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Date 3 October 2014  
Your Ref  
Our Ref IC/lb/03102014

Enquiries to Jan Lyell  
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Dear Colleague

**CALL FOR EVIDENCE: PUBLIC PETITION PE1517 POLYPROPYLENE MESH MEDICAL DEVICES**

Thank you for giving NHS National Services Scotland (NSS) the opportunity to respond to your call for evidence. Our completed response to the questions is attached.

If you would like clarification on any of the comments made, please contact Mrs Jan Lyell, Associate Director of Corporate Affairs and Identity on 0131 275 6449.

Yours sincerely

**IAN CRICHTON**  
Chief Executive



Chair Professor Elizabeth Ireland  
Chief Executive Ian Crichton  
*NHS National Services Scotland is the common name of the Common Services Agency for the Scottish Health Service.*

## PETITION PE1517 ON POLYPROPYLENE MESH MEDICAL DEVICES

The Scottish Parliament Public Petitions Committee has asked for the views of NHS National Services Scotland (NSS) on the calls on Petition PE1517 on Polypropylene Mesh Medical Devices

NSS deals with Polypropylene Transvaginal Mesh (TVM) in two main areas: NSS procures and supplies these CE marked medical devices to the NHS Scotland; and our Incident Reporting and Investigation Centre (IRIC) receives and investigates reports of adverse incidents relating to medical devices and advises the service on appropriate actions to maintain and improve safety. IRIC also works closely with the medical device regulator the Medicines and Healthcare Products Regulatory Agency (MHRA).

NSS maintains records of source and destination of products supplied including Polypropylene TVM. We also have a detailed file on reported issues which have been investigated by the national working group supported by IRIC.

The NSS view on each of the specific points of the petition is given below:

1. *Suspend use of polypropylene Transvaginal Mesh (TVM) procedures;*

NSS is concerned with the procurement and supply of polypropylene TVM and the receipt and investigation of reports on adverse incidents relating to medical devices only. NSS does not have a view about the use of TV Mesh tape seeing this as a matter for clinical decision makers in consultation with their patients.

2. *Initiate a Public Inquiry and/or comprehensive independent research to evaluate the safety of mesh devices using all evidence available, including that from across the world;*

NSS is supportive of establishing a clearer understanding of the risks associated with procedures involving polypropylene TVM. IRIC has provided technical support for the national working group chaired by Deputy Chief Medical Officer, Dr Frances Elliot. NSS is available to support the enquiry or any research.

3. *Introduce mandatory reporting of all adverse incidents by health professionals;*

NSS believes that increased reporting would allow better analysis of adverse incidents and improve safety.

4. *Set up a Scottish Transvaginal Mesh implant register with view to linking this up with national and international registers;*

As a source of additional clarity on the risks associated with Polypropylene TVM, a register might help with item 2 above.

5. *Introduce fully Informed Consent with uniformity throughout Scotland's Health Boards;*

NSS has no comment on this point.

6. *Write to the MHRA and ask that they reclassify TVM devices to heightened alert status to reflect ongoing concerns worldwide.*

NSS has no comment on this point.