Department of Health & Social Care

From Baroness Merron
Parliamentary Under-Secretary of State for
Patient Safety, Women's Health and Mental Health

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Ms Jane Hanna OBE
Director of Policy and Influencing
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By email to: jane.hanna@sudep.org

5 January 2025

Dear Ms Hanna,

Thank you for your correspondence of 4 September to the Secretary of State offering your kind congratulations on his appointment to the Department of Health and Social Care and offering to brief him on the work of your organisation. I am responding as the Minister for Patient Safety. I am sorry that you have not received a more timely reply and thank you for your patience.

I appreciate your concerns.

The MHRA is responsible for monitoring the safety of medicines and taking action to minimise risks to patients. Valproate is known to have significant risks if taken during pregnancy and, despite the introduction of a Pregnancy Prevention Programme (PPP) in April 2018, new pregnancies continue to be exposed to valproate in the UK. In addition to the recognised risks of valproate for female patients, there is increasing evidence of harm for male patients, including the known risk of male infertility and non-clinical studies showing toxicity to the testes of developing animals.

The data available on reproductive risks for valproate, in conjunction with feedback from patients, charities and stakeholders, led to the revised recommendations on the use of valproate from the Government's scientific advisory committee, the Commission on Human Medicines (CHM), which were communicated in December 2022. The aim of the measures is to move to a position where valproate is only prescribed to those who really need it or for whom the reproductive risks do not apply. The CHM recognised that for some patients, valproate remains the most effective medicine, and it is for this reason that valproate will remain available for those patients for whom no other effective or tolerated treatment exists.

The new system requiring two specialists to consider and document that valproate is the only effective and tolerated treatment for a particular patient was implemented in January this year for patients under the age of 55 newly starting valproate, and for women able to have children who are already receiving annual specialist reviews under the PPP. This followed months of discussion with the CHM's Valproate Implementation Expert Working Group and a meeting of the wider Valproate Stakeholder Network. The MHRA issued a National Patient Safety Alert in November 2023 giving clear actions to enable organisations to prepare for the new measures.

The precautionary advice that men taking valproate and their female partners should use contraception, which was issued in September, followed careful consideration of a study that indicated a possible association between valproate use by men around the time of conception and an increased risk of neurodevelopmental disorders in their children. The advice issued in the UK is consistent with that published by the European Medicines Agency in January and by several other regulators worldwide.

The MHRA published its Patient Involvement Strategy in October 2021, setting out its determination to put patients at the heart of the Agency's work. It also is closely monitoring the impact of the new measures, including unintended consequences to patients, using a number of different data sources, including feedback from stakeholders.

I hope this reply is helpful.

All good wishes,

BARONESS MERRON