

Dear Colleague

SERIOUS SHORTAGE PROTOCOL: QUETAPINE 300MG TABLETS – SUBSTITUTION AND RESTRICTION

Purpose

1. To advise of a Serious Shortage Protocol (SSP) in place for quetiapine 300mg tablets, from 16 July 2024 to 13 September 2024.

Background

2. Changes made to the Human Medicines Regulations 2012 and the NHS (Pharmaceutical Services) (Scotland) Regulations 2009, the latter of which became effective from 31 October 2019, allow the use of Serious Shortage Protocols (SSPs).
3. An SSP is an additional tool to manage and mitigate medication shortages and may be used when other measures have been exhausted or are likely to be ineffective. There are two types of SSP; one that covers prescription only medicines and another that covers pharmacy and general sales list medicines and appliances.
4. Each SSP is individually developed and authorised clinically, to enable community pharmacists and dispensing doctors to dispense a different strength or formulation or alternative medicine or appliances in accordance with the protocol, rather than having to refer prescribing decisions back to the original prescriber. These protocols are time limited.
5. Community pharmacists are expected to use their professional skill and judgement to decide whether it is reasonable and appropriate to substitute a person's prescribed medicine using the SSP. The person will also have to agree to the alternative supply.

22 July 2024

Addresses

For action

Chief Executives, NHS Boards
Director Practitioner Services,
NHS NSS

For information

Directors of Pharmacy
NHS Medical Directors

Enquiries to:

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6. Certain classes of medicines, for example cytotoxic medicines, biologics, anti-epileptic medicines and certain antipsychotic medicines, are not considered to be suitable for SSPs due to concerns about ensuring bioequivalence. In these cases, people should be referred back to the prescriber for any decision about their treatment before any therapeutic or generic alternative is supplied.
7. The addition of new SSPs and any amendments or extensions to existing SSPs are documented on the NHS Business Services Authority website using the following link: [Serious shortage protocols \(SSPs\) | NHSBSA](#).

Medicine supply situation requiring the use of an SSP

8. A supply issue with quetiapine 300mg tablets has been identified. In order to manage stock supplies fairly and effectively, there are three UK-wide SSPs in place for this particular product:
 - [SSP 065](#) – Where the duration of treatment on the prescription is for one month's supply or less and quetiapine 300mg tablets are not available.
 - [SSP 066](#) – Where the duration of treatment on the prescription is for more than one month's supply and quetiapine 300mg tablets are available.
 - [SSP 067](#) – **Where the duration of treatment on the prescription is for more than one month's supply and quetiapine 300mg tablets are not available.**
9. **This circular refers to [SSP 067](#)**, where the duration of treatment on the prescription is for more than one month's supply and quetiapine 300mg tablets are not available, and a substituted product to the equivalent to one month's supply of the prescribed medicine can be supplied.

Operational overview

10. Between 16 July 2024 and 13 September 2024, for people presenting with an NHS or private prescription for more than one month's supply and quetiapine 300mg tablets are not available, community pharmacists may substitute this product with alternative strengths of quetiapine tablets. While the total quantity supplied under this protocol is limited to be equivalent to one month's supply of the prescribed medicine.
 11. For every quetiapine 300mg tablet, the following quantity must be supplied (listed in order of preference) in accordance with this protocol:
 - 3 x 100mg quetiapine tablets
- OR
- 2 x 100mg and 2 x 50mg quetiapine tablets
12. Pharmacists should note that the order of preference for substitutions is for patient safety reasons and that the total quantity supplied under this protocol is to be equivalent to one month's supply of the prescribed medicine.

13. **Pharmacists should be aware of the vulnerability of this patient group and take particular time to ensure the patient understands the change in the dosing regime and for the supply limit. Pharmacists must also ensure that the patient's prescriber and/or GP practice is notified when supplying a patient in accordance with this SSP.**
14. If a patient or their carer declines to receive the medicine under this SSP, a pharmacist should use their professional judgement to determine if other courses of action are appropriate whilst taking into consideration wider supply issues. If this does not address their concerns, the patient should be referred back to their prescriber for advice.
15. Community pharmacists are asked to review and familiarise themselves with the scope and the clinical situation to which this SSP applies, as outlined in the guidance provided within SSP 070.
16. If a pharmacist, using their professional judgement, considers that supplying a patient in accordance with the SSP would not be appropriate, the patient should be referred back to their prescriber promptly.

Additional information

17. Patients from any UK Nation who present their prescriptions for quetiapine 300mg tablets are eligible to receive a substituted product and a shorter duration of treatment under the terms of this SSP 070.
18. The scope of this SSP 070 applies to valid prescriptions that meets the requirements of the Human Medicine Regulations 2012, so it would cover both NHS and private prescriptions, unless where it stated otherwise on the SSP itself.
19. In accordance with this SSP 070, pharmacists will only be able to supply one month's supply of the substituted product. Patients should be made aware that under the terms of this SSP 070, the prescription will be deemed complete, and no further supply can be made from the same prescription above the one month quantity. If a pharmacy contractor is able to source supply of quetiapine 300mg tablets, a pharmacist should consider if supply in accordance with SSP 070 would be appropriate.
20. Pharmacists should explain the correct dosage for those patients who are receiving their quetiapine in a different strength to that prescribed, emphasising that the effect of the medicine will be the same. Pharmacists should use their professional judgement to select the appropriate substitution on the basis of the products available to them and the patient. Only the strengths and form of quetiapine tablets listed above can be dispensed in accordance with this SSP 070.
21. Where a patient does not consent to receive a lower quantity in accordance with this SSP 070, a pharmacist should use their professional judgement to determine if other courses of action are appropriate whilst taking into consideration wider supply issues. For example, pharmacists must consider under their NHS terms of service if it is "reasonable and appropriate" to supply in accordance with this SSP 070 or another SSP, such as SSP 068 or SSP 069. If a pharmacist concludes that it is not reasonable or appropriate to supply the medication in accordance with any other associated SSP, they must consider if they can dispense the prescription in the usual way 'in a reasonable timescale.' If they can, the ordinary obligation to dispense in accordance with the prescription applies. If they cannot, because a pharmacist has insufficient supply to fulfil the

prescribed quantity within a reasonable timescale, they may return the prescription, but if they do so, they must provide the patient with appropriate advice about going back to the prescriber.

22. In the event that a pharmacist concludes that it is reasonable and appropriate to dispense in accordance with the SSP, but the patient persists in refusing to accept the option of the lesser quantity, the pharmacist may advise the patient that they will dispense in accordance with the SSP or not at all, if that is in accordance with their professional judgement.
23. The patient retains the right to either accept the professional decision of the pharmacist or to ask for their prescription to be returned to them.
24. Where it is not clear from the prescription what constitutes a one month supply, a pharmacist will need to discuss with the patient and use their professional judgment.
25. If a pharmacist, using their professional judgement, considers that supplying the patient in accordance with the SSP would not be appropriate, the patient should be referred back to their prescriber promptly.

Supporting information on notifying other healthcare professionals

26. Any items supplied in accordance with an SSP in response to an NHS prescription also needs to be supplied in accordance with NHS Pharmaceutical Services Regulations.
27. Those Regulations provide that where a therapeutic equivalent is supplied, a pharmacist will need to inform a patient's GP practice. This would be expected within the next working day, but further guidance would be given in any case where this applied.
28. 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.

Fees and Endorsements

29. When an SSP is introduced, the pharmacist should use the Other endorsement function quoting SSP and the relevant reference number – in this case add SSP 070. A community pharmacy contractor will receive a multiplier per item of 5 (x5), via the dispensing pool, for any necessary supply in accordance with SSPs. Endorsements must be made in line with the SSP to be eligible for payment.
30. The paper form should be endorsed PMR with details added of what was supplied as well as 'SSP 070' annotated. This is to ensure accurate reimbursement for non-barcoded forms or where an electronic claim message is unavailable.

Enquiries

31. For any queries on the detail of this SSP, please contact the Scottish Government Pharmacy Team at PharmacyTeam@gov.scot.

Action

32. Health Boards are asked to note the contents of this Circular and to bring it to the attention of community pharmacy contractors on their Pharmaceutical Lists and Area Pharmaceutical Committees. This Circular should also be brought to the attention of General Practices.

Yours sincerely

A handwritten signature in blue ink, appearing to read 'Alison Strath', with a long horizontal flourish extending to the right.

Alison Strath
Chief Pharmaceutical Officer