

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



Department of
Health

An Roinn Sláinte

Mánnystrie O Poustie

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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.

Dear Colleagues,

SERIOUS SHORTAGE PROTOCOLS – 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.

You will recall that I previously wrote to you on 4 May 2022 to advise that in light of concerns across the UK regarding the availability and supply of a number of Hormone Replacement Therapy (HRT) medicines, the Department of Health and Social Care (DHSC) made the decision to develop three Serious Shortage Protocols (SSPs) for certain HRT medicines. I can now confirm that in response to continued high demand and disruption to the supply of some HRT medicines, DHSC has now issued a further **ten** new SSPs to allow community pharmacists to consider different options to enable continued supply of HRT medicines to mitigate the ongoing supply disruptions affecting five HRT medicines, namely:

- Ovestin 1mg cream
- Oestrogel Pump-Pack 0.06% gel
- Lenzetto 1.53mg transdermal spray
- Sandrena 0.5mg and 1mg gel sachets
- 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 ten additional SSPs which, depending on the prescribed quantity of the affected HRT medicines, will allow pharmacists to either supply a reduced quantity of the same HRT medicine, or substitute with a specific alternative product, or provide a reduced quantity of a specific alternative product. These SSPs came into operation in all parts of the UK on **19 May 2022** and all have an expiry date of **19 August 2022**.

For each SSP, specific patients counselling points are included which must be taken into account when deciding whether supply in accordance with an SSP is suitable for a patient. Pharmacists will need to call on their clinical expertise to determine which SSP is the most appropriate to use in each scenario and to counsel patients on any changes made to their treatment and what it means for their medicine regimen. A summary breakdown of SSPs available for each HRT medicine is listed below.

DRUG NAME	SSP		
	Restriction of the quantity supplied (for prescriptions ordering > 3 months)	Substitution with a specific alternative (for prescriptions ordering < 3 months)	Substitution with a specific alternative product AND Restriction of the quantity supplied (for prescriptions ordering > 3 months)
Premique® Low Dose 0.3mg/1.5mg modified-release tablets	SSP 021	N/A	N/A
Ovestin® 1mg cream	SSP 020	SSP 024	SSP 025
Oestrogel® Pump-Pack 0.06% gel	SSP 019	SSP 022	SSP 023
Lenzetto® 1.53mg transdermal spray	SSP 026	SSP 027	SSP 028
Sandrena® 0.5mg and 1mg gel sachets	SSP 029	SSP 030	SSP 031

Details on these SSP's are attached separately as a separate document 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

Pharmacists should also refer to the Operational Guidance on Serious Shortage Protocols, which is available at <https://hscbusiness.hscni.net/services/3192.htm>

In particular, pharmacists should be aware that where a therapeutic equivalent is supplied under an SSP then the patient's prescriber should be notified. There is no time limit in legislation but, where it is practicable, pharmacists should aim to forward details within 3 working days. A form which can be used to notify prescribers is attached below and at Annex 2 of the operational guidance but pharmacists may also consider other methods of notification to be appropriate.

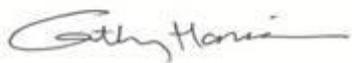
Community pharmacists should use their professional skill and judgement to decide whether it is reasonable and appropriate to substitute or limit the patient's prescribed order for a supply under these active SSPs. The patient/carer will also need to agree to supply under the SSP. Should the quantity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

Action Required

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

Yours sincerely,



Cathy Harrison
Chief Pharmaceutical Officer

Annex 2

Serious Shortage Protocols – Information to be forwarded to Prescribers (SSP/F/01)

The following information should be provided to Prescribers when a supply is made to a patient for a **therapeutic equivalent** medicine or when notification of the Prescriber is required under the terms of a specific SSP. Pharmacists should aim to forward this information to the patient's GP within 3 working days of a supply being made under a SSP. Further information on SSPs is available from:

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

Patient details		Pharmacy details	
Patient Name		Pharmacy Name	
Address & Postcode		Address & Postcode	
Date of Birth		Contractor Number	
GP Practice & Address		Name of pharmacist making supply	
		PSNI registration number	

SSP Number	SSP XX
Medicine supplied under SSP	<i>(Name, Strength, Form and Dose)</i>
Date of supply	

Declaration
I confirm that: <input type="checkbox"/> I have received the medicine listed above as supplied under a Serious Shortage Protocol <input type="checkbox"/> I have advised the pharmacist that I have no known reasons why I/the patient would be unable to take the medication.

Signature of Patient / Patient's representative:	Print name:
Relationship (patient's representative): <input type="checkbox"/> Parent <input type="checkbox"/> Guardian <input type="checkbox"/> Appointed representative/carer <input type="checkbox"/> Next of kin	

Action taken:	
Record kept in PMR	Yes/No
Date forwarded to patient's prescriber	