

Dear Colleague

SERIOUS SHORTAGE PROTOCOL: PARACETAMOL SUPPOSITORIES 120MG

Purpose

1. To advise of a Serious Shortage Protocol (SSP) in place for paracetamol suppositories 120mg, from 16 February 2023 to 5 May 2023.

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.

7 March 2023

Addresses

For action

Chief Executives, NHS Boards
Director Practitioner Services,
NHS NSS

For information

Directors of Pharmacy
NHS Medical Directors

Enquiries to:

Pharmacy Team
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Email:

PharmacyTeam@gov.scot

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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 paracetamol suppositories 120mg has been identified. In order to manage stock supplies fairly and effectively, there is a UK-wide SSP in place.
9. Where paracetamol suppositories 120mg are not available, this medicine can be substituted with paracetamol suppositories 125mg.
10. This SSP can be accessed using the following link:
<https://www.nhsbsa.nhs.uk/sites/default/files/2023-02/SSP050%20Paracetamol%20120mg%20suppositories%2016022023.pdf>

Operational overview

11. Between 16 February 2023 and 5 May 2023, for patients presenting with an NHS or private prescription for a supply of paracetamol suppositories 120mg, community pharmacists may substitute this product with paracetamol suppositories 125mg .
12. Total quantity supplied in accordance with this protocol is to be equivalent to the number of days treatment prescribed on the original prescription. For every paracetamol 120mg suppository, the following quantity must – subject to the noted inclusion criteria – be supplied in accordance with this protocol: 1 x paracetamol 125mg suppository.
13. 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 050](#).
14. Pharmacists must ensure that the patient’s prescriber and/or GP practice is notified within 24 hours when supplying a patient in accordance with this SSP.
15. Patients considered to be unsuitable or at higher risk as outlined in the “Criteria for exclusion” section of [SSP 50](#) need to be referred back to their prescriber promptly for further advice.

Additional information

16. As paracetamol 120mg suppositories are largely prescribed for infants and children, concerns may be raised by parents/carers about the slightly increased dose (5mg) of the alternative. For the average patient the slight increase in dose will not be clinically significant and it is negligible in the context of the overall dosing schedule. For example, in the 1-year-old (10kg) where the

recommended dose is either 120mg or 125mg given every 4-6 hours with a maximum of 4 times in 24 hours this only constitutes a maximum of a 4% variation from usual dose, and as children get heavier this variation decreases further. However, there may be some patients where dose is critical and these should be referred back to the prescriber.

17. If the 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.
18. If a patient/carer declines to receive medicine under this SSP, then they should be referred back to their prescriber promptly.
19. Pharmacists are not able to deviate from the recommendations on what to supply to patients as outlined in the SSP for Paracetamol 120mg suppositories. However, if pharmacists think that an alternative product not listed in this SSP would be suitable for the patient, they should either contact the prescriber to discuss this (with the patient's consent) or direct the patient back to the prescriber.

Supporting information on notifying other healthcare professionals

20. Any items supplied in accordance with an SSP in response to an NHS prescription also needs to be supplied in accordance with NHS Pharmaceutical and Local Pharmaceutical Services Regulations.
21. Those Regulations provide that where a therapeutic equivalent is supplied, a pharmacist will need to inform a patient's GP practice. This would generally be expected within the next working day, but further guidance would be given in any case where this applied.
22. 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.
23. In the absence of any preferred local alternate communication channels, all feedback to prescribers should be sent by NHSmail. The NHS Service Finder is a way for pharmacies to look up the email address of the patient's GP.

Fees and Endorsements

24. 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 050. 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.
25. The paper form should be endorsed PMR with details added of what was supplied as well as 'SSP 050' annotated. This is to ensure accurate reimbursement for non-barcoded forms or where an electronic claim message is unavailable.

Enquiries

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

Action

27. **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



Alison Strath
Chief Pharmaceutical Officer