PE1517/QQQQ
Cabinet Secretary for Health and Sport submission of 27 November 2020

Thank you for your letters of 16 September and 29 October concerning polypropylene mesh medical devices, and please accept my apologies for the delay in replying to the former.

Patient Safety Commissioner

The development of proposals for a Patient Safety Commissioner (PSC) is being informed by meaningful engagement with those with lived experience of the issues covered in Baroness Cumberlege's Independent Medicines and Medical Devices Safety Review. The Scottish Government has now set up a patient reference group, which includes members with lived experience of the issues arising from the use of mesh implants, Sodium Valporate and Primodos. The group had its first meeting on 29 October 2020. This was well attended with good engagement levels from the members who gave some positive feedback afterwards. The group has agreed to meet regularly to progress this work as quickly as possible.

In addition, the Scottish Government is in the process of forming a group to run parallel to the patient group. I envisage that this group will be made up of organisations that currently have a role in the patient safety landscape in Scotland and will provide expert input to help shape and guide this work as it progresses. Officials intend to publish all papers from both groups on the Scottish Governement website in due course.

I intend that this engagement will begin to shape the draft remit of the Patient Safety Commissioner and that this draft will then be open to a wider audience in a public consultation.

At this stage, I cannot give a definitive timetable but please be assured that I intend that this will be taken forward as quickly as possible, whilst still allowing time for meaningful engagement. I will update the Committee as soon as I am able to.

Patient Engagement

It is disappointing to note that the petitioners feel let down by the Scottish Government groups that they have participated in. This is unacceptable and I am sorry that this is the case. I can confirm that I have recently met with one of the petitioners and discussed with her the future engagement work that we intend to take forward.

To date, we have sought to work with the Health and Social Care Alliance ("the Alliance") to draw on the experience of those with lived experience and inform our work on the mesh fund, case record review and the new specialist service. We are, however, 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.

We recognise the importance of lived experience and patient engagement, and we have therefore commissioned the Alliance to undertake further work that will build on their 'My Life, My Experience' report. The precise detail of how this work will be undertaken is presently being finalised. However, it is intended to capture the views both of women who have recent experience of the specialist service, and also of those with mesh complications more generally, including the petitioners, shold they wish to take part. This is with a view to understanding what the service is doing well, what could be done better, the concerns that

women have about the service at present, and what can be done to allay those concerns and ensure that women can access appropriate treatment that they have confidence in.

I will announce further detail of this engagement work shortly.

Dr Veronikis

I noted the evidence given to your Committee by Dr Dionysios Veronikis on 22 October. The Scottish Government was grateful to Dr Veronikis for his offer to come to Scotland and I am, of course, disappointed that he appears to have decided against this option now. The Scottish Government has remained ready to welcome him here for an observational visit, as he discussed with the Chief Medical Officer in February 2020.

After those discussions the Chief Medical Officer subsequently confirmed, in writing, that NHS Scotland would be able to offer a contract, subject to detailed discussions during that visit and agreement on processes and working within the NHS Scotland environment. The visit would have allowed Dr Veronikis to see the clinical arrangements here, meet NHS staff, review our facilities in order to determine if there is more that he needs, consider the cases and patients he would deal with, familiarise himself with our multi-disciplinary team process and, from all of that, agree the contractual basis on which he would then come back to Scotland. General Medical Council approval would have been sought after the award of a contract, given that the approval process requires confirmation of employment in the UK, as well as a letter of introduction from a Royal College.

The process set out above, which I also explained during the debate on Baroness Cumberlege's recommendations on 8 September, as linked to in your letter, is with patient safety and wellbeing in mind, and is the same as would be asked of any visiting clinician. I am sure you will appreciate that a surgeon cannot simply operate on a woman with whom he has had no prior contact, and will also appreciate the importance of ensuring that appropriate pre- and post-operative care is in place.

It is unfortunate that Dr Veronikis did not feel able to agree to an observational visit. However, the action taken by the Scottish Government indicates a clear intent to welcome him here, and to engage purposefully and constructively with him.

Future Care of Women with Mesh Complications

NHS Scotland is establishing a nationally designated specialist service, and it is being introduced on a gradual basis, in line with wider remobilisation plans, as we continue to manage the pandemic. The national service will be delivered by a multi-disciplinary team located within NHS Greater Glasgow and Clyde (NHS GGC). This service will assess all of a woman's relevant health needs and, subject to a fully informed agreement, offer vaginal mesh surgery for those who are suffering mesh complications from mesh insertion (vaginally or abdominally) for stress urinary incontinence and pelvic organ prolapse.

The Scottish Government supported Jackson Carlaw's amendment to the motion that I tabled in the Parliament on 8 September, which stated that women affected by complications arising from mesh should have *"*the early prospect of full transvaginal mesh removal surgery being undertaken by surgeons who enjoy the full confidence of the women affected, fully funded by the NHS*"*. We do hope that this confidence can be secured by the national specialist mesh removal service at NHS GGC, and the aforementioned engagement work is being undertaken by the Alliance with this in mind.

Despite the foregoing, and as you rightly point out, there may remain some women who continue to feel reluctant to have treatment in Scotland. It is for this reason that, since planning for the new national service began, there has been an intention to establish close working relationships with the equivalent services being developed by NHS England. It is envisaged that this working relationship will allow referral to NHS England services, as a further choice, where necessary and clinically appropriate. In addition, those relationships will allow Scottish clinicians to work with their peers in England to establish consensus around the risks, benefits, techniques and processes associated with full and partial mesh removal, as recommended by Baroness Cumberlege in her report:

“A consensus needs to be reached on whether it is better to carry out full or partial removals. This is a clinical matter, and it must be done collaboratively. This consensus should be validated by carrying out follow up on those who have removals at the specialist centres. We strongly recommend that NICE actively monitor the situation and update their guidance promptly once a consensus has been reached.”

Officials are now also considering what further steps can be taken to provide additional options for patients, including in terms of referral outside of the NHS. Any service commissioned by the NHS would, of course, be provided free of charge to any patient. However, it is important to note that the referral of patients for treatment outwith NHS Scotland, particularly where it involves foreign travel, is a complex issue. This is particularly so in terms of ensuring the safety and wellbeing of patients. We must be assured regarding the quality and safety of care available and that, in each case, any proposed treatment is in the patient’s best interests. Treatment must also take account of, and be integrated with, pre- and post-operative care.

I would take this opportunity to reassure the Committee that we are absolutely committed to ensuring women get the services they want and need, and continue to work at pace to deliver improved services.

JEANE FREEMAN