A Scottish Government Delivery Plan to implement the recommendations of the Independent Medicines and Medical Devices Safety Review, "First Do No Harm"

March 2021

Introduction

The report of the Independent Medicines and Medical Devices Safety Review, *First Do No Harm*, led by Baroness Julia Cumberlege, was published in July 2020. It was a report commissioned by the UK Government because many of the most relevant regulatory and policy issues addressed by it are the immediate responsibility of the UK Government. But, as with all issues concerned with the National Health Service, the Scottish Government has a critical interest and an enduring determination to see that people in Scotland are cared for in the best way possible.

The review investigated what had happened in respect of two medications, sodium valproate and Primodos, and their association with the risk of birth defects, miscarriages and other harms to children; and, in relation to the use of pelvic mesh implants, which has been linked to severe complications in women. The establishment of the review followed many years of campaigning by those affected.

Sodium valproate is an effective treatment for epilepsy but has been known, since licensing in 1973, to carry a risk of birth defects if taken by women of child bearing age. Use in pregnancy leads to physical birth defects in approximately 10 per cent of children and neurodevelopmental disorders in approximately 30 to 40 per cent. Exact figures for those affected are unknown, however several estimates were shared with the review team. The national campaign group In-FACT advised the Scottish Government, anecdotally, that there are around 600 women and 135 children impacted by sodium valproate in Scotland.

Primodos was a hormonal pregnancy test drug prescribed to women from the 1950s, until it was withdrawn in 1978, to determine whether they were pregnant, and is thought to have been associated with birth defects and miscarriages. In the same year as the medication was withdrawn the Association for Children Damaged by Hormonal Pregnancy Tests was formed and has campaigned since then on behalf of the mothers who were given Primodos, and their children.

Prior to 2014, **transvaginal mesh** was in routine use in Scotland to treat both stress urinary incontinence (SUI) and pelvic organ prolapse (POP). Concerns about complications and painful side effects associated with the use of vaginal mesh emerged from the mid-2000s and built significantly from then onwards. In light of continuing concerns the use of mesh for SUI and POP was halted in NHS Scotland in September 2018.

First Do No Harm described a train of events that led to people suffering avoidable harm. Harm that has involved acute pain and emotional suffering, which has broken families and damaged children grievously. *First Do No Harm* reported too how people so badly affected often found it difficult to get the health system to acknowledge and respond to their experiences sympathetically, having to rely on media and parliamentary representatives to press their case.

The Scottish Parliament considered the report in a debate on 8 September 2020 and agreed, with support from all parties, the following motion:

> *"That the Parliament welcomes the recommendations made by Baroness Cumberlege in her report on the independent medicines and medical devices safety review; notes the review's assertion that there is a 'widespread and wholly unacceptable labelling of so many symptoms as 'normal' and attributable to 'women's problems'; acknowledges that the review's findings highlight the repeated dismissal of women's pain and discomfort; is concerned by the failure to obtain informed consent from many of the women affected by Primodos, sodium valproate and transvaginal mesh; agrees that, without the campaigning of these women and their families, many of the issues would*

not have come to light; acknowledges the Scottish Government's apology to women and families affected by Primodos, sodium valproate and transvaginal mesh; welcomes the Scottish Government's commitment to establish a Patient Safety Commissioner, and notes the actions taken by the Scottish Government to offer improved services for women who have suffered complications as a result of transvaginal mesh and believes that this must include 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."

First Do No Harm made nine recommendations, which are available online (link).

The Cabinet Secretary for Health and Sport, Jeane Freeman MSP, confirmed during the debate on 8 September that the Scottish Government is now committed to implement all of the recommendations of Baroness Cumberlege's review where they relate to the responsibilities of the Scottish Government. The Cabinet Secretary further undertook to work with the UK Government to support it on acting on the recommendations that relate to the responsibilities of the UK Government.

In the course of the debate, and in fulfilment of one of the recommendations of the review, the Cabinet Secretary reaffirmed an apology offered on behalf of the Scottish Government to all those directly harmed by mesh, sodium valproate and Primodos, and also extended a sincere apology to all those who have seen their children, family members, friends and colleagues suffer.

The UK Government offered an interim response to *First Do No Harm* in its statement of 11 January 2021.

This delivery plan has four parts:

- **Part 1** is about the steps that the Scottish Government will take towards the establishment of a Patient Safety Commissioner.

- **Part 2** is about what the Scottish Government will do to help those people affected by mesh.

- **Part 3** is about what the Scottish Government will do to help those people affected by sodium valproate and Primodos.

- **Part 4** is about how the Scottish Government will work with the UK Government and the other Devolved Administrations to improve regulation of medicines and medical devices across the UK, and also how we will seek to improve the regulation of healthcare professionals.

The Scottish Government is grateful to those impacted and their families and experts who informed the development of this delivery plan.

The Scottish Government is also grateful for the advice of Baroness Cumberlege and members of her review team in the development of this delivery plan.

Part 1: A Patient Safety Commissioner for Scotland

The proposal in *First Do No Harm* for a Patient Safety Commissioner (PSC) stemmed from evidence gathered by Baroness Cumberlege and her team that patients felt their voices and experiences had been ignored. The review heard of many occasions where patients and their families identified and reported harms, but these reports were not acted on.

The Scottish Government is now committed to establishing a PSC role in Scotland, and included this proposal in its 2020-21 *Programme for Government*. The Government envisages that the role will initially focus on matters to do with the use of medicines and medical devices as set out in *First Do No Harm*.

The situation now: the Scottish patient safety context

First Do No Harm was, understandably, written in the first place in the context of the NHS in England. The report recommended that the PSC role there should sit *outside* the current patient safety system. In relation to Scotland, however, the Scottish Government envisages that the PSC should focus on *the patient voice within* the patient safety system.

The Government takes this view because we consider that the new role can add to the effectiveness and impact of our evolving national and local systems. A large number of organisations and policies (established before the publication of *First Do No Harm*) contribute and some of the main elements include:

- the **Scottish Patient Safety Programme (SPSP)**, an evolving national initiative, launched in 2008. It aims to improve the safety and reliability of health and social care, and reduce harm whenever care is delivered. The programme brings NHS organisations together to learn from each other, while local teams test and implement changes using improvement methodology to improve services areas like leadership, communication, safety culture and the safer use of medicines.

- the implementation of the **Patient Rights (Scotland) Act 2011**, which gives everyone in Scotland rights about the health care they receive. The 2011 Act provides for a Charter of Patient Rights and Responsibilities; a Patient Advice and Support Service; a right for people to make complaints; and, it places a duty on NHS Boards to thoroughly investigate and respond to any concerns raised. When a person has concerns about their treatment or care, this should be addressed at a local level through the NHS Complaints Handling Procedure. When that is not possible the Scottish Public Services Ombudsman (SPSO) is the second and final stage in the complaints process.

- the **Adverse Events Framework**, a national system in which events that could have caused, or did result in harm are detected and, in certain circumstances, reported to Healthcare Improvement Scotland. The aim of the framework is to review the care provided to determine what lessons and improvement actions can be identified for the organisation (or organisations) to improve the quality of care and services.

- legislation that provides for an **Organisational Duty of Candour**, which came into effect in April 2018. This duty supports the implementation of consistent responses across health and social care providers when there has been an unexpected event or incident that has resulted in death or harm that is not related to the course of the condition for which the person is receiving care. When harm occurs the focus must be on personal contact with those affected, support and a process of review and action

that is meaningful and informed by the principles of learning and continuous improvement.

Despite these and other elements of the Scottish approach to patient safety, the Scottish Government accepts the recommendations of *First Do No Harm* and agrees that more needs to be done to make sure that the patient voice is truly and consistently heard within our systems.

What we will do next: a Patient Safety Commissioner (PSC) in Scotland

It is imperative in developing plans for a PSC in Scotland that we take time to listen to the voices of people who have experience of when things have gone wrong, often with very serious and painful consequences. That is why we have consulted about the role that a new PSC might play. We want to understand what patients want from this role and to make sure that it adds value to what we do in Scotland now. The consultation closes on 28 May 2021.

The Scottish Government has established two stakeholder groups: a Patient Reference Group; and, a Specialist Reference Group.

The Patient Reference Group has had input into the development of a public consultation on the PSC, and will continue to feed into the future development of proposals. In a first discussion the members of this group highlighted views very consistent with the observations and recommendations included in *First Do No* Harm. These included:

- The existing landscape needs to be more co-ordinated and joined up;
- Better communication between everyone involved is needed: between different parts of the healthcare system and particularly with patients;
- Patients need to be listened to, and treated with respect, dignity and honesty; and,
- The PSC should have influence within the system, and the means to be able to identify trends in healthcare harms before they become an issue for more patients.

The remit of the Specialist Reference Group is to map out the roles and responsibilities of existing bodies as well as the existing policies; and identify any gaps.

The Scottish Government has published a public consultation about what the role of Patient Safety Commissioner could look like in Scotland, and will consider whether or not this should be a statutory role. You can read the consultation document here.

Following the consultation, the present Scottish Government plans to publish full findings from the consultation and proposals (informed by the process) later in 2021.

Part 2: Help for people affected by pelvic mesh

This part of the Delivery Plan is about what the Scottish Government will do to help women affected by transvaginal mesh. *First Do No Harm* recommended that specialist centres be developed to provide comprehensive treatment, care and advice for those affected by implanted mesh. It further recommended that a Government funded scheme be established to meet the cost of providing additional care and support for those who have experienced avoidable harm. *First Do No Harm* also recommended that a national database should be established to maintain a record of devices implanted into patients.

A developing specialist centre in Scotland

The situation now

Throughout 2020, work has continued to establish an NHS Scotland Specialist Centre for mesh complications in NHS Greater Glasgow and Clyde (NHS GGC). The centre, which is being funded for the first three years by the Scottish Government, is being delivered by a Multi-Disciplinary Team (MDT). It assesses women's needs and, where appropriate, and subject to shared decision making and informed consent, performs mesh removal surgery. The establishment of the service was unavoidably delayed by the COVID-19 pandemic, but a number of patients have now undergone mesh removal surgery and in 2021 the number of patients treated is expected to increase.

The service is intended to be holistic in nature. It takes account of social as well as health needs (both physical and psychological), and will benefit from additional dedicated staff including specialist nursing, physiotherapy, pain management, pharmacy, clinical psychology and administrative support. Four uro-gynaecology consultants will be employed within the new service early in 2021, and they will make an important contribution to the MDT.

Coinciding with the establishment of the centre in Scotland, NHS England has also progressed plans to establish equivalent centres. The locations of England's designated centres have recently been announced and it is planned for these to be operational from Spring 2021.

First Do No Harm highlighted that there is an urgent need to reach consensus among clinicians and patients on the relative risks and benefits of full and partial removal of mesh. Progress is being made in this area and the first in a series of consensus building events involving clinicians and patient representatives took place in November 2020. Clinicians from the Scottish national centre and from other UK centres took part, with a view to continued collaboration, throughout the UK, as the work progresses. This consensus will inform the development of patient information and decision aids.

The Scottish Government also agrees with *First Do No Harm* when it emphasises that the NHS must seek to re-build trust and confidence in the services that our hospitals and clinicians provide, particularly of course among women who have been harmed by transvaginal mesh. It is imperative that the NHS listens to the voice of patients and learns from those with lived experience, to build new services in a way that responds constructively to their needs.

The centre in NHS GGC has been helped in this work by the Health and Social Care Alliance[1] ("the Alliance"). In December 2020 the Alliance met with patients who had been recently treated in the new centre in Glasgow. A further focus group meeting was held in January 2021: this second meeting was intended for a broader cohort of women with mesh

[1] The Alliance is the national third sector intermediary for a range of health and social care organisations. They are a strategic partner of the Scottish Government and have fed into several mesh policy developments including the specialist centre and the mesh fund.

complications and it was held in conjunction with an online survey, which closed on 7 February.

What we will do next

Findings from the patient engagement work undertaken by the Alliance will be used to help shape and refine the new national service. However, this will not be the end to patient involvement: The Scottish Government will ask the Alliance to establish a stakeholder participation group which will continue to gather views on the specialist service and these will be considered in conjunction with the results from patient satisfaction surveys as well as other relevant outcome data. Information gathered from these linked sources will not only be important in quality assurance but it will also advise measures necessary for quality improvement.

NHS Scotland will continue to maintain close links with colleagues and services developing in NHS England, and in Wales and Northern Ireland. This will provide an opportunity for "benchmarking" through comparison of outcomes, direct observation, peer review, and development of consensus with regard to the indications, risks, benefits and techniques associated with full and partial mesh removal. Clinicians across the UK are working together, with the UK National Institute for Health and Care Excellence (NICE) and patient representatives to further develop patient information and decision aids, which it is hoped will be informed by an emerging consensus among clinicians. The same information will then be used across the four nations.

The Scottish Government supports the development of a General Medical Council (GMC) approved ‘credential’ in mesh removal surgery and has written to the GMC in these terms. Credentialing will define the skills required to perform mesh removal surgery, and set out how these skills can be acquired and assessed. By formally recognising the skills of our surgeons, credentialing will provide assurance for the service and reassurance for patients.

The national specialist service in Scotland will enable women to access the treatment that they want and need, as close to home as possible. However, and as the Parliament has observed and the Scottish Government acknowledges, there are some women who – as a result of the trauma they have experienced – do not wish to be treated in Scotland. The Scottish Government is committed to working with women and their families to understand their concerns and build trust and confidence in the new NHS Scotland centre. The Scottish Government does consider, however, that it is appropriate in these exceptional circumstances for alternative arrangements to be available, so that all women receive the treatment they need.

The development of links between the Scottish specialist service and the equivalent service in England are intended in part to mean that any woman who expresses a preference to be treated outside Scotland should be able to request referral to an English NHS service. NHS England has recently confirmed the location of the specialist centres that will form this service in 2021 and it is expected that further designated centres will follow.

In addition, and exceptionally, the Scottish Government and NHS Scotland are taking steps to provide an additional option for patients that will include the possibility of referral outside the NHS, including outside the UK.

NHS National Services Scotland (NSS) has commenced a tender process for specified mesh removal services. This tender process will follow standard commissioning procedures, whereby all applications will be assessed by a Clinical Advisory Panel (CAP). The process will be open to applications from competent providers in the UK and abroad. All applications will require supporting evidence of necessary standards in relation to quality of care and

patient safety. Integration of surgery with pre- and post-operative care will be essential and treatment that does not involve engagement and collaboration with a responsible MDT will not be acceptable. It is planned at present to consider and decide tenders received further to this invitation during the spring and early summer of 2021.

Mesh support fund

The Scottish Government has established a £1 million fund for women affected by transvaginal mesh complications, which offers individual payments of £1,000 towards the costs of practical or emotional support. The fund was established following consultation with women affected by mesh and led to a fund that is not means tested and with a single payment level for all applicants who have had surgery and then experienced complications. As at February 2021, the fund had issued over 400 payments. It is scheduled at present to remain open to applications until 31 May 2021.

In addition to this, the present Scottish Government plans, if it is returned to office following the May 2021 election to the Scottish Parliament, to take such steps as are necessary to reimburse personal costs of patients in relation to past mesh removal surgery that they have arranged privately. The present Scottish Government plans to provide further details about these arrangements after the May 2021 election, including eligibility criteria and methods of application, if it is returned to office.

Database of medical devices

<u>The situation now</u>

The Scottish Government established in November 2019 a Unique Device Identifier (UDI) programme to develop a system to track implantable medical devices. The programme is led by NHS National Services Scotland and is seeking to recommend a technical specification by June 2021 for a national system that will collate the unique device identifier code of devices implanted into patients

<u>What we will do next</u>

The Scottish Government is now also collaborating with the UK Government, the other Devolved Administrations and with NHS England in the establishment of a UK-wide medical devices information system.

The Medicines and Medical Devices Act 2021 gives the UK Medicines and Healthcare products Regulatory Agency (MHRA) a duty to hold a registry of all medical devices in use in the UK and to establish an information system that will allow for tracking of medical devices.

The aim of the information system is to make it more possible in the future to monitor the performance of devices and the outcomes they achieve, and to identify issues with devices more quickly than now, so that clinicians are better able to intervene and, if necessary, seek to prevent patient harm before it happens. A pilot is planned for the new database that will concentrate on pelvic mesh. Following evaluation, the database will develop further, adding functionality and a widening range of devices.

Part 3: Help for people affected by sodium valproate and Primodos

This part of the Delivery Plan focuses on those affected by sodium valproate and Primodos, many of whom have lived with life-changing consequences from the harmful effects from both medicines for decades. *First Do No Harm* recommended the establishment of specialist centres to provide comprehensive treatment, care and advice for those affected by sodium valproate and Primodos. It also recommended the development and use of registries and redress agencies and compensation schemes to meet the cost of providing additional care and support to those who have experienced avoidable harm.

The situation now

Specialist centres

Scottish Government officials have met with several groups[2] representing individuals and families affected by sodium valproate and Primodos. These groups expressed views across the recommendations outlined in *First Do No Harm*, including the establishment of specialist centres:

- For those affected by sodium valproate, the importance of designing specialist centres and services to accommodate the needs of all of those affected by sodium valproate were considered essential. Ensuring that the focus of any future services or specialist centres go beyond providing support in maternal and early years settings was highlighted as particularly important - as many of those affected by sodium valproate are now living with the long-term effects in their 20's and 30's. There was also a view, in line with *First Do No Harm*, that the support should extend to include signposting patients and families to other relevant services, including benefits and other services provided by local authorities including educational support and social workers.
- For those affected by Primodos, specialist centres were not considered to be of value to them specifically, although they recognised the benefit of such services for those affected by other teratogenic medicines, including sodium valproate.

Prior to the publication of *First Do No Harm*, the Scottish Government established a Sodium Valproate Advisory Group (SVAG)[3]. Scottish Government officials have met informally with members of the SVAG since the publication of *First Do No Harm* to discuss the recommendations. Members noted that:

- It would be important to ensure that any work to establish specialist centres were sustainable in the longer term and so a focus on alignment of services rather than buildings may be more proportionate.
- There was the potential to combine clinical resources and ensure robust diagnosis, assessment and treatment services for those impacted by sodium valproate.

Registries and databases

During the debate in the Scottish Parliament on 8 September 2020 the Cabinet Secretary for Health and Sport committed to "give early and active consideration to establishing a national

[2] For sodium valproate: Epilepsy Scotland, Valproate Scotland, Independent Fetal Anti-Convulsant Trust & FACS Syndrome Association (INFACT), the Foetal Anti-Convulsant Syndrome Association (FACSA); and for Primodos, the Association for Children Damaged by Hormone Pregnancy Tests.

[3] The Scottish Government Sodium Valproate Advisory Group is chaired by the Chief Pharmaceutical Officer and consists of a range of health professionals to consider any Scottish specific actions which can be taken within the current UK regulatory framework.

sodium valproate registry." The Medicines and Healthcare products Regulatory Agency (MHRA) and NHS (England) Digital are developing a sodium valproate registry to observe the use of sodium valproate in girls and women in the UK, to monitor compliance with the current regulatory position[4], and to identify and monitor any children born to women on sodium valproate. The Scottish Government has commissioned Public Health Scotland to explore the compatibility of Scottish datasets and systems with the UK registry. The **Scottish Government is committed to working with colleagues in the MHRA and NHS Digital** to ensure alignment with a UK wide valproate registry.

In parallel to the work led by the MHRA to develop a UK valproate registry, the Scottish Government is currently funding the use of a Scottish Epilepsy Register in three Health Boards (NHS Greater Glasgow and Clyde, NHS Tayside and NHS Lanarkshire). This will help identify patients taking sodium valproate, as well as other anti-epileptic medicines (some of which may cause harm). Alongside the data already collected on prescribing, this has the potential to form the basis of a Scotland-wide registry and with further adaptation to collect outcome data could help to support better shared decision making to reduce the risk of harm.

Redress Agencies and compensation schemes

The issues of redress and compensation schemes were also discussed with both sodium valproate and Primodos representative groups. They considered financial redress to be important and noted their preference for this to be supported by a levy on pharmaceutical manufacturers. Notably, there were many different ideas across the groups regarding what form and level of support redress and compensations schemes should provide.

What we will do next: sodium valproate and Primodos

Addressing the recommendations outlined in *First Do No Harm* for individuals and the families affected by sodium valproate and Primodos requires a programme of work that aims to mitigate any future potential harm through a multi-layered approach to rapidly reduce and eventually eradicate harm applicable and relevant to the Scottish context. Therefore, the Scottish Government will:

- Develop a work programme for the Scottish Government's SVAG to address the appropriate recommendations from *First Do No Harm*;
- Work with the Scottish Safety Patient Programme 'High Risk Medicine Framework', to ensure that appropriate tools and interventions are developed to minimise future harm from sodium valproate and other teratogenic medicines (medicines capable of causing anomalies or birth defects);
- Continue to work with Public Health Scotland to enhance NHS Scotland's data capabilities and interconnectivity with any future valproate registries developed by the MHRA. This includes sharing the learning from the implementation of the Scottish Epilepsy Register with Public Health Scotland, the MHRA and NHS Digital; and,
- Work collaboratively with colleagues across the Scottish Government, the NHS and representative groups to explore potential options for establishing sodium valproate specialist centres and/or services in Scotland.

[4] To ensure prescribing is happening within the licence - i.e. that a girl or woman of child bearing potential is enrolled within the pregnancy prevention programme.

Part 4: Improving the regulation of medicines, medical devices and of healthcare professionals

Part 4 of the delivery plan is about the recommendations in *First Do No Harm* that relate to the responsibilities of the UK Government. These recommendations relate primarily to steps to improve regulation of medicines, medical devices and of healthcare professionals. There are also recommendations connected to systems that might provide redress to people that have suffered harm.

The Scottish Government has stated that it will work with the UK Government to support it on acting on these recommendations where the UK Government elects to accept them.

Regulation of medicines and medical devices

The situation now

Following the UK's departure from the European Union and the UK Government's approach to the UK's new relationship with the EU, the MHRA has become fully responsible for the regulation of medicines and medical devices in the UK.

In preparation for the end of the EU transition period the UK Government introduced into the UK Parliament a Medicines and Medical Devices Bill. This Bill, now enacted, will give UK Ministers power to make regulations about the way in which the MHRA will undertake its functions. Alongside new legislation, the MHRA has commenced work to revise its corporate plan and ways of working.

First Do No Harm establishes for the MHRA a properly ambitious and demanding agenda for their reform and improvement in particular in the way that the MHRA involves patients and ensures their safety. The Scottish Government considers that reform must in particular ensure that the views of patients are listened to systematically and their experiences of medications and devices are used to inform regulatory decisions.

What we will do next

The Scottish Government will work in partnership with the UK Government, the other Devolved Administrations and with the MHRA as they develop their response to *First Do No Harm* and their new corporate plan. We will in particular look to the MHRA to:

- Establish a widely-based patient and public stake holder group, to advise on the process of MHRA reform and then, in the longer term, to guide their continuing improvement;
- Ensure that the regulation of medical devices is clinically focused and person-centred, is afforded equal priority to the licensing of medicines, and is at least as stringent as the measures set out in forthcoming EU Medical Devices Regulations;
- Ensure that patients and expert clinicians are appropriately involved in the assessment of new medicines and medical devices. It will be important that the patient voice and those with lived experience are listened to, particularly with regard to quality of life;
- Require manufacturers to undertake post market surveillance and transparently collect and share all relevant data;
- Ensure close partnership working with the incident and adverse safety systems in the Devolved Administrations, enabling healthcare professionals to know how to report locally;

- Reform the “Yellow Card” system so that it provides patients and medicines healthcare professionals in Scotland with a user-friendly, accessible, transparent repository of adverse event reports; and,
- Review the financial interests in the pharmaceutical and healthcare (medical devices) industries that MHRA staff and members of their immediate family are permitted to hold.

The Scottish Government will also continue to support the development of the life sciences in Scotland.

Regulation of healthcare professionals

The situation now

First Do No Harm recommended that the transparency of the financial and non-pecuniary interests of clinicians be enhanced by the publication of the details of payments and payments-in-kind in relation to their practice. The report also recommended that doctors’ particular clinical interests and their recognised and accredited specialisms be published, as should payments and benefits-in-kind from the pharmaceutical and medical device industries to teaching hospitals, research institutions and individual clinicians.

The Cabinet Secretary for Health and Sport met the General Medical Council (GMC) on 13 October 2020, and discussed the recommendations within *First Do No Harm*. The GMC is strongly of the view that it is not the appropriate body to hold a register of interests for doctors practising in the UK, citing, amongst other things, low levels of public awareness of the GMC’s existence or statutory role. The GMC considers that such information is better recorded under employers’ corporate governance processes on the grounds that the employer is normally the first port of call when concerns and complaints about a doctor arise.

What we plan to do next

The Scottish Government has taken note of the GMC position. As UK Ministers are not minded to accept the specific recommendation that the GMC should be the *holder* of a register of doctors’ interests and regulation of the medical profession is a reserved matter, the legislation required to implement this approach will not be brought forward in the UK Parliament.

However, UK Ministers have acknowledged that there *should* be a compulsory duty on *all* registered health professionals to record potential conflicts of interests and UK Government officials are now exploring potential options for the appropriate recording, compliance monitoring and oversight systems in England. The Scottish Government’s initial view agrees with the conclusions of *First Do No Harm*. We have also agreed with the UK Government that the GMC should be the appropriate *enforcement authority* for doctors as the UK-wide statutory regulator of that profession.

UK Ministers’ decision to expand the scope of the recommendation, by imposing a duty to declare on all the regulated health professions, brings this work into devolved competence through the small group of professions regulated under devolved competence; for example, Operating Department Practitioners and Practitioner Psychologists under the Health and Care Professions Council.

The Scottish Government plans to re-convene a short life working group on conflicts of interest in NHS Scotland, which was paused during the national response to the Coronavirus pandemic.

A new independent Redress Agency funded by a levy

First Do No Harm recommended that a new independent Redress Agency for those harmed by medicines and medical devices should be created, and should be funded via a levy on manufacturers of medicines and medical devices. *First Do No Harm* recommended that the Redress Agency administer decisions using a non-adversarial process with determinations based on avoidable harm looking at systemic failings, rather than blaming individuals. The Scottish Government takes note of the UK Government's decision not to proceed with a Redress Agency funded by a levy from manufacturers, but further notes that the UK Government has not yet confirmed a position with respect to the establishment of separate schemes for each of the interventions highlighted in *First Do No Harm*.

The Scottish Government
March 2021