# Written Ministerial Statement

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# Department of Health

## THE INDEPENDENT MEDICINES AND MEDICAL DEVICES SAFETY REVIEW

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**Mr Swann (The Minister of Health):** I wish to provide an update on the ongoing work in response to the publication of the report of the Independent Medicines and Medical Devices Safety review.

The review, chaired by Baroness Cumberlege, was commissioned in February 2018 by the then Secretary of State for Health and Social Care in England to examine how the healthcare system in England responds to reports about harmful side effects from medicines and medical devices, and to consider how to respond to them more quickly and effectively in the future.

The review investigated three areas of treatment: the use of the pelvic mesh medical device; and two medicines - sodium valproate and Primodos, and their association with the risk of birth defects, miscarriages and other harm.

In May 2018 my Department requested that patients in Northern Ireland be given the chance to provide evidence to the review. The review team visited Northern Ireland in December 2018 to listen to patients' evidence and concerns.

The review report, entitled *First Do No Harm*, was published on 8th July 2020, and while its focus is on the healthcare system in England, it is recognised that many women from Northern Ireland took the time to submit their experiences to the review panel, and in doing so highlighted failures they experienced within and across our service, particularly a difficulty in getting the healthcare system to listen, understand acknowledge and respond to patients' concerns about their experiences with these treatments. Therefore it is right that the review report and its nine recommendations are fully considered by my Department in the context of the health and social care system in Northern Ireland. I issued a statement on 8th July 2020, committing to giving the review report the full and careful consideration it deserves.

To this end, an Independent Medicines and Medical Devices Safety Review Group (IMMDS Review Group) has been established in Northern Ireland with the purpose of formulating and shaping the Department's response to the recommendations in the report. The group is chaired by Dr Lourda Geoghegan, Deputy Chief Medical Officer, and membership consists of relevant policy and professional leads. The first meeting of this group was held on 10th September 2020. Unfortunately, it has not been possible to hold a second full meeting owing to the demands on my Department as a result of the Covid-19 pandemic. However, representatives have continued with work on individual areas as appropriate, and to engage with colleagues across the UK on the recommendations in which work is being progressed on a national and/or four nations basis.

Considering each of the report's recommendations in turn:

- Recommendation 1 was that the Government should immediately issue a fulsome apology on behalf of the healthcare system to the families affected by Primodos, sodium valproate and pelvic mesh. The UK Government has issued an apology. I apologised in a statement made on 8th July 2020 to those in Northern Ireland who were affected. I reiterate that apology today.

- Recommendation 2 posited the appointment of a statutory independent Patient Safety Commissioner, who would champion the value of listening to patients and promoting users'

perspectives in seeking improvements to patient safety around the use of medicines and medical devices. The UK Government has indicated that work will progress to establish the role of a Patient Safety Commissioner for England. The recommendation is being considered by the devolved administrations. My Department will be taking forward engagement with patients and other members of the public to gain a clear understanding of their perspectives and to inform further consideration of the merits of such a function. The work to scope the options for implementation of this recommendation will map existing bodies and systems and their respective functions, current roles and responsibilities in the context of ensuring patient safety here. It will identify any gaps and operating constraints, and link to the ongoing work on implementation of relevant recommendations arising from the Inquiry into Hyponatraemia-related Deaths.

- Recommendation 3 proposed that a new independent redress agency for those harmed by medicines and medical devices should be created, based on models operating effectively in other countries. Such an agency would administer decisions using a non-adversarial process with determinations based on avoidable harm looking at systemic failings, rather than blaming individuals. The UK Government recently confirmed that there are no current plans to establish a redress agency in England. In Northern Ireland, there is currently policy scoping work in this area.

- Recommendation 4 was that separate schemes should be set up for each intervention examined by the review team, to meet the cost of providing additional care and support to those who have experienced avoidable harm and are eligible to claim. The Scottish Government has set up a fund to assist those injured by mesh and we are continuing to liaise with colleagues in the other UK nations regarding their approaches. This matter is still under consideration in both England and Wales. In Northern Ireland, the development of any fund will require consultation with local service users to understand their concerns and needs. Options may include setting up a fund similar to that established by the Scottish Government, opening existing cost support schemes to those affected irrespective of income, or ensuring that the focus of any funding should be directed to patient services for those suffering as a result of mesh surgery, Primodos or Sodium Valproate. The resource implications will also need to be carefully considered.

- Recommendation 5 was that networks of specialist centres should be set up to provide comprehensive treatment, care and advice for those affected by implanted mesh; and separately for those adversely affected by medications taken during pregnancy. Members will be aware of the establishment of the specialist mesh service at the Belfast City Hospital. This was established following a review carried out by the Public Health Agency into the delivery of vaginal mesh services, and after a number of issues were raised by patients. Ongoing recurrent funding from 2022/23 will be needed, and this has been built into my Department's budget forecasts as an inescapable funding pressure.

  With regard to medicines, it is recognised that there is a need to improve the care and support for the individuals and families affected by a range of medicines taken during pregnancy. Further work to scope the potential need for a specialist centre in Northern Ireland is needed. However, the initial assessment is that a specialist centre focused only on those affected by medicines used in pregnancy may not be the most effective way to provide the whole range of services that patients need; for example, localised care closer to home is more in keeping with the ambitions set out in the 'Delivering Together' agenda. The key to the provision of comprehensive treatment is through services working together with clear pathways of care supported by agreed guidelines and protocols. As such the initial focus should be on assessing and where possible improving existing care pathways for women and children affected by use of medicines during pregnancy, which may best meet the recommendation to ensure that comprehensive treatment, care and advice is available.

- Recommendation 6 stated that the Medicines and Healthcare products Regulatory Agency (MHRA) needs substantial revision, particularly in relation to adverse event reporting and

medical device regulation, patient engagement and awareness raising of its role. While implementation of this recommendation is outside the Department's remit, officials are engaging with MHRA as their work to address this recommendation progresses.

- Recommendation 7 was that a central patient-identifiable database should be created by collecting key details of the implantation of all devices at the time of the operation. This can then be linked to specifically created registers to research and audit the outcomes both in terms of the device safety and patient reported outcomes measures. My officials are continuing to engage with colleagues in England regarding the Medical Device Information System (MDIS), which is being developed. The Assembly passed a Legislative Consent Motion for the Medicines and Medical Devices Bill on 30 November 2020, which provides a power for regulations to establish a MDIS in Northern Ireland which would be operated by NHS-Digital on our behalf. The aim of the MDIS is to improve the safety and standards of practice in relation to medical devices, by ensuring better information is captured and shared on implanted devices, in order to identify risks posed by specific devices much earlier. It is expected that the MDIS will provide critical benefits to patients who have been, or will be in the future, implanted with medical devices. Officials from the Department are currently engaging to upload NI patient data to the Pelvic Floor Registry (the minimum viable product of MDIS), and are hoping to begin participation in the pilot system shortly with the Belfast HSC Trust so that an assessment of working procedures can be made.

  With regard to registries for medicines, the UK Health and Care Bill contains proposals that would allow the MHRA to develop and maintain publicly funded and operated UK-wide medicine registries that would provide patients and prescribers, as well as regulators and the NHS, with information and intelligence to make evidence-based policy and operational decisions.

- Recommendation 8 stated that "transparency of payments made to clinicians needs to improve. The register of the General Medical Council (GMC) should be expanded to include a list of financial and non-pecuniary interests for all doctors, as well as doctors' particular clinical interests and their recognised and accredited specialisms. In addition, there should be mandatory reporting for pharmaceutical and medical device industries of payments made to teaching hospitals, research institutions and individual clinicians". A UK-wide approach is pragmatic and appropriate in this instance, reflecting the practical reality that the vast majority of the regulation of healthcare professions is performed by regulatory bodies which operate UK-wide, and that to depart from UK-wide regulation would require professional regulators to agree to conduct their business in different ways in the different UK nations – something which they are unlikely to be prepared to do in this instance.

  DHSC (London) has indicated that its preferred position is that any register of interests should not just be for doctors, but for all clinical staff. If established, such a register of interests would need to be accessible to patients, easily understood and maintainable. Based on this position colleagues in DHSC feel that the GMC is not the right place to locate such a register and that it would be more effective if held with the employer, with professional regulators working to establish a professional requirement for their members to adhere to. The current position of the IMMDS Review Group is that the registers should sit with the professional regulators in line with the recommendation of the review. Officials met with colleagues in the DHSC to highlight concerns on this approach and DHSC has set up a four-nation working group to work through those concerns and resolve them through implementation. There is also a commitment to a review progress within the next year.

  With regard to mandatory reporting, the UK Government is using clauses in the Health and Care Bill to provide enabling powers to make regulations for the operation and enforcement of a statutory system, that would apply on a UK-wide basis. A Legislative Consent Motion will be moved in the Assembly in the coming weeks in this regard. Importantly, any regulations to be made will require the consent of the Devolved Administrations, and it will be permissible for each Devolved Administration to operate any system differently, depending on their needs.

- Recommendation 9 was that the Government should immediately set up a task force to implement this Review's recommendations, and that its first task should be to set out a timeline for their implementation. In Northern Ireland, the IMMDS Review Group has been established with the purpose of formulating and shaping the response in Northern Ireland to the recommendations of the review. Membership of the IMMDS Review Group and any sub-groups to be established will change and evolve as work progresses. Service users and patient representatives will be included as we consider options to progress the recommendations and how these recommendations align with the health and care system in Northern Ireland.

Members will wish to note that there are many similarities in the themes of the First Do No Harm Report, and those identified by the Inquiry into Hyponatraemia-Related Deaths (IHRD). I intend to provide a further update to the Assembly on IHRD progress shortly.

Members will appreciate that the implementation of these recommendations represents a significant work programme for my Department. My officials are happy to brief the Health Committee in further detail if that would be helpful.

**ENDS**