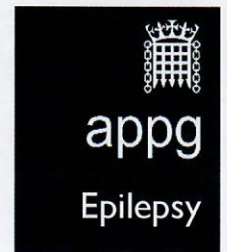


Rt Hon Matt Hancock MP
Secretary of State for Health and Social Care
Department of Health and Social Care
39 Victoria Street
London SW1H 0EU



By post and email

8 October 2020

Dear Secretary of State

Re: Independent Medicines and Medical Devices Safety Review

The APPG on Epilepsy is writing to you in relation to the Independent Medicines and Medical Devices Safety (IMMDS) review, which published its report, First Do No Harm on 8 July 2020. Following the publication of the report, we would like to hear more from the Government about its plans to implement the recommendations of the Cumberlege report.

Recommendations of the Cumberlege Report

The APPG, its members, supporters and the entire epilepsy community (>600,000 people in the United Kingdom) are understandably very interested in the specific recommendations around the anti-epileptic drug, Sodium Valproate. The Cumberlege review found that while there were concerns about the risks of Sodium Valproate, doctors were advised that the risk did not justify 'discouraging a woman who needs anticonvulsant treatment from having a child or changing a satisfactory drug regimen when the epilepsy is well controlled.' In view of the serious possible harm to the unborn child, this was unacceptable and has led to an estimated 20,000 children being affected by the drug.

Many of the individual members of the APPG have written to you separately about this issue, and we are all concerned at the lack of any commitment from the Government to implement the Cumberlege report's recommendations. Given the significant and increasing risk of maternal death among women with epilepsy, it is also vital Government consider how to carefully balance the risks faced by both women and their unborn child while planning this implementation process.

We would therefore ask that you confirm the Government's commitment to implementing the recommendations and set out a clear timeline for this to happen.

Epilepsy and Covid-19

Many of the recommendations in the report will take time to fully implement and resource, such as the recommended registry for all women on antiepileptic drugs who become pregnant. It is therefore imperative that planning for these starts as soon as possible. There are also logistical challenges in implementing measures across all four nations which need to be taken into account. In addition, many families have been

waiting years for help with the financial costs of caring for people affected by sodium valproate, and work to establish a redress scheme and financial support is vitally important for so many of those affected.

We are aware that the current national focus is on COVID-19, so implementation of the Cumberlege report is likely to be affected by this. However, it is important to note that research by members of the APPG has highlighted worsening outcomes for people with epilepsy as a result of the pandemic, impacting on access to health services, mental health, education and worsening of risks linked to premature mortality. Unfortunately many people with epilepsy in the UK do not have access to specialist services and adequate information, with fewer than 1 in 4 having seen an epilepsy specialist in the last year.

As a result of the current pandemic, transparency and action in addressing the recommendations of the Cumberlege report so both mother and baby are kept safe from harm is of utmost importance.

We would welcome further discussion with you and your department about the concerning impact COVID-19 is having on the wider epilepsy community and how Government can act to improve outcomes for this vulnerable group.

Epilepsy12 Report

We would also draw your attention to the Epilepsy12 report which was published on 10 September 2020. This report provides a key focus for the resumption of paediatric epilepsy services as the recovery period develops. The Epilepsy12 report also charts the prescribing of valproate in children's first year of care.

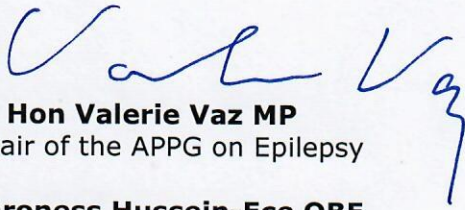
The APPG and our members have a great deal of expertise and experience on these issues, and we would therefore welcome the opportunity to discuss these with you in more detail, in addition to discussing how we can help ensure that the recommendations are implemented fully and properly. All patient groups should be given the opportunity to be involved in the Taskforce and setting up of the Patient Safety Commissioner, to ensure fair play and that there's no conflict of interest. It is vitally important that any task force includes patient groups and charities to ensure that the views and concerns of patients are foremost in the group's work.

We would welcome the opportunity to be involved in a task force to monitor the implementation and progress of the recommendations.

In conclusion, while the Cumberlege report goes a long way to addressing the issues that so many women have faced, this is only the first step in addressing these problems. The Cumberlege report has provided the Government with an excellent opportunity to address decades of suffering and put measures in place to ensure such suffering does not happen again.

We would urge you to not miss this opportunity and ensure that the families who have suffered for so long finally get the support they need.

Yours sincerely



Rt Hon Valerie Vaz MP
Chair of the APPG on Epilepsy

Baroness Hussein-Ece OBE
Vice-chair of the APPG on Epilepsy

Sarah Olney MP
Member of Parliament for Richmond Park

Sara Garland
The Daisy Garland

Daniel Jennings
Epilepsy Action

Annie Perez
Epilepsy Action (Member)

Trevor Hutton
Epilepsy Awareness

Torie Robinson
Epilepsy Sparks

Fiona Kettell
Epilepsy Wales

Nicola Swanborough
Epilepsy Society

Caoimhe Twohig-Bennett
Epilepsy Research UK

Rona Johnson
Epilepsy Scotland

Eve Maria Spiccelli

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**Dr Sarah Aylett and
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Matthew Walker
International League Against Epilepsy

Andy McDonald MP
Vice-chair of the APPG on Epilepsy

Dame Diana Johnson MP
Member of Parliament for Hull North

Nada Abuknesha
London Metropolitan University

Emma Williams MBE
Matthew's Friends - Ketogenic Dietary
Therapies

Dr Rhys Thomas
Newcastle University

Karen Keely
OACS Ireland

Jo Cozens
OACS Charity UK

Carol Lapidge
OACS Charity UK

Dr Arjune Sen
Oxford University Hospitals Foundation Trust

Paul Milton

Jane Hanna OBE
SUDEP Action

Sammy Ashby
SUDEP Action

Karen McLeod
South Tees Hospitals NHS Foundation Trust

Dr Sallie Baxendale
UCL Institute of Neurology

Mark Devlin
Young Epilepsy

Susan Cole
Valproate Victims