PE1517/FF

Department of Health Letter of 12 April 2016

Dear Michael

Thank you for your letter of 8 March, which you wrote in your role as Convener of the Public Petitions Committee, asking how best the Committee can influence the debate at a UK level on the regulation of mesh devices.

As you are aware, the work of the Medicines and Healthcare products Regulatory Agency (MHRA) on medical device regulation is reserved, covering the whole of the UK, and the MHRA has represented the UK in the long-running negotiations for new EU regulations of medical devices and *in vitro* diagnostic devices.

The MHRA has engaged closely with the Scottish Government throughout the process, to ensure that the latter's views continue to be reflected in the UK negotiating position. If the Public Petitions Committee were to continue to share information with Scottish Government officials this would ensure that they would be able to influence the debate at a UK level.

The UK has played an important role in these negotiations and is now working closely with the Dutch Presidency with a view to bringing them to a successful conclusion. These regulations should make medical devices even safer for patients and the public, while ensuring that the EU will continue to be viewed as an innovation-friendly regulatory environment.

The MHRA continues to work very closely with the Scottish Government on mesh devices and to take a fully active part in the ongoing work of the Scottish Independent Review of Mesh Implants.

You may also wish to be aware of two other significant reports related to mesh implants that were published in December:

- the NHS England *Mesh Working Group Interim Report*, in which the Scottish Government had full involvement. It can be found on NHS England's website at www.england.nhs.uk by searching for 'Mesh working group'; and

- the Final Opinion on *The safety of surgical meshes used in urogynaecological surgery* published by the EU Scientific Committee on Emerging and Newly Identified Health Risks. It can found at: http://ec.europa.eu/health by searching for 'Final opinion on surgical meshes'.

Please be assured that the MHRA is committed to helping address the serious concerns that have been raised by some patients about mesh implants and has undertaken a great deal of work continuously to assess findings of studies undertaken over many years. This includes considering the feedback from all sources. The MHRA also continues to work in collaboration with patients, the devolved administrations, the NHS, professional bodies, manufacturers and international partners to ensure emerging issues are detected and acted upon quickly.

I hope this reply is helpful.

Yours sincerely,

George Freeman MP
Parliamentary Under Secretary of State for Life Sciences