Briefing On Sodium Valproate and the Potential Risks to Pregnant Women: October 2017

Parliamentary Debate: Thursday 19th October 2017 (Circa 2.00pm) - House of Commons - General Debate (Subject Nominated by the Backbench Business Committee)
Norman Lamb MP - Valproate and fetal anticonvulsant syndrome.

About The Epilepsy Society

1. Epilepsy Society is the UK’s leading provider of epilepsy services. Through our cutting edge research, awareness campaigns, information resources and expert care, we work for everyone affected by epilepsy in the UK. Our research is driven by the desire to understand what has caused the epilepsy in each individual person, to be able to identify the best therapy from the outset, and to make this expertise widely available.

2. We are part of a unique arrangement with University College London and the National Hospital for Neurology and Neurosurgery. This ensures academic and clinical excellence, patient input and relevance of our medical research. We are also a World Health Organisation (WHO) Centre of Excellence.

3. For more information visit: www.epilepsysociety.org.uk

About Epilepsy

4. About 1% of the population - more than 600,000 people in the UK have epilepsy and one third have seizures that cannot be controlled through available anti-epileptic drugs. There are 1,000 deaths from the condition every year, including many children and young adults. Epilepsy can have a devastating effect on people and their families, affecting all aspects of their lives.

5. Epilepsy is the tendency to have recurrent seizures. There are more than 40 different types of epileptic seizure, and everyone experiences them differently. They range from experiencing strange sensations to falling unconscious, but all have a major impact on daily life.
6. Almost one-fifth (18%) women and girls of childbearing age currently taking the epilepsy medication, sodium valproate, do not know it can harm the development and physical health of their unborn child should they become pregnant.

- More than a quarter (28%) of women and girls of childbearing age taking the epilepsy drug have not been given information about risks for their unborn child.

- More than two thirds (68%) of women and girls of childbearing age taking the epilepsy drug have not received specially produced valproate materials released in February 2016.

- The Epilepsy Society is calling on the government to make annual reviews mandatory for women and girls of childbearing age taking the drug.

7. Almost one-fifth (18%) women and girls of childbearing age currently taking the epilepsy medication sodium valproate do not know it can potentially harm the development and physical health of their unborn child should they become pregnant. This was the worrying statistic revealed in a recent survey published on 20th September 2017 and carried out by the Epilepsy Society in partnership with Young Epilepsy and Epilepsy Action, the UK's three leading epilepsy charities.

8. More than 2,000 women and girls of childbearing age with epilepsy took part in the survey which revealed that just over a quarter (28%) of women and girls of childbearing age who responded, and are currently taking sodium valproate, had not been given information about risks for children exposed to the drug during pregnancy.

9. It is estimated that around 10% of babies born to women who take sodium valproate during pregnancy are born with physical disabilities. Up to 40% are at risk of developmental issues that can lead to learning difficulties. They can affect a child's learning and understanding, behaviour and language and manifest in ways such as attention deficit hyperactivity disorder (ADHD) or autistic spectrum disorders.

10. In the UK approximately 35,000 women take sodium valproate medication and it is the third most-prescribed anti-epilepsy medicine. The medication is also prescribed for people with bipolar disorder.

**MHRA Toolkit to raise awareness of valproate risks**

11. These results are in spite of efforts by the Medicines and Healthcare Products Regulatory Agency (MHRA) to raise awareness of the issue among healthcare professionals and women with epilepsy. In February 2016, the MHRA released a valproate toolkit to help healthcare professionals talk to women with epilepsy about the risks during pregnancy. The toolkit includes a credit card-sized patient card to be issued by pharmacists, booklets for healthcare professionals and women taking sodium valproate, and a checklist of important discussion points. However, 18 months later, the survey shows that more than two thirds (68%) of respondents currently taking sodium valproate have still not received any of the toolkit materials.
What We Want the Government to do:

We are now calling on the government to ensure that repeat prescriptions for sodium valproate for women and girls of childbearing age are not routinely renewed for more than 12 months without a face-to-face consultation with a doctor or nurse.

12. This consultation must include personal and tailored information about the risks around sodium valproate during pregnancy. Information should also be provided in written format.

13. This will help to ensure that women and girls of childbearing age with epilepsy who are prescribed sodium valproate are fully informed about the risks to their unborn baby should they continue to take the drug while pregnant.

14. This is a very simple and straightforward ask of the government. No additional funding is required for the NHS. All we are asking is that doctors and nurses have a yearly conversation with women and girls of childbearing age who are taking sodium valproate, to make absolutely certain they are aware of the risks associated with the drug during pregnancy.

15. We know that for some women, sodium valproate will be the only drug that controls their seizures and they must carefully weigh the benefits against the risks. But what is unforgiveable is for women not to be informed of those risks. They must be able to make an informed choice about their treatment in conjunction with their doctor.

CASE STUDY - Deborah from Watford, was diagnosed with epilepsy at the age of 12 and two years later was prescribed sodium valproate. Deborah lost three babies in her twenties. When she was expecting her fourth baby, she was taking 5,000mg of sodium valproate a day. Rhonnie was born with two holes in her heart and was diagnosed with fetal valproate syndrome. Her fifth child, Branwen was also born with fetal valproate syndrome.

Both daughters have congenital malformations, dysmorphic features, learning difficulties, Asperger's, odd feet and are short sighted. Branwen, 21, has hypotonia which means her nerves are not stimulating her muscles properly. Rhonnie, 23, has hyperextendable joints that pop out all the time. She has asthma and some of her organs don't function properly. Rhonnie is also deaf.

Rhonnie finds the world around her very difficult. She experiences a lot of pain and dizziness. Branwen looks after children with learning difficulties. She is now finding it difficult to write and her memory is bad. She is losing her cognitive abilities and has chronic migraine. An MRI has shown that she has a malformation in her brain and a pituitary cyst. She has been told she could die at any time.

16. On 26th September 2017 the Safety Committee of the European Medicines Agency (EMA) held its first ever public hearing as part of a safety review of a drug to consider this issue and the Epilepsy Society presented the findings of the survey. The recommendations from this hearing are expected to be published in January 2018.

17. For further information about the surveys, the risks and women who have been affected, please contact the Epilepsy Society.