



# Medicines & Healthcare products Regulatory Agency

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23 April 2018

Dear Dr Vautrey,

## **IMPORTANT NEW MEASURES TO REDUCE RISKS OF VALPROATE IN PREGNANCY**

I am writing to you as Chair of the British Medical Association's GPs Committee to inform you of the new strengthened regulatory position for prescribing of valproate in girls and women of childbearing potential, and to seek your support for its implementation. Use of valproate in pregnancy is associated with a 40% risk of persistent neurodevelopmental disorders and a 10% risk of physical birth defects. Despite repeated communications on this risk, it is estimated that 400 women in the UK took valproate during pregnancy in 2016.

Following a review of the situation across the EU, valproate is now contraindicated in women of childbearing potential unless they meet the conditions of a Pregnancy Prevention Programme, the UK's Chief Medical Officers will be issuing instructions and educational materials to support the implementation of the Pregnancy Prevention Programme will be sent to GPs and other healthcare professionals by post in the coming weeks.

There are approximately 27,000 women of childbearing age receiving prescriptions for valproate in primary care in the UK. We will be asking that GPs should identify all relevant women and girls on valproate in their practice, check that they are on effective contraception as appropriate, and refer them for specialist review unless they have already had a review in the last year. The specialist prescriber review will include a risk acknowledgement form to be completed and signed by the specialist prescriber and the patient and a copy will be forwarded to the GP.

We have been working with NHS Digital to ensure that GP systems have consistent high visibility alerts across primary care and that search and audit functions are available to facilitate identification of women and girls on valproate.

We have worked closely with the Royal College of General Practitioners whose support has been integral to the progress which has been achieved, to identify and manage barriers to successful implementation of the new regulatory position.



We will be closely monitoring the effectiveness of the new measures for avoiding prescribing of valproate to women of childbearing age and in preventing pregnancies from being exposed to valproate. Relevant data will be published, and ministers expect ongoing follow up to ensure progress is being made. We would welcome the ongoing support of the BMA in this important patient safety work and would be happy to discuss further with you as soon as convenient.

Yours sincerely

A handwritten signature in black ink, appearing to read 'I Hudson'.

Dr Ian Hudson,  
Chief Executive Officer  
Medicines and Healthcare products Regulatory Agency