

UK Medicine shortages – Serious Shortage Protocol (SSP)

Key messages briefing sheet

WHO The Department of Health and Social Care

WHAT Serious Shortage Protocol (SSP)

WHEN Effective from Saturday 9 February 2019

HOW Where a Minister believes that there is a serious shortage of a specific prescription medicine, this SSP will be activated - allowing pharmacists the power to change/dispense medications, without having to notify the original prescribing clinician, or necessarily the patient themselves.

How and why did the Government do this?

The Government included Serious Shortage Protocols as **part of planning for a potential No-Deal Brexit** on 29th March. However, these changes have happened much quicker than usual, **privately** and with limited public engagement, unlike how they usually consult on important matters. **Government have created a permanent change in our medicines regulating laws** (Human Medicines Regulation), without the usual levels of scrutiny new changes receive – which makes this not just limited to Brexit, but a law which could be a longer-term issue for UK patients and clinicians.

These legal changes mean that if a Serious Shortage occurs, ministers can activate the SSP and “it would enable pharmacists, using their professional judgement, to supply an alternative quantity, strength, pharmaceutical form or medicine that is both available and suitable as prescribed in the protocol.” (Explanatory Memorandum No.62 to the Human Medicines Regulation)

These Protocols will be “developed with and signed off centrally by clinicians”. Although, Government has yet to provide specific details regarding who these clinicians would be, or how safeguards would be put in place during this process, to protect patients and ensure they are involved in these Protocols.

Government has verbally confirmed epilepsy would be exempt from any shortage protocols and acknowledges in the legal documentation that epilepsy as a high-risk condition where certain medication changes would not be appropriate:

“Protocols for therapeutic or generic equivalents will not be suitable for all medicines and patients. For example, those types of protocols would not be suitable for treatments for epilepsy or treatments requiring biological products where the medicines that are prescribed need to be prescribed by brand for clinical reasons. In these cases, patients would always be referred back to the prescriber for any decision about their treatment before any therapeutic or generic alternative is supplied.”

(Explanatory Memorandum No.62 to the Human Medicines Regulation)

However, **no details are provided as to how these medications would be protected** from shortages (as ultimately, if there are no medications available to prescribe, an exemption or recognition that epilepsy is high-risk, means very little), or what safeguards would be put in place for the many people with epilepsy who have additional health conditions; changes to which could also negatively impact on seizure control and overall wellbeing.

What are the risks of this SSP?

Person-centred prescribing and medicines management is the most effective first-line intervention to keep patients safe and helping them to live well with a long-term condition. This is often a delicate balance, refined over many years through a relationship between a clinician and their patient.

[National clinical guidelines](#) for Epilepsy which have been in place since 2004 start with the ‘fundamental requirement of decision making in partnership between the patient and the clinician.’

Changes in medication need to be clinically appropriate and carefully supervised by a clinician who understands the individual risks of the patient & the potential impact changes could have on that individual, their condition and their overall wellbeing. **Risks can materialise from the bypassing of the relationship between prescriber and patient**, these will vary for each individual. For example, in the case of epilepsy, risks could range from increasing side effects, to breakthrough seizures and worsening of anxiety, depression, and even fatality.

Because many clinicians and people living with epilepsy are also unaware of epilepsy risks, and the increased risks of mortality linked to the condition, it is incredibly important that any medication changes happen in the knowledge that these risks may apply to individuals, and that they may also need careful management and review over time.

Changes to other medications a person with a long-term health condition needs to take could also have a negative impact on many lives across the UK. **Many people with epilepsy, have another health condition** – if these medications were also changed under SSP, this could likewise impact on how their epilepsy medications work, their seizure control, their overall wellbeing and their safety.

What is the evidence to show there could be risks?

Changes to medication supply are known to cost lives. In epilepsy, 90% of those dying from Sudden Unexpected Death in Epilepsy (SUDEP) had demonstrated an increase in convulsive seizures and other risks in the previous three to six months before death, 80% of these were also not in contact with health services in the year before they died ([Shankar et al, 2014](#)).

Medication changes are a known risk factor from research into epilepsy deaths. Abrupt medication changes or stopping of medication are flagged regularly in [maternal death inquiries](#) (over half of recent deaths in pregnant women), [fatal accident inquiries](#), and [audits](#) since 2002.

The discussion about, monitoring and reduction of such risks is encouraged through our [SUDEP & Seizure Safety Checklist](#) (for clinicians) and [EpSMon](#) app (for people with epilepsy). These tools are underpinned by the latest research into epilepsy mortality.

Supply of medication by an individual pharmacist under the guidance of a centralised protocol, removes the safeguard above of the prescriber-patient relationship. **Switching of medications is unsafe unless it complies with the MHRA guidelines 2013 (& its 2017 update)**, which requires a process for switching depending on the risks associated with particular medicines. It is vital that patients are kept at the centre of decisions about their care and condition management.

Is this just Brexit propaganda? Is this really an issue?

Shortages are really rising. This has been well documented in various articles in the National newspapers. A number of drugs, including some of those for people with epilepsy, are already in short supply, leaving **many patients complaining of delays and problems accessing** their prescribed medication.

So, while much about the SSP that has been in the news is linked with Brexit (due to how Government has brought the changes quickly into law *in case* it is needed after the 29th March), the fact that **this law change is permanent means this issue goes beyond Brexit**. It can impact on patients for many years if time is not taken to put safeguards in place which put patients at the centre of these plans.

What are SUDEP Action doing about this?

SUDEP Action with the support of some other epilepsy organisations and expert clinicians, are working to unpick this issue, gather information and [campaign for careful plans to be put in place](#) to make sure people with epilepsy are able to live safely; regardless of what is happening nationally, within Government, and in relation to Brexit.

There needs to be an open framework to manage these shortages and ensure plans are put in place to reduce potential harms to patients in the case of medication shortages. Clinicians also need clarity and support on how to manage any shortages and discuss these issues with their patients. Many people are worried – it is up to Government to provide them with clarity and reassurance.

Government also needs to provide better clarity and visibility on the pricing and the evaluation of medicines, which can create and impact on medication shortages. Patients health should be first, and not be second to trade deals.

What can I do?

1. If you are facing a medication change due to a shortage which is not being managed by the clinician who manages your epilepsy, you have the right to question this change and request this is checked with, or that you can have a discussion with, your usual prescribing clinician before accepting the alternative medication. Your usual prescribing clinician can provide reassurance as to whether the change is appropriate for you or not, based on your medical history.
2. Your local Councillors and your local MP can play important roles in helping us make sure Government have carefully planned to protect patients should there ever be a medication shortage (whether related to Brexit or at any other time in future). They can also ask questions or raise any concerns you may have about medication changes or shortages you are facing.

If you are able, please contact your MP or local Councillors and ask them to support SUDEP Action in calling for Government to properly scrutinise the permanent changes they are making to law, and carefully plan on how patients can be protected by any impact of these changes. You can [find your MP here](#) or [your Councillors here](#). A template email you could send them is [available here](#) (please edit and add your details as required).

3. If you are able to share our messages about this issue on your social media platforms, that will be really helpful in raising awareness of this issue among the general public. Please see our social media pages for posts you can share.