and a summary of product characteristics for each medical device;
 - facilitate notification of national authorities by patients' associations and health professionals regarding adverse effects;
 - establish a single European database that brings together information about the medical devices available on the market, registration of economic operations, vigilance and market surveillance initiatives, clinical investigations, notified bodies and EC certificates issued;
7. Calls on the Commission to shift to a system of pre-market authorisation for certain categories of medical devices, including, at least, medical devices of class IIb and III;
 8. Calls for the introduction – where it does not already exist at national level – of an implant recipient's passport specifying the unique product code of the implant, its special characteristics and potential adverse effects, and bearing a warning of the potential health risks and post-operative follow-up care measures associated with the implant; the passport would have to be signed by the surgeon and the patient, and would be valid as a consent form for the operation;
 9. Recommends that hospitals should keep an electronic version of the passport for future reference, noting that an electronic version can easily be forwarded at the request of a patient to a new care facility, whether in the same or in a different country;
 10. Calls on the Member States to raise awareness more effectively of the potential risks

attached to cosmetic surgery, and to better regulate the advertising of cosmetic surgery in order to ensure that patients are fully aware of the risks as well as the benefits; stresses that women should be made aware that breast implants need to be replaced after a period of time that varies from person to person, enabling them to assess risks more effectively;

11. Recognises that patients who have already received breast implants may need retrospective information, advice, medical supervision and counselling, as well as screening for intra- and extra-capsular rupture;
12. Stresses that the testing procedures and standards for breast implants should be refined to allow a better understanding of the interaction of the shell material with the filling gel and the surrounding body fluids, and of the fatigue and tear resistance of the shell and the total implant; considers that more proposals should be made for research to develop non-destructive methods of testing of implants;
13. Urgently recommends that details of breast implant operations be recorded in the EU in the form of a compulsory National Breast Implant Register in each Member State; underlines the fact that a compulsory register would make reporting mandatory for all clinics, but stresses that the inclusion of a patient's personal details should be subject to their consent; recommends that such national registers be interconnected and allow for exchange of information when needed, for example in cases where significant defects are detected in implants;
14. Urgently recommends a revision of the Medical Devices Directive aiming at introducing a capacity to detect and minimise the risk of fraud, focusing in particular on provisions regarding market surveillance, vigilance, and the functioning and tasks of notified bodies, so as to avoid a repetition of the PIP case;
15. Calls on the Commission to consider the possibility of establishing an efficient tracking system for medical devices used as implants, particularly for the most dangerous medical devices such as those in class III;
16. Calls on the Commission to consider the following aspects in the upcoming revision of the legislation on medical devices: the need for a marketing authorisation request for dangerous medical devices which complies with, or is similar to, the requirements for medicinal products; use of mandatory unannounced inspections; the need for increased traceability of implanted medical devices; the need for increased coordination between Member States when it comes to reporting on, and warning about, serious side effects or damage caused by medical devices; enhanced control of notified bodies; and additional sample testing of products already on the market;
17. Calls on the Commission also to consider, in the upcoming revision of the legislation on medical devices, the need for adequate human testing during clinical trials, particularly of implantable medical devices, before they are put on the market;
18. Urges the Member States to carry out, at least annually, thorough unannounced inspections of those medical devices that are associated with the greatest risks and of those devices in relation to which users' reports indicate that the number of incidents is growing;
19. Urges the Member States to apply penalties in case of non-compliance;

20. Considers that this fraud provides further evidence of the need for a system of collective redress designed to help consumers and patients to obtain compensation, as stressed by its above-mentioned resolution of 2 February 2012;
21. Calls on the Member States to pool their adverse incident reports and other regulatory data in the centralised database, as required by the Medical Devices Directive, in order to enable more effective vigilance and health protection measures;
22. Calls on the Commission to require adequate toxicological assessments of all medical devices, and to propose that the use of substances that are carcinogenic, mutagenic or toxic for reproduction (category 1A or 1B) be phased out, unless no substitutes are available;
23. Instructs its President to forward this resolution to the Council, the Commission and the parliaments of the Member States.