

Dear Colleague

SERIOUS SHORTAGE PROTOCOL: LEVOTHYROXINE 12.5 MICROGRAM TABLETS

Purpose

1. To advise of a serious shortage protocol in place for levothyroxine 12.5 microgram tablets.

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.
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

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Addresses

For action

NHS Board Chief Executives
Director Practitioner Services,
NHS NSS

For Information

NHS Directors of Pharmacy

Enquiries to:

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their treatment before any therapeutic or generic alternative is supplied.

Medicine shortage situation requiring the use of an SSP

7. A shortage of **levothyroxine 12.5 microgram tablets** has been identified. Between the 3rd February and 5th March 2021, prescriptions for this item can be fulfilled using levothyroxine 25 microgram tablets to be taken on alternate days.
8. In order to support this change, there is a UK SSP in place (<https://www.nhsbsa.nhs.uk/sites/default/files/2021-02/SSP010%20Levothyroxine%2012.5microgram%20tablets.pdf>) which allows a community pharmacist to substitute levothyroxine 12.5 microgram tablets using levothyroxine 25 microgram tablets.

Operational overview

9. When a person/representative presents with a valid prescription for levothyroxine 12.5 microgram tablets, which meets the requirements of the Human Medicines Regulations 2012, which cannot be fulfilled and the person/representative consents to receiving the alternative of levothyroxine 25 microgram tablets under the SSP, then the pharmacist should make the supply in accordance with the SSP, if the pharmacist is satisfied the person understands and is able to accommodate alternate daily dosing regimen.
10. The total quantity supplied under the protocol must be equivalent to the number of day's treatment supplied on original prescription. For every 2 x levothyroxine 12.5 microgram tablets originally prescribed, then 1 x 25 microgram levothyroxine tablet must be supplied in accordance with this protocol. Where the original dosage regime is 1 x levothyroxine 12.5 microgram tablet daily, the dosage regime will be amended to: 1 x 25 microgram levothyroxine tablet to be taken on alternate days. Levothyroxine has a long half-life and because of this it is not uncommon for patients to have varying doses on different days.

Fees and Endorsements

11. 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 010. 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.
12. The paper form should be endorsed PMR with details added of what was supplied as well as 'SSP 010' annotated. This is to ensure accurate reimbursement for non-barcoded forms or where an electronic claim message is unavailable.

Further Details

13. Community Pharmacy Scotland (CPS) guidance on the process for meeting SSP requirements can be found at the following website:

<https://www.cps.scot/media/4292/agreed-ssp-process-2021.pdf>

<https://www.cps.scot/media/2937/shortages-guidance-flowchart.pdf>

14. For any queries on the detail of this SSP, please contact the Scottish Government Pharmacy Team at PharmacyTeam@gov.scot or the ePharmacy Helpdesk at nss.psdhelp@nhs.scot.

15. Community Pharmacy Scotland has been consulted on the detail on this circular.