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MPs question government's failure to collect data on mesh and sodium valproate harms

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MPs have called on the government to explain why it is not monitoring the potential transgenerational effects of sodium valproate, despite data suggesting people affected by exposure as an unborn baby could potentially pass on effects to their children.¹

The Health and Social Care Committee report looked at what progress has been made in the two years since the Independent Medicines and Medical Devices Safety (IMMDS) review into patients harmed by pregnancy test drug Primodos, epilepsy drug sodium valproate, and pelvic mesh was published.²

It found that only three of the nine main recommendations set out in Julia Cumberlege's review have been accepted, with three still under review, and three—including a redress agency and schemes to meet the cost of providing additional care and support to those harmed—officially rejected.

The review had found that patient concerns over harms were often dismissed, that there were many occasions where regulatory bodies could have acted sooner, and that poor communication with doctors and between doctors prevented patients knowing about the risks of the interventions.

Flying blind

The report by MPs raised concerns over the government's failure to collect data on the number of women who experienced complications following surgical mesh surgery or sodium valproate exposure during pregnancy, despite agreeing to these recommendations.

"Without records of which patient has undergone which procedure, or been prescribed which drug, the health system will continue to, in the words of the IMMDS review team, 'fly blind'," MPs said. They added that the IMMDS team has warned that the ongoing lack of data collection "represents a serious risk to patient safety."

The committee did acknowledge the retrospective audit of mesh implants—to be published this year—as an "encouraging first step." It said, however, that this is "unlikely" to fully reflect all of adverse effects women have experienced "because of the nature of data used in the audit."

MPs called for the government to consider an "alternative strategy for how to proactively contact those who have had the procedure about their postoperative experiences and possible side effects."

They also pointed to a letter written by June Raine, chief executive of the Medicines and Healthcare Products Regulatory Agency, to the committee, in which she highlighted European studies into the potential transgenerational effects of sodium

valproate, expected to be published by the end of 2023.

The committee welcomed the news that research is forthcoming, but said it was "concerned" that similar data are not being collected in the UK. "We cannot understand how it is not in the interest of government to monitor transgenerational effects in those affected here in the UK, and would welcome an explanation from the minister on this," they said.

Redress scheme

The committee's report comes after a hearing in December, during which the health minister Maria Caulfield said that the government will review proposals for an independent redress agency for people harmed by pelvic mesh and sodium valproate, after initially rejecting the idea.³

Before this potential change in direction, women affected by the interventions had told the committee they vehemently opposed the push by the government to put those harmed through the NHS resolution system rather than through a dedicated scheme, calling it "an insult." They argued that people who have been harmed should not have to endure lengthy court proceedings and would be better served by a no blame approach.

The committee has now called on Caulfield to provide "details on what such a review would include and seek to achieve" as well as a timeline for completion. It has also urged her to ensure Henrietta Hughes, the patient safety commissioner, has enough resources to put together the redress scheme proposals. This comes after the committee warned that without adequate resourcing there was a "serious risk" the commissioner role could fail.

Health and Social Care Committee chair Steve Brine said, "We have been encouraged to hear Health Minister Maria Caulfield say she is now willing to look at the idea of a redress agency and urge swift progress to rectify years or even decades of hurt."

1 Follow-up on the IMMDS report and the government's response. 20 January 2023. <https://publications.parliament.uk/pa/cm5803/cmselect/cmhealth/689/report.html>.

2 Mahase E. Government must apologise to those affected by Primodos, valproate, and mesh, says review. *BMJ* 2020;370. doi: 10.1136/bmj.m2726 pmid: 32636188

3 Mahase E. Cumberlege review: Government reconsiders no blame compensation for people harmed by mesh and sodium valproate. *BMJ* 2022;379. doi: 10.1136/bmj.o3011 pmid: 36521867