



Llywodraeth Cymru  
Welsh Government



# NHS Wales Serious Shortage Protocol Operational Guidance

Operational Guidance for Dispensers when a Serious  
Shortage Protocol is issued

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# Operational Guidance for Dispensers when a Serious Shortage Protocol is issued

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## Purpose

1. A Serious Shortage Protocol (SSP) is an additional tool to manage and mitigate medicine and medical device shortages. An SSP would only be used in the case of a serious shortage if in the opinion of Ministers, it would help manage the supply situation and if clinicians advising Ministers think it is appropriate.
2. An SSP enables community pharmacists to supply a specified medicine or device in accordance with a protocol rather than a prescription, with the patient's consent and without needing to seek authorisation from the prescriber.
3. An SSP is time limited and would clearly set out the period during which it is in effect.
4. An SSP may cover the supply of one or more of the following:
  - An alternative quantity
  - An alternative pharmaceutical form
  - A different strength
  - A generic equivalent
  - A therapeutic alternative of the prescribed medicine

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

## Background

5. More than 80 million prescription items are dispensed in Wales every year and the vast majority of these are not subject to supply problems. The UK Government receives regular reports from the pharmaceutical industry about impending medicine supply issues that may affect patients in the United Kingdom and information about potential shortages is communicated to Welsh Government by the Department of Health and Social Care (DHSC). The DHSC and Welsh Government have well established processes in place to manage and mitigate the small number of supply problems that may arise at any one time due to manufacturing or distribution issues. Not all issues that are notified will result in a shortage that has an impact on patients as work will often be undertaken to alleviate a supply problem before it become a shortage.
6. Prior to legislation making provisions for SSPs, if community pharmacy staff were unable to dispense medicines on prescriptions due to serious shortages, the only options available to ensure patients continued their treatment were:
  - support the patient to identify another local pharmacy that had stock (if any)
  - refer the patient back to the prescriber
  - contact the prescriber requesting an alternative medicine be prescribed.

## Legislation

7. The Human Medicines Regulations 2012 as amended, enable Ministers to issue SSPs. This allows for the supply of a prescription only medicine by a

community pharmacist in accordance with an SSP, for medicines affected by serious shortages, rather than what is specified on the prescription. Any SSP issued could be applicable across the whole of the UK. However, the SSP could also be limited by geographical area within the UK.

8. The Human Medicines Regulations 2012 as amended are a reserved matter with regards to Wales and Scotland but not Northern Ireland. The reference to Ministers in the legislation refers to Ministers of the Department of Health and Social Care in England and Ministers of the Department of Health in Northern Ireland. They have the power to issue SSPs, either together or separately, and an SSP could either be for a specific geographical area or country, or for the UK as a whole.
9. The NHS (Amendments Relating to Serious Shortage Protocols) (Wales) Regulations 2019 came into force on 31 October 2019. These amended the National Health Service (Pharmaceutical Services) (Wales) Regulations 2013 ('the 2013 Pharmaceutical Regulations') to:
  - (i) Make consequential changes to the terms of service for NHS pharmacists and NHS appliance contractors, to make provision for SSPs and to facilitate compliance by pharmacists with SSPs for prescription only medicines which may be issued by the Secretary of State and/or the Minister for Health, Social Services and Public Safety in Northern Ireland, under the Human Medicines Regulations 2012; and
  - (ii) Introduce a power for Welsh Ministers to issue SSPs for medicines other than prescription only medicines and appliances. This power will allow Welsh Ministers to make arrangements for the supply of non-prescription only medicines, by an NHS pharmacist or an NHS appliance contractor providing pharmaceutical services within the NHS in Wales. An SSP can be issued by Welsh Ministers where the health care product is ordered on a prescription form and there is, or may in the future be, a serious shortage of the product.
10. Dispensing doctors supply medicines under the direction of a doctor. Although dispensing doctors use the recognised WP10 forms as a way of being reimbursed by the NHS, there is no need for a prescription under the Human Medicines Regulations 2012. Consequently there is no need for an exemption from the requirement to have a prescription. Dispensing doctors do not need to follow an SSP as in practice when there is a shortage of a medicine that has already been written on an WP10 form, they can simply destroy the original WP10 form and write another for a product that is available.

## Preparing a Serious Shortage Protocol

11. The DHSC host a clinically chaired Medicines Shortage Response Group which includes Welsh Government representation. This group considers how to manage any shortage including whether an SPP might help mitigate it.
12. Any SSP would be developed by senior, specialist doctors and pharmacists, with input from national experts, Royal Colleges and specialist societies. Where possible, there would also be engagement with the relevant professional

bodies and patient groups however the engagement is likely to be on very short deadlines, to facilitate SSPs being issued in a timely manner for patients to access treatment. Each SSP would clearly set out what action can be taken by the community pharmacist outlining the circumstances, suitable patients, defined time period, and relevant geographical region. An SSP may be issued for use in the whole or different parts of the UK.

## Serious Shortage Protocol notification

13. Pharmacy contractors in Wales will be notified of a new SSP in a Medicines Shortage Letter which will be distributed to all community pharmacies and GP practices by the NHS Wales Shared Services Partnership. The [Medicines Shortage Log](#) which is available on the NHS intranet will provide up to date information on the status of SSPs and link to SSPs on the [NHS BSA Serious Shortage Protocol webpage](#).

<http://howis.wales.nhs.uk/sites3/page.cfm?orgid=428&pid=77202>

<https://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/serious-shortage-protocols-ssps>

## Using a Serious Shortage Protocol

14. Making a supply in accordance with an SSP is similar to any other supply where the dispensing pharmacist makes the decision to treat, 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 SSP 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.
15. When an SSP is issued, the pharmacist should generally exhaust their own supply of the medicine that is subject to the SSP first, except in circumstances where the SSP specifies supplying a reduced quantity or prioritising original stock for certain patient cohorts.
16. Pharmacists should review the criteria set out in the SSP and use their professional judgement to consider whether supplying in accordance with an SSP (instead of against a prescription) is reasonable and appropriate for the patient.
17. If there are concerns with supplying to a patient based on their medical history or individual circumstances, pharmacists should refer the patient back to their prescriber to seek alternative treatment. The decision not to dispense against the SSP should be recorded, for example on the pharmacy's patient medication record (PMR).
18. In situations where a pharmacy has no stock of either the medicine subject to the SSP or the alternative medicine which can be supplied under the SSP, they

should direct the patient to another pharmacy that has stock of either the prescribed medicine or the alternative medicines specified in the SSP.

19. The following criteria are applicable to all SSPs:

- the prescription must be for a medicine/medical device named within the SSP;
- the presented prescription must be valid (i.e. contain all the requirements of the Human Medicines Regulations 2012, if a POM) and in date;
- the patient or their guardian/carer must consent to receiving the medicine supplied under the SSP;
- the pharmacist must confirm that the patient has no known previous adverse experience, hypersensitivity, or a clinically significant history of allergic reaction to the alternative medicine 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 available;
- special considerations will also need to be taken into account for patients with complex health needs e.g. elderly, neurological disability, mental health and so on.

20. SSPs will not be suitable for all medicines and patients. For example, they would not be suitable for patients with complex medicine regimes, and SSPs for generic or therapeutic alternative medicines would not be suitable for patients that need to be prescribed medicines by brand for clinical reasons e.g. epilepsy. In these cases, patients would be referred to their prescriber for any decision about their treatment.

21. Patients/carers who do not consent to receiving an alternative medicine under an SSP should be directed back to the prescriber to consider alternative treatment.

## Advice and information to be given to the patient

22. The patient/carer must be informed of, understand and consent to the changes proposed to their medicine supply. Particular attention needs to be given where the appearance or quantity of the medicine is different, there is an appliance change, or the storage conditions are different.

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

24. Advice should be given that once a supply under the SSP is made (even if a lower quantity of the medication prescribed), the original prescription is no longer valid and no further supply can be dispensed from it. The pharmacist will need to endorse it to that effect when they make the supply under the SSP, followed by the prescription being submitted to the NHS Wales Shared Services Partnership for reimbursement (see further information below under the Endorsement and Payment section).

25. Where patients have received a reduced quantity under the SSP, this intends to provide enough supply for them to go back to their prescriber to seek alternative

treatment to be prescribed. Pharmacists should use their professional judgement to determine whether it is appropriate to supply a reduced quantity under the SSP, or whether the prescriber should be contacted (either by the pharmacy or patient) to discuss alternative treatment options.

## Notifying other health professionals

26. Where a therapeutic equivalent is supplied, the pharmacist will need to inform the patient's GP practice (even if the prescriber was not in that practice). There is no time limit in the legislation, but as part of good practice this should ideally be done within the following working day.
27. Where a different quantity or an alternative pharmaceutical form, strength or a generic equivalent is provided, it may not always be necessary that the patient's GP practice is informed as the existence of the SSP would make the GP practice aware that these changes in dispensing may take place. However, guidance may be issued on particular SSPs to indicate that patients' GPs should be informed of any patients that receive supply under it.
28. Prescribers will need to take a view as to how this information is entered into patients' records.

## Labelling and record keeping

29. 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 state its associated reference number. 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 from the [NHS Business Services Authority website](#) or [Medicines Shortage Log](#) using the reference number.
30. The supply against an SSP should also be referenced in the pharmacy's Patient Medication Record (PMR) system.

## Endorsement and Payment

31. Supply in accordance with an SSP will attract the usual reimbursement and remuneration as if the item had been dispensed in line with a prescription with the exception that items supplied in line with an SSP will attract an additional fee (currently £5.35) as per Part IIIA of the Drug Tariff and the reimbursement price will account for VAT payment.
32. For paper prescriptions, contractors should endorse the prescription with "NCSO" to indicate that a supply was made in accordance with an SSP stating the supplied quantity (and the product name if the SSP provides options) and follow usual endorsement rules.
33. For electronic prescriptions, contractors have the option to endorse either electronically or manually using a paper-based method. If endorsing

electronically endorse the Electronic Transmission of Claims Message (ETC) with an NCSO endorsement. "CS" should be generated in the dispensed message in accordance with the ETC requirements specification.

34. Paper prescriptions must be placed in Group 1A before submitting to the NHS Wales Shared Services Partnership in the usual way. Claims for payment will need to be sent by the 5th of the following month subsequent to supplying under the SSP, as is typically required for prescriptions.

## Prescription charge

35. Where any SSP supply is made, the normal charges and exemption arrangements would apply as though the original prescription had been dispensed. The majority of prescriptions dispensed by NHS Wales will be free of charge.

## VAT

36. For the purposes of VAT, supply under an SSP would be treated in the same manner as supply under a Patient Group Direction (PGD). Therefore, pharmacy contractors would be reimbursed as per usual arrangements for the item supplied under the SSP, plus an uplift to offset any VAT payment.

## Clinical trials

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