# Citizen Participation and Public Petitions Committee

3rd Meeting, 2021 (Session 6), Wednesday 8 September 2021

# PE1517: Polypropylene Mesh Medical Devices

## Note by the Clerk

#### PE1517: Lodged 30 April 2014

Petitioners Elaine Holmes and Olive McIlroy on behalf of Scottish Mesh Survivors - "Hear Our Voice" campaign Calling on the Scottish Parliament to urge the Scottish Government to: Petition summary 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. https://petitions.parliament.scot/petitions/PE1517 Webpage

### Introduction

1. The Session 5 Public Petitions Committee (PPC) last considered this petition at its meeting on <u>24 March 2021</u>. At that meeting, the Committee agreed to continue this petition and include it in its legacy paper for the Session 6 successor committee, along with a suggestion to refer the petition to the Health and Sport Committee.

#### Committee consideration

- 2. This petition was considered extensively by the PPC during both Session 4 and Session 5 of the Scottish Parliament.
- 3. During that time, the PPC considered more than 100 written submissions and has held several oral evidence sessions, taking evidence from—
  - The petitioners, <u>Elaine Holmes and Olive McIlroy</u>, and journalist, <u>Marion</u> <u>Scott</u> [3 June 2014];
  - Two Cabinet Secretaries for Health: <u>Alex Neil MSP</u> [17 June 2014] and <u>Shona Robison</u> MSP [6 October 2015] along with Scottish Government officials including the then <u>Chief Medical Officer, Catherine Calderwood</u> [6 October 2015], and the then <u>Deputy Chief Medical Officer, Dr Frances Elliot</u> [17 June 2014];
  - 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 [24 February 2015];
  - Adam M Slater, Mazie Slater Katz & Freeman, LLC [24 February 2015];
  - Dr Lesley Wilkie, Chair, Independent Review of Transvaginal Mesh Implants, Dr Rachael Wood, Consultant in Public Health Medicine, NHS Information Services Division and Dr Phil Mackie, Lead Consultant in Public Health, Scottish Public Health Network [6 October 2015]; and
  - Dr Dionysios Veronikis MD, FACOG, FACS, Director Female Pelvic Medicine & Reconstructive Surgery, Center for Vaginal Surgery and Urogynecology [22 October 2020].
- 4. The PPC held a Committee debate on the petition in the Chamber on <u>5</u> <u>December 2017</u>.
- 5. It also produced a <u>report</u> on the petition, which was published on 21 August 2018. The then Cabinet Secretary for Health and Sport <u>responded</u> to the Committee's report on 25 June 2019.
- 6. During the PPC's consideration, the Scottish Government accepted and committed to implementing the recommendations of the <u>Independent Review of Transvaginal Mesh Implants</u>, which will address the actions called for in the petition.
- 7. During the PPC's consideration, the Scottish Government also stated that it was—

- committed to working with the petitioners on the development of the national specialist service;
- developing proposals for the remit for a Patient Safety Commissioner. These proposals were open to public consultation from 5 March 2021 until 28 May 2021;
- working with the Health and Social Care Alliance to ensure its work is being informed by people with lived experience, and is committed to doing more to ensure that women know their views are being listened to, and to ensure that they get the services they need;
- establishing close working relationships with the equivalent services being developed by NHS England, which will allow referral to NHS England services, as a further choice, where necessary and clinically appropriate; and
- taking a proposal to the UK Medical Education Reference Group, which is the first step in the current process for submitting proposals for a GMC regulated credential with respect to mesh removal surgery.
- 8. Furthermore, the National Institute for Health and Care Excellence is leading on work to ensure that patient information and decision aids is informed by patients and consistent across the four nations of the UK;
- 9. Following publication of its report the PPC had been encouraged by the petitioners to focus on the ability of mesh survivors to receive care from clinicians that they have confidence in and are comfortable with.
- 10. Although the Scottish Government has established a national specialist mesh removal service, many mesh survivors, including the petitioners, expressed concern that the service would essentially be staffed by the same surgeons who had originally implanted their mesh devices. They stressed the need for women to be able to be treated by surgeons of their choice, outside of the NHS if necessary.
- 11. In her <u>written submission of 17 February 2021</u>, the then Cabinet Secretary for Health and Sport, Jeane Freeman, confirmed that NHS National Services Scotland intended, at the earliest opportunity, to issue an invitation to tender for specified mesh removal services to allow, in exceptional cases, patients to be referred outside the NHS, including the possibility of referral outside the UK, for treatment.
- 12. Significantly, in Session 6, the Scottish Government has introduced the <u>Transvaginal Mesh Removal (Cost Reimbursement) (Scotland) Bill</u>, on 23 June 2021. The Bill will allow the Scottish Government to set up a scheme which could reimburse people who have paid private healthcare costs to have their transvaginal mesh implant removed. It could also cover travel costs and hotel accommodation paid for in relation to the surgery.

## Petitioner submission

- In their most recent submission, <u>PE1517/YYYY</u>, the petitioners state that they are heartened the <u>Scottish Government's Women's Health Plan for 2021 –</u> 2024 highlights the importance of learning from the mesh crisis.
- 14. They welcome the categoric assurance from the Cabinet Secretary that there will be no reintroduction of transvaginal mesh procedures in Scotland.
- 15. Questions are raised, however, regarding issues such as—
  - Waiting times for the National Mesh Complication Centre;
  - The need for a Patient Referral Pathway to be published to ensure that the referral process to receive treatment outwith Scotland is a simple one;
  - How many women can be treated by providers outwith the NHS, and from when?
  - Is it more cost-effective to refer patients to NHS Bristol rather than to the privately-owned Spire Hospital?
  - When will the National Mesh Complication Centre respond to suggestions to improve service quality?
  - Changes that can be made to help the Multi-Disciplinary Team;
  - When will the Patient Safety Commissioner be appointed?

#### Action

16. The Committee is invited to consider what action it wishes to take.

#### **Clerk to the Committee**

#### Annexe

The following submissions are circulated in connection with consideration of the petition at this meeting-

- PE1517/WWWW: Anonymous submission of 23 June 2021
- PE1517/XXXX: Jacqui Dillon submission of 25 June 2021
- PE1517/YYYY: Petitioner submission of 2 September 2021

The Scottish Parliament launched a new website at the end of Session 5.

All written submissions received on the petition before May 2021 can be viewed on the petition on the <u>archive webpage</u>. Written submissions received on the petition after May 2021 can be viewed on its <u>new webpage</u>.