

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



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Dear Colleague

NEW MEASURES TO HELP MANAGE MEDICINES SHORTAGES – UPDATE ON NEW RESTRICTIONS ON PARALLEL EXPORT FOR MEDICINES AT RISK OF SHORTAGE AND PLANS FOR SERIOUS SHORTAGE PROTOCOLS

This letter is to update you on two new measures being taken by Government to help ensure the continued supply of medicinal products for patients in the UK.

The Department of Health and Social Care (DHSC) has today written to wholesale dealer authorisation holders across the UK to inform them of new restrictions on the parallel export of medicines at risk of shortage. The communication outlines obligations under regulation 43(2) of the Human Medicines Regulations 2012 to ensure the continued supply of medicinal products so that the needs of patients in the UK are met. To assist with this, DHSC has today published a list of medicines that cannot be parallel exported from the UK because they are needed for UK patients. (<https://www.gov.uk/government/publications/medicines-that-cannot-be-parallel-exported-from-the-uk>). The list will be updated weekly.

These new restrictions on parallel export of products will help to ensure that medicines at risk of shortage continue to be available for patients in Northern Ireland and not sold to other countries.

I would also like to clarify the status in Northern Ireland of three Serious Shortage Protocols (SSPs) that have been issued today on behalf of the Secretary of State for Health and Social Care, as a mitigation against the current shortage of Fluoxetine 10mg, 30mg and 40mg capsules. These SSPs, which are in effect until 31 October 2019, **apply to England only and do not apply to Northern Ireland**, Scotland or Wales. In Northern Ireland information and a management plan to assist clinicians and

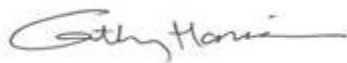
pharmacists in managing the current supply issue with fluoxetine capsules is available on the BSO website and is reproduced in Annex 1.

Recent amendments to the UK wide Human Medicines Regulations 2012 include a provision for SSPs. These provide for the supply of a specified medicine in accordance with a protocol, rather than a prescription, and without the need to seek authorisation from the prescriber where there is or may be a serious shortage of a particular medicine. SSPs may allow for substitution, in restricted circumstances, of a different strength, quantity, pharmaceutical form, a generic equivalent or therapeutic equivalent medicine to that ordered by the prescriber.

To enable SSPs to be used in Northern Ireland, amendments are being made to the Pharmaceutical Services Regulations (NI) 1997 and will be achieved through the Pharmaceutical Services (Amendments Relating to Serious Shortage Protocols) Regulations (NI) 2019. These amendments will come into operation on 31st October 2019. The Department is also finalising detailed operational guidance for SSPs.

The new restrictions on parallel exporting and SSPs will add to the existing systems in place in Northern Ireland for managing medicines shortages, that may occur for many reasons, in the context of a global market for medicines.

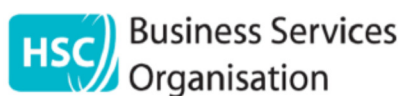
Yours sincerely



Mrs Cathy Harrison
Acting Chief Pharmaceutical Officer

Annex 1

MPS 2572



Pharmaceutical Services, 2 Franklin Street, Belfast BT2 8DQ
Telephone No. 028 95 363364

To: All Community Pharmacists

24th September 2019

Dear colleague

Please be aware that there is a supply issue affecting fluoxetine 10mg, 30mg and 40mg capsules due to manufacturing issues. Please see table below which summarises overall fluoxetine availability:

Fluoxetine strength	Form	MA Holder	Stock Availability
10mg	capsules	Morningside	Unavailable until end of October 2019
10mg	capsules	Advanz	Unavailable until early December 2019
30mg	capsules	Advanz	Unavailable until early November 2019
40mg	capsules	Advanz	Unavailable until early November 2019
10mg	tablets	Endo Ventures Ltd	Available
20mg	capsules	Various suppliers	Available
20mg/5ml	oral solution	Various suppliers	Available

Management plan:

Due to the long-term issues affecting fluoxetine 10mg, 30mg and 40mg capsules, we recommend the following actions be undertaken:

- General Practitioners and prescribers should identify all patients currently prescribed fluoxetine 10mg, 30mg and 40mg capsules

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Telephone No. 028 95 363364

- Early contact should be made with the patient or patient's parent/carer to determine if the stocks at home will last until early November.
- If the patient has sufficient supplies to last them until early November, then no further action is required. These patients should **not** be issued with a repeat prescription during this period.
- For patients who do not have sufficient supplies for the duration of the expected out of stock period, prescribers should consider the following:

Current prescription	Suggested alternatives:
<u>Fluoxetine 10mg capsules</u>	Fluoxetine 10mg tablets Or Fluoxetine 20mg/5ml oral solution* Or Unlicensed fluoxetine 10mg capsules (see further info below)
<u>Fluoxetine 30mg capsules</u>	Fluoxetine 10mg tablets + fluoxetine 20mg capsules Or Fluoxetine 20mg/5ml oral solution*
<u>Fluoxetine 40mg capsules</u>	Fluoxetine 20mg capsules Or Fluoxetine 20mg/5ml oral solution*

*Please note that the oral solution has the same bioavailability as the capsules/tablets - so can be used to make up the equivalent dose e.g.

10mg = 2.5ml

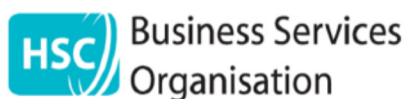
30mg = 7.5ml

40mg = 10ml

Unlicensed Preparations

- DHSC have also contacted specialist importer companies who have advised that unlicensed imports can be sourced from abroad.
- Importers who have currently confirmed they can source these lines, include:

Fluoxetine 10mg capsules	Target Healthcare Ltd
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Fluoxetine 10mg tablets	Mawdsley's
	Alium Medical
	Waymade PLC

- Clinicians will need to work with local pharmacies to understand more about the specific unlicensed products that can be sourced and associated lead times.
- Any decision to prescribe an unlicensed medicine must consider the relevant guidance and NHS Trust or local governance procedures. Please see the links below for further information:
 - <https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/prescribing-and-managing-medicines-and-devices/prescribing-unlicensed-medicines>
 - https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/373505/The_supply_of_unlicensed_medicinal_products_specials_.pdf
 - <https://www.rpharms.com/Portals/0/RPS%20document%20library/Open%20access/Support/toolkit/specials-professional-guidance.pdf>
- In order for pharmacies to dispense an unlicensed drug, HS21 prescriptions must indicate that an unlicensed special is required/prescribed by the GP. This could include the GP annotating the prescription with the following wording: "special order".

This information should be shared with all health care professionals in primary, secondary or specialist healthcare services who prescribe, dispense or administer fluoxetine. To minimise the disruption this may cause locally in terms of patients seeking GP appointments, GP practices may want to consider using local IT systems to identify patients who may be impacted by this shortage and manage in accordance with this guidance.

If you have any queries, please contact DHSCmedicinesupplyteam@dhsc.gov.uk

We hope this information is helpful and thank you for your assistance with this issue.

Yours sincerely,

DHSC Medicines Supply Team