# Health and Social Care Committee

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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

14 October 2020

Dear Matt,

**Re: The Independent Medicines and Medical Devices Safety Review**

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,

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

Department of Health & Social Care

*From the Rt Hon Matt Hancock MP*
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The Rt Hon Jeremy Hunt MP
Chair, Health and Social Care Committee
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28 October 2020

Dear Jeremy,

Thank you for your letter of 14 October.

I want to thank you for commissioning the Independent Medicines and Medical Devices Safety Review. No one can read Baroness Cumberlege's report without being moved by the patient testimonies.

As you will appreciate, this report took Baroness Cumberlege and her review team over two years to compile and contains wide-reaching and complex recommendations for the health and care system. The Government will respond in due course and I would like to assure you that we consider it imperative – for the sake of patients and especially those who have suffered greatly – that the report is considered fully before we respond.

On Sodium Valproate, I can assure you that we have not delayed in taking forward further actions.

You will be aware that valproate is contraindicated in women of childbearing potential unless the conditions of the Pregnancy Prevention Programme (PPP) are fulfilled and it is contraindicated in pregnancy unless there is no suitable alternative treatment. Data from quarter 2 of 2020 indicate that there were about 16,000 women of childbearing age prescribed valproate in the UK. The number of pregnancies estimated to have been exposed to valproate in the UK during 2018 and 2019 were 370 and 190 respectively.

For some people, Valproate is the only drug that works for their epilepsy. Switching creates a risk of breakthrough seizures and sudden unexpected death. There is the potential for social and economic impacts too, for example, loss of driving licence and risk to employment.

Strengthened regulatory measures for valproate were introduced by MHRA in April 2018. This followed a European-wide review of the latest evidence on harms from valproate exposure during pregnancy, including congenital anomalies and neurodevelopmental disorders, such as autism, in children. The measures include the valproate pregnancy

prevention programme (PPP), the goal of which is to rapidly reduce and eventually eliminate pregnancies exposed to valproate.

Currently, the MHRA is monitoring the impact of, and adherence to, the PPP. There has been a gradual decline in prescribing of valproate to women of childbearing age over a number of years but I agree that more needs to be done to reduce prescribing to situations where no alternative medicine is safe or effective. The MHRA is reconsidering the place of valproate in the treatment of bipolar disorder in women of childbearing potential and will be seeking further advice from the Commission on Human Medicines (CHM) shortly. Other regulatory measures to reduce prescribing to the minimum are also being considered.

The MHRA is working on developing a valproate registry, the main aims of which would be to monitor the use of valproate in women in the UK; monitor the compliance with the current regulatory recommendations; and identify any children born to women on valproate.

CHM has advised that once a UK wide registry is in place, valproate should be contraindicated in women of childbearing potential not enrolled in the registry. The first stage of the registry is due to be in place by the end of 2020.

MHRA has conducted a review of anti-epileptic drugs in pregnancy to help healthcare professionals identify safer alternatives to valproate for the treatment of epilepsy in women and girls. We expect the outcome of this review to be published later this year, and I understand that MHRA is planning a communications campaign based on the safety profile of other anti-epileptic drugs to re-emphasise that sodium valproate should only ever be used where other anti-epileptics were ineffective or not tolerated by the patient.

Sadly, there is some evidence from patient surveys, including those conducted by the Independent Fetal Anticonvulsant Trust (In-FACT), that women are still not always receiving the information they need to make informed decisions. This is clearly of concern and the MHRA is working with In-FACT, NHS England and NHS Improvement, and the professional regulators to ensure that full compliance with the PPP is achieved. Further advice will be sought from the Commission on Human Medicines on a range of measures to further reduce the prescribing of sodium valproate to women of child-bearing potential.

We clearly need multi-layered action. With this in mind, the National Director for Patient Safety has recently set up a clinically led Valproate Safety Implementation group (VSIG) to consider the range of issues relating to valproate prescribing and to explore options to review and reduce. Actions underway and planned by this group include:

- Working with NICE to update prescribing guidelines
- Recruitment of patient and public voice representatives
- Developing patient decision aids for risk communication and shared decision making with patient groups
- Strengthening pathways between neurology, mental health and contraceptive services to improve engagement with the Pregnancy Prevention Programme (PPP)
- Contacting all women of childbearing potential (WCP) on valproate to remind them of risks and ask them to make an appointment with their GP to discuss their PPP

- Working with community pharmacists to ensure the correct warning is given with each prescription dispensed, with a possible requirement for original pack dispensing
- Ensuring all women on valproate have an annual specialist review, virtual consultations will be considered. Working with stakeholders to improve data collection and linkage of data sets in order to identify WCP who are prescribed valproate

Once again, I can assure you that these actions are a priority.

Yours ever,

**MATT HANCOCK**