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Dear Convener,

INDEPENDENT MEDICINES AND MEDICAL DEVICES SAFETY REVIEW

The Committee may recall that in March 2021 the Scottish Government published a delivery plan concerned with the recommendations of the Independent Medicines and Medical Devices Safety Review. This UK-wide review, commissioned by the UK Government and led by Baroness Julia Cumberlege, published its report in July 2020. The delivery plan explained the steps that the Scottish Government intended to take to implement the recommendations of the review that were concerned with devolved matters.

The 2021 delivery plan can be read here.

The plan described Scottish Government activity in four areas:

- the establishment of a Patient Safety Commissioner;
- help for people affected by transvaginal mesh;
- help for people affected by sodium valproate and Primodos; and,
- improvement in the regulation of medicines and medical devices, and in the regulation of healthcare professionals.

I offer in this letter a description of the steps that the Scottish Government has taken in each of these areas in the time since March 2021, and in some aspects what further steps it is planned to take. I have written in similar terms to Baroness Cumberlege.

Establishment of a Patient Safety Commissioner in Scotland

The Scottish Government's 2020-21 Programme for Government (PfG) *Protecting Scotland, Renewing Scotland* committed the Government to the establishment of a Patient Safety Commissioner for Scotland, seeking to implement in Scotland one of the main recommendations made in the Cumberlege Report. This commitment was repeated and

reinforced in *A Fairer, Greener Scotland*, the 2021-22 PfG, where the Scottish Government announced plans to bring forward legislation to establish a Commissioner.
A public consultation on the role of the Patient Safety Commissioner ran from 5 March to 28 May 2021. It received 96 responses, and an analysis of those responses has been published on the Scottish Government's website. There was strong support for a statutory office to be established, independent of government and the NHS.

On the question of whether the Commissioner's remit should be limited to the safety of medicines and medical devices, as is the case with the Patient Safety Commissioner for England, 57 per cent of those who answered agreed that it should. However the wide range of other patient safety issues identified in the responses submitted, together with further stakeholder engagement, brought the Scottish Government to the conclusion that limiting the role in this way would mean that the Commissioner would not be able to look at important potential patient safety issues. The Government therefore concluded that limiting the role in this way would diminish its effectiveness.

Work has continued over the past year to develop legislation that will establish a Patient Safety Commissioner for Scotland who will:

- work to bring together patient feedback and other sources of information to identify patient safety issues;
- amplify the voice of patients within the patient safety system; and,
- hold health boards and other healthcare providers to account for their responsibility to listen to patients and support providers to make improvements.

Under the Scottish Government's proposals the Commissioner will be able to consider patient safety issues relating to any healthcare provided in Scotland, including NHS, NHS-contracted healthcare delivered by providers like NHS general practitioners and NHS dentists, and wholly independent or private healthcare providers. The Commissioner will be expected to work with other organisations within the healthcare sector in Scotland, and will have powers to request information from these organisations. Under the Scottish Government's proposals, the Commissioner will also be able to carry out their own investigations into patient safety-related concerns where they decide there is a need, and will be able to make recommendations which named organisations will be obliged to respond to.

Importantly, it is proposed that the Patient Safety Commissioner will be open to patients, their families and carers and the general public to raise concerns and relate their experiences. This is a vital part of the role, giving the Commissioner access to lived experience and allowing patients and the wider public to have their voices heard.

It is proposed that the Commissioner will not undertake complaints casework or advocacy on behalf of individual patients, their families or carers, as there are existing mechanisms for this. However they would be able to make use of complaints data as part of their work to investigate broader trends and issues in healthcare.

The Bill establishing a Commissioner was introduced to the Scottish Parliament on 6 October and can be viewed with its accompanying documents at:

https://www.parliament.scot/bills-and-laws/bills/patient-safety-commissioner-for-scotland-bill

Help for people affected by transvaginal mesh

The Scottish Government continues to support women who have experienced complications arising from the implantation of transvaginal mesh, and is commited to ensuring they can access care they have confidence in.

Transvaginal mesh can be removed in NHS Scotland's Complex Pelvic Mesh Removal Service in Glasgow, where women have a choice of surgeon and where care is delivered in a dedicated suite. The service gives access to a range of health professionals, including specialist nurses, physiotherapists and to mental health support. Women can also ask instead to be referred to a specialist NHS centre in England or to an independent provider. All of these options are provided free of charge, when removal of mesh is judged to be in the best interests of the patient.

Further, the Scottish Government introduced in 2022 a scheme to reimburse women who, in the past, made their own arrangements for private removal surgery, when the option of referral to an independent provider via the NHS was not available. It allows patients to claim reasonable costs of surgery, and connected travel, accommodation and subsistence. Meanwhile the Mesh Fund, which gave women with complications the opportunity to apply for a one-off payment of £1,000, to help with the cost of emotional or practical support, closed. Over 600 applications were received.

The Scottish Government believes that accrediting the skills of our clinicians will contribute to the restoration of confidence in services provided by the NHS in Scotland and in the rest of the UK. The Scottish Government therefore continues to urge the GMC to expedite a credential in mesh removal surgery.

Finally, the Scottish Government is taking forward improvements in the recording of procedures and implanted devices. This is with a view to improving traceability, allowing rapid and efficient recall of patients in the event of an issue with a particular procedure or device, and also to improving our knowledge of clinical outcomes.

Four Health Boards will therefore shortly begin a pilot of a UK-wide Pelvic Floor Registry, which will allow the recording of all treatments for pelvic organ prolapse and stress urinary incontinence, as well as mesh removal procedures. Furthermore, an NHS Scotland Scan for Safety Programme is being developed: all medical devices are in scope, but with a primary focus, until 2025, on high risk implantable devices used in acute healthcare settings. This will include transvaginal mesh, joint replacements and cardiac devices.

Help for people affected by sodium valproate and Primodos

The Scottish Government continues to take steps that seek to prevent harm as a result of sodium valproate and Primodos, and to offer those who have been impacted the care they need.

Recent data from Scotland on sodium valproate prescribing and pregnancy outcomes among women of child bearing age were published in the British Medical Journal. The study showed:

- a 54.8 per cent annual reduction of all sodium valproate prescribing rates in women aged 14–45 years between 2011 and 2019, with an even higher reduction of 83.5 per cent for those receiving valproate for the first time;
- a 71.4 per cent reduction in sodium valproate exposed pregnancies conceived between 2011-2018; and,
- the number of live births in sodium valproate treated women reduced by 73 per cent during that same period.

The Scottish Government is working with the Medicines and Healthcare products Regulatory Agency (MHRA) on the establishment of UK-wide medicine registries. The first registry to be established by the MHRA will be an anti-epileptic medicine registry and we are working to ensure that the registry works effectively in Scotland and interacts with NHS systems here.

In addition to this UK-wide work on medicine registries, the Scottish Government is supporting the development of a Scottish Epilepsy Register that will help identify people taking sodium valproate, as well as any other anti-epileptic medicines that have the potential to cause harm. This will then allow interventions to reduce potential harm to be targeted to those at risk. This work is on track to have pregnancy, dispensing, and mortality data linked to an electronic dashboard in NHS Greater Glasgow and Clyde, with adoption in two other NHS boards as the next phase (NHS Tayside and NHS Lanarkshire). Proposals have also been developed to support implementation across all health boards in Scotland.

The Scottish Government's Teratogenic Medicines Advisory Group (TMAG), chaired by the Chief Pharmaceutical Officer, is also considering what further measures can be taken to prevent wider harm as a result of sodium valproate and it will then consider other medicines with teratogenic potential. The next TMAG meeting is scheduled for later in 2022. Notably, the MHRA is also currently considering the need to further strengthen regulatory measures for sodium valproate and we are working closely with them to better understand any potential developments in this regulatory landscape and implications for Scotland.

Work is also under way to establish specialist services for those harmed by sodium valproate in Scotland. Scottish Government officials are now in initial discussions with Health Boards to consider what services are currently available, to identify any gaps and then to commission a service delivery model that will support those affected.

Improvement of regulation

The Scottish Government continues to work closely with the UK Government and with the MHRA in relation to the reform of medicines and medical devices regulation further to the passage of the Medicines and Medical Devices Act 2021. In relation to the regulation of regulated healthcare professionals, the Scottish Government is working with the UK Government and the other Devolved Administrations to establish systems and guidance for collecting and publishing information on the interests of regulated healthcare professionals. The aim is to initially run a six-month pilot, and it has been agreed that the pilot will focus on doctors.

The Scottish Government is progressing work to identify suitable candidates for a six month pilot and has been working to develop guidance that would support the participants. Currently, it is not normal practice to routinely publish information on the declared interests of staff, and we are exploring how this could be efficiently and effectively achieved.

I hope this update is of interest to the Committee.

HUMZA YOUSAF