Changes to valproate prescribing:

The MHRA have today announced regulatory changes for valproate prescribing. Valproate will continue to be available but subject to increased regulations that will now also include men as well as women. These changes will have significant implications for how valproate is prescribed, particularly for men, and will require new pathways for prescriptions and signatures of the annual risk acknowledgement forms (ARAF). Implementation will require closer integration of care and flow of information across primary and secondary care, as well as working with patient charities and organisations. No action is required at present as these changes won’t start to be phased in until Spring of 2023.

Neurologists, including members of the ABN epilepsy advisory group, have been working with the MHRA to guide the implementation of the changes to ensure it is done as safely as possible for people with epilepsy. This has led to the changes being phased in to allow time for more details to be issued on how this should be implemented. The ABN remains committed to ensuring safe practice for our patients as well as their children and will continue to work with the MHRA and NICE/SIGN on pathways and guidance to support our members. To this end, the ABN has raised concerns regarding the impact these changes will have on people currently taking Valproate as well as clinical services, particularly the lack of systems in place to support the implementations.

With the expansion of regulatory measures limiting valproate use, we have requested that the NHS prioritises funding of digital resources to enable the changes to be made as safely and efficiently as possible. This will be crucial in the effective implementation of the programme as well as ensuring that one harm is not replaced by another, including increased educational, psychological and physical morbidity, and mortality, from uncontrolled seizures.

The digital ARAF that has been under development for some time needs to be developed quickly to enable dual signatures and allow all involved in the care for the person taking valproate to have access to the form.

We also stress the need for expansion of a valproate registry to have sufficient detail to look at outcomes; both adverse outcomes from valproate use, and in those who have stopped valproate. In addition, urgent research is required into the reasons for the number of pregnancies which have occurred in women whilst still on valproate to see if there has been a failure in the process and at which point that has occurred to enable learning and reduce risks of repeating any mistakes.


Association of British Neurologists - December 2022