PE1517/III
Petitioners' submission of 13 September 2017

On behalf of Scottish Mesh Survivors we would like to thank the Petitions Committee for giving us the opportunity to respond to the Cabinet Secretary's latest communications and comments made by the Chief Medical Officer (CMO). We take a dim view of some of the content and hope to set the record straight regarding:

1. Miscommunication by the Cabinet Secretary and the Chair of the Scottish Government Mesh Review regarding our request to remove **ALL** our input from the Final Report
2. Using date discrepancies to justify failure of the Final Report to include the EU reclassification of all surgical mesh devices to highest risk (Class III)
3. Wrong information given by the Chief Medical Officer to this Committee that Australia only "restricted" the use of some implants.
4. Wrong information given by the Chief Medical Officer to this Committee with regards to mesh implants
5. Outdated patient safety information for transvaginal mesh tapes displayed by the Scottish Government and Scotland's health websites

1- The miscommunication to publish our input in the whitewash mesh report against our will:

Despite being fully-informed by the Cabinet Secretary that **ALL** our input must be removed from the report, Dr Gillies, the Chair of the review, went ahead and published all of our input in the Final Report, removing only our Minority Opinion, which was 'too late' to be included in the Interim Report. She sent us a letter with a mistake in the dates. It is unacceptable that a Chair of a review expects lay-members of the group to respond to a serious email within only 24-48 hours, depending on the way the mistake in the dates is understood.

When asked by the Committee, Dr Gillies was inconsistent in her answers as to why she published our input when the Cabinet Secretary asked her not to. In one instance, she appeared to blame the Cabinet Secretary for lack of clear communication but in another instance she appears to shift the responsibility for the decision to publish our input to the members of the review themselves. If the Review Group members decided to include our input against our wish, we would like to see written minutes of the meeting or email evidence please.

Such inconsistency is a clear indication of unnecessary miscommunication which resulted in the loss of accuracy in relation to our request for our input to be removed. When asked about this matter, the Cabinet Secretary clearly and consistently shifted the responsibility to the review Chair.

Here is a timeline of events in relation to this miscommunication:

16 March – Scottish Mesh Survivors (SMS) ask Cabinet Secretary to remove **ALL** our input from the Final Report, this was acknowledged and said it would be conveyed to Dr Gillies.

22 March 18:22 – Dr Gillies wrote that she understood from the Cabinet Secretary that we wanted our contribution removed. She listed **ALL** items we had contributed and asked us to confirm **AGAIN** that we wanted them **ALL** removed. She asked that we respond by 10:00 on Thursday 24th.**Thursday was the 23rd not 24th**. This email was unnecessary, harassing, confusing and pressurising. This gave us less than 24 hours (or 48 hours, depending on which date was correct) to respond.

23 March 23:57 – We did respond although it felt unnecessary to do so, we again asked Dr Gillies and the Cabinet Secretary to remove **ALL** our input from the Final Report, including our Minority Opinion from the Interim Report.

27 March – Cabinet Secretary wrote to say we had subsequently asked for 'more' input to be removed and this would not be possible – we were too late. We repeatedly asked that **ALL** our input from the Final Report be removed. We did **NOT** want associated with the report and it was **NOT** in our name. Quite simply we were used in order that the Final Report could publish without it appearing completely biased.

27 March – SG Final Report published. **NONE** of our input into this Final Report was removed! The only thing removed was our Minority Opinion from the Interim Report.

29 March – **POSTAL LETTER received, dated 23 March BUT the envelope dated 27 March** from Dr Gillies writes; "Further to my email to you yesterday, I have not heard from you". She goes on to say that we had asked only that our Minority Opinion from the Interim Report be removed.

18 May – Dr Gillies told this Committee that the review group had had a meeting to discuss our request to remove **ALL** our input before the Final Report published on 27 March. "It is right to listen to requests but, that does not mean I would necessarily accede to those requests."

18 May – Cabinet Secretary: "I met the Chair on **22 March**, I relayed to her **ALL** the concerns that the women had expressed. She then contacted them to ask about a number of pieces of information and to seek clarification of what should be removed. The women responded on, I think, **23 March** with a list of information that they wanted to be removed. It was, ultimately, the chair's decision on whether to accede to that request. She clearly agreed with some of it: she agreed to remove, for example, the minority report and gave her reasons earlier about why she did not remove the other material."

A timeline of email correspondence in relation to this miscommunication has been provided to the Committee.

2 - Cabinet Secretary and CMO appear to have used date discrepancies for the failure of the whitewash mesh report to accept the EU Reclassification of all surgical meshes to highest risk class III category:

The cabinet secretary and CMO stated that the EU reclassification took place in the first week of April 2017, a few days after the whitewash mesh report was published, and that is why the report did not mention the reclassification.

Our understanding is the reclassification was approved on 22 February (5 weeks before the report was published) and adopted on 7 March by EU Council. We asked the Chair to include the reclassification on 27 February. The Final Report says; "It is anticipated the new EU Medical Device Regulations will include a change to the classification so all "surgical mesh" devices intended for "long term or permanent use" will be Class III".

The report then goes on to down-play the significance of reclassifying surgical mesh to highest risk category by saying; **"From a European perspective the current position is that reclassifying these medical devices would not confer any material difference as they are already in the medium to high risk category as non-active implantable devices."**

Here is a timeline for the related events:

15 June 2016: Proposal for a Regulation of the European Parliament and of the Council on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009. EU Reclassification of all surgical meshes to class III, Annex, Page 338, 4.4., Rule 8: http://data.consilium.europa.eu/doc/document/ST-9364-2016-REV-2/en/pdf

22 February 2017: Position of the Council at first reading with a view to the adoption of a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC. EU Reclassification of all surgical meshes to class III, Annex VIII, Page 12, 5.4, Rule 8: http://data.consilium.europa.eu/doc/document/ST-10728-2016-INIT/en/pdf

8 March 2017: Position of the Council at first reading with a view to the adoption of a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC - **Adopted by the Council on 7 March 2017. EU Reclassification of all surgical meshes to class III, Annex VIII, Page 12, 5.4, Rule 8:** http://data.consilium.europa.eu/doc/document/ST-10728-2016-REV-4/EN/pdf

Question S5W-08557: Neil Findlay, Lothian, Scottish Labour, Date Lodged: 31/03/2017
To ask the Scottish Government, further to the statement by the Cabinet Secretary for Health and Sport on 30 March 2017 (*Official Report*, c. 57), what its response is to concerns that the final mesh report does not make clear that the EU classifies mesh as "high-risk".

Answered by Shona Robison (28/04/2017):

The Independent Review's Final Report made clear that, at the time of writing, it was anticipated that the new EU Medical Device Regulations would include a change to the classification of surgical mesh devices intended for long-term or permanent use.

It is now confirmed that the new EU Regulations, subject to their formal adoption, will up-classify surgical meshes to Class III. The new Regulations can be viewed here: http://data.consilium.europa.eu/doc/document/ST-10728-2016-REV-4/EN/pdf.

Current Status: Answered by Shona Robison on 28/04/2017

The link Cabinet Secretary Shona Robison provides in her answer to Neil Findlay above is the **same** link that we provided, which confirms that the reclassification of all surgical meshes to highest risk Class III was adopted by EU Council on 7 March 2017, and the letter confirming this was dated 8 March, well before the Final Report was published. Dr Gillies confirmed to the Committee that reclassification was 8 March.

- Why did the Final Report use date discrepancies for failure to accept the reclassifying of surgical meshes to **HIGHEST** risk category Class III when this was **NOT** anticipated, it was **approved** on 22 February and **adopted** by EU Council on 7 March?

- Why did the Final Report down-play the significance of reclassifying surgical meshes to the **HIGHEST** risk category Class III when the European Parliament deemed this necessary for better protection of public health and patient safety?

3 - CMO failed to inform this Committee that 75% of mesh devices have been deregistered in Australia:

75% of meshes, including **ALL** Boston Scientific mesh devices, suspected to be potentially counterfeit, have been deregistered in Australia: http://apps.tga.gov.au/PROD/SARA/arn-entry.aspx **NOT** merely 'restricted' as the CMO told the Committee.

Class I *recall action occurs when the product deficiency is potentially life-threatening or could cause a serious risk to health.*
Class II *recall action occurs when the product deficiency could cause illness, injury or result in mistreatment, but are not Class I.*

Australia's Therapeutic Goods Agency (TGA), which is equivalent to the MHRA, deregistered:

- **ALL Cook Mesh Products** (Class II)
- **ALL Boston Scientific Mesh products** (Class II)
- **ALL Coloplast Mesh Products** (Class I)
- **SOME Johnson and Johnson Mesh Products** (Class I and II)

- Why was this not announced appropriately?

4 - Inaccurate statement by CMO – use of mesh for incontinence:

When interviewed by BBC News Reporter in Dec 2016, Chief Medical Officer Catherine Calderwood said that '*mesh was the only option for these women'. This* is **NOT** the case! In response to Neil Findlay, the Cabinet Secretary suggested that the CMO's comments had been taken out of context and did not accurately reflect her position.

Despite Alex Neil calling for a mesh suspension in June 2014, more than **400** women have received mesh implants since that time, and less than 100 women have received non-mesh alternatives. We believe the high number of mesh procedures is as a result of directive counselling and **NOT** shared decision making. All hospitals that flouted the government suspension can do non-mesh surgery so the CMO's statement to the BBC is wrong and misleading.

Because the UK Medicines and Healthcare products Regulatory Agency (MHRA) has failed to act, and wrongly claim that 'the benefits outweigh the risks', all mesh devices are still being used throughout the UK. The Scottish Government Final Report has exposed women to unnecessary harm by allowing the use of all mesh devices, whilst other health regulators have taken action to deregister mesh implants and/or issue safety alerts. Despite the US Food and Drug Administration (FDA) **Safety Alert: Urogynecologic Surgical Mesh Implants by Boston Scientific: Notification Potential for Counterfeit Raw Material**, these devices are still being used in Scotland.
https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm493784.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery.

Despite the suspension, Boston Scientific is now the biggest supplier of mesh tapes for incontinence in Scotland.

- Why has the Cabinet Secretary endorsed the CMO's view instead of recognising she's rubber-stamped mesh for more than 400 women?

5 - CMO acknowledgement that consent for mesh surgeries was not informed:

The CMO said; "We know that there are women who have had mesh inserted into them who should not have had it because they were not properly consented. They did not have a full description of what might happen to them in the worst-case scenario. For that, I have already apologised."

"We want the other women to have all the options laid out with all the complications and risks and the things that these women were not fully aware of because, at the time, they did not have what we now see as fully informed consent."

Consent for mesh surgeries is still not informed:
A Patient Information Leaflet (PIL) developed by the Scottish Government Expert Group: **'Synthetic Vaginal Mesh Tape Procedure for the Surgical Treatment of Stress Urinary Incontinence in Women'** was adopted by and published in the rest of the UK in May 2017 but not in Scotland – (with the exception of our Scottish Mesh Survivors website)
http://bsug.org.uk/budcms/includes/kcfinder/upload/files/SUI%20Mesh%20Tapes%20Leaflet%20Version%2024_160517.pdf

The information leaflet published on the Scottish Government website is outdated and the explanation of risks is inadequate. The current leaflet is either unavailable or if it is available, it is not easy to find on NHS Health Scotland websites.

- How can consent be informed if women aren't aware of **ALL** known risks and alternative treatment options available?
- How can there be shared decision making if all alternative treatment options are not discussed equally and impartially?

The Scottish Government should update their own website as it currently displays outdated patient information regarding all known risks and best practice before issuing advice to Health Boards. How can Scottish hospitals be expected to inform patients and have shared decision discussions when they don't have up-to-date information themselves?