

Statement on Epilepsy from Sarah Fishburn (Senior Clinical Quality Improvement Manager)

1. *Whether patient safety concerns about the MHRA policy are being listened to nationally?*

The South East regional team has been working with colleagues across the region to gain a clear understanding of the issues being encountered in practice, and has also been working with experts by experience and organisations supporting people taking valproate to understand the issues. We have now met twice with the team at MHRA to express the concerns and alert them to the issues. They have told us that they are monitoring the situation and rely on data to make any decisions.

2. *Does NHSE welcome the Patient Safety Commissioner consultation on the requirements of improved patient safety that are being consulted on nationally?*

We fully support any increased focus which leads to improved safety and quality of care for patients.

3. *What would need to happen in respect of the MHRA policy for patient safety and patient priorities to be relevant and in place for people with epilepsy who need timely access to life saving and life enabling medication?*

The key requirement from MHRA is to have data on any actual harm caused by the changes in policy. We have made them aware of the increased delays in neurology clinics as a result of the requirement for a second check for all valproate prescribing and the cancellation of clinics. They are monitoring the situation and any data which becomes available. They have had sight of a report from Liverpool which details no increases in deaths but an increase in people attending hospital with seizures.

4. *What is NHSE able to put in place now and what else would be needed to support local systems?*

NHSE SE region is developing a pilot digital programme to enable the annual ARAF process to be more streamlined. This will enable clinicians and service users to view the ARAF form, and will help to set up the regular reviews digitally.