# WRITTEN QUESTION TO THE MINISTER FOR HEALTH AND SOCIAL SERVICES BY DEPUTY H.L. JEUNE OF ST. JOHN, ST. LAWRENCE AND TRINITY QUESTION SUBMITTED ON MONDAY 24th MARCH 2025 ANSWER TO BE TABLED ON MONDAY 31st MARCH 2025

### Question

"Will the Minister advise -

- (a) what steps, if any, the Government is taking to ensure that patients and healthcare professionals in Jersey are fully informed about the risks associated with sodium valproate, especially for women;
- (b) what measures are in place to support those affected by its side effects; and
- (c) how many people have been negatively affected by the use of sodium valproate in Jersey?"

#### Answer

(a) Steps taken by the Government to ensure awareness of Sodium Valproate risks In response to the National Patient Safety Alert (NatPSA/2023/013/MHRA) published on 28th November 2023. HCJ promptly designated Mr. Simon West, the current Medical Director, as the executive lead to coordinate the response. The target date for developing an "action and improvement plan" was set for 31st January 2024, which was successfully met, as per the NPSA alert.

A new clinical working group was established, comprising representatives from various stakeholder areas as outlined in the alert. This group developed a new Valproate policy (Doc ref HSS-PP-CG-0655-02) and created a flow chart to simplify decision-making for clinicians.

All primary care pharmacies, GPs, hospital doctors, and the hospital pharmacy were informed of the requirement to have an "Annual Risk Assessment Form" (ARAF) signed for females of reproductive potential and for males at initiation.

In February 2025, the MHRA issued further advice on valproate (ref MHRA Safety Update volume 18, issue 7: February 2025:1), amending the advice for males over the age of 55 years due to a perceived lower risk for older males. Following the revised MHRA advice in February 2025, the flow chart was further updated.

Other actions taken:

An audit undertaken in 2024 identified 263 patients across Paediatrics, CAMHS, Adult Mental Health, Neurology, Learning Disability, and Primary Care who had been prescribed a valproate. Of these, 71 (27%) are female.

Most hospital electronic prescribing systems have been updated to remind clinicians of the risks associated with Sodium Valproate and the necessity of annual reviews. Over the past five years, no prescribing errors regarding Sodium Valproate have been reported in the hospital.

For over a decade, Sodium Valproate packaging has included warning labels regarding females and pregnancy. The hospital dispensary will only supply valproate in their original packs to ensure all relevant medicines safety information is shared with patients. Under the HCJ policy (Doc ref HSS-PP-CG-0655-02), when initiating treatment with Sodium Valproate, two specialists must independently agree that it is the best option for the patient. The patient must be provided with information regarding the risks and sign a consent form acknowledging these risks.

## (b) What measures are in place to support those affected by its side effects?

There are a multitude of side effects associated with the use of valproate (exceeds 50) e.g. tremor, anaemia, weight gain.

Patients prescribed valproate medicines are monitored e.g. via blood tests (every 6 months at their GPs) and have an opportunity to discuss side effects and their management at specialist and GP appointments. Patients are counselled at initiation regarding side effects, and they will be receiving patient information leaflets at every dispensing.

The GPs EMIS prescribing system prompts GPs every 6 months to check patient's bloods, weight and to remind patients about the importance of using *"highly effective contraception"*.

# (c) How many people have been negatively affected by the use of Sodium Valproate in Jersey?

No Datix (HCJ's health error/harm reporting system) reports have been submitted for sodium valproate over the past 5 years.