

## 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.

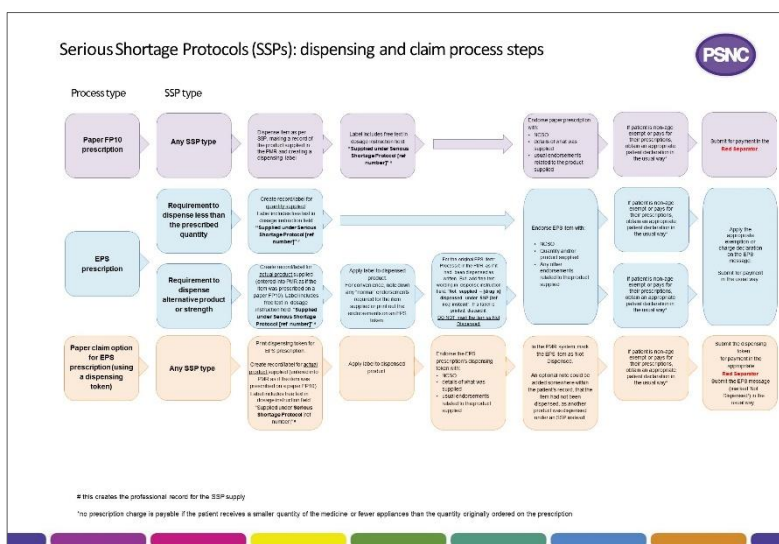
### Introduction

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?

An additional fee for dispensing a medicine or appliance in accordance with an SSP is under discussion between PSNC and DHSC.

### 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 be 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:

<b>SSP heading and number</b>	This section will provide the number of the SSP.
<b>Name of medicine</b> <b>Quantity (if applicable)</b> <b>Legal category</b>	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.
<b>Part of the country to which the SSP applies</b>	There may be geographical restrictions on the use of the SSP, e.g. only for use in a specific region.
<b>Scope</b>	This section could specify community pharmacy.
<b>Criteria for inclusion</b>	This section could specify that the patient must present a valid prescription and consent/agree to receiving the alternative medicine.
<b>Criteria for exclusion</b>	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.
<b>Cautions including any relevant action to be taken</b>	This section may include relevant reference to expert advice.
<b>Special considerations for specific populations of patients</b>	This section may include special considerations to be taken for certain patient groups.

<b>Action to be taken if the patient is excluded</b>	This section could include advice to refer the patient back to the prescriber.
<b>Action to be taken if a patient or carer declines the supply</b>	This section could include advice to refer the patient back to the prescriber.
<b>Valid from</b> <b>Review date</b> <b>Expiry date</b> <b>Reference number</b> <b>Version number</b> <b>Gateway number</b>	There will be dates between which the SSP is valid and any changes to the SSP since it was first issued will be identified.
<b>Conditions</b>	This section may state that the decision to supply against an SSP rests with the supervising pharmacist.
<b>Details of the medication to be supplied under the SSP</b>	In this section of the SSP, one or more of the following will be specified for supply: a) an <b>alternative quantity</b> of the medicine specified within the original prescription is to be supplied; b) an <b>alternative formulation</b> of the medicine specified within the original prescription is to be supplied; c) an <b>alternative strength</b> of the medicine specified within the original prescription is to be supplied; d) a <b>generic version, alternative branded version or the separate constituent parts</b> of the named medicine specified within the original prescription is/are to be supplied; or e) a <b>therapeutic alternative</b> 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. An additional fee payable to contractors for dispensing SSPs is still under discussion between PSNC and DHSC.

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 by the Drug Tariff.

## 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 and the following advice may be revised once the relevant Drug Tariff provisions are available.



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 a paper prescription - on the paper prescription;
- For an electronic prescription - either on the dispensing token or using the EPS Reimbursement Claim Message.

### **What endorsements are required to indicate supply against an SSP?**

Pharmacy teams will endorse the prescription with 'NCSO' (No Cheaper Stock Obtainable) to indicate that a supply was made in accordance with an SSP. They will need to endorse the supplied quantity, the pack size from which the order was supplied and, where required, the brand name or name of the manufacturer or suppliers from which the supply was purchased; as well as an invoice price if there is no list-price available on dm+d.

The use of the NCSO endorsement was selected by DHSC because it has not been used for its original purpose since April 2013 (the price concession system applies a new temporary drug reimbursement price for a month, if granted by DHSC).

The use of the 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.

### **What is the correct process for endorsement?**

To ensure correct payments (fees and reimbursement) for products supplied under an SSP, a contractor is required to endorse either the original electronic prescription or its associated dispensing token, or where issued, the paper prescription, with the following information:

- **NCSO** – to indicate that the supply was made in accordance with an SSP;
- **Details of product supplied in accordance with the SSP** (drug name, quantity, strength, formulation, supplier name or brand)\*;
- **Quantity supplied\***;
- **Pack size** – best practice where multiple pack sizes are available; and
- **Invoice price** – only if NHSBSA has no list-price available on dm+d.

*\* The drug details and quantity supplied and endorsed will depend on the specific SSP.*

Further details on SSP endorsements may be made available once the relevant Drug Tariff provisions have been published.

### **Can I use 'PC' or 'PNC' endorsement instead?**

No. The 'PC' (Prescriber Contacted) or 'PNC' (Prescribed Not Contacted) endorsement cannot be used as a substitute endorsement for supply in accordance with SSPs. 'PC' endorsement is used when there is a missing dose, drug strength and/or quantity and the prescriber is contacted to confirm the missing details; 'PNC' endorsement is used when a prescription is presented with a missing presentation, strength or quantity and the prescriber cannot be contacted.

### **Example:**

Using an example SSP, the following steps outline how to apply NCSO endorsements using a paper prescription, an EPS prescription or its corresponding EPS dispensing token.

The example below is for an alternative strength of a drug to be supplied - Atenolol 50mg tablets (identified as being in serious shortage) - and the SSP specifies an alternative supply of double the quantity of the lower strength Atenolol 25mg tablets. The dose remains the prescribed 50mg daily, therefore, the instructions to the patient change from 'Take one daily' (1 x 50mg) to 'Take two daily' (2 x 25mg).

### Example 1. Paper prescriptions

Pharmacy Stamp		Age 74	Title, Forename, Surname & Address A.N. Other 123 High Street Onetown AB12 3CD
Please don't stamp over age box		DoB 1.1.1945	
Number of days' treatment N.B. Ensure date is stated			
NCSO	Atenolol 50mg tablets		
Atenolol 25 mg tablets	28 tablets		
56/28	Take one daily		

RED SEPARATOR

The steps involve:

- a) Endorse the paper prescription with 'NCSO', along with details of the alternative strength and quantity supplied (Atenolol 25mg tablets x 56).
- b) Ensure the reverse of the prescription is completed by the patients as usual, by making the correct charge paid or exemption declaration.
- c) Place the endorsed paper FP10 in a **red separator** to ensure correct payment.

### Electronic prescriptions

For electronic prescriptions, contractors have the option to endorse either electronically or using a paper-based method (dispensing token). A transitional provision permits the use of dispensing tokens instead of the original electronic prescription to submit claims for payment to the NHSBSA. Where used, a dispensing token is regarded as the prescription for payment purposes and will also be used as a record of supply for prescription charge purposes (including charge exemptions and remission of charges). The transitional arrangements are likely to remain in place for as long as required by contractors.

If the product or quantity supplied in accordance with an SSP is endorsed on a dispensing token, the EPS Reimbursement Claim Message should be marked as 'Not Dispensed' before being submitted to the NHSBSA.



## Example 2. Electronic prescriptions – endorse using the dispensing token

Age 74		Title, Forename, Surname & Address	
D.o.B 01.01.1945		Mr A.N. Other 123 High Street Onetown AB12 3CD NHS Number:	
Prescribed Medication		<b>DISPENSING TOKEN</b>	
<b>NCSO</b>	Atenolol 50mg tablets	<b>BARCODE</b>	
<b>Atenolol 25 mg tablets</b>	28 tablets		
<b>56/28</b>	Take one daily		
DISPENSING TOKEN – Not to be used as a prescription, even if signed by an authorised prescriber.		Date	
		FP10DT0515	

The steps involve:

- a) Endorse the dispensing token with 'NCSO' along with details of the alternative strength and quantity supplied (Atenolol 25mg tablets x 56).
- b) Mark the EPS Reimbursement Claim Message as 'Not dispensed' (for the product on the electronic prescription to which the SSP supply relates).
- c) Submit the EPS Reimbursement Claim Message to the NHSBSA, even if the electronic prescription contains just the one product covered by the SSP. (The NHSBSA may conduct an audit of SSP claims to ensure there is no double-claiming by matching the submitted dispensing tokens with NCSO endorsement in accordance with the EPS 'Not dispensed' claims submitted electronically).
- d) Ensure the reverse of the dispensing token endorsed NCSO is completed by the patients as usual, by making the correct charge paid or exemption declaration.
- e) Place all NCSO-endorsed dispensing tokens in the **red separator** to ensure payment. (If NCSO-endorsed tokens are mixed in with the other tokens sent as part of usual monthly submission process (paid and exempt

tokens except for age-exempt) these claims for SSP supplies will not be processed by the NHSBSA for payment).

- f) Do not submit multiple tokens for the same electronic prescription form for payment.

### Example 3. Electronic prescriptions – endorse electronically using the EPS Reimbursement Claim Message

All pharmacy system suppliers allow endorsement of NCSO using EPS, but the format is determined by the pharmacy system used.

The steps involve:

- a) Select the NCSO endorsement on the EPS Reimbursement Claim Message and fill in the details of the strength and quantity supplied (Atenolol 25mg tablets x 56).\*
- b) Do NOT mark the originally prescribed product as ‘Not dispensed’.
- c) Apply the correct exemption or charge declarations on the EPS Reimbursement Claim Message and associated dispensing token (other than for age-exempt tokens). These dispensing tokens should be submitted in the usual way.
- d) Do NOT endorse ‘NCSO’ on the associated dispensing token - this could lead to delays in payment due to further investigation by the NHSBSA.

*\* Some systems allow selection of the alternative product dispensed and pre-populate the NCSO endorsement fields (e.g. pharmacists initials, date, alternative drug selected) reducing the need for pharmacists to manually input the required information to the NCSO free-text field. Other pharmacy systems do not allow selection of an alternative product to the originally prescribed product and the endorsements including details of the alternative product supplied may need to be manually added to the NCSO endorsement free-text field.*

Your PMR supplier may issue additional system-specific guidance to explain how to use the NCSO endorsement for SSP purposes.

Contractors are advised to adopt a policy for endorsing electronic prescriptions, to ensure accurate claims are made and that these are paid by the NHSBSA.

## 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](mailto:Gordon.Hockey@psnc.org.uk)) or William Goh, Regulations Officer ([William.Goh@psnc.org.uk](mailto:William.Goh@psnc.org.uk))
- **Reimbursement and endorsement issues** – Suraj Shah, Drug Tariff and Reimbursement Manager ([Suraj.Shah@psnc.org.uk](mailto:Suraj.Shah@psnc.org.uk)) and/or PSNC’s Dispensing and Supply Team ([info@psnc.org.uk](mailto: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](mailto:Daniel.Ah-Thion@psnc.org.uk))
- **Media enquiries** – PSNC’s Communications Team ([commsteam@psnc.org.uk](mailto:commsteam@psnc.org.uk))