



Department
of Health &
Social Care

*From the Baroness Blackwood
Parliamentary Under Secretary of State for Innovation*

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Ms Jane Hanna OBE
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By email to: jane.hanna@sudep.org

Dear Ms Hanna

Thank you for your further recent correspondence to the Prime Minister and me about Serious Shortage Protocols (SSPs). As this matter relates to health, your letter to the Prime Minister has been passed to the Department of Health and Social Care. I apologise for the delay in replying.

We understand that it is vital for patients to continue to receive the treatment that they need. As you know, the new legislation provides ministers with a further tool to ensure patients get the medicines they need.

The intention of the SSP provision is that in the event of a serious shortage of a medicine that affects or may affect the whole or any part of the UK, ministers may authorise a protocol that, in appropriate circumstances, enables community pharmacists to supply an alternative quantity, pharmaceutical form, strength, or therapeutic equivalent or generic equivalent as indicated in the protocol, without consulting the prescriber.

Any protocol would be developed by senior, specialist doctors and pharmacists, with input from national experts, royal colleges and specialist societies. If an SSP is to be authorised there would also be engagement with the relevant patient groups.

However, we have always been clear that an SSP for therapeutic or generic equivalents will not be suitable for all medicines, including anti-epilepsy medicines. This was set out in the explanatory memorandum attached to the legislative

provision. For example, those types of protocols would not be suitable for treatments for epilepsy or medicines that 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.

The complete explanatory memorandum is available at www.legislation.gov.uk by searching for 'The Human Medicines (Amendment) Regulations 2019'.

However, it is not the case that anti-epilepsy medicines would be exempt from being subject to an SSP. Under such an SSP, patients may get a smaller amount or a different strength to make up their prescription.

Additionally, pharmacists need to use their professional judgement and there may be patients with complex health needs who they may consider are not suitable for supply under an SSP. In these cases, patients would always be referred back to the prescriber for any decision about their treatment.

The operation of the SSP legislation will be reviewed one year after the first protocol has been issued. Guidance on SSPs has been published on the NHS Business Services Authority website, www.nhsbsa.nhs.uk, by searching for 'Serious Shortage Protocols (SSPs)'.

I note that you have asked to be provided with a written policy specifying the circumstances in which a death from a medicine shortage should be reported via the National Reporting and Learning System (NRLS).

Requirements for reporting patient safety incidents to the NRLS, including those resulting in death, can be found at <https://improvement.nhs.uk/home> by searching for 'report a patient safety incident'. For some types of NHS providers, including NHS trusts, reporting to the NRLS also fulfils the Quality Care Commission's (CQC's) statutory requirements for reporting incidents that affect the health, safety and welfare of patients (including deaths). In addition to the statutory reporting to the CQC that GPs and community pharmacies are required to undertake, many GPs and community pharmacies also make voluntary reports to the NRLS for learning purposes.

Patients and members of the public can make their own reports to the NRLS. In the case where SUDEP must explain to a bereaved family how incident reports are used for national learning, relevant information is available at <https://improvement.nhs.uk/home> by searching for 'patient safety review and response reports'. Information on local investigation can be found at

<https://improvement.nhs.uk/home> by searching for 'the future of NHS patient safety investigation'.

Implicit in all of this is the recognition that a death is related to an SSP or a medicines shortage in the broader sense. Bereaved families are able to contribute their knowledge of the circumstances giving rise to a loved one's death as part of the Learning from Deaths process. Similarly, medical examiners being rolled out across the country (initially focusing on deaths which occur in acute trusts) will discuss the cause of death with the next of kin/informant, establishing if they have any concerns with care that could have impacted/led to death.

I hope this reply is helpful.

Best wish

Nicola

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