



Briefing for the Public Petitions Committee

Petition Number: [PE01517](#)

Main Petitioner: Elaine Holmes and Olive McIlroy on behalf of Scottish Mesh Survivors - "Hear Our Voice"

Subject: Polypropylene Mesh Medical Devices

Calls on the 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.

Background

The use of Transvaginal Mesh

Transvaginal mesh (TVM) can be used in [pelvic organ prolapse](#) (POP), and and transvaginal tapes (TVT) can be used in the treatment of [stress urinary incontinence](#) (SUI).

For both conditions there are non-surgical interventions, though it may be necessary to consider surgery in certain cases. However, traditional surgery techniques are associated with a range of short and long term complications¹. Indeed, in terms of surgery for POP, there is a 20%-30% failure rate from primary prolapse surgery and women may need second and subsequent procedures to address prolapse recurrence. As a result, synthetic (non-

¹ Scottish Government (July 2013) '[Letter from the Chief Medical Officer to NHS Boards: Transvaginal mesh](#)' (p 3)

absorbable) and biological (absorbable) meshes were introduced into surgery as supporting materials in surgical treatments.² It is estimated that about 1,500 TVT for SUI and 350 TVM for POP are implanted annually in Scotland³.

Regulating the safety of Transvaginal Mesh Products

TVM and TVT products are medical devices. The regulation of medical devices (including a determination of safety before a CE mark is applied and ongoing vigilance monitoring thereafter) is a matter reserved to the UK Parliament. Regulation of Medical Devices is governed through a number of EU Directives transposed into UK law by regulations. The Medicines and Healthcare Products Regulatory Agency (MHRA) is the competent authority in this area for the UK. A short description of the regulatory system is provided in [Appendix 1](#).

The petition calls for the Scottish Government to initiate a Public Inquiry and/or comprehensive independent research to evaluate the safety of mesh devices. Whilst the Scottish Government could initiate the latter, under section 28 of the Inquiries Act 2005, Scottish Ministers do have the powers to set up a public inquiry, but only where the matter concerned is devolved.

After a medical device has had a CE mark applied, there should be on-going vigilance monitoring including any adverse incidents that are reported on the use of a device. Whilst the MHRA has an overarching role in this, in Scotland adverse incidents are handled by Health Facilities Scotland. Its role is outlined in [Appendix 2](#). HFS has received 14 adverse incident reports concerning TVM and TVT between 24 December 2012 and 27 March 2014⁴.

Current UK guidance and evidence on the safety of TVM and TVT

The petitioner makes note of the recent decision by the United States Food and Drug Administration (FDA) to issue two proposed orders, which if approved, “will require manufacturers to provide premarket clinical data to demonstrate a reasonable assurance of safety and effectiveness for surgical mesh used to treat transvaginal POP repair”. This followed a number of reviews by the FDA which “identified clear risks associated with surgical mesh for the transvaginal repair of pelvic organ prolapse”.⁵ It is important to note that the proposed order does not cover surgical mesh for SUIs and a number of other conditions.

The FDA’s decision has led to calls for regulators at European and UK levels to review their guidance. The current MHRA view⁶ is that whilst it has received a number of reports of complications arising from the use of TVM for POP, it has “no evidence the devices themselves have inherent problems that

² Medicines and Healthcare Products Regulatory Agency (Online) [‘Vaginal mesh for pelvic organ prolapse’](#)

³ Scottish Government (July 2013) [‘Letter from the Chief Medical Officer to NHS Boards: Transvaginal mesh’](#) (p 3)

⁴ Scottish Government. Personal communication 28 May 2014

⁵ US Food and Drug Administration (April 2014) [‘FDA issues proposals to address risks associated with surgical mesh for transvaginal repair of pelvic organ prolapse’](#)

⁶ As outlined in MHRA (Online) [Vaginal mesh for pelvic organ prolapse](#)

would necessitate consideration of any steps up to and including consideration of product removal from the market”. However, due to concerns being raised, the MHRA commissioned The University of York’s Health Economics Consortium to undertake an independent review of the safety and of any adverse effects associated with TVM for POP and TVT for SUI. The [report](#) was published in November 2012. This research confirmed that for TVT for SUI the rates of adverse events were low, but that for TVM for POP the rates of adverse events were higher and this is a factor which patients considering surgery will wish to take into account in discussion with their surgeons.⁷

The Scottish Government’s advice concerning safety is discussed in the Chief Medical Officer’s [letter](#) to NHS Boards from July 2013.

Determining whether a medical device is used in the NHS

Whilst the regulation of medical devices is reserved, whether or not a product is used in the NHS in Scotland is a devolved matter. However, unlike in the case of newly licensed medicines, newly CE marked applied medical devices are not routinely appraised for use in the NHS, though it is possible to request an assessment or apply evidence from elsewhere. For example, NHSScotland is a partner in the National Institute for Health and Clinical Excellence’s interventional procedures programme which has provided guidance on the use of mesh in certain POP operations⁸.

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 Group⁹, though it has not undertaken any work on TVM or TVT.

The petitioner calls on the Scottish Government to suspend the use of TVM procedures. The Scottish Government could issue guidance in this regard. However, in recent Parliamentary Questions, its position is for the regulatory bodies at UK and EU level to consider the evidence concerning the use of these products. Recently, the Minister for Public Health, Michael Matheson MSP stated: “...if there is any change to the guidance or a recommendation is made by the MHRA or the European Community, the Government will act swiftly on that”¹⁰.

⁷ Scottish Government (July 2013) '[Letter from the Chief Medical Officer to NHS Boards: Transvaginal mesh](#)' (p 5-6)

⁸ [IPG267: Surgical repair of vaginal wall prolapse using mesh](#) (June 2008) and [IPG282: Insertion of mesh uterine suspension sling \(including sacrohysteropexy\) for uterine prolapse repair](#) (January 2009)

⁹ 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.

¹⁰ [S4T-00695](#)

Informed consent

Another key part of the petition concerns ensuring that patients give informed consent when they are offered surgery involving TVM. In 2009, the Scottish Public Services Ombudsman upheld a [complaint](#) by a patient who had TVM surgery without giving proper consent. The Scottish Government has outlined what it expects as regards obtaining proper consent from patients¹¹. Included is a reference to two of the health care principles ([Schedule](#)) of the Patient's Rights (Scotland) Act 2011, namely: patients participate as fully as possible in decisions relating to the patient's health and wellbeing; and, patients are provided with such information and support as is necessary to enable them to participate in accordance with paragraph 12 and in relation to any related processes (general or specific). Further information is provided in the Health Rights Information Scotland leaflet '[Consent – it's your decision](#)'.

Specific for patients who are being considered for mesh or tape surgery, the MHRA has outlined the questions patients should ask of their doctor, as well as links to professional body guidance for [TVM](#) and [TVT](#).

Scottish Government Action

In addition to the actions discussed above, the Scottish Government¹² has set up an expert working group, chaired by the Deputy Chief Medical Officer, to address the issues affecting women who have undergone transvaginal mesh surgery. The group is developing:

- A revised patient information and consent booklet for NHSScotland, to be given to women considering undergoing a synthetic vaginal mid-urethral tape procedure for stress urinary incontinence.
- New care pathways for those women who decide to go ahead with a mesh procedure and for those who have suffered complications.
- A strengthened process for adverse incident reporting.

The Cabinet Secretary for Health and Wellbeing has also written to the MHRA and the European Commission asking that they urgently consider the United States FDA's proposed reclassification of surgical mesh for the treatment of pelvic organ prolapse.¹³ Other actions have included:

- Undertaking work on the feasibility of recording the type of medical device used in treatment, and how it was used, on a patient's electronic record, to assist in identifying clearer picture of the number of patients who may be affected should problems occur with a particular implant in the future.¹⁴
- Undertaking discussions with stakeholders on the establishment of an implant registry.¹⁵

Scottish Parliament Action

No committee of the Scottish Parliament has considered the specific issues contained within the petition. However, the Health and Sport Committee did

¹¹ [S4W-18278](#)

¹² [S4W-20948](#)

¹³ [S4T-00695](#)

¹⁴ [S4T-00695](#)

¹⁵ [S4W-18271](#)

take evidence on the response of the Scottish Government and the private health sector to the PIP Breast Implants case during 2011-12.

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18 May 2014

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Appendix 1: The regulation of medical devices

Transvaginal Mesh (TVM) products are regulated as medical devices. The term “medical devices” covers a range of products, from non-invasive support products such as bandages, to implanted devices such as pacemakers breast implants and TVM. It is estimated that there are over 90,000 types of medical devices on the market in the UK¹⁶. Regulation includes establishing the safety of the product both prior to market authorisation (i.e. CE marking) and thereafter, and is a reserved matter to the UK Parliament. Regulation is governed through a number of EU Directives, transposed into UK law through regulations.

Medical devices are classified by the Directives according to the level of risk they pose to the patient. There are four classes of risk (I, IIa, IIb, and III), with the lowest risk devices (e.g. stethoscopes) falling into Class I, and products such as dental fillings being defined as Class IIa. Medical implants, such as TVM) are always classified as Class IIb or III, because they are placed within the body, require invasive surgery, and are designed to be in continuous use. As a result these products must be regulated in a particular way (see Figure 1).

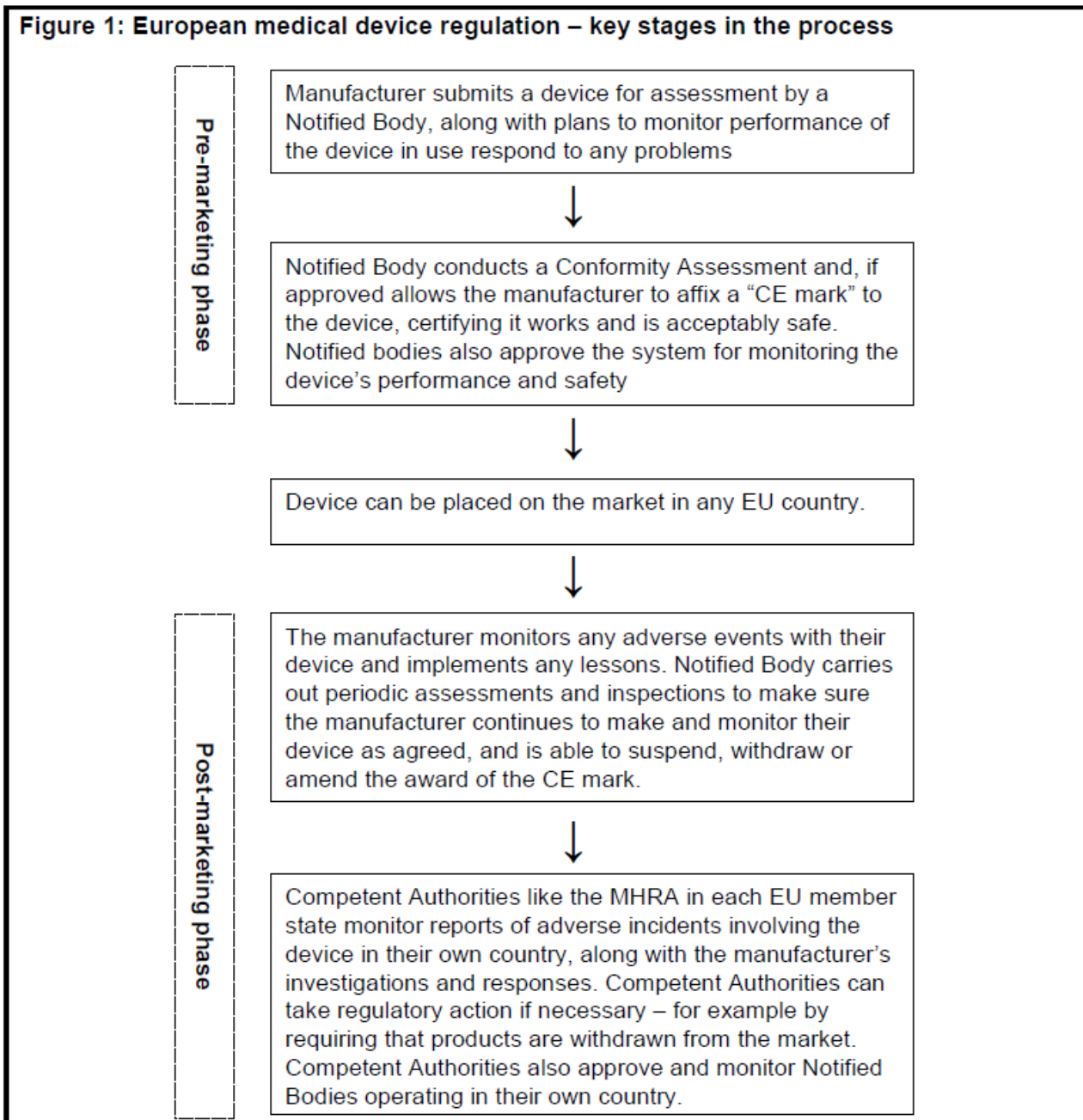
The safety of TVM and other invasive medical devices is assessed by an independent third party organisation (or “notified body”) of which there are around 80 across Europe. These bodies are appointed and audited by the competent regulatory authority in each member state, which is the Medicines and Healthcare products Regulatory Agency (MHRA) in the UK. The role of the notified body is to determine whether a particular medical device meets the relevant regulatory requirements and, whether, when used as intended, it works properly and is acceptably safe. A manufacturer can select any notified body across Europe irrespective of location, provided that their field of expertise covers the device being considered. Once a CE mark is applied the medical device can be sold in all EU countries without further controls.

Following market authorisation, the notified body should ensure that the manufacturer adheres to quality systems and provides it with agreed information. The notified body may also pay unannounced visits to the manufacturer and carry out or ask for tests in order to check the quality system is working properly. A notified body may suspend or withdraw a CE certificate, place restrictions on it or trigger an intervention from the competent authority. In such circumstances the notified body must inform the competent authority in its own country, and the competent authority must inform other competent authorities and the European Commission of such action.

However, the device manufacturer is central to the vigilance and incident reporting system. Manufacturers must report certain adverse incidents to the relevant national competent authority (the competent authority where the

¹⁶ Keogh, Sir Bruce (6 January 2012) [‘Poly implant prostheses \(PIP\) breast implants: Interim report of the Expert group’](#)

Figure 1: European medical device regulation – key stages in the process



incident has occurred, unless otherwise specified) for recording and evaluation.

Source: Earl Howe (2012) [‘Poly Implant Prothèse \(PIP\) silicone breast implants: Review of the action of the MHRA and the Department of Health’](#)

One of the roles of the competent authority is to establish a ‘vigilance’ programme in relation to post-market surveillance of the performance and safety of medical devices. In the UK this involves investigating both mandatory serious adverse event reports from manufacturers and adverse events reported voluntarily by healthcare professionals and members of the public. Adverse incidents in Scotland are handled by Health Facilities Scotland (a division of NHS National Services Scotland). Its role is outlined in Appendix 2. If adverse events are proved, the MHRA can take a series of actions including the removal of the CE mark, the recalling of faulty products

and providing advice to the health service through Medical Device Alerts. Where regulations are breached, the MHRA has the power to prosecute. It can also withdraw unauthorised / illegal products from the market.

The rationale for employing the notified body system for medical device regulation is because of the sheer size and breadth of the market for the products and the large number of new products that come onto the market. It is also seen as an efficient and flexible system.

However, over recent years there have been a number of concerns raised into the system, most notably following the PIP breast implants case. The European Commission published a [proposed revision of the medical devices directives](#) in September 2012. This has now been considered by the European Parliament, and now awaits consideration by the European Council. This was not a reaction to the PIP and other cases themselves, as the public consultation on it began in 2008, but it has since taken account of the issues in those cases.

Meanwhile in the UK, there have been a number of reviews into PIP and the regulatory system of medical devices, including:

- House of Commons Health Committee (March 2012) [Sixteenth Report: PIP Breast Implants and regulation of cosmetic interventions](#) [webpage includes link to the UK Government response]
- Earl Howe (May 2012) ['Poly Implant Prothèse \(PIP\) silicone breast implants: Review of the action of the MHRA and the Department of Health'](#)
- House of Commons Science and Technology Committee (November 2012) [Regulation of medical implants in the EU and UK](#) [webpage includes link to the UK Government response]
- Review of the Regulation of Cosmetic Interventions Committee (April 2013) [Review report](#)

Appendix 2: The reporting of adverse incidents concerning medical devices in NHS Scotland

Adverse incidents reported through the NHS in Scotland are handled by the Incident Reporting and Investigation Centre (IRIC) at Health Facilities Scotland (HFS) is part of NHS National Services Scotland. HFS is responsible for receiving adverse incident reports from NHS Boards and Local Authorities in regards to equipment and facilities. Medical devices are included in the definition of health and social care equipment used by HFS.

In October 2009, the Scottish Government published new [guidance](#), which outlines the role of HFS and its responsibilities (as well as the responsibilities of public bodies).

The role of HFS

IRIC is responsible for receiving adverse incident reports and co-ordinating investigations so that, as far as possible, root causes can be established and remedial action taken to prevent or reduce any identified risks.

The MHRA is responsible for the regulation of medical devices throughout the UK and for issuing Medical Devices Alerts (MDAs). HFS works closely with MHRA, and will notify MHRA of each adverse incident reported in Scotland and the results of any investigation. For example, HFS may identify a need for an MDA and will liaise with MHRA in their assessment of the need for and drafting of the alert. If a health professional or other person in Scotland was to report an incident directly to MHRA, then MHRA would send that to HFS to consider.

HFS also liaises with other UK Health Departments, NHS bodies and agencies on the safety of estates and facilities equipment. In particular, information is exchanged on adverse incidents reports and investigations. In relation to adverse incidents involving medical devices, HFS provides each NHS Board Equipment Co-ordinator (or risk manager) a list of reports sent to HFS by their organisation during the previous quarter, as well as a list of all investigations still in progress.

HFS also has a role in maintaining a list of Equipment Co-ordinators for all NHS Boards (as well as local authorities) and should be notified immediately of any change. HFS also runs a network to support the work of Equipment Co-ordinators and their organisations. This includes various events to promote the management of risk and equipment safety in each organisation and generally throughout Scotland.

NHS Board responsibilities

Under the 2009 guidance NHS Boards are responsible for ensuring all staff are aware of all relevant policies and procedures. The guidance outlines the role of the Equipment Coordinator, the duties for which include:

- ensuring managers and staff are aware of the procedures for reporting adverse incidents and for implementing safety advice
- monitoring all adverse incidents reports from within own organisation
- receiving emails from HFS notifying of alerts and bulletins, and cascading within own organisation
- monitoring internal cascade systems to ensure alerts are received, assessed and acted upon

Boards must also ensure there are clear written and policy procedures for the prompt recording of all adverse incidents, including:

- preserving evidence and keeping records
- informing the organisational Equipment Co-ordinator
- maintaining a central register for equipment incidents in each organisation

There must also be clear policies for receiving, assessing and implementing all alerts and bulletins sent by HFS and MHRA (see paragraph 6.2).

Reporting incidents to HFS

The policy for reporting adverse incidents by a clinician or NHS Board is set out in Chief Executive Letter CEL 43 (2009). However, there can be a number of reasons why an adverse incident has not be reported. This could be because it is not clear that an adverse incident has been caused by a fault with the device. Other factors include the condition of the patient at the time of the procedure and clinician error.

As regards the timing of reporting, some Boards may report incidents immediately while others may wait until they have collected evidence of a trend or undertaken their own investigation as to whether it is an issue with the device. There may also be differences within Boards by hospital and clinician.

Nevertheless, when it is believed that there may be an issue with a device, this should be reported to HFS. How an incident should be report to HFS is outlined in Annex B of the 2009 guidance.

Adverse events framework

Healthcare Improvement Scotland has provided a framework for the management of adverse events and is linking into the work on adverse incidents. The reports are available [here](#)

Reporting by clinicians

Clinicians cannot be compelled to report an incident. Why this is appears to be related to the fact that there may be reasons for the adverse incident that may not be related to the device itself.

However, non-reporting of an adverse incident concerning a medical device would contravene the standards laid down by the General Medical Council which regulates all doctors. The regulation of doctors is a reserved matter.

The principal document which lays out what is expected from a doctor is [‘Good Medical Practice’](#), which was updated this year. Contained in domain 2 concerning safety and quality, it states that to help keep patients safe a doctor must:

“...report adverse incidents involving medical devices that put or have the potential to put the safety of a patient, or another at risk” (23c).

This is backed up by [‘Good practice in prescribing and managing medicines and devices’](#) guidance which came into effect in February 2013. Paragraphs 46 to 50 outline what doctors must do in reporting adverse incidents. The separate arrangements for Scotland are included.

The MHRA has undertaken work with professional medical bodies, Royal Colleges and others to encourage greater reporting of incidents by clinicians. The work that has been undertaken is outlined on pages 4 to 7 of a [progress report](#) MHRA published in June 2013.

The responsibility of manufacturers

The 2009 guidance notes that the alerts system is not a replacement for direct action by manufacturers, who have responsibilities under EU regulations to address safety issues concerning their devices. This is discussed further in Annex D of the guidance.