

Dear Colleague

**SERIOUS SHORTAGE PROTOCOL: OESTROGEL®
PUMP-PACK 0.06% GEL**

Purpose

1. To advise of a Serious Shortage Protocol (SSP) in place for Oestrogel® Pump-Pack 0.06% gel, from 29 April to 29 July 2022.

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.

4 May 2022

Addresses

For action

Chief Executives, NHS Boards
Director Practitioner Services,
NHS NSS

For information

NHS Directors of Pharmacy
NHS Medical Directors

Enquiries to:

Pharmacy Team
1st Floor East Rear
St Andrew's House
EDINBURGH
EH1 3DG

Email:

PharmacyTeam@gov.scot

www.gov.scot

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.

Medicine supply situation requiring the use of an SSP

7. A supply issue with Oestrogen[®] Pump-Pack 0.06% gel has been identified. In order to manage stock supplies fairly and effectively, there is a UK SSP in place which minimises the total quantity supplied under this protocol to be equivalent to three months' supply of the prescribed medicine. This SSP can be accessed using the following link: [SSP019 - Oestrogen pump-pack 750mcg actuation gel.pdf \(nhsbsa.nhs.uk\)](https://nhsbsa.nhs.uk/SSP019-Oestrogen-pump-pack-750mcg-actuation-gel.pdf).

Operational overview

8. Between 29 April and 29 July 2022, for patients presenting with an NHS or private prescription for more than three months' supply of estradiol (Oestrogen[®]) pump pack 0.06% gel, community pharmacists may limit supply to three months of supply in accordance with the SSP for eligible patients (see additional information below). If it is not clear from the prescription, the pharmacist should discuss with the patient and use their professional judgement to determine the appropriate supply quantity.
9. If a patient or their carer declines to receive the medicine under this SSP, the 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.

Additional information

10. Please see links for further advice on alternative hormone replacement therapies:
 - [CKS Hormone replacement therapy](#)
 - [British Menopause Society – HRT preparations and equivalent alternatives](#)
11. Please see the link for advice on the [availability of alternatives](#).

Fees and Endorsements

12. 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 019. 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.
13. The paper form should be endorsed PMR with details added of what was supplied as well as 'SSP 019' annotated. This is to ensure accurate reimbursement for non-barcoded forms or where an electronic claim message is unavailable.

Enquiries

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

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

Action

16. 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.

Yours sincerely



Alison Strath
Chief Pharmaceutical Officer