Dispensing and Supply

June 2021

PSNC Briefing 023/19: Serious Shortage Protocols (SSPs) – a guide for community pharmacy teams

This PSNC Briefing describes how Serious Shortage Protocols (SSPs) will work in practice and provides guidance to community pharmacy contractors and their teams on what you need to do if and when an SSP is put in place.

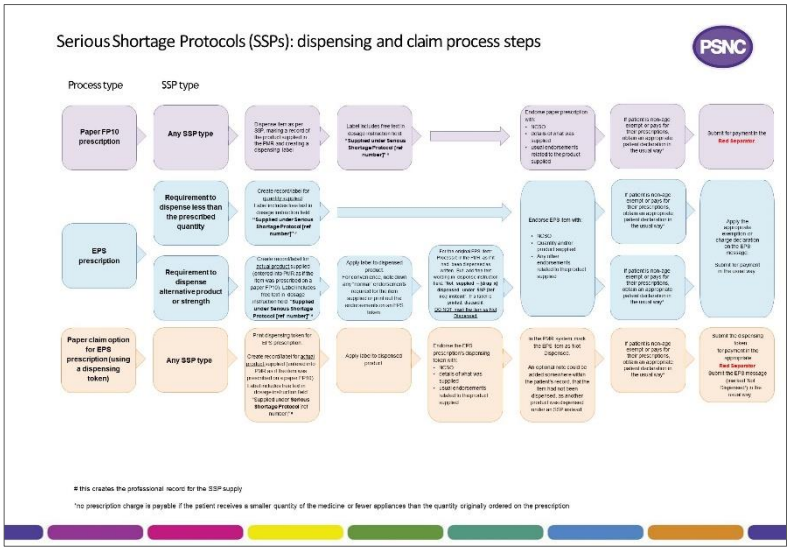
Introduction

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 214 of the Human Medicines Regulations 2012). 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 1st July 2019, an SSP will only be considered and issued if there is a serious shortage of a specific medicine.

If, in the Secretary of State for Health and Social Care's opinion, there is, or may be, a **serious shortage** of a medicine or appliance then he or she 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 pharmacy contractors **must consider the SSP and**, if, in the **supervising pharmacist's opinion** – exercising his or her 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. For reimbursement and remuneration, the appropriate endorsement must be made as provided for in the Drug Tariff and, following the supply of the alternative product or quantity, the prescription (in relation to which the SSP supply was made) is no longer valid. A flow diagram of the process is available on the PSNC website.



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 February 2019, the Human Medicines Regulations 2012 (HMRs) were amended to introduce Serious Shortage Protocols (SSPs) in relation to prescription only medicines (POMs).

In June 2019, the NHS (Amendments Relating to Serious Shortage Protocols) Regulations 2019 were laid before Parliament and come into force on 1st July 2019. These amendments broaden the scope of SSPs to all medicines and appliances. They also provide a framework for use of SSPs within NHS pharmaceutical services; and SSPs become part of the Essential Dispensing Service in Schedule 4 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (NHS Pharmaceutical Regs).

PSNC will alert contractors as soon as an SSP is issued via our usual website and email newsletter communication channels.

When may an SSP be introduced?

In England, the Secretary of State may issue an SSP if, in his or her opinion, there is, or may be, a serious shortage of a medicine or appliance in England or any part of England. 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 contractors obtaining those medicines for NHS supply.

DHSC has indicated that SSPs will be introduced only with the involvement of clinicians (doctors and pharmacists); and, as appropriate, after consultation with relevant patient groups, the devolved administrations, NHS England and Improvement, relevant manufacturers and relevant pharmacy organisations including PSNC.

Are SSPs related to no-deal Brexit planning?

SSPs are part of wider Government measures that seek to avoid and manage shortages of medicines. These measures include well established procedures, such as concession prices; as well as more recent contingency arrangements associated with Government planning for any no-deal Brexit (the UK leaving the EU without an agreement). Although SSPs are linked to planning for any no-deal Brexit, they are not dependent on it.

Is there an additional dispensing fee for SSPs?

If an SSP is introduced, contractors will receive a fee of £5.35 per item for any necessary supply in accordance with SSPs (in addition to usual dispensing fees for the item).

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 NHS Business Services Authority's (NHSBSA) website, and PSNC and NHS England and Improvement will use their various communications channels to alert pharmacy contractors to its publication.

PSNC has a page on its website so that contractors can easily access all the latest information and communications on SSPs. NHS England and Improvement should be able to send contractors an email to their pharmacy premises shared NHSmail account with the link to the NHSBSA's website when new SSPs or amendments to existing SSPs are published.

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 **Quantity (if applicable)** **Legal category**	This section will specify inclusion criteria which must be met if an SSP is to be used. 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** **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: a) an **alternative quantity** of the medicine specified within the original prescription is to be supplied; b) an **alternative formulation** of the medicine specified within the original prescription is to be supplied; c) an **alternative strength** of the medicine specified within the original prescription is to be supplied; 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 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 contractor must confirm that:

- the presented prescription is valid (i.e. contains all the requirements of the Human Medicines Regulations) 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.

DHSC will provide guidance and may provide a standard template for SSPs.

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.

Prescription charge – no prescription charge is payable if the patient receives a smaller quantity of the medicine or fewer appliances than the quantity originally ordered on the prescription. Otherwise, if the patient pays a prescription charge, this remains payable for supply in accordance with an SSP.

Community Pharmacy

Contractors must consider the SSP – the contractor must consider the SSP against any relevant prescriptions. The contractor 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 contractors 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. In the absence of any preferred local communication route, or a communication route specified in the SSP, prescribers could be notified using NHSmail.

Notification is also necessary for those SSPs that the Secretary of State and PSNC, acting jointly, have published a recommendation that such notification is necessary for clinical reasons. It is likely that this would be specified in the SSP.

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 contractor has a number of alternatives, as follows:

- The contractor 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 contractor 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?

Contractors 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. Contractors 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. The exception to this is that no prescription charge is payable if the patient is supplied with a smaller quantity of drug or fewer appliances than originally prescribed. This exception was proposed by PSNC and accepted by DHSC Ministers in order that patients that pay the prescription charge are not disadvantaged by the use of an SSP.

Do the other provisions of the terms of service apply to SSP supplies?

Yes. SSPs are now part of the Essential Dispensing Service, part of Schedule 4 of the NHS Pharmaceutical Regulations and, broadly, the terms of service apply; including, for example, that contractors must provide appropriate advice as required and maintain appropriate records.

Specific amendments in the NHS (Amendments Relating to Serious Shortage Protocols) Regulations 2019, to ensure the terms of service are relevant to SSPs, include:

- Measuring and fitting for appliances (Reg. 8 (4))
- Relevant standards and formula (Reg. 8 (5))
- Original pack dispensing (Reg. 8 (10))
- Suitable containers (Reg. 8 (15))
- Alternative to referral for an appliance (Reg. 10 (2)(b)

What about reimbursement, remuneration and endorsements for SSP supplies?

Reimbursement – is for the medicine supplied in accordance with an SSP, not the originally prescribed medicine or appliance.

Remuneration – the same fees and allowances are paid for SSP supplies as are paid for medicines and appliances supplied against prescriptions. In addition to the usual dispensing fees for the item, contractors receive an SSP fee of £5.35 per item for any necessary supply in accordance with SSPs.

The next section of this briefing 'Endorsing a product supplied in accordance with an SSP' provides information on endorsements. Contractors who supply in accordance with an SSP must endorse the prescription with the information required as per Clause 9E, Part II of the Drug Tariff.

Q. I have received a prescription for 'Drug X' 28 tablets. I only have 14 tablets in stock, however, there is a valid SSP in place for 'Drug X' allowing substitution of tablets to capsules. Can I dispense the 14 tablets of 'Drug X' that I have in stock and use the SSP to supply the remaining balance as capsules?

A. No. Should you wish to use the stock you currently have on your shelf you should dispense the prescription as per usual processes, clearly endorsing the quantity to show that 14 tablets only were dispensed. Alternatively, you can consider supply of the capsules in accordance with the SSP for 'Drug X'.

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

Correct endorsements are required to claim the relevant remuneration and reimbursement set out in the Drug Tariff. 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 NHS prescription.

Endorsement on the prescription may be:

For an electronic prescription - either using the EPS Reimbursement Endorsement Message, or its associated dispensing token (until October 2021)

For a paper prescription - on the paper prescription

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

When SSPs were first introduced, pharmacy contractors were required to endorse the prescription or token with 'NCSO' (No Cheaper Stock Obtainable) to indicate that a supply was made in accordance with an SSP.

However, from 1 June 2021, the Department of Health and Social Care (DHSC) has approved the use of a new endorsement to claim for any supplies made in accordance with an SSP. **The new endorsement uses the code 'SSP' followed by the three-digit reference number applicable to the SSP for example, SSP007 for Fluoxetine 30mg capsules would be endorsed as 'SSP 007'**.

To allow for implementation of this new SSP endorsement functionality, a transition period (1 June – 5 October) has been agreed to enable use of the existing 'NCSO' endorsement until the beginning of October 2021 (to include September SSP claims, submitted by the 5 October). During the transition period, the NHS Business Services Authority (NHSBSA) will accept either the new 'SSP' or existing 'NCSO' endorsement for any SSP claims submitted using electronic prescriptions, EPS tokens of FP10 paper prescriptions.

The use of the 'SSP XXX' or 'NCSO' endorsement will indicate to the NHSBSA that an SSP was used, i.e. that the originally prescribed product was not dispensed by the pharmacy and a different quantity or product was supplied in accordance with an SSP.

After the transition period only the new SSP endorsement will be accepted by the NHSBSA on electronic and paper prescriptions. Any SSP claims made using EPS tokens after October 2021 will no longer be accepted for payment.

Details of the new SSP endorsement and transitional arrangements are outlined in **June 2021 Drug Tariff** (Part II Clause 9E). These changes are also reflected in PSNC's updated SSP endorsing guidance (see link below)

PSNC Briefing 011/21: Serious Shortage Protocols (SSPs) updated endorsing guidance

When supplying in accordance with these SSPs, contractors should refer to the updated endorsement guidance for each SSP available on **NHSBSA's SSP page**.

Why has a new endorsement for SSPs been introduced?

When SSPs were first introduced in 2019, the use of the 'NCSO' endorsement was agreed as a temporary workaround to claim for supplies made in accordance with an SSP. Since then, work has been underway by the NHSBSA and NHS Digital to introduce the new SSP endorsement functionality into dispensing systems.

Although most dispensing systems now have this new SSP endorsement functionality, its availability will depend on the speed of its roll-out to users by system suppliers. From June 2021, contractors are encouraged to start using this new SSP endorsement functionality, where available, to claim for any supplies made in accordance with SSPs. If the new SSP endorsement functionality is not yet available to users of certain dispensing systems, contractors can continue to use the existing 'NCSO' endorsement option until the beginning of October 2021 (to include September SSP claims, submitted by the 5 October).

Other key updates

- For a Multiple Dispensed Product SSP – where a prescribed item is replaced by two or more items (for example, SSP007 for Fluoxetine 30mg capsules allows for the 10mg and 20mg capsules to be supplied instead of the prescribed Fluoxetine 30mg capsules), some dispensing systems may accommodate the new SSP endorsements for both replacement items whereas other systems may only accommodate endorsement of one replacement item. Where only one of the replacement products can be endorsed, the NHSBSA will add and reimburse the other replacement items.
- Specific SSP endorsement guidance also applies to replacement product(s) which are not listed in Part VIII of the Drug Tariff.

Section F: Further support and guidance

PSNC aim to support contractors in the implementation of SSPs and further guidance may be published in due course for each SSP issued by HM Government.

If you have queries on this PSNC Briefing or you require more information, please contact as follows depending on the nature of your query:

- **Legislation and regulatory issues** – Gordon Hockey, Director of Operations and Support (Gordon.Hockey@psnc.org.uk)
- **Reimbursement and endorsement issues** – Suraj Shah, Drug Tariff and Reimbursement Manager (Suraj.Shah@psnc.org.uk) and/or PSNC's Dispensing and Supply Team (info@psnc.org.uk)
- **EPS and IT issues** – Daniel Ah-Thion, Community Pharmacy IT Lead including PMR supplier queries (Daniel.Ah-Thion@psnc.org.uk)
- **Media enquiries** – PSNC's Communications Team (commsteam@psnc.org.uk)