NHS Circular: MSAN (2025) 44

Chief Medical Officer Directorate Pharmacy and Medicines Division



27 October 2025

# **Medicine Supply Alert Notice**

# **Antimicrobial Agents Used in Tuberculosis (TB) Treatment**

Priority: Level 3\*

Valid until: TBC - Please refer to medicines supply tool on the Specialist Pharmacy Service (SPS) website for updates on anticipated resupply dates (registration required)

#### Issue

- 1. Following the UK-wide <u>National Patient Safety Alert</u> issued on 29 July 2025, the supply situation for antimicrobial medicines used to treat TB has significantly improved. **Please note that this MSAN supersedes the noted National Patient Safety Alert (NatPSA)**.
- 2. UK licensed packs of rifampicin 150mg capsules, rifampicin 600mg IV vials, and Rifinah® 300 (rifampicin 300mg / isoniazid 150mg) tablets remain constrained and will be available intermittently.
- 3. Unlicensed imports of Rifampicin 150mg capsules, rifampicin 600mg IV vials, and Rifinah® 300 (rifampicin 300mg / isoniazid 150mg) tablets have been sourced in sufficient quantities to meet gap in supply of licensed packs; however, lead times may vary.
- 4. Licensed stock of other TB treatments is now available. To ensure fair distribution of licensed stock, monthly allocations will be implemented across the UK for specific TB medicines as they become available. Allocation details will be shared directly with Health Boards via NSS National Procurement.
- 5. For full information on stock levels, allocations, importer details, and expected resupply dates, please refer to the Medicines Supply Tool (registration required see paragraph 17 for details on how to register).
- 6. Normal services can now resume, including latent TB screening / treatment and, where needed, the prescribing of rifampicin capsules for non-TB indications in both primary and secondary care. Utilisation of available licensed stock and unlicensed imports should be optimised to ensure continuity of patient treatment.

#### **Advice and Actions**

- 7. Hospital pharmacy procurement teams, clinical teams (including clinicians, TB nurses, and other non-medical prescribers), should:
  - coordinate prescribing and supply to ensure prescriptions are issued for appropriate durations, and to identify required stock and incoming supplies.
  - review stock levels of TB medicines regularly to maintain continuity of care.

<sup>\*</sup>https://www.nss.nhs.scot/media/1842/medicine-supply-alert-notices-definitions-of-classifications-21-october-2019.pdf

- order licensed stock in line with monthly Health Board-level allocations for affected products, and only from the designated wholesalers (see Additional Information section).
- maintain buffer stock of key TB medicines using unlicensed imports where licensed products remain unavailable. Specifically:
  - o At least one month of rifampicin 150mg capsules and rifampicin 600mg vials
  - o At least three months of rifampicin 300mg / isoniazid 150mg tablets (see Additional
  - Information section);
  - o At least one month of rifampicin 120mg / isoniazid 50mg / pyrazinamide 300mg tablets.
- liaise with National Procurement in urgent cases to explore options for mutual aid between Health Boards;
- counsel patients appropriately on any changes to their usual TB medication, particularly when switching from licensed to unlicensed products; and
- liaise with primary care clinicians to review non-TB patients affected by the NatPSA (e.g., those whose rifampicin treatment was changed or stopped).
- 8. Primary care clinicians can begin prescribing rifampicin capsules for all licensed indications where no alternatives are available and treatment is required.

#### **Additional Information**

## **Supply Information**

## **Availability of Licensed Stock and Stock Allocation Details**

- 9. There is sufficient UK licensed stock of the following TB medicines to meet ongoing demand:
  - Ethambutol 100mg and 400mg tablets
  - Isoniazid 50mg and 100mg tablets
  - Pyrazinamide 500mg tablets
  - Rifinah<sup>®</sup> 150 tablets (rifampicin 150mg / isoniazid 100mg)
  - Rifampicin 100mg/5 ml syrup
  - Rifampicin 300mg capsules
- 10. For the following TB medicines, current forecasts indicate that the availability of licensed stock may be intermittent and unable to meet full demand. Therefore, monthly allocation will be implemented across the UK, and any additional demand or supply gaps can be met with imported stock:
  - Rifampicin 150mg capsules and 600mg IV vials
  - Rifater® tablets (rifampicin 120mg / pyrazinamide 300mg / isoniazid 50mg)
  - Rifinah® 300 tablets (rifampicin 300mg / isoniazid 150mg)
  - Voractiv<sup>®</sup> tablets (ethambutol hydrochloride 275mg / isoniazid 75mg / pyrazinamide 400mg / rifampicin 150mg)
- 11. To support equitable distribution:
  - Allocations for Voractiv<sup>®</sup> tablets in Scotland will be managed by AAH.

- For Sanofi products Rifampicin 150 mg capsules, Rifinah® 300 tablets, Rifater® tablets, and Rifampicin 600 mg vials - allocations will be managed directly by Sanofi and distributed via AAH and Phoenix for secondary care.
- Sanofi, in agreement with National Procurement, manages available stock for primary care by verifying valid prescriptions before releasing medicines to ensure fair distribution.
- 12. National Procurement will share allocation details directly with individual Health Boards. National Procurement will monitor compliance with the allocation process and intervene where duplicate or noncompliant orders are identified, particularly for Sanofi products.

## Unlicensed Imports

- 13. Due to the improved availability and to enable more flexible local management, central allocation of unlicensed imports has now ceased. Health Boards are now responsible for ordering directly and should maintain at least a one-month buffer stock of key TB medicines using unlicensed imports where licensed products remain unavailable. This applies particularly to Rifampicin 150mg capsules, Rifater® tablets, Rifampicin 600mg vials, and Rifinah® 300 tablets.
- 14. NHS England's Medicines Procurement and Supply Chain (MPSC) team will continue to monitor stock levels held by importers, as well as importer capacity to maintain supply. Health Boards should refer to the Medicines Supply Tool, available on the Specialist Pharmacy Service (SPS) website, which remains the central source for up-to-date information on current supply status, allocation details, importer contacts, and expected resupply dates.

#### Latent TB

15. Regarding latent TB services, it is acknowledged that some services were paused due to medicine shortages. However, current stock held within Health Boards, combined with the availability of unlicensed imports and limited licensed stock, should now be sufficient to allow services to resume. Prescribers can consider issuing full treatment courses where appropriate.

### Guidance on ordering and prescribing unlicensed imports

- 16. Any decision to prescribe an unlicensed medicine must consider the relevant guidance and Health Board local governance procedures. Unlicensed imports do not undergo any central quality assessment or suitability evaluation. Therefore, any import must be locally assessed in line with local unlicensed medicines processes. Please see the links below for further information:
  - <u>The supply of unlicensed medicinal products</u>, Medicines and Healthcare products Regulatory Agency (MHRA)
  - <u>Professional Guidance for the Procurement and Supply of Specials</u>, Royal Pharmaceutical Society
  - Prescribing unlicensed medicines, General Medical Council (GMC)

## Links to further information

- BNF Ethambutol preparations
- SmPC Ethambutol preparations

- BNF Isoniazid preparations
- SmPC Isoniazid preparations
- BNF Pyrazinamide preparations
- SmPC Pyrazinamide preparations
- BNF Rifampicin preparations
- SmPC Rifampicin preparations
- BNF Rifater® Tablets
- SmPC Rifater<sup>®</sup> Tablets
- BNF Voractiv® Tablets
- SmPC Voractiv® tablets
- TB Alert: Important Patient information

# Specialist Pharmacy Service (SPS) website

- 17. The UK Department of Health and Social Care (DHSC) in conjunction with the Specialist Pharmacy Service (SPS) have launched an online Medicines Supply Tool, which provides up to date information about medicine supply issues. To access the online Medicines Supply Tool you need to register with the <a href="SPS website">SPS website</a>. Registration for access to the website is available to UK healthcare professionals and organisations providing NHS healthcare. The tool is located under the Tools tab and then click on the Medicines Supply option.
- 18. We encourage prescribers, pharmacy professionals, and pharmacy procurement leads in Scotland to register with the SPS website and use its Medicine Supply Tool to stay up to date concerning medicines supply disruptions. Please be aware that while medicines supply issues will appear on the SPS website, some of the recommended actions may not always be appropriate / relevant within the Scottish context.

#### **Enquiries**

19. Enquiries from Health Boards or healthcare professionals should be directed in the first instance to <a href="mailto:PharmacyTeam@gov.scot">PharmacyTeam@gov.scot</a> (primary care) or <a href="mailto:NSS.NHSSMedicineShortages@nhs.scot">NSS.NHSSMedicineShortages@nhs.scot</a> (secondary care).