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

Consumer, Environmental and Health Technologies
Health Technology and Cosmetics

Brussels,
GROW/D/4/PP/az
grow.ddg1.d.4(2018)6419055

Subject: **Petition "For a Compensation Fund for PIP Breast Implants and CE" from the website change.org**

Dear PIP Implants World Victims Association,

At the request of Commissioner for Internal Market, Industry, Entrepreneurship and SMEs, Elżbieta Bieńkowska, we are responding on her behalf to the petition published on the site change.org, as medical devices are within our portfolio.

The safety of medical devices, including breast implants, is of highest priority for the European Commission. Committed to deliver, following the discovery of the Poly Implant Prothèse (PIP) fraud, 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 our website[1].

In addition, in order to avoid further unfortunate frauds due to criminal practices, such as that of the PIP Company, the Commission's services looked at the time of the incident for shortcomings of the legislation[2]. The conclusions reached were incorporated in 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.

On 5 May 2017, two new Regulations on medical devices were published, namely Regulation (EU) 2017/745[3] and Regulation (EU) 2017/746[4] of the European Parliament and of the Council on medical devices and on *in vitro* diagnostic (IVD) medical devices respectively.

The new Regulations contain a series of important improvements aimed at modernising the current system, the most important of which are also listed on our website[5]. One notable aspect is the obligation for manufacturers to have measures in place to provide sufficient financial coverage in respect of their potential liability[6].

[1] https://ec.europa.eu/growth/sectors/medical-devices/pip-action-plan_en
[2] https://eur-lex.europa.eu/resource.html?uri=cellar:487acc33-213b-4fdf-bdbb-8840209a8807.0001.04/DOC_4&format=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
[5] https://ec.europa.eu/growth/sectors/medical-devices/regulatory-framework_en#new_regulations
[6] Regulation (EU) 2017/745, Article 10 General obligation of manufacturers, para (16)

In order to ascertain the risk posed by the PIP silicone breast implants, the Commission requested its Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) two opinions which were delivered in February 2012[7] and in May 2014[8] respectively. The second SCENIHR opinion on "*The safety of Poly Implant Prothèse (PIP) Silicone Breast Implants*" concluded that:

"There is currently no convincing medical, toxicological or other data to justify routine removal of intact PIP implants."

Furthermore, the Scientific Committee on Health, Environmental and Emerging Risks (formerly known as SCENIHR) assessed in September 2017 if sufficient 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[9].

Concerning your request to provide financial 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 Union shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care. Therefore, aspects such as financial support and collective redress are to be addressed by national competent authorities and eventually within national judicial courts.

We trust this information provides more clarity on various initiatives undertaken by the Commission, after the PIP scandal, in the area of medical devices in order to strengthen the protection of patients. Please do not hesitate to contact us should you have additional questions.

(e-signed)
Unit GROW D.4
Health Technology and Cosmetics

[7] https://ec.europa.eu/health/sites/health/files/scientific_committees/emerging/docs/scenihr_o_034.pdf
[8] https://ec.europa.eu/health/sites/health/files/scientific_committees/emerging/docs/scenihr_o_043.pdf
[9] https://ec.europa.eu/health/sites/health/files/scientific_committees/scheer/docs/scheer_o_008.pdf