Outline of Operational Guidance for Dispensers when a Serious Shortage Protocol for a medicine is issued

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Executive summary

1. Over two million prescription items are dispensed in England every day and the vast majority of these are not subject to supply problems. The Government receives regular reports from the pharmaceutical industry about impending medicine supply issues that may affect patients in the United Kingdom. It has 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.

2. A Serious Shortage Protocol (SSP) is an additional tool to manage and mitigate medicine and medical devices shortages. Protocols would be developed with input from expert clinicians but will be only be considered in exceptional circumstances.

3. 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. 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. This work is overseen by the Medicines Shortage Response Group (MSRG) chaired by one of the NHSE-I Deputy Chief Pharmaceutical Officer.

4. Any protocol would be developed by senior, specialist doctors and pharmacists, with input from national experts, Royal Colleges and specialist societies. If an SSP is to be authorised, then where possible, there would also be engagement with the relevant professional bodies and patient groups. It should be noted that 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 protocol 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.

5. 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 medicine that is prescribed. In the case of devices, it may simply be a different product.

6. Pharmacists can use their professional judgement in determining whether it is appropriate to supply to patients in accordance with the protocol. If there are concerns with supplying to patients based on their medical history or individual circumstances, they should either

direct the patient to another pharmacy that has stock (if any) or refer patients back to their prescriber to seek alternative treatment.

7. SSPs will not be suitable for all medicines and patients. For example, they would not be suitable for patients with complex medicine regimes, and protocols 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 the prescriber for any decision about their treatment.

8. Prior to legislation[1] introducing SSPs into community pharmacy Terms of Service, 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.

9. These options can be time consuming for all parties involved, meaning that patients face potential delays in continuing their treatment. If an SSP is issued, pharmacists can use their professional judgement to consider whether the alternative set out in the SSP would be appropriate to supply to patients based upon their individual circumstances, without having to refer the patient back to their prescriber. Patients/carers who do not consent to receiving an alternative medicine in accordance with an SSP can refuse to do so and be directed back to the prescriber to consider alternative treatment. An SSP is time limited and would clearly set out the period during which it is in effect.

[1] **The National Health Service (Amendments Relating to Serious Shortage Protocols) Regulations 2019 (http://www.legislation.gov.uk/uksi/2019/990/note/made)**

Scope of an SSP

10. The Human Medicines Regulations 2012 have been amended to allow 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 would be applicable across the whole of the UK. However, the SSP could be limited by geographical area within the UK.

11. We have also made amendments to the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 to enable supply in accordance with an SSP to be within a pharmacy's NHS pharmaceutical service provision.

12. These amendments broaden the scope of SSPs to all medicines and appliances/devices that are on an NHS prescription, including pharmacy & general sales medicines, as well as appliances. Where an SSP is issued for an appliance, dispensing appliance contractors may supply an appliance in accordance with an SSP, rather than the prescription.

13. Dispensing doctors supply medicines under the direction of a doctor. However, they use the recognised FP10 forms, which are often described as a "prescription form", as a way of being reimbursed by the NHS for any supplies made to patients. Nevertheless, because there is no need for a prescription under the Human Medicines Regulations 2012, there is equally no need for an exemption from the requirement to have a prescription. Therefore, strictly speaking dispensing doctors do not need to follow an SSP as in practice, when there is a shortage of a medicine on an FP10 prescription that has already been written, they can simply destroy the original FP10 prescription form and write another for a product that is available. However, where dispensing doctors are unable to re-write an FP10 prescription - amendments have also been made to dispensing doctors' Terms of Service. This would enable them to be paid correctly if they have supplied in accordance with the relevant SSP, (subject to endorsing the original FP10 prescription with the changes necessary), so that patients do not face undue delay in being able to access their medicines.

14. The Misuse of Drugs Regulations 2001 have been amended to allow for the supply of Schedule 2, 3 or 4 (Part 1) controlled drugs 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.

SSP notification

15. Pharmacy contractors will be notified of a new SSP or changes to an existing SSP through the following routes:
    - **NHS Business Service Authority's (NHS BSA's) website** – there will be a dedicated section on NHS BSA's website which will contain all SSPs. For ease new SSPs or

amended existing SSPs will be flagged, with each SSP having their own unique reference number.

- **NHSmail** – pharmacy contractors will receive an email sent to their premises' shared NHSmail mailbox with the link to the NHS BSA's website, when new SSPs or amendments to existing SSPs are published;
- **Pharmacy sector publications** - e.g. Chemist + Druggist and the Pharmaceutical Journal, where they will be asked to publish a short note on their websites, similar to what is done with concessionary prices. This will notify contractors of a new SSP or changes to an existing SSP by providing a link to the NHS BSA's website.

Supplying in accordance with an SSP

16. Making a supply in accordance with an SSP is no different from any other supply where the dispensing pharmacist makes the decision to treat, 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 in.

17. When an SSP is issued, the pharmacist should generally exhaust their own supply of the medicine that is subject to the SSP first, except for where the SSP specifies supplying a reduced quantity or where the SSP specifies prioritising original stock for certain patient cohorts. The SSP should then be considered by the pharmacist as part of determining whether it is appropriate to supply to the patient or not based upon their individual circumstances.

18. Under the Human Medicines Regulations 2012 (in the case of prescription only medicines) and NHS community pharmacy Terms of Service, pharmacists would need to review the criteria set out in the protocol and use their professional judgement to consider whether supplying in accordance with an SSP (instead of in accordance with a prescription) is reasonable and appropriate for the patient.

19. There are generic criteria which will be applicable to all SSPs, which include :
    - the prescription must be for a medicine/medical device named within the SSP;
    - the presented prescription must be valid (i.e. contain all the requirement of the Human Medicines Regulations 2012) and in date;
    - the patient or their guardian/carer consents to receiving the medicine supplied in accordance with the SSP;
    - 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 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. Where the pharmacist deems a patient is unsuitable to receive medicine in accordance with the SSP, either because the patient does not fulfil the SSP criteria or the pharmacist determines using their professional judgement there is some other consideration which would deem the supply inappropriate or the patient (or their carer) declines to receive medicine in accordance with the SSP, they should be referred back to their prescriber or the prescriber could be contacted to discuss an alternative where appropriate. The decision not to supply in accordance with 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 medicine 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/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 in accordance with 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 in accordance with 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 in accordance with the SSP, followed by the prescription being submitted to the NHS BSA for reimbursement (see further information below under the Endorsement and Payment section). Where patients have received a reduced quantity in accordance with the SSP, they may go back to their prescriber to seek alternative treatment to be prescribed. They should be counselled that they may receive a reduced quantity / have no supply if they obtain the same prescription item that is affected by the shortage.

25. Patients who usually pay a prescription charge under normal circumstances but receive a smaller quantity of the drug or fewer appliances than stated on the prescription would be exempt from prescription charge payment. In all other circumstances where an SSP is in place, patients would still be required to pay the charge.

Notifying other health professionals

26. Where a therapeutic equivalent is supplied, a pharmacist will need to inform a patient's prescriber. There is no time limit in the legislation, but as part of good practice this should ideally be done within the following working day. 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 prescriber is informed as the existence of the SSP would make the prescriber aware that these changes in dispensing may take place. However, guidance may be issued on particular SSPs to indicate that prescribers should be informed of any patients that receive supply in accordance with it. In the absence of any preferred local alternate communication channels, all feedback to prescribers should be sent by NHSmail. The NHS 111 Directory of Service finder is a way for pharmacies to look up the email address of the patient's GP.

27. Prescribers will need to be aware that until a longer-term solution is found, notification of supplies in accordance with SSPs (where relevant) rather than the dispensing of prescriptions may come to the practice via NHSmail mailboxes, unless established local communication arrangements are in place. Therefore, they will need to take a view as to how these are entered into patients' records.

Labelling and record keeping

28. The dispenser label that is applied to any product supplied in accordance with an SSP needs to indicate that the supply was made in accordance with an SSP and state its associated reference number. This will ensure that patients know which of their medicines was supplied in accordance with 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. A separate label should be generated for the item intended to be supplied in accordance with the SSP. The supply in accordance with an SSP should then be referenced in the pharmacy's Patient Medication Record (PMR) system.

Endorsement and Payment

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

31. 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 follow usual endorsement rules.

32. For electronic prescriptions, contractors have the option to endorse either electronically or manually using a paper-based method.

33. If endorsing electronically a contractor must:
    - endorse the EREM with “NCSO” and input into the endorsement field the supplied quantity and follow usual endorsement rules.

34. If endorsing manually a contractor must:
    - Amend the claim notification on the Electronic Reimbursement Endorsement Message (EREM) to ”not dispensed”.
    - Indicate that a supply was made in accordance with an SSP by manually endorsing the EPS dispensing token with “NCSO”, stating the supplied quantity, and follow usual endorsement rules as outlined within the Drug Tariff.

35. Paper prescriptions and EPS tokens must be placed in the red separator on top of the bundle before submitting to the NHS BSA in the usual way.

Prescription charge

36. Where any SSP supply is made, the normal charges and exemption arrangements will apply. Patients would either pay the usual prescription charge or will qualify for one of the normal exemptions if they have the underlying entitlement. As usual, they would make the appropriate declaration to which their signature would be required (apart from the automatic exemptions such as age). However, where a lower quantity is supplied, the patient would automatically be exempt from the prescription charge as set out under the new amendment 13A of the National Health Service (Charges for Drugs and Appliances) Regulations 2015. Therefore, no signatures or declarations of exemption are required from the patient.

VAT

37. 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.

Clinical trials

38. 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 individual protocol 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 in accordance with the SSP.