



Health and Social Care Committee

House of Commons London SW1A 0AA

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From Rt Hon. Jeremy Hunt MP

Rt hon Matt Hancock MP

Secretary of State for Health and Social Care

Letter by email to mb-sofs@dhsc.gov.uk

14 October 2020

Dear Matt,

Re: The Independent Medicines and Medical Devices Safety Review

Dear Secretary of State

I am writing to request an update regarding the government's response to The Independent Medicines and Medical Devices Safety Review. It is now over three months since the review was published. On the day of publication, the Minister for Patient Safety stated that the government would "update the House at the very earliest opportunity" and that either she or you would be back in the House of Commons "as soon as possible with our recommendations". I understand that current litigation regarding the Primodos cases means those aspects of your response to the review have had to be delayed. I also appreciate that the COVID-19 pandemic has likely impacted how much attention you are able to give to this issue. However, it is vital that the government responds to the recommendations on Sodium Valproate and Pelvic Mesh and the rest of the review as soon as possible. As Baroness Cumberlege wrote in her report, "Implementation needs to be approached with a new urgency and determination" and I am concerned that this is not currently the case. I would be grateful if you could respond by outlining the timetable your Department is working towards regarding responding to these aspects of the report.

I am particularly concerned about the delay in responding to the recommendations regarding the continued use of Valproate by pregnant women. The review stated that around 27,000 women of childbearing age take valproate in the UK and it estimated that 10% of babies exposed to this drug are affected by major congenital abnormalities and 40% by neurodevelopmental effects. The MRHA suggests there are still 17,000 women taking this drug. Current guidance suggests that women should only be prescribed valproate if the Pregnancy Prevention Programme is in place. This includes counselling on the risks of taking the drug, being on a highly effective contraception, and being reviewed by their specialist annually. However, I am worried that women are still becoming pregnant whilst on Valproate without knowledge of the risks.

The review estimated that "hundreds" of babies a year are still being born with Foetal Valproate Spectrum Disorder (FVSD) and campaigners from INFACT claim there were 450 pregnancies between April 2018 and October 2019 in women on valproate who had not received sufficient warnings about the potential effects of the drug. If this rate remains roughly the same then for each month of delay there are potentially 25 pregnancies affected by valproate. The review therefore called for action from the centre to ensure that all women on sodium valproate are aware of the risks. I would urge you to go further and through NHS England ban the prescription of this drug where it is known they are pregnant. If potentially 25 babies are being born with disabilities every month it is essential to act quickly so I would be very grateful if you

could let me know what you intend to do in this specific issue, regardless of your timings for responding to the entire review.

You will understand that many of those families who have been affected by valproate are desperate for the government to respond quickly to these concerns and the recommendations made by the independent review. I would be very grateful if you could therefore respond to me within two weeks.

Yours sincerely,

A handwritten signature in blue ink that reads "Jeremy Hunt". The signature is written in a cursive, slightly stylized font.

Rt hon Jeremy Hunt MP
Chair, Health and Social Care Committee