

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



FOR ACTION

Deputy Secretary, Strategic Planning and Performance Group (*for onward transmission to relevant staff*)

Chief Executive, Business Services Organisation (*for onward transmission to relevant staff*)

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Dear Colleagues,

SERIOUS SHORTAGE PROTOCOLS– QUETIAPINE 150MG, 200MG AND 300MG IMMEDIATE RELEASE TABLETS

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 light of ongoing supply concerns across the UK regarding the availability of **quetiapine 150mg, 200mg and 300mg immediate release tablets**, nine new SSPs, introduced with immediate effect and effective until **Friday 13 September 2024**, allow community pharmacists to consider different options to enable continued supply of quetiapine immediate release tablets to mitigate the ongoing supply disruptions affecting certain quetiapine immediate release tablet strengths.

Depending on the prescribed quantity of the affected quetiapine immediate release tablet, the protocols allow pharmacists to either supply a reduced quantity of the same quetiapine immediate release tablet, or substitute with an alternative strength, or provide a reduced quantity of a specific alternative product. For each SSP, DHSC has included specific patients counselling points 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.

For three strengths of quetiapine immediate release tablets affected by ongoing supply disruptions, a total of 9 individual SSPs have been issued by DHSC which allow either:

- **Restriction of the quantity supplied** – where a prescription has a duration of more than one month and supplies are available, an equivalent of one months’ supply will be permitted in accordance with the SSP for the prescribed medicine; or
- **Substitution with a specific alternative product** – where the prescribed duration of treatment is one month or less and supplies are unavailable, a pharmacist can supply a specific alternative product sufficient to provide a quantity equivalent to the number of days supplied on the original prescription, if deemed clinically appropriate; or
- **Substitution with a specific alternative product AND restriction of the quantity supplied** – where a prescription has a duration of more than one month and supplies are unavailable, the SSPs will allow pharmacists to provide one months’ supply of specific alternative product.

A summary breakdown of SSPs available for each strength of quetiapine tablets is listed below.

Drug name	SSP		
	Substitution with a specific alternative quetiapine immediate release strengths	Restriction of the quantity supplied	Substitution with a specific alternative product AND restriction of the quantity supplied
Quetiapine 150mg immediate release tablets	<u>SSPO62</u>	<u>SSPO63</u>	<u>SSPO64</u>

Quetiapine 200mg immediate release tablets	<u>SSPO65</u>	<u>SSPO66</u>	<u>SSPO67</u>
Quetiapine 300mg immediate release tablets	<u>SSPO68</u>	<u>SSPO69</u>	<u>SSPO70</u>

Only one SSP can be used against an individual prescription. Therefore, in each scenario, the pharmacist will need to consider both the pharmacy's stock levels of different quetiapine immediate release tablets strengths and the patient's circumstances before determining which of the SSPs is most appropriate to use. Depending on the SSP used, the change in supply may require additional counselling to ensure that the patient is confident to take their medication.

Pharmacists should refer to the latest version of these SSPs which are available on the Business Services Organisation (BSO) dedicated page on its website:

<https://bso.hscni.net/directorates/operations/family-practitioner-services/pharmacy/contractor-information/drug-tariff-and-related-materials/serious-shortage-protocols-ssps/>.

Please note that DHSC have outlined in each SSP that pharmacists must ensure that the patient's prescriber and/or GP practice is notified when supplying a patient in accordance with these SSPs as soon as practically possible, and within 3 working days. The NI operational guidance is available on the BSO website '[Outline of Operational Guidance for Dispensers in response to issue of a Serious Shortage Protocol](#)'. Pharmacists should be aware of the vulnerability of this patient group and should notify the patient's prescriber as advised above.

Pharmacists should note that the order of preference for substitutions is for patient safety reasons. Pharmacists should explain the correct dosage for those patients who are receiving their immediate release quetiapine in a different strength to that prescribed, emphasising that the effect of the medicine will be the same.

Pharmacists should be aware of the vulnerability of this patient group and take particular time to ensure the patient understands the change in the dosing regime.

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 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 skill and 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. The patient/carer will also need to agree to supply under the SSP.

If a patient/carer declines to receive the medicine under these protocols, 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 ask the SPPG to bring this information to the attention of GP Practices and Community Pharmacists directly.

Yours sincerely,

A handwritten signature in black ink, appearing to read "Cathy Harrison". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Professor Cathy Harrison
Chief Pharmaceutical Officer