

From the Chief Pharmaceutical Officer  
Mrs Cathy Harrison



Department of  
**Health**

An Roinn Sláinte

Mánnystrie O Poustie

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Our Ref  
Date: 04 May 2022

## **FOR ACTION**

Chief Executives, Strategic Planning and Performance Group/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.

Dear Colleagues,

## **SERIOUS SHORTAGE PROTOCOL – HORMONE REPLACEMENT THERAPY (HRT) MEDICATION**

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 longer prescribing cycles putting pressure on availability of some HRT products, the Department of Health and Social Care (DHSC) has developed SSPs for three products to ensure that women are able to access the HRT they need, namely:

- Oestrogel® pump-pack 750mcg/actuation gel;
- Ovestin® 1mg cream; and
- Premique® low dose 0.3mg/1.5mg modified release tablets

A decision has been taken by the Minister for Health to authorise the issue of these three SSPs to enable community pharmacists in Northern Ireland to supply patients

with no more than three months' supply of these HRT medicines, and so help more women to access these treatments. These SSPs came into operation in all parts of the UK on **29 April 2022** and all have an expiry date of **29 July 2022**.

Details on these SSP's are attached separately as a pdf 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](http://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 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.

It is recognised that the maximum quantities supplied under these SSPs may vary depending on the prescribed dose. For Oestrogel® pump-pack 750mcg/actuation gel, if the daily dose is 2 pumps then typically a maximum of three packs should be supplied under the SSP and if the daily dose is 4 pumps then a maximum of six packs should be supplied.

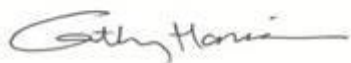
For Ovestin® 1mg cream, two packs will typically be required if treatment is being initiated at a dose of one application daily for the first three to four weeks. One pack should be supplied for treatment at a dose of one application twice weekly.

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.

### **Action Required**

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

Yours sincerely,



**Cathy Harrison**  
**Chief Pharmaceutical Officer**