

Sandor Beukers  
Department of Health and Social Care  
39 Victoria Street  
London  
SW1H 0EU

cc. Stephen Atkinson, Long Term Conditions and End of Life Care Team

17<sup>th</sup> December 2018

Dear Mr Beukers,

### **No-deal Brexit scenario: shortages prescribing protocol**

The Neurological Alliance has serious concerns about the shortages prescribing protocol the Department for Health and Social Care has outlined in relation to a potential no-deal Brexit scenario. We understand that Ministers would order pharmacists to dispense a reduced quantity of the medicine, an alternative dosage form, a therapeutic equivalent or a generic equivalent. We believe this suggested protocol could result in serious and damaging consequences for patients with neurological conditions. We appreciate that making plans in case of an emergency situation with regards to the availability of medicines, as a result of a no-deal is the right and responsible thing to do. However, we do not believe that this suggested contingency measure is the right one, and therefore urge your Department to rethink.

### **The role of pharmacists**

People with neurological conditions use drugs to ameliorate specific symptoms and to treat their condition. For some neurological conditions there are a vast range of drug available, with many patients on polytherapy, often prescribed by neurologists and re-issued by GPs following the neurologist's guidance. It can often take years, even for a neurologist, to find the right combination of medication and titrate it to the optimal dose to manage an individual's neurological condition. While highly-trained pharmacists have an essential role to play in dispensing medicines according to prescription, encouraging adherence, highlighting any adverse drug effects, and even understanding withdrawal or switch issues, it is both unrealistic and unfair to put them in a position of defining and monitoring a medicine regime at present. The role of pharmacists in this regard is currently limited and decisions of the nature proposed in the shortages prescribing protocol should be made between a patient and their neurologist/multi-disciplinary team as appropriate. It is also unfeasible for the necessary conversations to take place in a pharmacy setting. We are in agreement with National Voices about the importance of shared decision making. This principle is not a nice optional extra to be disregarded in difficult circumstances. It is an essential duty, core to optimising care and treatment.

## **The importance of quantity**

Getting the right amount of a medication, according to the prescription, is essential for people with neurological conditions. If a person misses a dose, or takes their medication late, the level in their body can drop, causing break-through symptoms to occur. Break-through symptoms can seriously impact people's health and their day to day lives. For example, if people with Parkinson's don't get their medication on time, they may be unable to move, speak, eat or swallow. They may experience uncontrolled movements and also have distressing psychotic symptoms. The NICE Quality Standard for Parkinson's recognises the importance of ensuring people with Parkinson's in hospital and care homes receive their levodopa within 30 mins of their prescribed dose time.

Sometimes the deterioration people experience can be irreversible. These deteriorations result in increased use of hospital services. At worst, break-through symptoms can put a patient's life at risk, such as with Sudden Unexpected Death in Epilepsy (SUDEP). The epilepsy patients themselves may also not be aware of these risks, and therefore may not understand the implications of any enforced medication changes. This is not something pharmacists are currently trained to manage and could lead to increasing avoidable epilepsy-related deaths in the community.

Similarly, taking a reduced quantity of a medication at the same intervals as before is likely to render it ineffective. Many medications have a narrow therapeutic range, meaning that taking less results in sub-therapeutic levels.

## **Alternative dosage forms**

Any changes to how the medication looks or is taken can cause issues for patients. Nonpharmacological impacts of switching include anxiety and confusion. Given people with neurological conditions may already have cognitive issues or memory difficulties, these impacts may be amplified. The same applies people with co-morbid learning difficulties and autism – which commonly occur alongside some neurological conditions. As well as resulting in implications for medicine adherence, anxiety and stress can exacerbate neurological symptoms.

The MHRA's Drug Safety Update volume 11, issue 4; November 2017: 5, in relation to anti-epilepsy drugs, states:

"Differences between alternative products (for example, product name, packaging, appearance, and taste) may be perceived negatively by patients and/or carers, and may lead to dissatisfaction, anxiety, confusion, dosing errors, and reduced adherence. In addition, difficulties for patients with co-morbid autism, mental health problems, or learning disability should also be considered."

## **A therapeutic equivalent or a generic equivalent**

While swapping patients' medication for therapeutic/generic equivalents may seem a reasonable solution to an emergency scenario, in reality it is problematic. Small differences between drugs can make a significant difference to patients with neurological conditions, particularly where they find that a generic equivalent leads

to break-through symptoms.<sup>1</sup> Side-effects can also be significant when such switches occur. And the points raised above in relation to nonpharmacological impacts of switching also apply. It is therefore essential that clinical factors such as treatment history, the potential implications for the individual of break-through symptoms, and non-clinical factors such as potential anxiety or confusion are taken into consideration when making any decisions about drug switching. This underlines the need for GP/neurologist involvement.

In summary, we believe that alternate solutions must be found, to avoid emergency medication shortages. Patients' health shouldn't and mustn't be compromised by Brexit.

Yours sincerely,



Sarah Vibert  
Chief Executive  
The Neurological Alliance

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<sup>1</sup> See <https://www.epilepsyresearch.org.uk/wp-content/uploads/2015/02/Patient-experiences-of-switching-between-different-versions-of-AEDs.pdf> for examples of this.