Outline of Operational Guidance for Dispensers in response to issue of a Serious Shortage Protocol

Executive summary

1. During 2018, almost 42 million prescription items were dispensed in Northern Ireland and the vast majority of these were not subject to supply problems.

2. The Department of Health and Social Care (DHSC) in England and the Department of Health (NI) receives regular reports from the pharmaceutical industry about impending medicine supply issues that may affect patients in the United Kingdom. There are well established processes in place to manage and mitigate the impact of the small number of supply problems that may arise at any one time due to manufacturing or distribution issues.

3. For example, a UK-wide Medicines Shortage Response Group has been established to consider supply problems that might arise and actions to be taken in response. The Chief Pharmaceutical Officer in NI is a member of that group.

4. Not all issues which are notified will result in a shortage that has an impact on patients because work will often be undertaken to alleviate the shortage before it happens. However, a **Serious Shortage Protocol (SSP)** is an additional tool to manage and mitigate the impact of medication shortages for patients and may be used in the exceptional and rare situation when other measures have been exhausted or are likely to be ineffective.

5. An SSP enables community pharmacy contractors to supply a specified medicine in accordance with a protocol rather than a prescription and without the need to seek authorisation from the prescriber. An SSP would only be used in the case of a serious shortage if, in the opinion of Ministers[1], it would help manage the supply situation and, if clinicians advising Ministers think it is appropriate, after discussion with the manufacturer and/or marketing authorisation holder, to do so.

6. An SSP may cover one or more of the following options for the medicine that is prescribed:

    - an alternative quantity;
    - an alternative pharmaceutical form;
    - a different combination of dosage to make up the required strength or a different strength;
    - a generic equivalent; or,
    - a therapeutic equivalent

    In the case of devices, it may simply be a different product.

7. Protocols will not be suitable for all medicines or patients, and there will be instances where, for clinical reasons, the medicines that are prescribed need to be prescribed by brand. In these cases, patients should always be referred to the prescriber for any decision about their treatment before any therapeutic or generic alternative is supplied.

8. Previously, if community pharmacy staff were unable to dispense medicines on prescriptions that were facing serious shortages, the only options available to ensure patients continued to receive their treatment were to:

    - support the patient to identify another local pharmacy that had stock;
    - refer the patient back to the prescriber; or
    - contact the prescriber requesting an alternative medication be prescribed.

9. These options can be time consuming for all parties involved, and mean that patients face potential delays in continuing their treatment and with potential risks to their health where immediately needed treatments are not available. If an SSP is issued, it will allow pharmacists to use their professional judgement to consider whether the alternative set out in the SSP would be appropriate for patients based upon their individual circumstances, without having to refer the patient back to

[1] In the absence of Ministers the Department of Health will undertake this role.

their prescriber. Should patients/carers not wish to receive medicine under the SSP, they can refuse to do so, and will be directed back to the prescriber to consider alternative treatment.

10. An SSP is time limited and will clearly set out the period during which it has effect.

Scope of any SSP

11. The Human Medicines Regulations 2012 (S.I. 2012/1916)[2] which are UK-wide in their territorial extent have been amended to allow for the supply of a prescription only medicine by a community pharmacy contractor in accordance with an SSP for medicines affected by serious shortages, rather than what is specified on the prescription. An SSP may be issued by the Secretary of State for the DHSC and the Minister of Health (NI) acting jointly or alone. It can also be issued for the UK as a whole or any part of the UK i.e. for Northern Ireland only.

12. The Pharmaceutical Services Regulations (Northern Ireland) 1997 (S.R. 1997/381) (as amended) enable supply under an SSP to be within the terms of service for pharmacists and for dispensing doctors providing pharmaceutical services in Northern Ireland.

13. An SSP issued by Ministers can relate to a prescription only medicine (POM), Pharmacy (P) and General Sales List (GSL) medicine or appliance. Appliance contractors therefore will also be able to supply under an SSP if the need should arise.

14. Dispensing doctors supply medicines under the direction of a doctor. However, they use the recognised HS21 forms, which people often understand to be a "prescription form", as a way of being reimbursed by the HSC for any supplies made to patients. Nevertheless, because there is no need for a prescription under the Human Medicines Regulations, there is equally no need for an exemption from the requirement to have a prescription. Therefore, strictly speaking, following an SSP is not needed as, in practice, all a dispensing doctor has to do when there is a shortage is to destroy the original HS21 form and write one for a product that is available. However, in order to avoid dispensing doctors having to re-write an HS21 so that they are on a par with prescribing GPs, amendments have also been made to dispensing doctors' terms of service to enable them to be paid if they have supplied in accordance with a relevant SSP having endorsed the original HS21 with the change to the order.

SSP notification

15. Details of a new SSP or changes to an existing SSP will be made available through the following routes:

    a) Business Service Organisation's website http://www.hscbusiness.hscni.net/services/3063.htm - this dedicated section on BSO's website will contain details of all SSPs. A sample template is attached at Annex 1 of this guidance. For ease, new SSPs or amended existing SSPs will be flagged;

    b) Contractors will be advised when a new SSP is published, or an amendment is made to an existing SSP, including a link to the BSO's website;

    c) Information on SSPs is expected to appear within Trade journals (for example Chemist + Druggist or the Pharmaceutical Journal) and their associated websites.

Supplying in accordance with an SSP

16. Making a supply under an SSP is no different from any other supply where the dispensing pharmacist makes the decision to treat, rather than a prescriber, such as under a national Patient Group Direction. The supply is the professional responsibility of the pharmacist under whose supervision it takes place.

[2] The Human Medicines Regulations (Amendment) Regulations 2019 provide for SSPs - www.legislation.gov.uk/uksi/2019/62/contents/made

17. Where an SSP is issued, the pharmacist should exhaust their own supply of the medicine that is subject to the SSP for supply first (unless it specifies supplying a reduced quantity or prioritising original stock for certain patient cohorts), before following the SSP to consider whether a supply of something other than what is prescribed on the prescription is appropriate.

18. Under the Human Medicines Regulations (in the case of prescription only medicines) and the Terms of Service for community pharmacy contractors, pharmacists would need to review the criteria set out in the protocol and **using their professional judgement**, consider whether supplying in accordance with an SSP (instead of against a prescription) is **reasonable and appropriate**.

19. There are 'generic' criteria which will apply to supply under all SSPs such as:

    - the prescription must be for a medication named in the SSP;
    - the presented prescription must be valid (i.e. contain 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 community pharmacist is not aware of the patient having any known previous adverse experience, hypersensitivity to, or a clinically significant history of allergic reaction to the alternative medication choice(s) outlined in the SSP;
    - the prescription is not for a controlled drug;
    - the supply is not an emergency supply (i.e. there is a prescription); and,
    - special considerations will also need to be taken for certain patients with complex health needs (e.g. elderly, neurological disability, mental health, etc.)

20. Where a pharmacist deems a patient is **unsuitable** to receive medication under an SSP (i.e. because the patient does not fulfil the criteria or, in the pharmacist's professional judgment, there is some other consideration which would deem the supply inappropriate or the patient (or their carer) decline to receive medication under the SSP) they should be referred back to their prescriber or the prescriber could be contacted to discuss an alternative where appropriate. A decision **not** to dispense against an SSP should be documented on the pharmacy's Patient Medication Record (PMR) system.

21. If the pharmacist cannot supply because they do not have any of the medication prescribed or any alternative outlined in the SSP, they can either refer the patient to another pharmacy or back to the prescriber.

Advice and Information to be given to the patient

22. The patient, and/or their representative which may be their parent, guardian, or carer must be informed of, understand and consent to the changes proposed to their medicine supply. They must be counselled appropriately and understand that it is their right to refuse to receive their medicines under an SSP and the implications of doing so. A pharmacist should use their professional judgement to assess who the medicine is prescribed for, if someone else is collecting the medication for the patient before supplying under an SSP. Particular attention needs to be given in cases where the appearance or quantity is different, there is an appliance change, or the storage conditions are different. An information leaflet will be available but pharmacists may wish to prepare their own communication to advise patients on why an SSP is currently being used.

23. The patient, and/or their parent or guardian or carer should be informed of the possible adverse effects of the alternative medication supplied under the SSP. They should also be advised to seek medical advice in the event of any adverse effect.

24. Advice needs to be given 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.

Notifying other health professionals

25. Where a therapeutic equivalent is supplied (or where it is required within the terms of the specific SSP), a pharmacist will need to inform a patient's prescriber. There is no time limit in legislation but, where it is practicable, pharmacists should aim to forward details within 3 working days. A form which can be used to notify prescribers is attached at Annex 2 of this guidance but pharmacists may consider other methods of notification to be appropriate.

26. Where a different quantity, an alternative pharmaceutical form, an alternative strength or a generic equivalent is provided, it will not be necessary that the patient's prescriber is informed routinely, as the existence of the SSP will be enough for the prescriber to be aware that these changes in dispensing may take place. However, guidance may be issued for a particular SSP to indicate that prescribers should be informed of any patients that receive supply under it. This will be mandatory if it has been agreed with the relevant negotiating body.

27. Prescribers will need to be aware that, until a more long-term solution is found, supplies under an SSP rather than dispensing of a prescription may come to the practice via normal mail. Prescribers will need to take a view as to how supplies made under a SSP are entered into patients' records.

Labelling and record keeping

28. 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.

29. 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 Pharmacy Patient Medication Record (PMR) system.

Payment

30. Reimbursement for any product supplied under an SSP will be as if the product had been dispensed against a prescription.

31. Contractors will need to endorse the prescription to indicate that a supply was made in line with an SSP and any other usual endorsements as appropriate for the product. Details on what endorsement to use to indicate that a supply was made in line with an SSP will be detailed on the BSO website (SSP section) http://www.hscbusiness.hscni.net/services/3063.htm

32. Contractors will need to submit their SSP prescriptions at the top of their amended bundle, **with the second submission** clearly separated from other prescription in the amended bundle (with for example a paper clip).

33. The number of SSP forms submitted should be noted at the bottom of the second submission HS30.

34. The contractor should endorse the prescription as appropriate. Any associated activity fee will be advised by HSCB.

Clinical trials

35. No patient groups will automatically be exempted from SSPs including patients participating in clinical trials. However, the impact on clinical trials would be taken into account in the development of any SSP. An individual protocol may exclude individual clinical trials that patients may be undergoing. Pharmacists should use their professional judgement to determine if it would be appropriate to supply under an SSP

Annex 1

Department of Health
An Roinn Sláinte
Männystrie O Poustie
www.health-ni.gov.uk

SERIOUS SHORTAGE PROTOCOL (SSP)

Reference Number: SSP XX *[Each SSP will be assigned a unique number]*

This SSP applies to the following medicine:

Name of medicine (including strength and formulation)	*Name of prescribed medicine subject to serious shortage to which the SSP will apply.*
Legal category	*Legal category of medicine e.g. POM*

1. **Details of medication to be supplied under this SSP**

Name of medicine (including formulation and strength) to be supplied	*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.*
Quantity of this formulation (if applicable)	*Quantity of formulation to be specified (if applicable)*
Substitution results in a change to whether the use is licenced	*Yes or No*

Scope for which this Serious Shortage Protocol (SSP) applies

The SSP applies to the following parts of the UK	*There may be geographical restrictions on the use of the SSP e.g. on use in a specific region.*

Clinical situation to which this Serious Shortage Protocol (SSP) applies

Scope of SSP	*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 the patient or carer declines the supply	*This section could include advice to refer the patient back to the prescriber.*

Valid from:	*There will be dates between which the SSP is valid and any changes SSP since it was first issued will be identified.*
Expiry date:	As above
Reference number:	*SSP XX*
Version number:	*Version No*

Any queries regarding the content of this SSP which was issued by the Department of Health – Northern Ireland should forwarded to communitypharmacy@health-ni.gov.uk

You can also contact us at: Medicines Policy Branch, D3, Castle Buildings, Stormont, Belfast, BT4 3SQ. Contact Telephone Number 028 90 522799

Change history

Version number	Change details	Date

2. Conditions under which this Serious Shortage Protocol (SSP) will operate

- The decision to supply any medicine under this protocol rests with the individual registered pharmacist who must abide by the protocol.
- Whilst pharmacy staff may support the dispensing process of the protocol, this must be carried out under the supervision of the registered pharmacist.
- Pharmacists using this SSP must ensure that it is only used within its authorised dates and within the criteria set out within the SSP. Pharmacists must check that they are using the current version of the SSP, particularly when referring to a hard copy version. Amendments may become necessary prior to the published expiry date. Current versions of SSP templates can be found at http://www.hscbusiness.hscni.net/services/3063.htm
- Users must not alter, amend or add to the content of this document; such action will invalidate the SSP.

Departmental ratification by:			
Name	**Position**	**Signature**	**Date**

ADDENDUM TO SSP TEMPLATE

Supporting information on notifying other healthcare professionals

- Any items supplied in accordance with an SSP in response to a HS21 prescription also needs to be supplied in accordance with The Pharmaceutical Services (Amendments Relating to Serious Shortage Protocols) Regulations (NI) 2019 - S.R. 2019 No. 186

- Those Regulations provide that where a therapeutic equivalent is supplied, a pharmacist will need to inform a patient's GP practice. Pharmacists should aim to forward details within 3 working days.

- Where a different quantity, an alternative pharmaceutical form, an alternative strength or a generic equivalent is provided, it may not always be necessary that the patient's prescriber is informed, as the existence of the SSP may be enough for the prescriber to be aware that these changes in dispensing may take place, unless national arrangements agreed with the relevant representative bodies state otherwise. However, guidance may be issued on particular SSPs to indicate that prescribers should be informed of any patients that receive supply under it.

Annex 2

Serious Shortage Protocols – Information to be forwarded to Prescribers (SSP/F/01)

The following information should be provided to Prescribers when a supply is made to a patient for a **therapeutic equivalent** medicine or when notification of the Prescriber is required under the terms of a specific SSP. Pharmacists should aim to forward this information to the patient's GP within 3 working days of a supply being made under a SSP. Further information on SSPs is available from: www.hscbusiness.hscni.net/services/3063.htm

Patient details		**Pharmacy details**	
Patient Name		**Pharmacy Name**	
Address & Postcode		**Address & Postcode**	
Date of Birth		**Contractor Number**	
GP Practice & Address		**Name of pharmacist making supply**	
		PSNI registration number	

SSP Number	**SSP XX**
Medicine supplied under SSP	(*Name, Strength, Form and Dose*)
Date of supply	

Declaration

I confirm that:

□ I have received the medicine listed above as supplied under a Serious Shortage Protocol

□ I have advised the pharmacist that I have no known reasons why I/the patient would be unable to take the medication.

Signature of Patient / Patient's representative:	**Print name:**
Relationship (patient's representative): □ Parent □ Guardian □ Appointed representative/carer □ Next of kin	

Action taken:	
Record kept in PMR	**Yes/No**
Date forwarded to patient's prescriber	