

To: All Community Pharmacists

23rd October 2025

Dear colleague

Medicine Supply Notification

This Medicines Supply Notification supersedes the National Patient Safety Alert issued on 29 July 2025.

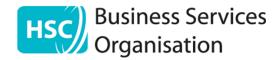
Antimicrobial Agents Used in Tuberculosis (TB) Treatment

Tier 3 – high impact

<u>Medicines Supply Tool – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice</u>

Summary

- Following the National Patient Safety Alert issued on 29 July 2025, the supply situation for antimicrobial medicines used to treat tuberculosis has significantly improved.
- 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.
- 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.
- Licensed stock of other tuberculosis treatments is now available. To ensure fair distribution of licensed stock, monthly Trust-level allocations will be implemented across the UK for specific TB medicines as they become available. Allocation details will be shared directly with Trusts via their Regional Pharmacy Procurement Specialist (RPPS).
- For full information on stock levels, allocations, importer details, and expected resupply dates, please refer to the Medicines Supply Tool.
- 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.



Secondary care pharmacy procurement teams, clinical teams (including prescribers, TB nurses, and clinicians), and any outsourced partners 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.
- order licensed stock in line with monthly Trust-level allocations for affected products, and only from the designated wholesalers (see Supporting Information).
- maintain buffer stock of key TB medicines using unlicensed imports where licensed products remain unavailable. Specifically:
- -At least one month of rifampicin 150mg capsules and rifampicin 600mg vials
- -At least three months of rifampicin 300mg / isoniazid 150mg tablets (see Supporting Information);
- -At least one month of rifampicin 120 mg / isoniazid 50 mg / pyrazinamide 300 mg tablets.
 - liaise with Specialist Pharmacy Service (SPS) Regional Pharmacy Procurement Specialist in urgent cases to explore options for mutual aid between NHS provider trusts;
 - 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).

Primary care clinicians can begin prescribing rifampicin capsules for all licensed indications where no alternatives are available and treatment is required

Actions Required

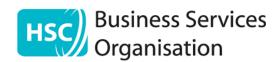
Supporting information

Supply Information

Availability of Licensed Stock and Stock Allocation Details

There is sufficient UK licensed stock of the following TB medicines to meet ongoing demand:

- Ethambutol 100 mg and 400 mg tablets
- Isoniazid 50 mg and 100 mg tablets
- Pyrazinamide 500 mg tablets
- Rifinah® 150 tablets (rifampicin 150 mg / isoniazid 100 mg)
- Rifampicin 100 mg/5 ml syrup



Rifampicin 300 mg capsules

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 150 mg capsules and 600 mg IV vials
- Rifater® tablets (rifampicin 120 mg / pyrazinamide 300 mg / isoniazid 50 mg)
- Rifinah® 300 tablets (rifampicin 300 mg / isoniazid 150 mg)
- Voractiv® tablets (ethambutol hydrochloride 275 mg / isoniazid 75 mg / pyrazinamide 400 mg / rifampicin 150 mg)

To support equitable distribution:

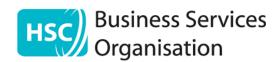
- Allocations for Voractiv® tablets in England will be managed by Phoenix Healthcare, while AAH will supply the devolved nations.
- For Sanofi products Rifampicin 150 mg capsules, Rifinah® 300 tablets, Rifater® tablets, and Rifampicin 600 mg vials — allocations will be managed directly by Sanofi and distributed via AAH and Phoenix for secondary care.
- Sanofi, in agreement with the Medicines Procurement and Supply Chain (MPSC) team at NHSE, manages available stock for primary care by verifying valid prescriptions before releasing medicines to ensure fair distribution.

Regional Pharmacy Procurement Specialists (RPPSs) will share allocation details directly with individual Trusts. They will monitor compliance with the allocation process and intervene where duplicate or non-compliant orders are identified, particularly for Sanofi products

Unlicensed Imports

SPS Procurement has worked with the Medicines Procurement and Supply Chain (MPSC) team to centrally coordinate the allocation of unlicensed TB medicines. However, due to improved availability and to enable more flexible local management, central allocation of unlicensed imports has now ceased. Trusts 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.

The MPSC team will continue to monitor stock levels held by both Trusts and importers, as well as importer capacity to maintain supply. Trusts should refer to the Medicines Supply Tool, which remains the central source for up-to-date information on current supply status, allocation details, importer contacts, and expected resupply dates.



Latent TB

Regarding latent TB services, it is acknowledged that some services were paused due to medicine shortages. However, current stock held within Trusts, 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

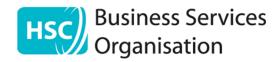
Any decision to prescribe an unlicensed medicine must consider the relevant guidance and NHS Trust or local governance procedures. Unlicensed imports do not undergo any central quality assessment or suitability evaluation. Therefore, any import must be locally assessed in line with local unlicensed medicines processes. Please see the links below for further information:

- The supply of unlicensed medicinal products, Medicines and Healthcare products Regulatory Agency (MHRA) <u>The supply of unlicensed medicinal products special GN14.pdf</u>
- Professional Guidance for the Procurement and Supply of Specials, Royal Pharmaceutical Society specials-professional-guidance.pdf
- Prescribing unlicensed medicines, General Medical Council (GMC) <u>Prescribing unlicensed</u> medicines professional standards GMC

When prescribing a product that is not licensed in the UK due to a supply issue with the licensed alternative prescribers must indicate on the HS21 prescription that an unlicensed product is required, with the following wording: "special order"

Links to further information

- BNF Ethambutol preparations Ethambutol hydrochloride | Drugs | BNF | NICE
- SmPC Ethambutol preparations Search Results (emc)
- BNF Isoniazid preparations Isoniazid | Drugs | BNF | NICE
- SmPC Isoniazid preparations Search Results (emc)
- BNF Pyrazinamide preparations Pyrazinamide | Drugs | BNF | NICE
- SmPC Pyrazinamide preparations Search Results (emc)
- BNF Rifampicin preparations Rifampicin | Drugs | BNF | NICE
- SmPC Rifampicin preparations Search Results (emc)
- BNF Rifater® Tablets Rifampicin with isoniazid and pyrazinamide | Drugs | BNF | NICE



- SmPC Rifater® Tablets <u>Rifater 50mg/120mg/300mg Tablets Summary of Product</u> Characteristics (SmPC) - (emc) | 1596
- BNF Voractiv® Tablets <u>Rifampicin with ethambutol, isoniazid and pyrazinamide | Drugs | BNF |</u> NICE
- SmPC Voractiv® tablets <u>Voractiv Film-coated Tablets Summary of Product Characteristics</u> (SmPC) (emc) | 10609

TB Alert: Important Patient information <u>TB medication supply - important patient information - TB AlertTB Alert</u>