Chief Medical Officer Directorate Pharmacy and Medicines Division Scottish Government Riaghaltas na h-Alba gov.scot

Dear Colleague

SERIOUS SHORTAGE PROTOCOL: Phenoxymethylpenicillin 125mg/5ml oral solution sugar free

Purpose

1. To advise of a Serious Shortage Protocol (SSP) in place for Phenoxymethylpenicillin 125mg/5ml oral solution sugar free, from 16 December 2022 to 31 January 2023.

Background

- Changes made to the Human Medicines Regulations 2012 and the NHS (Pharmaceutical Services) (Scotland) Regulations 2009, the latter of which became effective from 31 October 2019, allow the use of Serious Shortage Protocols (SSPs).
- 3. An SSP is an additional tool to manage and mitigate medication shortages and may be used when other measures have been exhausted or are likely to be ineffective. There are two types of SSP; one that covers prescription only medicines and another that covers pharmacy and general sales list medicines and appliances.
- 4. Each SSP is individually developed and authorised clinically, to enable community pharmacists and dispensing doctors to dispense a different strength or formulation or alternative medicine or appliances in accordance with the protocol, rather than having to refer prescribing decisions back to the original prescriber. These protocols are time limited.
- 5. Community pharmacists are expected to use their professional skill and judgement to decide whether it is reasonable and appropriate to substitute a person's prescribed medicine using the SSP. The person will also have to agree to the alternative supply.

St Andrew's House, Regent Road, Edinburgh EH1 3DG www.gov.scot

19 December 2022

Addresses

<u>For action</u> Chief Executives, NHS Boards Director Practitioner Services, NHS NSS

<u>For information</u> Directors of Pharmacy NHS Medical Directors

Enquiries to:

Pharmacy Team 1st Floor East Rear St Andrew's House EDINBURGH EH1 3DG

Email: PharmacyTeam@gov.scot

www.gov.scot



- 6. Certain classes of medicines, for example cytotoxic medicines, biologics, anti-epileptic medicines and certain antipsychotic medicines, are not considered to be suitable for SSPs due to concerns about ensuring bioequivalence. In these cases, people should be referred back to the prescriber for any decision about their treatment before any therapeutic or generic alternative is supplied.
- 7. The addition of new SSPs and any amendments or extensions to existing SSPs are documented on the NHS Business Services Authority website using the following link: <u>Serious shortage protocols</u> (<u>SSPs) | NHSBSA.</u>

Medicine supply situation requiring the use of an SSP

- 8. A supply issue with Phenoxymethylpenicillin 125mg/5ml oral solution sugar free has been identified. In order to manage stock supplies fairly and effectively, <u>there is a UK-wide SSP</u> in place. Before supplying in accordance with this SSP, the pharmacist must consider if a suitable supply can be made in accordance with SSP 040. Please see **Annex A** for the standard dosing of phenoxymethylpenicillin by age range.
- 9. Where it is not possible to utilise SSP 040 and where phenoxymethylpenicillin 125mg/5ml oral solution sugar free is not available and prescribed for a duration of no longer than 10 days, the following antibiotics, in order of decreasing preference, can be substituted depending on availability and the dosing needs for the patient as specified in **Annex B**.
 - Amoxicillin 125mg/5ml oral suspension
 - Amoxicillin 125mg/5ml oral suspension sugar free
 - Amoxicillin 250mg/5ml oral suspension
 - Amoxicillin 250mg/5ml oral suspension sugar free
 - Amoxicillin 250mg capsules
 - Amoxicillin 500mg capsules

OR

- Clarithromycin 125mg/5ml oral suspension
- Clarithromycin 250mg/5ml oral suspension
- Clarithromycin 250mg tablets
- Clarithromycin 500mg tablets

OR

- Flucloxacillin 125mg/5ml oral solution
- Flucloxacillin 250mg/5ml oral solution
- Flucloxacillin 125mg/5ml oral solution sugar free
- Flucloxacillin 250mg/5ml oral solution sugar free
- Flucloxacillin 250mg capsules
- Flucloxacillin 500mg capsules

OR

St Andrew's House, Regent Road, Edinburgh EH1 3DG www.gov.scot



(Broader spectrum antibiotics with increased risks of side effects and antimicrobial resistance – reserve for when alternatives unavailable.)

- Cefalexin 125mg/5ml oral suspension
- Cefalexin 125mg/5ml oral suspension sugar free
- Cefalexin 250mg/5ml oral suspension
- Cefalexin 250mg/5ml oral suspension sugar free
- Cefalexin 250mg capsules
- Cefalexin 250mg tablets
- Cefalexin 500mg capsules
- Cefalexin 500mg tablets

OR

- Co-amoxiclav 125mg/31mg/5ml oral suspension
- Co-amoxiclav 125mg/31mg/5ml oral suspension sugar free
- Co-amoxiclav 250mg/62mg/5ml oral suspension
- Co-amoxiclav 250mg/62mg/5ml oral suspension sugar free
- Co-amoxiclav 400mg/57mg/5ml oral suspension sugar free
- Co-amoxiclav 250mg/125mg tablets
- Co-amoxiclav 500mg/125mg tablets
- 10. For prescriptions of Phenoxymethylpenicillin 125mg/5ml oral solution sugar free longer than 10 days, the preferred substitution is one of the following erythromycin formulations, with reference to Annex C for dosing information. In the event erythromycin is unavailable in a suitable formulation/dosage, pharmacists should refer the patient back to the prescriber.
 - Erythromycin 125mg/5ml oral suspension
 - Erythromycin 125mg/5ml oral suspension sugar free
 - Erythromycin 250mg/5ml oral suspension
 - Erythromycin 250mg/5ml oral suspension sugar free
 - Erythromycin 250mg gastro-resistant tablets
 - Erythromycin 250mg tablets
 - Erythromycin 500mg tablets
- 11. This SSP can be accessed using the following link: <u>SSP044 Phenoxymethylpenicillin 125mg-5ml</u> oral solution SF 161222 v9.pdf (nhsbsa.nhs.uk)

Operational overview

12. Between 16 December 2022 and 31 January 2023, for patients presenting with an NHS or private prescription for a supply of Phenoxymethylpenicillin 125mg/5ml oral solution sugar free, community pharmacists may substitute this product with the products and formulations as outlined above.



- 13. Total quantity supplied in accordance with this protocol is to be equivalent to the number of days treatment prescribed on the original prescription. The quantity supplied may be different due to different dosing regimens for different antibiotics.
- 14. For the substituted antibiotic, the quantity and strength supplied is to be determined by the recommended dosing regimen as set out in **Annex B and C** accordingly
- 15. Community pharmacists are asked to review and familiarise themselves with the scope and the clinical situation to which this SSP applies, as outlined in the guidance provided within <u>SSP 044</u>.
- 16. Pharmacists must ensure that the patient's prescriber and/or GP practice is notified within 24 hours when supplying a patient in accordance with this SSP.
- 17. Patients considered to be unsuitable or at higher risk as outlined in the "Criteria for exclusion section of <u>SSP 044</u> need to be referred back to their prescriber promptly for further advice.

Additional information

- 18. The Royal Pharmaceutical Society has issued an infographic: <u>PowerPoint Presentation</u> (<u>rpharms.com</u>).
- 19. For diabetic patients, pharmacists should supply sugar free options where possible. If this is not available, patients/carers should be informed that there is a small amount of sugar contained in the product supplied but do not withhold treatment.
- 20. Ensure that patients considered unsuitable for inclusion are promptly referred to their prescriber for further advice.
- 21. If a patient/carer declines to receive medicine in accordance with this SSP, then they should be referred back to their prescriber promptly.

Switching from liquid to solid phenoxymethylpenicillin

22. When the medicine is for a child and the pharmacist deems it appropriate to substitute to the tablet form in accordance with this SSP, patients/carers should be directed to the following guidance: Using solid oral dosage form antibiotics in children – SPS - Specialist Pharmacy Service.

Supporting information on notifying other healthcare professionals

- 23. Any items supplied in accordance with an SSP in response to an NHS prescription also needs to be supplied in accordance with NHS Pharmaceutical and Local Pharmaceutical Services Regulations.
- 24. Those Regulations provide that where a therapeutic equivalent is supplied, a pharmacist will need to inform a patient's GP practice. This would generally be expected within the next working day, but further guidance would be given in any case where this applied.
- 25. Where a different quantity, an alternative pharmaceutical form, an alternative strength or a generic equivalent is provided, it may not always be necessary that the patient's prescriber is informed, as the existence of the SSP may be enough for the prescriber to be aware that these changes in

St Andrew's House, Regent Road, Edinburgh EH1 3DG www.gov.scot



dispensing may take place, unless national arrangements agreed with the relevant representative bodies state otherwise. However, guidance may be issued on particular SSPs to indicate that prescribers should be informed of any patients that receive supply under it.

26. In the absence of any preferred local alternate communication channels, all feedback to prescribers should be sent by NHSmail. The NHS Service Finder is a way for pharmacies to look up the email address of the patient's GP.

Fees and Endorsements

- 27. When an SSP is introduced, the pharmacist should use the Other endorsement function quoting SSP and the relevant reference number in this case add SSP 044. A community pharmacy contractor will receive a multiplier per item of 5 (x5), via the dispensing pool, for any necessary supply in accordance with SSPs. Endorsements must be made in line with the SSP to be eligible for payment.
- 28. The paper form should be endorsed PMR with details added of what was supplied as well as 'SSP 044' annotated. This is to ensure accurate reimbursement for non-barcoded forms or where an electronic claim message is unavailable.

Enquiries

29. For any queries on the detail of this SSP, please contact the Scottish Government Pharmacy Team at PharmacyTeam@gov.scot.

Action

30. Health Boards are asked to note the contents of this Circular and to bring it to the attention of community pharmacy contractors on their Pharmaceutical Lists and Area Pharmaceutical Committees. This Circular should also be brought to the attention of General Practices.

Yours sincerely

Alison Strath Chief Pharmaceutical Officer



Annex A- Standard dosing of phenoxymethylpenicillin by age range

| Age range | Phenoxymethylpenicillin dose | |
|-------------|---|--|
| 1-11 months | 62.5mg four times a day or 125mg twice a day. | |
| 1-5 years | 125mg four times a day or 250mg twice a day. | |
| 6-11 years | 250mg four times a day or 500mg twice a day. | |
| 12-17 years | 500mg four times a day or 1000mg twice a day. | |
| Adult | 500mg four times a day or 1000mg twice a day. | |

Annex B- Alternative antibiotic products and dosing information

The total quantity to be supplied in accordance with this protocol is to be equivalent to the number of days treatment prescribed on the original prescription.

| Alternative product | Age | Usual treatment dose | Available formulations | Interactions and side effects |
|------------------------|--|----------------------------|---|-------------------------------------|
| Amoxicillin | 1-11 months | 125mg three times a day. | Amoxicillin 125mg/5ml oral suspension | Interactions Side effects |
| Amoxicillin | 1-4 years | 250mg three times a day | Amoxicillin 125mg/5ml oral suspension sugar free | |
| Amoxicillin | 5-17 years and adult | 500mg three times a day. | Amoxicillin 250mg/5ml oral suspension Amoxicillin 250mg/5ml oral suspension sugar free Amoxicillin 250mg capsules Amoxicillin 500mg capsules | |
| Clarithromycin | 1 month- 11 years (body weight up to 8kg) | 7.5mg/kg twice daily. | Clarithromycin 250mg tablets Clarithromycin 125mg/5ml oral suspension Clarithromycin 250mg/5ml oral suspension Clarithromycin 500mg | Interactions Side effects |
| Clarithromycin | 1 month- 11 years (body weight 8-11kg) | 62.5mg twice daily. | | |
| Clarithromycin | 1 month- 11 years (body weight 12- 19kg) | 125mg twice daily. | tablets | |
| Clarithromycin | 1 month- 11 years (body weight 20- 29kg) | 187.5mg twice daily. | | |
| Clarithromycin | 1 month- 11 years (body | 250mg twice daily. | | |



| | weight 30- | | |
|------------------------------|--|--|---|
| | 40kg) | | _ |
| Clarithromycin | 12-17 years and adult | 250mg twice daily. | |
| Cefalexin | 1-11 months | 125 mg twice daily. | Cefalexin 250mg capsules Cefalexin 500mg capsules <u>Interactions</u> <u>Side effects</u> |
| Cefalexin | 1-4 years | 125 mg three times a day. | Cefalexin 500mg tablets Cefalexin 125mg/5ml oral |
| Cefalexin | 5-11 years | 250 mg three times a day. | suspensionCefalexin 125mg/5ml oral |
| Cefalexin | 12-17 years | 500 mg twice a day. | suspension sugar freeCefalexin 250mg/5ml oral |
| Cefalexin | Adult | 250 mg every 6 hours, OR 500 mg every 12 hours. | suspension Cefalexin 250mg/5ml oral suspension sugar free |
| Flucloxacillin | 1 month - 1 year | 62.5mg four times a day. | Flucloxacillin 250mg capsules <u>Interactions</u> <u>Side effects</u> |
| Flucloxacillin | 2-9 years | 125mg four times a day. | Flucloxacillin 500mg capsules |
| Flucloxacillin | 10-17 years | 250mg four times a day. | Flucloxacillin 125mg/5ml oral solution |
| Flucloxacillin | Adult | 250mg four times a day. | Flucloxacillin 125mg/5ml oral solution sugar free Flucloxacillin 250mg/5ml capsules oral solution Flucloxacillin 250mg/5ml capsules oral solution sugar free |
| Co-amoxiclav | 1-11 months | 125mg/31mg per 5ml suspension - 0.25mL/kg three times a day. | Co-amoxiclav 125mg/31mg per 5ml oral suspension Co-amoxiclav 125mg/31mg Interactions Side effects |
| | 2 – 23 months | 400mg/57mg per 5ml suspension- 0.15mL/kg twice daily. | per 5ml oral suspension sugar free Co-amoxiclav 250mg/62mg |
| Co-amoxiclav Co-amoxiclav | 1-5 years | 125mg/31mg per 5ml suspension - 0.25mL/kg three times a day. | per 5ml oral suspension Co-amoxiclav 250mg/62mg per 5ml oral suspension |
| | 2-6 years (body weight 13-21kg) | 400mg/57mg per 5ml suspension- 2.5mL twice daily. | sugar free Co-amoxiclav 400mg per 57mg per 5ml oral |
| | 6-11 years | 250mg/62mg per 5ml suspension – 5mL three times a day. | suspension sugar free Co-amoxiclav 250mg/125mg tablets |
| | 7 – 12 years (body weight 22 – 40kg) | 400mg/57mg per 5ml suspension- 5mL twice daily. | Co-amoxiclav 500mg/125mg tablets |

St Andrew's House, Regent Road, Edinburgh EH1 3DG www.gov.scot





| Co-amoxiclav | 12-17 years 12 – 17 years (body weight 41kg and above) | 250/125 mg tablet- 1 tablet every 8 hours. 400mg/57mg per 5ml suspension- 10mL twice daily. |
|--------------|---|---|
| o-amoxiclav | Adult | 250/125 mg tablet- 1 tablet every eight hour |
| | | 400mg/57mg per 5ml suspension- 10mL twice daily. |

Annex C - For patients receiving phenoxymethylpenicillin for long term prophylaxis offer erythromycin as per below: The total quantity to be supplied in accordance with this protocol is to be equivalent to the number of days treatment prescribed on the original prescription.

| Alternative product | Age | Dose | Available formulations | Interactions |
|------------------------|--------------------------|---------------------|--|------------------------------|
| Erythromycin | 3 months up to 1 year | 62.5mg twice a day. | Erythromycin stearate 250mg tablets | Interactions Side effects |
| Erythromycin | 1 year up to 5 years | 125mg twice a day. | Erythromycin stearate 500mg tablets | |
| Erythromycin | 5 years and above | 250mg twice a day. | Erythromycin 250mg gastroresistant tablets Erythromycin ethyl succinate 500mg tablets Erythromycin ethyl succinate 125mg/5ml oral suspension Erythromycin ethyl succinate 125mg/5ml oral suspension sugar free Erythromycin ethyl succinate 250mg/5ml oral suspension Erythromycin ethyl succinate 250mg/5ml oral suspension sugar free Erythromycin ethyl succinate 250mg/5ml oral suspension Erythromycin ethyl succinate 250mg/5ml oral suspension Erythromycin ethyl succinate 250mg/5ml oral suspension Erythromycin ethyl succinate 500mg/5ml oral suspension Erythromycin ethyl succinate 500mg/5ml oral suspension | |