

From the Chief Pharmaceutical Officer  
Mrs Cathy Harrison



Department of  
**Health**

An Roinn Sláinte

Mánnystrie O Poustie

[www.health-ni.gov.uk](http://www.health-ni.gov.uk)

## **FOR ACTION**

Chief Executives, Health and Social Care  
Board/Business Services Organisation (*for  
onward transmission to relevant staff*)

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

Head of General Medical Services, HSCB (*for  
onward distribution to GP Practices*)  
GP Medical Advisers, Health and Social Care  
Board.

Castle Buildings  
Stormont  
BELFAST  
BT4 3SQ  
Tel: 028 90 523219  
Email: [cathy.harrison@health-ni.gov.uk](mailto:cathy.harrison@health-ni.gov.uk)

Our Ref  
Date: 2<sup>nd</sup> October 2020

Dear Colleagues,

### **UPDATE TO SERIOUS SHORTAGE PROTOCOL (SSP) – Fluoxetine 40mg capsules**

I refer to my letter issued on 25 September 2020, when I wrote to notify you that due to ongoing supply issues with fluoxetine 40mg capsules the Serious Shortage Protocol (SSP) first issued on 20 May 2020 had been extended until Friday 2 October 2020. I am now writing to inform you that due to ongoing supply issues the expiry date of this SSP has been further extended and that the SSP will now end on Friday 16 October 2020.

See **Annex A** for the SSP. Details of the SSP are also 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)

We are continuing to monitor the supply situation and will inform you promptly if there are any further developments with the SSP.

### **Action Required**

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

Yours sincerely,

A handwritten signature in black ink that reads "Cathy Harrison". The signature is written in a cursive style with a long horizontal stroke at the end.

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

## SERIOUS SHORTAGE PROTOCOL (SSP)

Reference Number: SSP06

This SSP applies to the following medicine: Fluoxetine 40mg capsules

<b>Name of medicine (including strength and formulation)</b>	Fluoxetine 40mg capsules
<b>Legal category</b>	POM

### 1. Details of medication to be supplied under this SSP

<b>Name of medicine (including formulation and strength) to be supplied</b>	Fluoxetine 20mg capsules
<b>Quantity of this formulation (if applicable)</b>	Total quantity supplied under this protocol to be equivalent to the number of days supplied on original prescription.  For every 40mg capsule, the following quantity must be supplied in accordance with this protocol:  2 x 20mg fluoxetine capsules
<b>Substitution results in a change to whether the use is licenced</b>	No

### Scope for which this Serious Shortage Protocol (SSP) applies

<b>The SSP applies to the following parts of the UK</b>	Northern Ireland
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### Clinical situation to which this Serious Shortage Protocol (SSP) applies

<b>Scope of SSP</b>	All NHS and private prescriptions. This protocol does <b>not</b> allow for the quantity supplied to be less than the number of days prescribed on the original prescription.
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<b>Criteria for inclusion</b>	<ul style="list-style-type: none"> <li>• The patient presents with a valid prescription (meeting the requirements of the Human Medicines Regulations 2012) for fluoxetine 40mg capsules.</li> <li>• The patient/carer consents to receiving the medicine supplied under this SSP. All patients aged 18 years of age or above.</li> </ul>
<b>Criteria for exclusion</b>	<ul style="list-style-type: none"> <li>• The patient presents with a prescription for a medicine other than fluoxetine 40mg capsules.</li> <li>• The patient presents a prescription which is not valid.</li> <li>• The patient/carer does not consent to receiving the medicine(s) supplied under this SSP.</li> <li>• Where the pharmacist, using their professional judgement, determines that the patient is not suitable to receive the alternative medicine under this SSP.</li> <li>• Known previous hypersensitivity or severe adverse reaction to fluoxetine capsules or their excipients.</li> <li>• Patients aged less than 18 years.</li> <li>• Adults on a fluoxetine dose &gt; 60mg daily.</li> </ul>
<b>Cautions including any relevant action to be taken</b>	Ensure that patients considered unsuitable for inclusion are promptly referred to their prescriber for further advice.
<b>Special considerations for specific populations of patients</b>	<p>Switching the preparation (including different manufacturer) of the drug requires caution in certain patients who are considered at risk of deterioration due to the <b>nocebo</b> effect whereby patients believe that the exact preparation (including different manufacturer) of the drug is critical to their response.</p> <p>Patients considered unstable or at higher risk need to be referred back to their prescriber promptly for further advice.</p>
<b>Action to be taken if the patient is excluded</b>	If a patient does not meet the criteria within this SSP then they should be referred back to their prescriber promptly.
<b>Action to be taken if the patient or carer declines the supply</b>	If a patient/carer declines to receive medicine under this SSP then they should be referred back to their prescriber promptly.

<b>Valid from:</b>	20 May 2020
<b>Expiry date:</b>	16 October 2020
<b>Reference number:</b>	SSP06
<b>Version number:</b>	6.0

Any queries regarding the content of this SSP which was issued by the Department of Health – Northern Ireland should be forwarded to [communitypharmacy@health-ni.gov.uk](mailto:communitypharmacy@health-ni.gov.uk)

## Change history

Version number	Change details	Date
2.0	Expiry date extended to 10 August 2020.	17/07/2020
3.0	Expiry date extended to 4 September 2020	10/08/2020
4.0	Expiry date extended to 25 September 2020	03/09/2020
5.0	Expiry date extended to 2 October 2020	25/09/2020
6.0	Expiry date extended to 16 October 2020	02/10/2020

## 2. Conditions under which this Serious Shortage Protocol (SSP) will operate

- The decision to supply any medicine under this protocol rests with the individual registered pharmacist who must abide by the protocol.
- Whilst pharmacy staff may support the dispensing process of the protocol, this must be carried out under the supervision of the registered pharmacist.
- Pharmacists using this SSP must ensure that it is only used within its authorised dates and within the criteria set out within the SSP. Pharmacists must check that they are using the current version of the SSP, particularly when referring to a hard copy version. Amendments may become necessary prior to the published expiry date. Current versions of SSP templates can be found at [www.hscbusiness.hscni.net/services/3063.htm](http://www.hscbusiness.hscni.net/services/3063.htm)
- Users must not alter, amend or add to the content of this document; such action will invalidate the SSP.

Ministerial ratification by:			
Name	Position	Signature	Date
Minister Robin Swann	DOH Minister		02-10-20

