EUROPEAN PARLIAMENT 2009 - 2014

Plenary sitting

07.3.2012 B7-0000/2012

MOTION FOR A RESOLUTION

further to Question for Oral Answer B7-0000/2012

pursuant to Rule 115(5) of the Rules of Procedure

on Defective silicone gel breast implants made by French company PIP

Philippe Juvin, Thomas Ulmer
on behalf of the PPE Group
Linda McAvan, Gilles Pargneaux
on behalf of the S&D Group
Corinne Lepage, Antonyia Parvanova
on behalf of the ALDE Group
Margrete Auken, Michèle Rivasi
on behalf of the Verts/ALE Group
Marina Yannakoudakis
on behalf of the ECR Group
Marisa Matias
on behalf of the GUE/NGL Group
Oreste Rossi
on behalf of the EFD Group

B7-0000/2012

European Parliament resolution on Resolution on defective silicone gel breast implants (0000(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 sector (2011/C 202/03);

– having regard to Council Directive 93/42/EEC of 14 June 1993 concerning medical devices[1],

– having regard to Council Directive 90/385/EEC2 on the approximation of laws of the Member States relating to active implantable medical devices,

– having regard to the European Parliament and Council Directive 98/79/EC of 27 October 1998 on in vitro diagnostic medical devices[2],

– having regard to the European Parliament and Council Directive 2000/70/EC of 16 November 2000 amending Council Directive 93/42/EEC as regards medical devices incorporating stable derivates of human blood or human plasma[3],

– 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 the 1sf February 20124,

– having regard to the conclusions[5] 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)[6],

– having regard to its resolution of 2 February 2012 on 'Towards a Coherent European Approach to Collective Redress'[7],

– having regard to Rules 115(5) and 110(2) of its Rules of Procedure,

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

[2] OJ L 331, 7.12.1998, p. 1.

[3] OJ L 313, 13.12.2000, p. 22.

[4] http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_034.pdf

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

[6] OJ C 53 E, 28.2.2002, p. 231.

[7] (2011/2089(INI))

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 one it had declared in the documents submitted for conformity assessment (medical grade silicone),

B. whereas there is a lack of clinical data, along with the absence of epidemiologic data on the potential risks of PIP breast implants,

C. whereas for third generation implants there is a rate of rupture from 10-15%, within 10 years of implantation,

D. whereas the tests conducted by the French Authorities on the physical integrity of a sample of PIP silicone breast implants indicated weaknesses in PIP (Poly Implant Prothèse Company) shells not found in other commercially available implants,

E. whereas the investigation has shown that the manufacturer would have fraudulently used industrial silicone instead of the approved medical grade silicone,

F. whereas The SCENIHR[1] report (requested by the Commission in early January) stresses that there is some concern regarding the possibility of inflammation induced by ruptured PIP silicone implants,

G. whereas, on the basis of available data, it is estimated that around 400 000 PIP (Poly Implant Prothèse Company) silicone breast implants were sold worldwide**;** whereas these implants 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,

H. whereas patients need to know that, in some cases, implants are not permanent and may need to be replaced or removed; whereas patients also need to be informed about implant quality and the suitability of implants for the patient concerned,

I. whereas the lack of registration of implants at European level results in the fact that the overall number of women with implants is unknown;;

J. whereas the implementation of European legislation on medical devices into national legislation has not avoided this health fraud, which has led and will lead to an international serious negative impact on public health,

K. whereas this health fraud has shown a malfunctioning at European and national levels, notably a lack of cooperation between Member States and the international community in terms of information sharing and notification of adverse effects and a lack of traceability on raw material used for medical devices,

L. whereas the case of PIP implants has shown a failure of the current system of certification of compliance with essential safety and health requirements, as mentioned by the Medical

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[1] Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR)

Device Directive 2007/47/EC[1], especially concerning the role and the control task of notified bodies and their relations with national competent authorities,

M. whereas the Medical device directive 2007/47/EC will be reviewed in 2012; whereas it is essential to learn from this fraud and to strengthen surveillance and placing on the market requirements at national and European levels,

N. Whereas on the basis of available data, many PIP implants would have been manufactured from non-medical grade silicone and points out that this type of silicone may contain some components that can weaken the implant shell and diffuse into the body tissues,

1. Notes that several Member States have advised patients to consult their surgeon or have recommended that they seek removal of breast implants made by PIP as a precaution;

2. Calls on the Commission and Member States to strengthen the co-operation within the existing legal framework to tighten controls, in order to provide a better guarantee of the safety of medical technology, especially high risk devices;

3. Stress that after carrying out an assessment, Member States shall immediately inform the Commission and the other Member States of measures that have been taken or are contemplated to minimize the recurrence of such an incident;

4. Calls for the introduction and implementation of essential and immediate specific measures on the basis of the current legislation of medical devices, in particular designed to:

   - Strengthen the controls on medical devices already on the market;
   - Ensure that all notified bodies in the context of the conformity assessment make full use of their powers to conduct unannounced and frequent inspections at least all 12 months in the whole supplier chain, notably for the most dangerous medical devices (class III);
   - Strengthen the authorization criteria, transparency on the functioning and tasks of notified bodies and set up an European wide qualification management for notified bodies;
   - Reinforce market surveillance and information sharing on adverse effects between national authorities to guarantee a better traceability and a better follow-up of medical devices controls;
   - improve supervision by national authorities on notified bodies;
   - Improve the functioning of the vigilance system for medical devices for example by actively encouraging patients and healthcare professionals to report adverse events, and by giving systematic access for notified bodies to reports of adverse events and setting up a centralised procedure for gathering and treating notifications on adverse effects;

[1] Directive 2007/47/CE du Parlement européen et du Conseil modifiant la directive 90/385/CEE relative aux dispositifs médicaux implantables actifs, la directive 93/42/CEE relative aux dispositifs médicaux et la directive 98/8/CE concernant la mise sur le marché des produits biocides.

- Support the development of tools ensuring the traceability of medical devices as well as their long-term monitoring in terms of safety and performance, such as Unique Device Identification systems and implant registers and a summary of products characteristics for each medical device;
- Facilitate notifications on adverse effects by patients associations and health professional to national authorities;

5. Calls the Commission to evaluate the added value of a pre market authorisation system for certain categories of medical devices;

6. Calls for the introduction of an implant recipient's passport in which the special characteristics of the implant, its potential adverse effects and a warning of the potential health risks and post-operative follow-up care measures are specified; the passport must be signed by the surgeon and the patient, and be valid as a consent form for the operation;

7. Takes the view that it is necessary to raise general public awareness of the potential risks of silicone-gel breast implants; calls on Member States to better regulate the advertising of cosmetic implants to ensure that patients are fully aware of the risks versus benefits, in particular, women should be aware that in some cases, breast implants have to be replaced after a period of time that varies from person to person;

8. Recognises that patients who have already received breast implants may need retrospective information, advice and medical supervision, screening for intra- and extra-capsular rupture;

9. Stresses that the testing procedures and standards for breast implants should be refined to consider the interaction of the shell material with the filling gel and the surrounding body fluids, with respect to fatigue and tear resistance behaviour of the shell and the total implant;

10. Urgently recommends that details of breast implant operations should be recorded in the EU in the form of a compulsory National Breast Implant Register in each Member State. Underlines that a compulsory register would make reporting mandatory for all clinics, while patients have the right of consent to the inclusion of their personal details;

11. Urgently recommends increasing the capacity to detect and minimize the risk of fraud also through the revision of the Medical Devices Directive, in particular with regard to market surveillance, vigilance and functioning and tasks of notified bodies;

12. Stresses that there should be a clear accountability system for medical devices. So if a problem emerge it is clear who is responsible for the originated costs, calls for clear rules on criminal and civil liability;

13. Calls on the Commission to consider, in the upcoming revision of the legislation on medical devices, the need for a marketing authorization request for dangerous medical devices, the recourse to mandatory unannounced inspections, enhanced controls of notified bodies and additional sample testing on products already on the market;

14. Urges the Member States to carry out thorough and frequent unannounced inspections,

notably for the most dangerous medical devices such as devices from class III;

15. Considers that this fraud brings further evidence of the need for a system of collective redress to assist consumers and patients in obtaining compensation, as stressed by the European Parliament resolution of 2 February 2012 on 'Towards a Coherent European Approach to Collective Redress'[1];

16. Calls on Member States to pool their adverse incident reports and other regulatory data via the centralised database, as required by the Medical Devices Directive, to enable more effective vigilance and health protection;

17. Instructs its President to forward this resolution to the Council, Commission and the parliaments of the Member States.

[1] (2011/2089(INI))