

**From the Chief Pharmaceutical Officer
Mrs Cathy Harrison**



Department of
Health

An Roinn Sláinte

Máinnystrie O Poustie

www.health-ni.gov.uk

FOR ACTION

Chief Executive, 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 HE1/22/428413

Date: 15 September 2022

Dear Colleagues,

SERIOUS SHORTAGE PROTOCOLS – FOR THE CONTINUED TREATMENT OF MENOPAUSE IN NORTHERN IRELAND

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 am writing to inform you that in response to concerns across the UK regarding ongoing intermittent supply issues affecting some supplies of Estraderm patches, a decision has been taken by the Minister for Health to authorise the issue of two SSPs to enable community pharmacists in Northern Ireland to supply patients and so help more women to access treatments. Details on these SSPs are attached separately to

this letter and will also be available on the Business Services Organisation (BSO) dedicated page on its website - www.hscbusiness.hscni.net/services/3063.htm

These SSPs currently expire on 16 September 2022, however supplies are expected to be intermittent for several months and the Department may reactivate these SSPs at a later date to manage the supply position over the coming months.

The two SSPs attached are:

- SSP035 Estraderm MX 25mcg patches
- SSP036 Estraderm MX 100mcg patches

The alternative product to be provided in these periods of shortage will be Evorel 25mcg and 100mcg patches respectively.

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 these active SSPs. 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 these SSPs. 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 these SSPs, 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.

These SSPs are attached as separate documents to this letter and will also be available on the Business Services Organisation (BSO) dedicated page on its website at www.hscbusiness.hscni.net/services/3063.htm

Action Required

All relevant staff should be made aware of these updated SSPs. I would therefore ask SPPG to bring this information to the attention of GP Practices and Community Pharmacists directly.

Yours sincerely,

A handwritten signature in cursive script, appearing to read "Cathy Harrison".**Cathy Harrison****Chief Pharmaceutical Officer**