From the Chief Pharmaceutical Officer
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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*)
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– CLARITHROMYCIN ORAL SUSPENSIONS

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 current supply disruptions of **clarithromycin 125mg/5ml and 250mg/5ml oral suspensions**, two SSPs, **SSP053** and **SPP054**, have been reactivated by the Department of Health and Social Care (DHSC).

From 22 May 2024, **SSP053** provides that **for every 5ml of clarithromycin 125mg/5ml oral suspension that is originally prescribed. 2.5ml of clarithromycin 250mg/5ml oral suspension can be supplied, with enough packs supplied to cover the full duration of the course**. **SSP054** provides that **for every 5ml of**

clarithromycin 250mg/5ml oral suspension that is originally prescribed, one clarithromycin 250mg tablet can be supplied.

These SSPs, authorised by the Secretary of State on behalf of the four UK nations, has been developed by clinicians and provides pharmacists with procedures to follow in providing suitable alternative products to help reduce the number of patients having to return to their prescriber for a replacement prescription.

Both SSPs are due to expire on **Friday 21 June 2024**. Pharmacists should refer to the latest version of this SSP which is 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/

Key Points:

- These protocols do not allow for the quantity supplied to be less than the number of days prescribed on the original prescription. Enough packs should be supplied to cover the full duration of the course.
- For **SSP053**, pharmacists should ensure that whoever is administering the product understands that the suspension supplied is twice the strength of that prescribed and therefore only half the quantity should be administered.
- Pharmacists should ensure that patients or their carers have an appropriate measuring device e.g. oral syringe and they are appropriately counselled on how to use it and the dose that is to be taken.
- **SSP053** does not allow for the substitution of oral suspension for tablets.
- For **SSP054**, in supplying the tablet form the pharmacist should ensure that patients (particularly children) can swallow tablets. If tablets must be manipulated in some way by patients to be ingested (e.g. crushed) then use in this way may be outside the product licence and is thus “off-label”.
- When the pharmacist deems it appropriate to substitute to the tablet form in accordance with **SSP054** and further guidance is required on off-label administration to aid swallowing (e.g. crushing tablets prior to ingestion), pharmacists should counsel patients/carers in line with the guidance provided by the Specialist Pharmacy Service: Using solid oral dosage form antibiotics in children.
- 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 judgement to make an appropriate

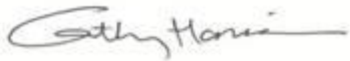
supply under these SSPs. Pharmacists should refer to the relevant Summary of Product Characteristics (SPC) and Patient Information Leaflets (PIL) to inform these decisions.

- Pharmacists do not need to routinely notify the prescriber and/or GP practice where an alternative pharmaceutical form has been supplied under these SSPs. Please refer to 'Outline of Operational Guidance for Dispensers in response to issue of a Serious Shortage Protocol' on the BSO website for more information.
- If a patient/carer declines to receive the medicine under an SSP, 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 the reactivation of these SSPs. I would ask the SPPG to bring this information to the attention of GP Practices and Community Pharmacists directly.

Yours sincerely,



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Chief Pharmaceutical Officer