Basic information

2012/2621(RSP) RSP - Resolutions on topical subjects	Procedure completed
Resolution on defective silicone gel breast implants made by French company PIP **Subject** 4.10.09 Women condition and rights 4.20.02.06 Clinical practice and experiments 4.20.04 Pharmaceutical products and industry 4.20.05 Health legislation and policy 4.60.04 Consumer health 4.60.08 Safety of products and services, product liability	

Key players

European Commission

Commission DG	Commissioner
Health and Food Safety	DALLI John

Key events

Date	Event	Reference	Summary
13/06/2012	Debate in Parliament		
14/06/2012	Decision by Parliament	T7-0262/2012	Summary
14/06/2012	Results of vote in Parliament		
14/06/2012	End of procedure in Parliament		

Technical information

Procedure reference	2012/2621(RSP)
Procedure type	RSP - Resolutions on topical subjects
Procedure subtype	Debate or resolution on oral question/interpellation
Legal basis	Rules of Procedure EP 142-p5
Stage reached in procedure	Procedure completed

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Motion for a resolution		B7-0302/2012	11/06/2012	

Text adopted by Parliament, single reading		T7-0262/2012	14/06/2012	Summary

European Commission

Document type	Reference	Date	Summary
Commission response to text adopted in plenary	SP(2012)626	30/10/2012	

Resolution on defective silicone gel breast implants made by French company PIP

2012/2621(RSP) - 14/06/2012 - Text adopted by Parliament, single reading

The European Parliament adopted a resolution on defective silicone gel breast implants made by French company PIP.

The resolution was tabled by the EPP, S&D, ALDE, Greens/EFA, ECR, GUE/NGL and EFD groups.

It recalls that 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). 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. Furthermore, a 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. Parliament notes that the **lack of EU-wide registration of breast implants** means that the overall number of women who have received implants is unknown. 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. Members note that whilst 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, inequalities exist between Member States as some have given their citizens conflicting advice as to what action to take, causing confusion among patients.

Parliament points out that the **transposition of EU legislation on medical devices** (Directive 2007/47/EC) into national legislation has not prevented this health fraud, which has had, and will continue to have, a serious negative impact on health worldwide. Since the Medical Device Directive will be reviewed in 2012, 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.

Parliament calls on the Commission and 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. 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.

Members call for the introduction of immediate specific measures on the basis of the current legislation on medical devices, and make a series of recommendations on those measures. The latter include:

- establishing 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;
- establishing 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;
- **reinforcing 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.

Members call 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.

They also call for the following:

- 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;
- **raising awareness** more effectively of the potential risks attached to cosmetic surgery, and ensuring that that women are 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;

- details of breast implant operations to be recorded in the EU in the form of a **compulsory National Breast Implant Register in each Member State**. A compulsory register would make reporting mandatory for all clinics, but Parliament stresses that the **inclusion of a patient's personal details** should be subject to their consent. It 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;

- 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;

- establishing an efficient tracking system for medical devices used as implants, particularly for the most dangerous medical devices such as those in class III;

Parliament urges 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. It 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.