

PE1517/EE

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Convener
Public Petitions Committee

By Email.

Your ref: PE1517
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Dear Michael

Thank you for your letter dated 27 January following the Committee's further consideration of petition PE1517 at its meeting on 26 January. I welcome your continued interest in this important issue and have set out a response to the matters raised.

I am very supportive of the work of the Expert Group being carried out in a transparent manner and can confirm that a website containing information about its work will be established shortly.

The review of the protocols of the Single-incision mini-slings (SIMS) trial, taken forward by the office of the Chief Medical Officer (CMO), is near completion and the CMO will arrange for this report to be sent to the Committee and the Scottish Mesh Survivors Group as soon as it has been published.

As you are aware the Medicines and Healthcare products Regulatory Agency (MHRA) is the Competent Authority in the UK for medical devices and has the power to remove products from the market. Where there is evidence that a product is faulty MHRA can issue a Medical Device Alert giving advice to the healthcare sector. The Scottish Government has written to MHRA regarding recent reports on mesh implant products and MHRA has responded that it keeps an overview of legal cases and collaborates with other international regulators, such as the US Food and Drug Administration (FDA).

In relation to the call to set up a Scottish medical watchdog to replace MHRA, Section J4 of Part II of Schedule 5 to the Scotland Act 1998 reserves medicines, medical supplies and poisons and therefore responsibility for medical devices remains with the UK Parliament.

In Scotland we are doing all that we can to support women experiencing complications and to improve the governance around these procedures. The work of the Expert Group is vital and will put in place robust governance around these procedures that will benefit women affected.

SHONA ROBISON