PE1517/PPPP
Interim Chief Medical Officer submission of 27 November 2020

Thank you for your letter of 29 October 2020 concerning petition PE1517, polypropylene mesh medical devices.

I am aware that you have also written to the Cabinet Secretary for Health and Sport in relation to this matter, and she will therefore more fully set out the Scottish Government's response to the evidence that Dr Dionysios Veronikis gave to your committee on 22 October. However, I will address the specific questions you raise about mesh removal surgery.

I have taken careful note of the concerns that women have raised, where they believed that they were to undergo full mesh removal, only to later discover they had had partial removal surgery. This issue became particularly apparent here in Scotland after the First Minister, the Cabinet Secretary for Health and Sport, and my predecessor met mesh injured women in November of last year.

However, it is important to note that this matter was also raised in *First Do No Harm*, the July 2020 report of the Independent Medicines and Medical Devices Safety Review. In the report, Baroness Cumberlege makes reference to the terminology used to describe mesh removal, and it is therefore apparent that this is a serious issue not only in Scotland, but across the UK and possibly further afield:

"We have had reports from some women about confusing terminology used by clinicians when discussing removals. Women have been offered a 'full vaginal removal' and understood that this operation would remove all their mesh. A 'full vaginal removal' is the removal of the vaginal portion of the mesh, leaving the rest of the mesh in situ."

I should explain that ultimate responsibility – and therefore accountability – for the accuracy of the information given to patients, and the content of patient notes, lies with the Health Board concerned. However, in light of the concerns expressed in last November's meetings, the Cabinet Secretary agreed to instigate a Case Record Review. The review will give women the opportunity to set out their concerns about their mesh removal, and have their records reviewed by clinicians.

The Review will be undertaken by a Panel led by a Moderator with a team of three clinicians and an administrator. The work of the Panel will be independent of Scottish Ministers and each member will be expected to make a contemporary and full declaration of their interests. These will be made available for scrutiny by the women whose cases are being considered and by other review group members, and will be placed in the public domain.

In the first instance, the Review will be offered to women who attended the meetings last November. This is to ensure that the review is purposeful, however, after careful evaluation, we will consider whether it would be beneficial for more women to be offered a similar review. I will very soon be in touch with all those who attended the meetings last November with further details.

With respect to skills and training, mesh removal is highly specialised and can involve input from more than one specialty (uro-gynecology, urology, colorectal surgery). The extant position for surgeons is that they undertake training by following a curriculum that is approved by the GMC. At the completion of training they are awarded a Certificate of

Completion of Training (CCT) by the General Medical Council. For all practical purposes doctors must hold a CCT (or equivalent) in the relevant discipline before being appointed to a consultant post in NHS Scotland.

All doctors who treat patients are required by Law to hold a Licence to Practice. For the past seven years doctors have been required to show that they are “up to date and fit to practice” by participating in the mandatory process called Revalidation. For this purpose a doctor relates to a responsible officer (usually a senior doctor appointed by the organisation where the doctor works) who makes a recommendation to the GMC every five years based on annual appraisal as to whether the Licence to Practice is renewed. Over the five year cycle the doctor is required to submit evidence to support their practice. This will include feedback from peers and other colleagues, as well as patients. The evidence will testify that their practice is contemporary and competent. Audit and other data detailing outcomes will be reviewed. They will be required to reflect upon their entire clinical practice.

It is also important to note, however, that doctors will, on occasion, be required to undertake new or innovative techniques after they have achieved a CCT. This has been recognised and considered by the UK Shape of Training Steering Group (led by Scottish Government) and addressed in their final report. The recommendations were accepted by all four UK Ministers. The recommended solution was to develop a process for post-CCT GMC approved credentials. This is an emerging process of governance that is being developed.

GMC approved credentials are significant elements of training that are required to rapidly upskill the medical workforce to enable the service to respond to innovation or changing patient need, where there is a legitimate public concern or the need for governance. The current process for submitting proposals for GMC regulated credentials is that they are considered in the first instance by the UK Medical Education Reference Group. This group comprises members of the four UK Governments and the four Statuary Education Bodies.

Given the concerns that have been expressed in relation to mesh removal surgery, the Scottish Government is firmly of the view that a GMC credential requires to be developed in this area. This is with the intention of ensuring formal recognition of the technical skills possessed by the surgeons working in this field, and thereby building public confidence that both the surgeons and the institution are approved by the independent UK Regulator.

In light of the above, the Scottish Government will, in due course, take a proposal to the aforementioned Referenced Group.

I hope this is helpful.