

Q & A: Serious Shortage Protocols

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The Protocol

Q: How would a Serious Shortage Protocol work in practice?

A: A Serious Shortage Protocol (SSP) enables community pharmacists, in the event of a serious shortage of any prescribed item that affects or may affect the whole or any part of the United Kingdom, to supply in accordance with the Protocol rather than supply in accordance with a prescription, without going back to the prescriber.

Q: Will it be mandatory to dispense drugs in accordance with an SSP if there is one in place?

A: Dispensing contractors will need to consider whether it is appropriate to supply the drug to a patient in accordance with the SSP. If the patient does not fulfil all the criteria set out in the protocol or, based on the pharmacist's professional judgement there are reasons why supply in accordance with the protocol is not appropriate, they will have to refer the patient back to the prescriber to discuss alternative treatment. The decision taken not to dispense in accordance with the Protocol should be recorded on the pharmacy's patient medication record (PMR).

Q: How will an SSP help to mitigate a supply problem?

A: If the Protocol allows it, community pharmacists can supply either an alternative quantity, strength, pharmaceutical form or medicine. Each Protocol would clearly set out what action can be taken by the pharmacist, under what circumstances, for which patients and during which period as part of managing the shortage for the affected medicine(s). Implementing the protocol will support patients in being able to access their medicines in a timely manner, whilst also easing pressure on both pharmacy and GP contractors as part of responding effectively to a medicine shortage(s).

Q: What happens if a patient requires a specific medicine and is unable to receive alternative medicine in accordance with the SSP?

A: Protocols will not be suitable for all medicines and patients. For example, Protocols for therapeutic or generic equivalents would not be suitable for anti-epileptic treatment or for treatment requiring biosimilar products, where the medicines would need to be prescribed by brand for clinical reasons. Additionally, patients with complex health needs may not be considered suitable for supply in accordance with an SSP. In these cases, patients would always be referred to the prescriber for any decision about their treatment, before any therapeutic or generic alternative is supplied.

Q: Will Protocols have a time limit?

A: Any Protocol would be limited in time and would clearly set out the period for which it has effect. The NHS Business Services Authority (BSA) website will have a list of the most up to date Protocols available.

Q: How long will it take to issue a Protocol?

A: A number of steps will need to be undertaken before issuing a Protocol. This includes exploring all other options to mitigate a supply issue by the Department's Medicines Supply Team. This would then be taken to the national clinically chaired Medicines Shortages Response Group (MSRG)¹, which will consider the situation as to whether it is appropriate to issue a Protocol affecting the serious shortage, which includes securing expertise from clinicians in relevant area(s) to provide the clinical content for any protocol. This must all be done in a timely manner to allow the Protocol to be used effectively in ensuring that patients' access to treatment is subject to minimal delay (if any).

Q: Would the issuing of a Protocol become a regular occurrence?

A: With the number of existing measures already in place to manage supply issues, issuing an SSP for a serious shortage would likely be an option of last resort and likely to only occur under exceptional circumstances.

Q: Why can patients not receive an alternative in accordance with an SSP for every medicine that is affected by a shortage?

A: The Department of Health and Social Care have a supply team led by pharmacists who work to mitigate a number of supply issues at any one time, through a number of existing measures. It would not be appropriate to issue an SSP for every medicine shortage. A number of other measures to mitigate medicine shortages can already be utilised by the Department's Medicines Supply Team without any direct impact upon patient supply. The introduction of an SSP would only be likely to be considered in exceptional circumstances. Furthermore, serious shortages could potentially affect medicines for which there is no alternative available to supply in accordance with a protocol and therefore, an SSP would not be issued.

Q: Will there be a limit on how many SSPs will be in place at any one point?

A: There is no limit on how many Protocols could be in place at any one point. However, an SSP will not always be issued for a serious medicine shortage. This depends on whether other measures have already been used to mitigate the supply problem, and whether the MSRG determines it appropriate to issue a protocol.

¹ The Medicines Shortages Response Group (MSRG) has been established since January 2019, to provide clear governance, communication and decision making to the Department of Health and Social Care (DHSC) Medicines Supply Team, and NHS England-NHS Improvement (NHSE-I)'s Commercial Medicines Unit (CMU) on individual critical issues for serious medicines shortages, managing the additional medical and communications support required in these circumstances.

Q: Would patients who typically pay for their prescriptions still be expected to do so when an SSP is in place for their medicine?

A: Amendments to the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 have been made so that patients who usually pay prescription charges but are supplied a lower quantity due to an active SSP in place, would be exempt from payment under this circumstance only. For all other situations where supply in accordance with an SSP is made, patients would be expected to pay their usual prescription charge (if applicable to them).

Patients who receive an 'owing' from their local pharmacy for a medicine/medical device that does not have an SSP in place would still be expected to pay a prescription charge in line with current requirements. A prescription charge would also still be payable by patients when an SSP is in place for their affected medicine(s) to be a different formulation or strength to be supplied instead, or for generic or therapeutic substitution.

Q: What do I do with a prescription for an item where an SSP is in place, once I have dispensed in accordance with the relevant protocol?

A: It is important to note that once an SSP has been used to supply a medicine to the patient, the relevant prescription is no longer valid for further dispensing. It should be endorsed with the relevant details for supply in accordance with an SSP for reimbursement and remuneration purposes (please refer to the operational guidance for more information), before this is sent to the NHS Business Service Authority (BSA) at the end of the month. Where an SSP is not deemed appropriate for an individual patient, the patient should be directed back to their prescriber to discuss alternative treatment.

Q: What payment will pharmacy contractors receive for dispensing products in accordance with an SSP?

A: Supply in accordance with an SSP will attract the usual single activity fee, plus the additional SSP fee of £5.35. Reimbursement for the product supplied in accordance with the SSP, will be as if it had been dispensed in accordance with a prescription.

Q: How will pharmacies get paid for supplying in accordance with an SSP rather than dispensing in accordance with a prescription?

A: Claims for payment will need to be sent to the NHS Business Service Authority by the 5th of the following month subsequent to supplying in accordance with the SSP, as is typically required for prescriptions.

For further information on endorsing prescriptions that have an SSP in place, please refer to the Operational Guidance for Dispensers.

Q: Does the introduction of SSPs allow pharmacists to dispense whatever alternative medicine they like without consulting patients/prescribers?

A: No, they can only supply in accordance with the Protocol.

SSPs are an additional tool that are to be issued in the exceptional and rare circumstance that existing measures to mitigate supply issues are not appropriate. It would be issued for a time limited period only and would explicitly state what alternative treatment can be supplied in accordance with the protocol **with** the patient / carer's consent. Under the Human Medicines Regulations 2012, pharmacists must dispense in accordance with the prescription. They are not able to deviate from this unless there is a valid SSP in place for the affected medicine, for which they must follow what is set out within the Protocol.

Where the patient does not consent to receive an alternative supply in accordance with an SSP , or where pharmacists use their professional judgement to determine that the alternative treatment options listed on the SSP are not suitable for the patient, they should either direct the patient back to their prescriber to discuss alternative treatment, or if there is an urgent need - contact the prescriber, discuss an alternative and then get the prescription changed by the prescriber.

Q: Can patients misuse/abuse the system by continually asking the pharmacist to supply a reduced quantity on their prescription, so that they remain exempt from payment?

A: Once an SSP is issued, it is valid only for a time limited period for pharmacists to supply the alternative. Where patients have been supplied a lower quantity in accordance with an SSP and have been exempt from prescription charge payment, some may wish to go back to their prescriber for the same prescription item that has an SSP in place. Patients should be advised on the likelihood that they will either receive a reduced quantity again in accordance with an SSP, or no stock will be available for them at all.

Q: Can an SSP be issued for a controlled drug?

A: Yes. Supply in accordance with an SSP for Schedule 4 (Part 2) and Schedule 5 controlled drugs is already permitted under the Human Medicines Regulations 2012. In addition, The Misuse of Drugs Regulations 2001 have been amended² to allow for the supply of a Schedule 2, 3 or 4 (Part 1) controlled drug by a pharmacist in accordance with an SSP during a pandemic. SSPs concerning these controlled drugs can only be issued when the Secretary of State makes an announcement to activate this measure. This announcement would be done as a consequence of a pandemic or potential pandemic, and a serious or potentially serious risk to human health.

² The Misuse of Drugs (Coronavirus) (Amendments Relating to the Supply of Controlled Drugs During a Pandemic etc.) Regulations 2020 (<http://www.legislation.gov.uk/uksi/2020/468/contents/made>)

Current Arrangements

Q: What responsibility do pharmaceutical companies have to report shortages in a timely way?

A: On 1st January 2019, Regulation 29 of the Health Service Products (Provision and Disclosure of Information) Regulations 2018 came into force. This made it a mandatory requirement that pharmaceutical companies must notify shortages and discontinuations 6 months in advance of an impending medicine supply issue that may impact UK patients, or as soon as is reasonably practicable if the company does not have that length of notice.

Q: Are the current arrangements to manage shortages not sufficient?

A: An SSP is an additional tool to formalise arrangements in the event of a serious shortage. It would only be used in exceptional circumstances. The Department has well established processes to manage and mitigate the small number of medicine supply problems that may arise at any one time due to manufacturing or distribution issues and this has always been the case.

Q: Couldn't a pharmacist just use their professional judgement without the need for an SSP?

A: Prior to legislation which introduced SSPs into community pharmacy Terms of Service, if a pharmacist couldn't dispense what is on a prescription, they would either send the patient back to the prescriber or if there was an urgent need, contact the prescriber, discuss an alternative and then get the prescription changed by the prescriber. Where appropriate, each SSP would save many such individual actions having to be made so that both pharmacists and prescribers have more time to spend with their patients.

Pharmacists

Q: What scope do pharmacists have to use their professional judgement?

A: If an SSP is in place for a medicine affected by a serious shortage, with the patient/carer's consent, pharmacists may supply an alternative quantity, strength, pharmaceutical form, generic or a therapeutic alternative in line with the SSP's instructions. However, even if a patient does fulfil the SSP's criteria to receive alternative medicine, pharmacists can use their professional judgement in determining whether they think it is clinically appropriate to supply to the patient or not. Where pharmacists do not think it is appropriate for specific patients based upon their individual circumstances, the patient/carer should either be signposted back to the prescriber to discuss alternative treatment, or the pharmacist should contact the prescriber in the usual way.

Q: Is it true that a pharmacist could unwittingly supply an alternative medicine in accordance with the SSP, to which a patient had previously received an adverse reaction, due to not being able to see the patient's full medical records?

A: Currently in England only, community pharmacies have access to patients' Summary Care Records (SCR) which includes information about their medicines, adverse reactions and allergies. With access to this information, pharmacists supplying an alternative medicine in accordance with an SSP would be no different to a GP initiating treatment for a patient, where the patient's allergy is unknown to them.

An SSP will enable community pharmacists to supply treatment to patients in a timely manner that is in accordance with a Protocol for a specific medicine, rather than in accordance with a prescription without having to go back to the prescriber. Any Protocol would set out what alternative quantity, pharmaceutical form, strength, therapeutic equivalent or generic equivalent can be supplied in what circumstances. Pharmacists' expertise in medicines allows them to carry out this function to a high standard.

Q: What professional indemnity does a Pharmacist have when supplying in accordance with an SSP?

A: Supply in accordance with an SSP is no different from any other supply where the dispensing pharmacist makes the decision to treat patients rather than a prescriber, such as in accordance with a national Patient Group Direction. The supply is the professional responsibility of the pharmacist under whose supervision it takes place. The Protocol 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.

When supplying in accordance with an SSP, pharmacists should confirm allergy status with the patient/carer and check their SCR. This should then be documented on the pharmacy's patient medication record (PMR) system. Pharmacists would be liable for any errors they made, e.g. if the patient had an allergy to the alternative medicine in accordance with the SSP, but the pharmacist failed to check the patient's allergies at the point of supply.

Q: Do SSPs apply to dispensing doctors' practices?

A: Yes, and their NHS Terms of Service has been amended to reflect this change. Where the prescribing and supply functions sit within a dispensing practice, there is scope for the dispensing doctor to review the prescription and amend accordingly, rather than to supply in accordance with a Protocol.

Q: Products dispensed in accordance a prescription are exempt from VAT. Will it be the same for SSPs?

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

Q: Will SSPs only apply to NHS or private prescriptions (or both)?

A: The scope of an SSP is a valid prescription that meets the requirements of the Human Medicine Regulations 2012, so a Protocol would cover both NHS and private prescriptions (unless otherwise stated on the SSP itself). Under the Misuse of Drugs Regulations 2001, protocols covering Schedules 2, 3 and 4 (Part 1) controlled drugs only apply to NHS prescriptions. Every SSP issued will state the circumstances in which the SSP is applicable, e.g. national or a specific geographical area. This is dependent upon the decisions made by the national clinically chaired Medicines Shortages Response Group (MSRG) before this is taken to Ministers for authorisation.

The Role of Ministers

Q: What powers do Ministers have to issue an SSP?

A: The Statutory Instrument, making amendments to the Human Medicines Regulations 2012 enables Ministers to issue SSPs, was laid before Parliament on 18 January 2019 and entered into force on 9 February 2019.

Q: Which Ministers will be involved?

A: The Human Medicines Regulations 2012 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 Protocols, either together or separately, and a Protocol could either be for a specific geographical area or country, or for the UK as a whole.

Where an SSP concerns a Schedule 2, 3 or 4 (Part 1) controlled drug, the Secretary of State must make an announcement to enable the supply in accordance with an SSP, specifying the geographical area to which the SSP applies and the duration, which can be up to three months and can be extended for a further three months at a time. Where the announcement relates to Scotland and/or Wales, the Secretary of State must consult the relevant Ministers in the Devolved Administrations.

Q: How will Ministers decide which medicines require an SSP? Will clinicians be consulted?

A: Ministers will authorise SSPs that have been brought to them by the national clinically chaired Medicines Shortages Response Group (MSRG), which will seek input from expert clinicians as part of developing the protocol. Before going to Ministers the SSP would need to be approved by the National Medical Director and Chief Pharmaceutical Officer. An SSP is an additional tool to manage and mitigate medicine shortages, and would only be used in exceptional circumstances if clinicians with experience in the relevant areas think it is appropriate.

Protocols will not be suitable for all medicines and patients. For example, Protocols for therapeutic or generic equivalents would not be suitable for anti-epileptic treatment or for treatment requiring biosimilar products, where the medicines would need to be prescribed by brand for clinical reasons. Additionally, patients with complex health needs may not be considered suitable for a supply in accordance an SSP. In these cases, patients should be referred to the prescriber for any decision about their treatment.

Q: Will the Protocol be subject to Parliamentary scrutiny?

A: There will be no specific Parliamentary scrutiny arrangements linked to the Protocol. It will of course be open to Parliament to look into Ministers' use of the powers under its normal scrutiny arrangements. However, the legislation does require the government to review the operation of the legislation one year after the first SSP has been issued.

Q: Will there be an appeal mechanism against a decision to issue a Protocol?

A: The decision to issue a Protocol will not carry a right of appeal but it could be judicially reviewed by a Court. The Department would work with industry on managing a shortage which would include discussions about a Protocol. Pharmacists will still have to use their professional discretion when supplying in accordance with a Protocol. Patients would be able to refuse to accept any alternative outlined in the Protocol, in which case they would need to go back to their prescriber to discuss their treatment.