EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Consumer Affairs
Director

Brussels,
SANCO/B2/PP/kr

Dear Mr Howlet,

Subject: Polypropylene mesh medical devices

Thank you for your letter of 5 June concerning the Petition on polypropylene mesh medical devices and the request for our view on the matter. Please accept my apologies for the delay in the reply.

The concerns raised in this petition with regard to surgical meshes used in urogynecological surgery have already drawn our attention. In this context we have undertaken regular consultation and coordination with the Member States via Working Groups, teleconferences and a dedicated Task Force.

To better assess the available data and to understand the risks associated with polypropylene meshes used for transvaginal surgical procedures and surgical meshes in general, we have requested the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) a scientific opinion[1]. It is our expectation that this opinion will better clarify the issues linked to the safety of these medical devices, including their use and the identification of high risk patient groups, thus supporting the Member States in the implementation of the most appropriate risk management measures.

Until the SCENIHR's opinion becomes available, currently foreseen for the end of January 2015, we will continue to coordinate with the Member States to ensure the best possible flow of available information.

Concerning the possibility of the suspension of the polypropylene meshes used for the transvaginal surgical procedures, under the current legislation on medical devices, a Member State has the possibility under Article 8 of the Council Directive 93/42/EEC[2], when it ascertains that a medical device installed, maintained and used for their intended purpose may compromise the health and/or safety of patients, users or, where applicable, other persons, to

[1] http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_q_036.pdf
[2] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1993L0042:20071011:EN:PDF

Mr. Andrew Howlet
Assistant Clerk to the Public Petitions Committee
petitions@scottish.parliament.uk

take all appropriate interim measures to withdraw such devices from the market or prohibit or restrict their being placed on the market or put into service. The Member State shall also immediately inform the Commission of any such measures, indicating the reasons for its decision.

With regard to the possibility of a re-classification of surgical meshes, a Member State has the possibility under Article 13 to submit a duly substantiated request to the Commission and ask it to take the necessary measures when it considers that a given device or family of devices should, by way of derogation from the provisions of Annex IX, be classified in another class. To this date there has been no such requests regarding the surgical meshes.

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. The matters of the introduction of the uniform informed consent, of reporting by health professionals and of setting up of a devices register are the responsibility of Member States concerned and the European Union may not intervene.

I would like to inform you that the Commission adopted on 26 September 2012 two proposals to revise the rules governing medical devices[3]. These proposals aim at considerably reinforcing the rules that medical devices must comply with, and include more stringent requirements on clinical evidence necessary for the higher risk devices. They also contain provisions on registries and reporting by healthcare professionals. Gathering more extensive clinical data will allow for a better characterisation of such devices, leading to safer and better performing medical devices on the market, including meshes. We hope that once these rules are adopted by the legislator they will help address risk issues linked to meshes.

We remain available for any clarification on this matter. The Head of Unit in charge is Ms Sabine Lecrenier

Yours sincerely,

Despina Spanou

[3] COM(2012) 541 final and COM(2012) 542 final http://ec.europa.eu/health/medical-devices/documents/revision/index_en.htm