First Do No Harm
All Party Parliamentary group

Briefing for Commons debate on 8th July

Introduction

On 8 July there will be a debate on the floor of the house on the following motion tabled by Emma Hardy MP and Alec Shelbrooke MP:

"That this House notes the publication of the Independent Medicines and Medical Devices Safety Review, First Do No Harm; notes the Government's refusal to implement the recommendations of that review in full; further notes the significant discrepancy between the incidence of complication following mesh surgery in the Hospital Episode Statistics and the British Society of Urogynaecology databases, as highlighted in the Royal College of Obstetricians and Gynaecologists' Project Report, Hospital Episode Statistics as a source of information on safety and quality in gynaecology to support revalidation; notes that a Government promise to publish a retrospective audit to investigate the links between patient-level data to explore outcomes has not been fulfilled; notes that the moratorium on mesh implant procedures should not be lifted until that audit has been undertaken and the true scale of suffering established; notes Ministers' continued refusal to acknowledge recommendations relating to victims of Primodos; and calls on the Government to fully implement the recommendations for victims of mesh, sodium valproate and Primodos without further delay."

The All-Party Parliamentary Group for First Do No Harm exists to press for the implementation of the recommendations made in *First Do No Harm*, the report of the Independent Medicines and Medical Devices Review, published In July 2020.

This briefing note sets out the APPG's position in relation to the recommendations that are yet to be implemented, and on important connected issues.

Recommendation 2: An independent Patient Safety Commissioner should be appointed to champion the value of listening to patients and promote users' perspectives in seeking improvements to patient safety around the use of medicines and medical devices.

Background: The Government has accepted this recommendation and added a provision to the Medicines and Medical Devices Act 2021 to put the Commissioner on a statutory footing. However, the DHSC is currently undertaking a public consultation to inform the content of secondary legislation setting out additional detail on the Commissioner's statutory responsibilities. An accompanying written ministerial statement was also published. The Commissioner cannot be appointed and established until this consultation

has happened. Meanwhile the risk of undetected avoidable harm among patients and families remains unaddressed.

Action required: It is crucial that the Government moves swiftly following the public consultation and publicly sets a date for the Commissioner's appointment.

Recommendation 3: A new independent Redress Agency for those harmed by medicines and medical devices should be created

Background: The Government has no current plans to establish a redress agency, arguing that government and industry have previously established redress schemes without the need for an additional agency. This recommendation has not been implemented and the Government appears unwilling to do so.

Action required: The case for an independent Redress Agency remains strong. Other countries have successfully set up such an Agency. Without such a mechanism people who have suffered avoidable harm following healthcare treatment have no option other than to go to court, a lengthy, expensive, confrontational and stressful process. We call on the Government to revisit its position on this recommendation.

Recommendation 4: Separate schemes should be set up for each intervention – HPTs, valproate and pelvic mesh – to meet the cost of providing additional care and support to those who have experienced avoidable harm and are eligible to claim.

Background: This recommendation has not been implemented but Ministers have said that redress schemes for sodium valproate, mesh and HPTs remain under consideration.

Action required: Patients who have suffered avoidable harm need help and support now, and we as a society owe it to them. This may take the form of additional financial support, above and beyond that which they are entitled to via welfare benefits, or other support such as respite care. Many have already waited decades for help. Ministers have indicated they are sympathetic and we urge the Government to commit during this debate to take action to set up these schemes for those who have suffered harm in connection with pelvic mesh, sodium valproate and Primodos..

Recommendation 5: 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.

Background: NHS England established a network of specialist mesh removal centres in April 2021 but not all are fully operational and there is concern that they are not collecting

outcomes data, in particular patient-reported outcomes. No progress has been made in establishing specialist centres for those adversely affected by medicines in pregnancy, and the DHSC appears to take the view that they are not needed, which is disappointing given the crucial role they will fulfil in providing much-needed care and support for families affected by teratogenic agents in pregnancy.

Action required: The Government must ensure the network of mesh centres are fully-operational and that patient reported outcomes are available to ascertain their effectiveness. The Government must also commit to introducing a network of specialist centres for those adversely affected by medications taken during pregnancy, in recognition of the additional levels of support and care they require.

Recommendation 8: 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.

Background: The Government is discussing Recommendation 8 with the GMC and other stakeholders. The APPG and the British Medical Journal, having held a meeting on the topic in May, agree that the General Medical Council needs to have the responsibility for a centrally-held, mandated register of doctors' interests.

Action required: The Government require the GMC to hold such a register. The annual appraisal process that doctors already undertake can be used to collect declarations of interests and keep them up to date. .

Recommendation 9: The Government should immediately set up a task force to implement this review's recommendations. Its first task should be to set out a timeline for their implementation.

The Government says it has no plans to establish an independent taskforce to implement the report's recommendations, but a 14-person Patient Reference Group has been established and has held a series of meetings over the course of this year and will publish its findings shortly. The APPG would be disappointed if there were to be no further patient engagement in the implementation of the Review's recommendations after that point. Too often, patients' views are overlooked. Patients should be at the heart of the implementation process.

Action required: The Government should explain in the debate how it intends to keep patients fully involved as it moves towards the full implementation of *First Do No Harm.*

Additional points:

- Sodium valproate, one of the medicines examined in the Review, carries a one in two risk of causing harm to a baby if a woman is taking it and becomes, or already is, pregnant. It is estimated that tens of thousands of babies have been harmed over the 40 years that valproate has been prescribed in the UK. This continues today, a year after the publication of *First Do No Harm.* NHS England recently wrote to women of child-bearing age who are prescribed sodium valproate to raise awareness of the risk and to explain what they should do. This is a step in the right direction but it has taken a year since the Review called for it. One letter will not resolve the issue. The Government should explain the debate what further action will be taken and over what timescale.

- The use of surgical mesh for stress urinary incontinence (SUI) has been paused since this was called for by the IMMDS Review in 2018. The Review set out six conditions which must be met before the implanting of mesh for SUI could resume. These are:

    1. Surgeons should only undertake operations for SUI if they are appropriately trained, and only if they undertake operations regularly;
    2. They report every operation to a national database;
    3. A register of operations is maintained to ensure every procedure is notified and the woman identified who has undergone the surgery;
    4. Reporting of complications via the MHRA is linked to the register;
    5. Identification and accreditation of specialist centres for SUI mesh procedures, for removal procedures and other aspects of care for those adversely affected by surgical mesh;
    6. NICE guidelines on the use of mesh for SUI are published.

- These conditions have not been met, yet there is pressure from some doctors to lift the pause before they are. The Government should confirm during the debate that there is no intention to lift the pause until all the conditions have been met. If or when it is reintroduced, mesh for SUI should only be considered after all the alternatives non-surgical and surgical treatments have been considered and only if the woman is fully informed of the risks and has given her informed consent.

For more information on the work of the APPG for First Do No Harm contact the Group's Secretariat at Luther Pendragon via fdnh@luther.co.uk.