

From the Chief Pharmaceutical Officer
Professor Cathy Harrison



Department of
Health

An Roinn Sláinte

Mánnystrie O Poustie

www.health-ni.gov.uk

FOR ACTION

Deputy Secretary, Strategic Planning and Performance Group (*for onward transmission to relevant staff*)

Chief Executive, Business Services Organisation (*for onward transmission to relevant staff*)

Assistant Director of Integrated Care, Head of Pharmacy and Medicines Management, SPPG (*for onward distribution to Community Pharmacies*).

Head of General Medical Services, SPPG (*for onward distribution to GP Practices*)

GP Medical Advisers, Strategic Planning and Performance Group.

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Our Ref

Date: 8 September 2023

Dear Colleagues,

SERIOUS SHORTAGE PROTOCOL– ESTRADOT® (ESTRADIOL HEMIHYDRATE) 100MICROGRAMS/ 24 HOUR PATCH – EXPIRY DATE EXTENSION

Serious shortage protocols (SSPs) under the Human Medicines Regulations 2012 (HMRs) are an additional tool to manage and mitigate medicines shortages. An SSP enables community pharmacists to supply a specified medicine in accordance with a protocol rather than a prescription, without needing to seek authorisation from the prescriber, saving time for patients, pharmacists and prescribers. They are used in the case of a serious shortage, where a medicine would be likely to be out of stock for some time, and if, in the opinion of ministers, it would help manage the supply situation.

I refer to my letter issued on 21 August 2023, when I wrote to notify that due to a supply issue with Estradot® (estradiol hemihydrate) 100micrograms/ 24 hour patch, a SSP had been put in place. In light of continued supply concerns across the UK regarding the availability of this product, the Department of Health and Social Care (DHSC) has today extended the expiry date of this existing SSP (**SSP057**) until **Friday 13 October 2023**.

This SSP, authorised by the Secretary of State on behalf of the four UK nations, has been developed by clinicians and provides pharmacists with procedures to follow in providing suitable alternative products to help reduce the number of patients having to return to their prescriber for a replacement prescription.

Pharmacists should refer to the latest version of this SSP which is available on the Business Services Organisation (BSO) dedicated page on its website:

www.hscbusiness.hscni.net/services/3063.htm

Community pharmacists should use their professional skill and judgement to decide whether it is reasonable and appropriate to substitute the patient's prescribed order for a supply under this SSP. The patient/carer will also need to agree to supply under the SSP.

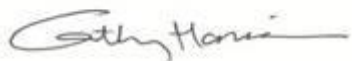
Should the quantity on the prescription be unclear, the pharmacist should consult with the patient and use their professional judgement to make an appropriate supply under this SSP. Pharmacists should refer to the relevant Summary of Product Characteristics (SPC) and Patient Information Leaflets (PIL) to inform these decisions.

If a patient/carer declines to receive the medicine under an 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/carer should be referred back to their prescriber for advice.

Action Required

All relevant staff should be made aware of the extended expiry date of this SSP. I would ask the SPPG to bring this information to the attention of GP Practices and Community Pharmacists directly.

Yours sincerely,



Professor Cathy Harrison
Chief Pharmaceutical Officer