European Parliament
2014-2019

Committee on Petitions

31.1.2019

NOTICE TO MEMBERS

Subject: Petition No 0663/2018 by Francoise Côte (French) on mammary prosthetics and effects on the health of women

Petition No 0844/2018 by J.S. (British), on behalf of PIP Action Campaign, on PIP breast implants

1. Summary of petition 0663/2018

The petitioner complains that the European institutions have not investigated the health risks associated with breast implants beyond the specific "PIP" implants scandal. She complains about the lack of information made available regarding these health risks. According to the petitioner, individuals who consider undergoing a surgical procedure to get breast implants should be able to make an informed choice based on sufficient and available scientific information. The petitioner also deplores the lack of support by insurance companies of women whose health has been adversely affected by breast implants. Therefore, the petitioner asks the European Parliament to set up a committee of inquiry on the health risks associated with breast implants. Moreover, the petitioner pleads for an official recognition of the "breast implant illness" referring to a number of health symptoms, which would be caused by breast implants. The petitioner also calls for a stronger duty of information on behalf of implants manufacturers and surgeons about implants' composition and their effects on health. In addition, the petitioner calls for a stronger risk assessment of implants before and after their placing on the market. Finally, the petitioner advocates for a greater involvement of insurance companies in the coverage of health costs as a consequence of breast implants' adverse effects.

Summary of petition 0844/2018

The petition concerns a 2010 public health scandal involving a French medical devices company (PIP) that had, since 2001, illegally produced and sold breast implants made from industrial-grade silicone instead of from medical-grade silicone. The petitioner argues that more than 100.000 EU women and over 500.000 women worldwide are believed to have been

exposed to these implants. In response to this public health issue, in May 2014 the European Commission's Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) issued an opinion on the safety of Poly Implant Prothèse (PIP) silicone breast implants, which concluded, among others, that there was no convincing medical, toxicological or other data to justify routine removal of intact PIP implants. Unsatisfied with the findings of this opinion, the petitioner challenged it before the European Ombudsman, arguing that there had been an alleged conflict of interest by a member of the SCHENIR committee drawing up the report on which the opinion was based. However, no evidence of maladministration was found. In October 2017 the EC Scientific Committee on Health Environmental and Emerging Risks (SCHEER) decided not to review the 2014 SCENIHR opinion on the ground that there was "insufficient new evidence" to justify such review. The petitioner maintains that the two documents are self-referenced and political and do not take into account substantial medical and clinical evidence of the dangers posed by PIP breast implants. Furthermore, the petitioner alleges that, as a direct consequence of these opinions, women and children exposed to PIP are actively obstructed from receiving the necessary healthcare, diagnostics, treatment, civil liability protections and access to justice.

2. Admissibility

Petition 0663/2018 declared admissible on 19 November 2018.
Petition 0844/2018 declared admissible on 12 December 2018.
Information requested from Commission under Rule 216(6).

3. **Commission reply**, received on 31 January 2019

Petition 0663/2018 and 0844/2018

The safety of medical devices, including breast implants, is of the highest priority for the Commission. Committed to deliver, following the discovery of the Poly Implant Prothèse (PIP) fraud in 2012, the Commission immediately launched a number of initiatives aimed at reinforcing the controls on medical devices under the legal framework applicable at that time. They are described in detail on the Europa website[1].

Furthermore, on 5 May 2017 two new Regulations on medical devices were published, namely Regulation (EU) 2017/745[2] and Regulation (EU) 2017/746[3] of the European Parliament and of the Council on medical devices and on *in vitr*o diagnostic (IVD) medical devices respectively. The new regulations will enter into application on 26 May 2020 and on 26 May 2022 respectively.

The new regulations contain a series of important improvements aimed at modernising the

[1] https://ec.europa.eu/growth/sectors/medical-devices/pip-action-plan_en

[2] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance), *OJ L 117, 5.5.2017, p. 1–175.*

[3] Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (Text with EEA relevance), *OJ L 117, 5.5.2017, p. 176–332.*

current medical devices system, which will also address many of the issues raised in the petition. Amongst them, and more directly relevant to the petition, are:

- stricter control for certain high-risk devices via a new "pre-market scrutiny" mechanism with the involvement of independent scientific experts at EU level. Breast implants will be covered in well-defined cases by this mechanism;
- reinforcement of the criteria for designation and oversight of notified bodies, the entities that verify the conformity of medical devices with the applicable legal requirements, including their safety and performance;

- the obligation for manufacturers to have measures in place to provide sufficient financial coverage in respect of their potential liability;

- conformity of breast implants as being in class III[4], the highest in terms of legal requirements and control;
- improved transparency through the establishment of a comprehensive EU database on medical devices and of a device traceability system based on Unique Device Identification;
- introduction of the implant card containing patient information about the implanted medical device, including on risks;
- introduction of a publicly available Summary of Safety and Clinical Performance for high-risk devices such as breast implants, clearly identifying, amongst others, the risks of these devices, and the clinical evidence available on them;
- reinforcement of the rules on clinical evidence, including an EU-wide coordinated procedure for authorisation of multi-centre clinical investigations and a publicly available registry of all clinical trials for medical devices that will also contain their conclusions;
- clear requirements regarding the information supplied with the device covering labelling and the instructions for use;
- strengthening of post-market surveillance requirements for manufacturers;
- improved coordination mechanisms between EU countries in the fields of vigilance and market surveillance.

An important point is that the instructions for use of all implanted medical devices have to indicate any residual risks, contra-indications and any undesirable side effects, including information to be conveyed to the patient in this regard. They also have to include information that allows the user and/or patient to be informed of any warnings, precautions, measures to be taken and limitations of use regarding the device. That information shall, where relevant, allow the user to brief the patient on the above. The new requirements concerning the instructions for use complement and clarify those which are already provided for by the current Directive on medical devices. The information needed for the clinician to accomplish her/his duty and inform the women on any residual risks relative to breast implants is therefore readily available.

At the specific request of the Commission, The Scientific Committee on Health, Environmental and Emerging Risks (formerly known as SCENIHR) provided recent scientific advice on breast implants and health[5]. The Scientific Committee assessed whether sufficient

[4] First up-classified from class IIb to class III by Directive 2003/12/EC, OJ L 28/43 of 04 February 2003.
[5] https://ec.europa.eu/health/scientific_committees/consultations/public_consultations/scheer_consu

new scientific information was available to warrant an update of the May 2014 Opinion on the safety of the PIP breast implants and concluded that this was not the case. Additionally, the same Committee assessed the current state of scientific knowledge on the possible association between breast implants and anaplastic large cell lymphoma (ALCL) and concluded that the very low incidence of ALCL and the methodological limitations of the available information/studies do not currently allow for a robust risk assessment. The Commission will continue to closely monitor these two matters and, if justified, request further assessment from the Scientific Committee.

Breast implants are continuously discussed by national authorities competent for vigilance together with the Commission so that any new developments are addressed in a timely manner. Furthermore, a specific EU Taskforce on breast implants and ALCL, supplemented by an international one, were established in 2014, both led by the Commission.

It is important to recognise that Member States took specific initiatives concerning the safety of breast implants, most notably in France[6], the United Kingdom[7] and the Netherlands[8]. In particular, on 7 and 8 February 2019, the French Competent Authorities will hold a public hearing on the use of breast implants[9].

On a more general note, it needs to be recalled that Article 168 of the Treaty on the Functioning of the European Union lays down limitations on what the European Union can do in the field of health. In particular, it requires that the Union shall respect the responsibilities of Member States for the definition of their health policy and for the organisation and delivery of health services and medical care.

Conclusion

The Commission will continue to consider the safety of breast implants as a high priority and invites the petitioner to send any relevant additional information or observations to the Commission as well as to the French Competent Authorities.

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[6]https://www.ansm.sante.fr/Activites/Surveillance-des-dispositifs-medicaux-implantables/Surveillance-des-protheses-mammaires/(offset)/0#paragraph_65339

[7] https://www.gov.uk/guidance/breast-implants-and-anaplastic-large-cell-lymphoma-alcl
https://www.nhs.uk/conditions/cosmetic-treatments/breast-enlargement/

[8] https://www.rivm.nl/en/medical-devices/silicone-breast-implants

[9]https://www.ansm.sante.fr/S-informer/Points-d-information-Points-d-information/L-ANSM-lance-une-audition-publique-sur-l-utilisation-des-implants-mammaires-Point-d-Information