December 2022

# Serious Shortage Protocols (SSPs) - a guide for Community Pharmacy Teams

This briefing is adapted from the PSNC Briefing 023/19: June 2021. The document describes how Serious Shortage Protocols (SSPs) will work in practice and provides guidance to community pharmacists and their teams on what you need to do if and when an SSP is put in place.

## Introduction

Generally, prescription only medicines may be sold or supplied only in accordance with a prescription issued by an appropriate practitioner, such as a GP (regulation 35 of the Medicines (Human and Veterinary) (Bailiwick of Guernsey) Law, 2008). This regulation is subject to various exemptions, including for example Patient Group Directions, which are specific and subject to conditions. Serious Shortage Protocols (SSPs) are another, new exemption.

SSPs are a potential way to help pharmacies to manage any serious shortages of medicines that may occur, without needing to refer patients back to prescribers. It is important to note that although legislation will permit the issuing of SSPs from December 2020, an SSP will only be considered and issued if there is a serious shortage of a specific medicine.

If, in the office-holders opinion, such as Chief Pharmacist, there is, or may be, a **serious shortage** of a medicine or appliance then they may consult, for instance with medical experts, and decide to issue an SSP. The SSP will specify an alternative product or quantity that may be supplied (an alternative strength or formulation, or generic or therapeutic alternative or less of the product) by community pharmacies. Community pharmacists **must consider the SSP and**, if, in the **supervising pharmacist's opinion** – exercising their professional skill and judgment – the alternative product or quantity is **reasonable and appropriate for the patient**, they may supply the alternative product or quantity (only as specified in the SSP and subject to any conditions in the SSP), provided that the **patient consents/agrees** to the alternative SSP supply.

The dispensed SSP product must be labelled to show that supply has been made in accordance with the SSP and identify the SSP (usually by its number) and the prescriber of the original product (that has not been dispensed) may need to be notified.

Changes to certain medicines, even where they are in short supply, will not be suitable for some patient groups – for example those with epilepsy, where changing a patient's medicine brand or generic manufacturer could cause harm to the patient. SSPs will only specify changes to specific medicines that medical experts believe to be appropriate; and pharmacists will always have the professional discretion not to supply an alternative to any individual patient.

## Section A: The use of SSPs

### Legislation

In March 2019, the Medicines (Human and Veterinary) (Bailiwick of Guernsey) Law, 2008 was changed to introduce Serious Shortage Protocols (SSPs) in relation to prescription only medicines (POMs), with effect from 31st December 2020.

## When may an SSP be introduced?

In the Bailiwick of Guernsey, the office-holder, such as the Chief Pharmacist, may issue an SSP if, in their opinion, there is, or may be, a serious shortage of a medicine or appliance in the United Kingdom or Bailiwick of Guernsey. A serious shortage is not defined, but arguably denotes more than a simple shortage that may be resolved by other measures.

Most medicine supply disruptions or shortages are resolved by the Department of Health and Social Care (DHSC) and are unlikely to be considered serious shortages; this often involves the agreement of concession (higher) prices in the Drug Tariff, to provide reimbursement for pharmacists obtaining those medicines for Health Benefit Supply.

SSPs will be introduced only with the involvement of clinicians (doctors and pharmacists); and, as appropriate, after consultation with relevant patient groups, the Department for Health and Social Care, NHS Business Services Authority, relevant manufacturers and relevant pharmacy organisations.

## What are the different types of SSP?

SSPs may be used to provide authority for supply of:

- **An alternative quantity** - to restrict the supply of a product if it may be subject to a serious shortage, to ensure any remaining stock is retained by community pharmacies for supply to patients who have particular need of it;
- **An alternative formulation** - if there is or may be a serious shortage of one formulation (e.g. capsule), another formulation may be supplied (e.g. tablet);
- **An alternative strength** - if there is or may be a serious shortage of one strength (e.g. 20mg), a different strength may be supplied (e.g. 10mg); the dose remains that prescribed by the doctor (on the prescription);
- **A generic equivalent** - if there is or may be a serious shortage of a product, a generic equivalent (or branded equivalent) or the separate constituent parts of the product may be supplied; or
- **A therapeutic equivalent** - if there is or may be a serious shortage of a product, a therapeutic equivalent (i.e. a medicine with a different active substance) may be supplied).

An SSP may provide for one or more of these options and will be issued from a specific date and have an end date, which may be revised.

Only the alternative product or quantity specified in the SSP may supplied in accordance with an SSP and only subject to any conditions specified in the SSP.

## How will I know if there is an SSP?

Any SSPs will be published on a dedicated section of the States of Guernsey website Medicines funded by the States of Guernsey - States of Guernsey (gov.gg) and the Committee *for* Health & Social Care will use their various communications channels to alert pharmacy teams to its publication.

## Section B: What's included in an SSP?

SSPs will be broken down into various sections, similar to Patient Group Directions, providing the following types of information:

| | |
|---|---|
| **SSP heading and number** | This section will provide the number of the SSP. |
| **Name of medicine**<br>**Quantity (if applicable)**<br>**Legal category** | This section will specify inclusion criteria which must be met if an SSP is to be used.<br>It will include the prescribed medicine subject to serious shortage to which the SSP will apply. |
| **Part of the country to which the SSP applies** | There may be geographical restrictions on the use of the SSP, e.g. only for use in a specific region. |
| **Scope** | This section could specify community pharmacy. |
| **Criteria for inclusion** | This section could specify that the patient must present a valid prescription and consent/agree to receiving the alternative medicine. |
| **Criteria for exclusion** | This section could specify that the SSP will not apply where the pharmacist determines that the patient is not suitable to receive alternative medication under this SSP. |
| **Cautions including any relevant action to be taken** | This section may include relevant reference to expert advice. |
| **Special considerations for specific populations of patients** | This section may include special considerations to be taken for certain patient groups. |
| **Action to be taken if the patient is excluded** | This section could include advice to refer the patient back to the prescriber. |
| **Action to be taken if a patient or carer declines the supply** | This section could include advice to refer the patient back to the prescriber. |
| **Valid from Review date Expiry date**<br>**Reference number Version number / Gateway number** | There will be dates between which the SSP is valid and any changes to the SSP since it was first issued will be identified. |
| **Conditions** | This section may state that the decision to supply in accordance with an SSP rests with the supervising pharmacist. |
| **Details of the medication to be supplied under the SSP** | In this section of the SSP, one or more of the following will be specified for supply:<br>a) an alternative quantity of the medicine specified within the original prescription is to be supplied;<br>b) an alternative formulation of the medicine specified within the original prescription is to be supplied;<br>c) an alternative strength of the medicine specified within the original prescription is to be supplied;<br>d) a generic version, alternative branded version or the separate constituent parts of the named medicine specified within the original prescription is/are to be supplied; or<br>e) a therapeutic alternative to the medicine specified within the original prescription is to be supplied. |

Generic information contained within an SSP is likely to state that the pharmacist must confirm that:

- the presented prescription is valid (i.e. contains all the requirements of the Medicines (Human and Veterinary) (Bailiwick of Guernsey) Law, 2008) and in date;
- the patient or their parent/guardian or carer consents to receiving the medicine supplied under the SSP;
- the patient has no known previous hypersensitivity or severe reaction or clinically significant allergy to the alternative medicine in the SSP;
- The prescription is not for a controlled drug;
- The supply is not an emergency supply (i.e. there is a prescription);
- Special considerations will also need to be taken for certain patient groups due to extreme age, neurological disability or mental health.

## Section C: Dispensing in accordance with an SSP

When a pharmacy receives a prescription covered by an SSP (for a product for which there is a serious shortage) the following are important considerations:

### Patient

**Patient consent** – a patient must consent/agree to supply of an alternative product or quantity, in accordance with the SSP.

### Community Pharmacy

**Pharmacists must consider the SSP** – the pharmacist must consider the SSP against any relevant prescriptions. The pharmacist is not obliged to make a supply because a supply may only be made if in the opinion of the supervising pharmacist this is reasonable and appropriate; and subject to other relevant considerations.

**Supply to the patient must be reasonable and appropriate in the opinion of the supervising pharmacist** – supply may only take place if in the opinion of the supervising pharmacist – exercising his or her professional skill and judgement – this is reasonable and appropriate. The key question is that while the instructions within the SSP may be generally applicable, are they both reasonable and appropriate, for supply of the alternative product or quantity to the individual patient.

**Supply in accordance with the SSP** – supply of an alternative product or quantity in accordance with an SSP must be in accordance with a valid (in date) SSP and subject to any conditions within that SSP.

**Reasonable promptness** – if pharmacists supply in accordance with an SSP, they must do so with reasonable promptness.

**Labelling** – the dispensing label must include information to the effect that the product is supplied in accordance with an SSP and identify the SSP (usually by its number). This generally will be achieved by free typing in the directions field of the label, e.g. 'Supplied under Serious

Shortage Protocol number 002'.

### Notifying the prescriber

If supply is in accordance with a therapeutic substitution SSP, and a different medicine of a similar therapeutic effect is supplied to the patient, the contractor must notify the patient's general practice of the alternative SSP supply.

### Supply in accordance with an SSP is not reasonable or appropriate

If the supervising pharmacist considers that it is not reasonable or appropriate to supply in accordance with the SSP, the pharmacist has a number of alternatives, as follows:

- The pharmacist may supply the originally prescribed medicine or appliance, if able to do so within a *reasonable timescale. Reasonable timescale* is not defined; it denotes some urgency but not as much as reasonable promptness; or
- The pharmacist may refuse to supply the patient, if unable to supply the originally prescribed medicine or appliance within a *reasonable timescale*; if so, the patient or the patient's representative requesting the product, must be provided with appropriate advice, as necessary, about returning to the prescriber for the prescriber to review the patient's treatment. It might not be necessary to advise the patient to return to the prescriber, if the patient can be directed to a community pharmacy which has stock of the originally prescribed medicine.

## Section D: Frequently asked questions

**When may supply in accordance with an SSP be refused?**

Pharmacists may refuse to supply an alternative product or quantity in accordance with the SSP, if the supervising pharmacist considers that supply of the different or alternative product or quantity is unreasonable or inappropriate. Pharmacists must refuse to supply an alternative product or quantity in accordance with the SSP, if such a supply has already been made in accordance with the presented prescription.

**Do patients have to consent/agree to SSP supplies?**

Yes, patient consent/agreement is required for supply of an alternative product or quantity in accordance with an SSP.

**Do patients pay prescription charges for SSP supplies?**

Generally, prescription charges are payable for the supply of alternative products in accordance with SSPs, if they were payable for supply under the original prescription.

## Section E: Endorsing a product supplied in accordance with an SSP

Correct endorsements are required to claim the relevant remuneration and reimbursement. The endorsement of a product or quantity supplied under an SSP will be as if the product had been supplied against a prescription; and the correct prescription charge or exemption declaration will need to be applied, as with an original prescription.

Endorsement on the prescription may be:

**For a paper prescription** - on the paper prescription

**What endorsements are required to indicate supply in accordance with an SSP?**

The endorsement uses the code GSSP followed by the three-digit reference number applicable to the SSP for example, SSP001 for phenoxymethylpenicillin would be endorsed as 'GSSP 001'. The prescription should then be endorsed with the product supplied, this will enable pay on dispensed, in place of pay for what is prescribed.

At the month end, place all prescriptions that have been supplied using the SSP at the front of the bundle prior to submitting to CfHSC via ESS.

When supplying in accordance with these SSPs, pharmacists should refer to the updated endorsement guidance for each SSP available on States of Guernsey website Medicines funded by the States of Guernsey - States of Guernsey (gov.gg)

## Section F: Further support and guidance

CfHSC aim to support pharmacists in the implementation of SSPs and further guidance may be published in due course for each SSP issued by an office holder.

If you have queries on this briefing or you require more information, You can get in contact by:

**Email:** PSU@gov.gg
**Telephone:** +44 (0)1481 220000