EUROPEAN COMMISSION
Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

Consumer, Environmental and Health Technologies
Health Technology and Cosmetics

Brussels, 27.10.2017

Subject: **Petition "*Toxic PIP Implants: World Health Crisis*" and associated letter from the website change.org**

Dear PIP Action Campaign,

At the request of the Commissioner for Health and Food Safety, Vytenis Andriukaitis, we are replying on his behalf to the petition published on the site change.org, as medical devices are within the portfolio of Commissioner Elżbieta Bieńkowska, who is responsible for Internal Market, Industry, Entrepreneurship, and SMEs.

The concerns you raised in your petition have drawn, as in the past, our highest attention. Please let us thank you again for your incessant efforts to support the women that were the victims of the fraudulent activities related to the Poly Implant Prothèse (PIP). We would also like to thank you for the information you have submitted to the European Commission over the years, information that was carefully assessed each time.

The safety of medical devices, including breast implants, is of high priority for the European Commission. Following the discovery of the PIP fraud, the European Commission immediately launched a number of initiatives aimed at reinforcing controls on medical devices under the legal framework applicable at that time. They are listed in the Annex to this letter and described in detail on our website[1].

Furthermore, in order to avoid that unfortunate fraud due to illegal practices, such as that of the PIP silicone breast implants, happen again, European Commission services looked further for shortcomings in the legislation[2] at the time of the incident. The conclusions were incorporated in the proposals for the revision of the medical devices legislative framework put forward to the legislators by the European Commission. Those findings, however, did not suggest that the EU system for regulating medical devices was fundamentally unsound.

As you are already aware, on 5 May 2017, two new Regulations on medical devices were published, namely Regulation (EU) 2017/745[3] and Regulation (EU) 2017/745[4] of the European Parliament and of the Council on medical devices and on *in vitro* diagnostic (IVD) medical devices respectively.

1 https://ec.europa.eu/growth/sectors/medical-devices/pip-action-plan_en
2 http://ec.europa.eu/growth/sectors/medical-devices_old/documents/revision/files/revision_docs/revision_ia_part3_appendices_en.pdf
3 http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L:2017:117:TOC
4 http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L:2017:117:TOC

The new Regulations contain a series of extremely important improvements to modernise the current system. Amongst them are:

- stricter control for high-risk devices via a new pre-market scrutiny mechanism with the involvement of experts at EU level;
- reinforcement of the criteria for designation and oversight of Notified Bodies;
- inclusion of certain devices without a medical purpose which present the same characteristics as analogous medical devices under the scope of these Regulations;
- introduction of a new risk classification system for *in vitro* diagnostic medical devices;
- 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 an "implant card" containing information about implanted medical devices for a patient;
- reinforcement of the rules on clinical evidence, including an EU-wide coordinated procedure for authorisation of multi-centre clinical investigations;
- strengthening of post-market surveillance requirements for manufacturers;
- improved coordination mechanisms between EU countries in the fields of vigilance and market surveillance.

The issue on the necessity to remove the PIP silicone breast implants was covered by the May 2014 SCENIHR opinion on "*The safety of Poly Implant Prothèse (PIP) Silicone Breast Implants*"[5], which concluded that: "There is currently no convincing medical, toxicological or other data to justify routine removal of intact PIP implants".

Recently, the Scientific Committee on Health Environmental and Emerging Risks has assessed that no sufficient new scientific information is available to warrant an update of the May 2014 SCENIHR opinion on the safety of PIP breast implants[6].

With regards to the requests concerning assistance to the victims of the PIP fraud, 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 European Union shall respect the responsibilities of Member States for the definition of their health policy and organisation and delivery of health services and medical care. Therefore, aspects such as financial support and collective redress are to be addressed to national competent authorities and eventually to national courts.

These matters were also elaborated in depth in the last years in previous communications from various European Commission services. Additional information may be found in the Annex.

We trust this information provides more clarity on various initiatives undertaken by the European Commission following the PIP scandal in the area of medical devices in order to strengthen the protection of patients.

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5 http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_043.pdf

6 https://ec.europa.eu/health/sites/health/files/scientific_committees/scheer/docs/scheer_o_008.pdf

Annex

1. SAFETY OF PIP IMPLANTS

The 2014 SCENIHR opinion on the safety of silicone breast implants concluded that:

"There is currently no convincing medical, toxicological or other data to justify routine removal of intact PIP implants. Implant removal in the absence of malfunction may be considered for women who are experiencing significant anxiety because they have a PIP breast implant. However, the decision to remove an intact PIP implant for this reason should be based on an individual assessment of the woman's condition by her surgeon or other treating physician after consultation."

"In the case of implant rupture, explantation is advised. Because of the widespread concern of undetected ruptures, there is a need for women with PIP breast implants to seek regular clinical examinations, and where deemed appropriate, individual counselling and imaging with ultrasonography or MRI."

"While there are differences in rupture rates, there is no reliable evidence that ruptured PIP implants create a greater health risk than a ruptured silicone breast implant from another manufacturer."

"In the previous opinion the effects of both released polymeric and unpolymerised silicones in general were considered. Since then several cyclic siloxanes (known as D4, D5 and D6) have been identified in PIP devices at higher concentrations than in other silicone breast implants. This has led to investigate the possible toxicological consequences of cyclic siloxanes release from damaged PIP implants. It has become apparent that these chemicals are commonly present in the bodies of women even without breast implants. This is a consequence of the widespread use of siloxanes in many domestic products. Cyclic siloxanes D4, D5 and D6 are non-toxic and not irritant in standard tests."

"Although D4 shows very weak estrogenic activity in a rat uterotrophic assay (McKim et al., 2001), the reproductive toxicity observed is believed not to be attributable to a direct oestrogen receptor (ER)-mediated effect. Rather it is proposed that the effects seen are due to D4 causing a delay or blockage of the luteinising hormone surge that is required for optimal timing of ovulation.

"*It can be concluded that the reproductive effects of D4 in female rats and mice are related to rodent specific imbalance in the normal hormone milieu. Such imbalances are common in rodents and are of little relevance to humans*" (SCCP 2005)."
http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_043.pdf

The studies carried out by UK authorities independently from SCENIHR's opinion reached similar conclusions.

https://www.gov.uk/government/publications/poly-implant-prosthese-pip-implants-toxicology-testing/poly-implant-prosthese-pip-implants-toxicology-testing

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As explained in the body of the letter, national competent authorities have the right, by way of the Treaty on the Functioning of the European Union, to decide on the line to take on matters linked to national delivery of health care.

2. POTENTIAL LINK BETWEEN PIP BREAST IMPLANTS AND CANCER

Concerning the potential for PIP breast implants to cause cancer, neither the SCENIHR opinion on the safety of Poly Implant Prothèse (PIP) Silicone Breast Implants[7], the studies published by Medicines and Healthcare products Regulatory Agency (MHRA)[8] nor the reports of the French Authorities[9] found additional risks for cancer linked to PIP silicone breast implants.

Indeed the French Authorities concluded in July 2015 that "L'avis d'experts coordonné par l'Institut National du Cancer de mars 2014, confirme l'absence de sur-risque d'adénocarcinome mammaire chez les femmes porteuses d'implants en comparaison avec la population générale." (The opinion of the experts coordinated by the National Cancer Institute, in March 2014, confirms the lack of supplementary risk for breast adenocarcinoma for the implanted women [with PIP] in comparison with the general population).

3. THE MANDATE FOR THE SCIENTIFIC COMMITTEE ON HEALTH ENVIRONMENTAL AND EMERGING RISKS (SCHEER)

A mandate asking SCHEER to indicate if there is sufficient new scientific information to warrant an update of the May 2014 opinion on the safety of PIP breast implants was submitted and accepted by SCHEER (former SCENIHR) in May 2016. This mandate also asked for a call for data as well as a literature review related to the safety of PIP silicone breast implants. The literature review gathered existing material as regards to what has been published on this topic by accredited scholars and researchers[10].

The Committee published the last version of this advice on its website[11].

This approach confirms our commitment to monitor the publication of additional scientific information that could necessitate a possible review of the second SCENIHR opinion on the safety of PIP breast implants, published in May 2014. This is also in line with the European Ombudsman's remarks in her Decision in case 174/2015/FOR, namely that the Commission should "closely follow possible new scientific data in this particular area" (i.e. the safety of PIP implants)[12].

As a fully independent body, SCHEER bases its conclusions on the availability of new and relevant scientific information independent of the European Commission. These conclusions are drawn solely under the responsibility of the scientists involved in the Working Group and in SCHEER.

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7 http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_043.pdf

8 https://www.gov.uk/government/publications/poly-implant-prosthese-pip-implants-toxicology-testing
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/214976/dh_134656.pdf

9 http://ansm.sante.fr/Dossiers/Implants-mammaires-PIP-pre-remplis-de-gel-de-silicone/Actions-mises-en-oeuvre-pour-le-suivi-des-femmes-porteuses-d-implants-mammaires-en-gel-de-silicone-PIP-depuis-2010/(offset)/0
http://ansm.sante.fr/content/download/79581/1007721/version/2/file/PIP_Bilan-Materiovigilance_Juillet-2015-2.pdf

10 http://ec.europa.eu/health/scientific committces/schecr/docs/scheer q 003.pdf

11 https://ec.europa.eu/health/scientific_committees/scheer/opinions_en#fragment2

12 http://www.ombudsman.europa.eu/cases/decision.faces/en/61195/html

4. COMMISSION POWERS CONCERNING RISK MANAGEMENT

At the end of 2011 and March 2013, the European Commission asked the relevant Scientific Committee – SCENIHR at that time – for an assessment of the potential health impact of faulty PIP silicone breast implants in order to better understand the problems raised by the PIP fraud and to support Member States in their regulatory decisions. Therefore, SCENIHR's opinion supplements the risk assessments performed by Member States such as those of the U.K. and France.

It needs to be underlined that the final decision on the risk management measures for medical devices and their implementation rests with Member States.

In order to support risk management activities of the Member States, the European Commission undertook the following actions:

A. Immediate coordination with and exchange of views between the Member States was organised by the European Commission, in particular within the framework of the Health Security Committee where high-level representatives nominated by Ministries of Health participated. However, a common approach concerning risk management measures was not reached.

B. The Commission participated in the international exchange of information within the International Laboratory Testing Panel for PIP breast implants (ITPP) led by the Therapeutic Goods Administration (TGA), the Australian competent authority. The role of the ITPP was to discuss laboratory testing of PIP breast implants.

C. A Joint Plan for Immediate Actions under the existing Medical Devices legislation was discussed and agreed with the Member States so as to identify best ways to tighten the controls concerning medical devices. More information may be found on the dedicated webpage[13] and inside the Commission Staff Working Document (SWD (2014) 195 final) describing the status of the implementation of the mentioned Plan[14].

D. In the context of the revision of the EU regulatory framework for medical devices, as a part of the impact assessment concerning the proposed regulations, European Commission services analysed the PIP breast implant case. The results were outlined in the so called "stress test" and amendments to be presented in European Commission proposals were identified. The results of the “stress tests” are included in the Impact Assessment on the Revision of the Regulatory Framework for Medical Devices, Part IV – Appendices, Appendix 11 (SWD(2012) 273 final)[15].

E. Constant coordination of Member States on the PIP case was ensured within the Medical Devices Expert Groups.

F. A mandate asking SCHEER to indicate if there is sufficient new scientific information to warrant an update of the May 2014 opinion on the safety of the PIP breast implants was submitted to SCHEER in May 2016 as explained under point 3 above.

13 http://ec.europa.eu/health/medical-devices/regulatory-framework/pip-action-plan/index_en.htm

14 http://ec.europa.eu/health/medical-devices/files/swd_pip_14_en.pdf

15 http://ec.europa.eu/health/medical-devices/files/revision_docs/revision_ia_part3_appendices_en.pdf