The Scottish Parliament
Pàrlamaid na h-Alba

PUBLIC PETITIONS COMMITTEE

AGENDA

5th Meeting, 2015 (Session 4)

Tuesday 24 February 2015

The Committee will meet at 10.00 am in the Robert Burns Room (CR1).

1. **Consideration of a current petition:** The Committee will consider—

   PE1517 by Elaine Holmes and Olive McIlroy, on behalf of the Scottish Mesh Survivors - "Hear Our Voice" campaign, on polypropylene mesh medical devices

   and take evidence from—

   Dr Neil McGuire, Consultant in Intensive Care and Anaesthesia, Clinical Director Devices, and Sally Mounter, Senior Medical Device Specialist, Biosciences and Implants Devices Division, Medicines and Healthcare Products Regulatory Agency;

   and then, via videoconference, from—

   Adam M Slater, Mazie Slater Katz & Freeman, LLC.

Anne Peat
Clerk to the Public Petitions Committee
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The Scottish Parliament
Edinburgh
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The following papers are attached for this meeting—

Agenda item 1

PE1517	Note by the Clerk	PPC/S4/15/5/1
PRIVATE PAPER		PPC/S4/15/5/2
MHRA Report: A Summary of the evidence on the benefits and risks of vaginal mesh implants		
Adam M Slater Letter of 13 June 2014		PE1517/E
Scottish Government Letter of 5 February 2015		PE1517/Z

Public Petitions Committee

5th Meeting, 2015 (Session 4), Tuesday 24 February 2015

PE1517 on Polypropylene Mesh Medical Devices

Note by the Clerk

PE1517 – Lodged 1 May 2014
Petition by Elaine Holmes and Olive McIlroy, on behalf of the Scottish Mesh Survivors – "Hear Our Voice" campaign, Calling on the Scottish Parliament to urge the Scottish Government to:
1. Suspend use of polypropylene Transvaginal Mesh (TVM) procedures;
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;
3. Introduce mandatory reporting of all adverse incidents by health professionals;
4. Set up a Scottish Transvaginal Mesh implant register with view to linking this up with national and international registers;
5. Introduce fully Informed Consent with uniformity throughout Scotland's Health Boards; and
6. Write to the MHRA and ask that they reclassify TVM devices to heightened alert status to reflect ongoing concerns worldwide.
Link to petition webpage

Purpose

1. The Committee will take evidence from MHRA and Mr Adam Slater by video conference and consider information received from the Scottish and UK Governments. After hearing evidence, the Committee is invited to agree what action to take on the petition.

Background

2. Transvaginal mesh (TVM) can be used in pelvic organ prolapse (POP), and transvaginal tapes (TVT) can be used in the treatment of stress urinary incontinence (SUI). TVM and TVT products are medical devices. The regulation of medical devices is reserved to the UK Parliament. The Medicines and Healthcare Products Regulatory Agency (MHRA) is the competent authority in this area for the UK.

3. Whether a particular technology is used is a matter for individual clinicians and NHS Boards taking account of evidence and guidance. There are structures within the NHS in Scotland that can provide advice, including the Scottish Health Technologies Group[1], though it has not undertaken any work on TVM or TVT.

[1] This is an advisory group that sits within Healthcare Improvement Scotland that provides advice on the evidence about the clinical and cost effectiveness of existing and new technologies that are likely to have significant implications for patient care in Scotland.

4. The Committee first considered this petition on 3 June 2014. At the Committee's subsequent meeting on 17 June 2014, the Cabinet Secretary for Health and Wellbeing announced that NHS boards would be requested to suspend the use of mesh implants, pending an independent review. The independent review is due to report in April/May of this year.

5. A number of the health boards either do not carry out procedures that would require the use of mesh implants, or had already suspended their use following safety concerns. Several boards suspended the use of mesh devices following the request from the Chief Medical Officer. However, some boards indicated that they would continue.

6. In October 2014 the MHRA published a report entitled "A summary of the evidence on the benefits and risks of vaginal mesh implants". The report concluded—

> "Whilst some women have experienced distressing and severe effects, the current evidence shows that when these products are used correctly they can help alleviate the very distressing symptoms of SUI and POP and as such the benefits still outweigh the risks."
>
> And
>
> "In line with other medical device regulators worldwide we are not aware of a robust body of evidence to suggest that these devices are unsafe if used properly as intended and therefore should be removed from the market."

7. The European Commission has requested an opinion on the safety of surgical meshes used in urogynecological surgery from the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR). The SCENIHR is expected to report shortly.

Committee action

8. The Committee agreed to invite Cabinet Secretary for Health, Wellbeing and Sport, the MHRA, the Chair of the Independent Review of Transvaginal Mesh Implants and the European Commission to give evidence.

9. The Cabinet Secretary wrote to the Committee on 5 February 2015 indicating that the findings of the review are not expected to be available until April/May. The European Commission SCENIHR report had been expected by January but has also been delayed. No officials from the European Commission were able to attend this meeting.

Action

10. After taking evidence, the Committee is invited to agree what action to take on the petition. It is suggested that the Committee draw the Scottish Government's attention to the evidence heard with the request that it is taken account of by the review.

11. The Committee has already agreed that it wishes to hear from the Cabinet Secretary, the Chair of the Independent Review of Transvaginal Mesh Implants and the European Commission. Does the Committee agree that this should be after publication of the independent review's findings?