

FREQUENTLY ASKED QUESTIONS (FAQs)

Q: How would a Serious Shortage Protocol work in practice?

A: A Serious Shortage Protocol (SSP) enables community pharmacists, in the event of a serious shortage of any prescribed item that affects or may affect the whole or any part of the United Kingdom, to supply in accordance with the Protocol rather than against a prescription, without going back to the prescriber.

Q: Will it be mandatory to dispense drugs against an SSP if there is one in place?

A: No. Under the Terms of Service for community pharmacists, dispensing contractors will need to consider whether it is appropriate to supply the drug to a patient in accordance with the SSP. If the patient refuses to accept the alternative, does not fulfil all the criteria set out in the protocol or, based on the pharmacist's professional judgement there are reasons why supply under the protocol is not appropriate, the pharmacist will have to refer the patient back to the prescriber to discuss alternative treatment. The decision taken not to dispense against the Protocol should be recorded, for example, on the pharmacy's patient medication record (PMR).

Q: How will an SSP help to mitigate a supply problem?

A: If the Protocol allows it, community pharmacists can supply either an alternative quantity, strength, pharmaceutical form or medicine. Each Protocol would clearly set out what action can be taken by the pharmacist, under what circumstances, for which patients and during which period as part of managing the shortage for the affected medicine(s). Implementing the protocol will support patients in being able to access their medicines in a timely manner, whilst also easing pressure on both pharmacy and GP contractors as part of responding effectively to a medicine shortage(s).

Q: What happens if a patient requires a specific medicine and is unable to receive alternative medicine under the SSP?

A: Protocols will not be suitable for all medicines and patients. Patients with complex health needs may not be considered suitable for supply under an SSP. In these cases, patients would always be referred to the prescriber for any decision about their treatment, before any therapeutic or generic alternative is supplied.

Q: Will Protocols have a time limit?

A: Any UK-wide or NI specific Protocol would be limited in time and would clearly set out the period for which it has effect. The end date for an SSP may be reviewed and amended as supply situations change.

Q: Would the issuing of a Protocol become a regular occurrence?

A: With the number of existing measures already in place to manage supply issues, issuing an SSP for a serious shortage would likely only occur under exceptional circumstances.

Q: Why can patients not receive an alternative under an SSP for every medicine that is affected by a shortage?

A: It would not be appropriate to issue an SSP for every medicine shortage as a number of other measures are in place to mitigate medicine shortages. The introduction of an SSP would only likely be considered in exceptional circumstances. Furthermore, serious shortages could potentially affect medicines for which there is no alternative available to supply under a protocol and therefore an SSP would not be issued. Consideration will also be given on whether using the alternative under an SSP could, in turn, potentially lead to a shortage of that product.

Q: Will there be a limit on how many SSPs will be in place at any one point?

A: There is no limit on how many Protocols could be in place at any one point. However, an SSP will not always be issued for a serious medicine shortage. This depends on whether other measures have already been used to mitigate the supply problem, and whether an SSP is deemed necessary.

Q: What do I do with a prescription for an item where an SSP is in place, once I have dispensed in accordance with the relevant protocol?

A: It is important to note that, once a supply under the SSP is made, even if it is for a lesser quantity of the medication than prescribed, the prescription for the item listed to which the SSP applies is no longer valid, and no further supply can be dispensed against it. The pharmacist will need to endorse it to that effect when they make the SSP supply. For patients to receive further medication on prescription, they would need to go back to their prescriber.

It is important to remember that all other items on the prescription remain valid.

A decision not to dispense against an SSP should be documented on the pharmacy's Patient Medication Record (PMR) system.

Q: Does the introduction of SSPs allow pharmacists to dispense whatever alternative medicine they like without consulting patients/prescribers?

A: No, they can only supply in accordance with the Protocol.

SSPs are an additional tool that are to be issued in the exceptional and rare circumstance that existing measures to mitigate supply issues are not appropriate. It would be issued for a time limited period only and would explicitly state what alternative treatment can be supplied under the protocol **with** the patient/carer's consent. Under the Human Medicines Regulations 2012, pharmacists must dispense in accordance with the prescription. They are not able to deviate from this unless there is a valid SSP in place for the affected medicine, for which they must follow what is set out within the Protocol.

Where the patient does not consent to receive an alternative supply under an SSP, or where pharmacists use their professional judgement to determine that the alternative treatment options listed on the SSP are not suitable for the patient, they should either direct the patient back to their prescriber to discuss alternative treatment, or if there is an urgent need - contact the prescriber, discuss an alternative and then get the prescription changed by the prescriber.

Q: When and how does a Pharmacist notify the GP of supply under an SSP?

A: The patient's GP must be informed when a therapeutic substitution is made under an SSP or when notification of the SSP is specifically required under the terms of a specific SSP. A notification template/form is available on the BSO website in order to assist with this. Notification in these cases must be made with reasonable promptness and pharmacists should aim to forward the information within 3 working days.

Q: How does a Pharmacist endorse a product supplied under an SSP?

A: Contractors will need to endorse the prescription to show that a supply was made in line with an SSP and any other endorsements as appropriate for the product. Details on what endorsement to use to show that a supply was made in line with an SSP will be detailed on the SSP section of BSO's website <http://www.hscbusiness.hscni.net/services/3063.htm>

Q. How does a Pharmacist label the medicine when supplying under an SSP and what record must be kept?

A. The dispensing label that is applied to any product supplied under an SSP needs to indicate that the supply was made under an SSP and include the reference number of the SSP. This will ensure that patients know which of their medicines was supplied under an

SSP. If they need further advice, any healthcare professional (including their prescriber) can access information specific to that SSP using the reference number.

To create a label for what it is intended to supply, the same process should be followed as would be the case in relation to a paper prescription. The supply against an SSP should then be referenced in the Patient Medication Record (PMR) system.

Q: What professional indemnity does a Pharmacist have when supplying under an SSP?

A: Supply under an SSP is no different from any other supply where the dispensing pharmacist makes the decision to treat patients rather than a prescriber, such as under a Patient Group Direction. The supply is the professional responsibility of the pharmacist under whose supervision it takes place. The Protocol offers a gateway to lawful supply under the Human Medicines Regulations 2012 and reassurance that action is being taken in accordance with a respectable body of professional and clinical opinion during a serious shortage.

When supplying in accordance with an SSP, pharmacists should confirm allergy status with the patient/carer and, if considered necessary, the pharmacist may wish to check with the patient's GP. This should then be documented as necessary, for example, on the pharmacy's patient medication record (PMR) system. Pharmacists are also advised to check with their professional indemnity insurance providers to ensure that cover applies to supplies made in accordance with SSPs.

Q: Do SSPs apply to dispensing doctors' practices?

A: Yes, and their Terms of Service has been amended to reflect this change. However, where the prescribing and supply functions sit within a dispensing practice, there is also scope for the dispensing doctor to review the prescription and amend accordingly, rather than to supply under a Protocol.