

Patient Safety Notice: NatPsA/2023/013/MHRA Valproate: organisations to prepare for new regulatory measures for oversight of prescribing to new patients and existing female patients

Compliance date: 31/01/2024

Date compliance will be achieved:

Date action plan update

Lead Committee:

Lead Person(s): Christopher Brown & Subhamay Ghosh

Compliance status



Alert Details		Action Required	Action Taken Please list any evidence to support action taken	Responsible person	Compliance Status
<p>This is a safety critical and complex National Patient Safety Alert. Implementation should be coordinated by an executive lead for quality (or equivalent) in Integrated Care Boards in England, Health Boards in Scotland, Health Boards in Wales, and Health and Social Care Trusts in Northern Ireland, alongside the Chief Pharmacists (or equivalent) and supported by the Medical Directors of organisations involved in the prescribing of valproate and clinical leads in neurology, psychiatry, paediatrics, learning disability and/or autism, contraception and Sexual Health, and general practice, with others included to meet local needs and clinical situations.</p> <p>The MHRA is asking organisations to put a plan in place to implement new regulatory measures for sodium valproate, valproic acid and valproate semisodium (valproate). This follows a comprehensive review of safety data, advice from the Commission on Human Medicines and an expert group, and liaison with clinicians and organisations.</p> <p>Due to the known significant risk of serious harm to a baby after exposure</p>	1.	<p>Designate a new existing group to co-ordinate the implementation of the new regulatory measures in providers, with oversight from a senior quality group. This group should include (but is not restricted to):</p> <ol style="list-style-type: none"> An appointed chair with delegated responsibility for the actions in this alert. Representation from clinical leads in all the specialities named above and any other relevant departments. A mechanism by which the group can involve and be informed by patients with lived experience. 	<p>a,b)Pharmacy Valproate Working Group has met to establish health board's current position. Minutes of meeting attached.</p> <p>Pharmacy Valproate Working Group has agreed that a dedicated group is required to develop the implementation plan for the health board with clinical leads from each specialty present to lead and take responsibility in their area with an executive lead.</p> <p>Clinical specialties include:</p> <ul style="list-style-type: none"> Neurology Mental Health and Learning Disabilities Paediatrics <p>Advice is needed from quality and governance on how to establish group.</p> <p>c. We will need to seek advice from quality and governance lead on how to achieve this.</p>	To be determined once executive lead has been identified	

<p>to valproate in pregnancy, these measures aim to ensure valproate is only used if other treatments are ineffective or not tolerated, and that any use of valproate in women of childbearing potential who cannot be treated with other medicines is in accordance with the Pregnancy Prevention Programme (PPP). Given these and other risks of valproate, these measures also aim to reduce initiation of valproate to only in patients for whom no other therapeutic options are suitable. The regulatory change in January 2024, for oral valproate medicines, means that:</p> <p>A) Valproate must not be started in new patients (male or female) younger than 55 years, unless two specialists independently consider and document that there is no other effective or tolerated treatment, or there are compelling reasons that the reproductive risks do not apply.</p> <p>B) At their next annual specialist review, women of childbearing potential and girls should be reviewed using a revised valproate Risk Acknowledgement Form, which will include the need for a second specialist signature if the patient is to continue with valproate and subsequent annual reviews with one specialist unless the patient's situation changes.</p> <p>Advise leaders that current safety measures for valproate continue to apply, including the valproate PPP for any girls and women of childbearing potential. See Valproate: reminder of current Pregnancy Prevention Programme requirements; information on new safety measures to be introduced in the coming months -</p>	<p>2.</p>	<p>The group should be tasked with, and document, progress towards:</p> <p>a) Updating all local guidance and protocols relating to prescribing of valproate to reflect the new regulatory position, including definitions of the roles and responsibilities of clinicians and provider organisations, and the recording of compliance with the risk forms.</p> <p>b) Commissioning work if necessary to understand the needs of the affected population, including those people most at risk of health inequalities.</p> <p>c) Reviewing the results of local audit(s) of compliance with the existing PPP measures for girls and women of childbearing potential prescribed valproate.</p> <p>d) Commissioning/determining the local pathways of care for women of childbearing potential and girls in relation to the prescribing and review of valproate.</p> <p>e) Planning for and identification of clinical resource to meet the identified needs of the population and implement the new regulatory measures.</p>	<p>a. HDUHB Formulary updated with NPSA alert. Further requirements to be established by new group. Identify and direct to update or create.</p> <p>b. Required to utilise speciality clinicians to aid this, such as perinatal mental health pharmacist. Feedback groups from existing patient groups.</p> <p>c. Currently primary care data has been taken from one point in time from all GP practices of women on valproate. This has been split by speciality to complete ARAF forms. MH&LD – list in place split to 3 further areas (women CMHT, LD (epilepsy) and general neurology). Patients RAG rated for their ARAF status (currently large proportion red).Neurology – no engagement due to lack of capacity within the service (commissioned service from SBU).Paediatrics – no list in place yet. See attached minutes for further information.</p> <p>d. HB neurology patients are currently commissioned from Swansea Bay and they have stated no capacity to review patients. Speak to commissioning regarding this and any other pathways.</p>	<p>a.Sue B & Jen H</p> <p>To be determined</p>	
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<p>GOV.UK (www.gov.uk), including advice for clinicians to consider all other suitable therapeutic options before newly prescribing valproate in patients younger than 55. Advise leaders in general practice and pharmacy that teams should continue to prescribe and dispense valproate but also discuss the current warnings and upcoming measures relating to valproate with their patients and consider together how it affects the patient's individual circumstances. New education materials should be integrated into local guidance to ensure patients are able to make an informed choice.</p>			e. Working with directorates and commissioners to ensure sufficient resources for implementation.		
	3.	Based upon the findings of the above, the group should produce and Action and Improvement Plan by the alert deadline that is communicated with all relevant staff to ensure smooth implementation of the new regulatory measures and to allow for continuous improvement in care of patients who are considering or being prescribed valproate, including ongoing improvement, monitoring and audit.	Plan from initial meeting will be developed and monitored to meet the requirements. Not compliant will need to be developed by new group.		
Date Safety Notice Signed Off as Fully Compliant		Committee Signing Safety Notice as Fully Compliant		Name of Chair	