



Why do medicines supply issues occur



The first stop for professional medicines advice







Reasons for supply issues

- Regulatory compliance issues and changes to standards
- API supply issues
- Batch testing failures and investigations (OOS results)
- Regulatory approval timescales
- Usage data and clinical guidelines
- Positioning of stock in the supply chain
- Logistical challenges
- Commercial factors
- Unforeseen factors





Reasons for supply issues

- Supply chain complexity time to respond?
- Global market API, contract manufacture, finished product, testing and release, logistics, wholesale
- Tendering processes and timelines

Examples:

- Desferrioxamine
- Epirubicin
- Pabrinex





Global medicines supply chain







Navigating Medicine Supply Issues in Secondary Care

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Who is involved in managing shortages









Who's who

- DHSC is responsible for the overall continuity of supply of medicines to the NHS and day-to-day management of medicine supply issues across primary and secondary care
- NHS England Medicines Procurement & Supply Chain (MPSC) has specific responsibilities relating to any secondary care medicines and certain homecare services procured on MPSC frameworks
- ☐ The Medicines Shortage Response Group (MSRG) is a multidisciplinary cross-sector group, chaired by the Head of the Specialist Pharmacy Service, that provides governance and oversight, as well as support, to the DHSC Medicines Supply Team and the NHSE MPSC Pharmacy and Supply Team, in the management of medicines shortages

None of these bodies has the power to buy medicines







Medicines Shortages Response Group (MSRG)

Issue notification

Risk assessment

Management options

A clinically chaired decision-making body to oversee and support both MST and MPSC

Commissions expert advice from NCDs, GIRFT leads, CRG chairs and or Royal Colleges / other professional bodies.

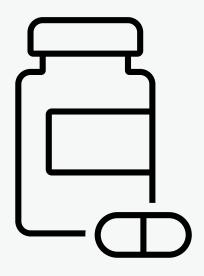
Agrees the content and dissemination routes for communications to 'the system' and

Provides sign off for management plans

A key role of MSRG is to determine and oversee escalation and deescalation

Representatives from patient safety, primary care, RPPS, H&J, Comms, SPS, DAs, MHRA

Pharmacy & Medicines and Supply Chain team



Responsibilities

- Team of 4, 2 pharmacists and 2 pharmacy technicians
- Delegated responsibility for managing secondary care MPSC framework medicine supply issues
- Supplier engagement and performance management of suppliers in relation to medicine supply and professional issues
- Data collection and creation of reports that support supply chain decisions e.g. COVID-19
- Supply chain reports KPI reporting and supply system level confidence to stakeholders
- Leading NHSEs long term supply chain resilience plans
- Professional pharmacy support to MPSC category teams and external stakeholders





Process for managing a supply issue

Issue notification

Risk assessment

Management options

- DaSH
- MPSC supplier reports
- MHRA
- NHS
- Patients and patient groups
- DAs
- Correspondence
- Clinical networks
- Representative bodies

- Nature of the problem
- Duration
- Indication (licensed and unlicensed)
- Usage
- Market share
- Alternative products
- Clinical need
- Assign as Tier 1-4

- Working with manufacturer and alternative suppliers
- Wholesalers
- Expediting regulatory procedure
- Unlicensed imports
- Escalate to MSRG
- Commissioning clinical advice
- Issuing NHS communications, e.g. Medicines Supply Notifications or National Patient Safety Alerts
- Briefing Ministers and top of the office (TOTO)







Medicines Supply Issue Tier System & mitigating actions

Tier	Definition	Characteristics	Decision making authority
1: Low Impact	Likely to carry low risk. Management options should result in patients being maintained on the same licensed medicine.	 Supply problems with a short expected duration and where temporary supply controls are expected to manage available stock. Other suppliers of the same medicine are likely to fulfil supply gap. Quantities of an alternative strength or formulation of the same medicine are available to meet the full supply gap and the switch is considered very low risk 	DHSC Meds Supply Team or NHS MPSC
2: Medium Impact	Require more intense management options which may carry a greater risk, but considered safe to be implemented locally without further escalation.	 Require clinical guidance in decision Therapeutic alternatives are available, and Specialist Pharmacy Service MI function has deemed that there are limited clinical risks associated with switching. Unlicensed imports of the same medicine are available in sufficient quantities to meet a supply gap. 	
3: High Impact	Considered more critical than tier two issues, with potential patient safety implications that may require clinical advice to the system.	 No or limited clinical alternatives The product is one designated by the MHRA where a patient should be maintained on the same brand or where switching between preparations is particularly difficult. The process of switching a patient to a therapeutic alternative requires monitoring. The medicine is used in life saving conditions such as anaphylaxis. The patient group affected is likely to be considered a vulnerable population 	MSRG
4: Critical Impact	Cannot be resolved as a level three shortage, and which requires additional support from outside the health system.	 A supply gap remains (and no viable therapeutic alternatives exist) following the exhaustion of supply and clinical management plans at previous levels of escalation. Likely to have a life-threatening impact on patients. Requires the support of agencies outside the health system (e.g. Department for Transport, police services) to support its management. 	ORC / EPRR / Ministers, based on MSRG advice

DHSC MST leads on investigations into potential medicines shortages, working with MPSC and other stakeholders. Tier 1 & 2 cases managed by DHSC MST and the MPSC, will undertake the following activities to investigate the disruption and develop recommendations for resolution (Note some higher level Tier 2 issues could be managed by MSRG).

Tier 1-2 incidents



Manufacturer: Investigate cause of supply issue and explore increasing production of affected product / sourcing alternatives



Specialist Pharmacy Services / Clinical Experts: Provide guidance on clinical management of disruption



Logistics: NSDR Case Assistant and Freight Desk assess whether disruption can be addressed via 'specials' express freight solutions



Regional Pharmacy
Procurement Specialists: Assess
regional product usage and stock
duration



MHRA: Support the resolution of supply issues (e.g. expedite regulatory approval for critical products / alternatives)



Wholesalers: Work with suppliers to manage supply of existing stocks in the country to mitigate disruption

Tier 3 & 4 cases are escalated by DHSC MST and the NHSE MPSC to MSRG who will oversee and provide input into management, escalation and communication dissemination plans. MST and MPSC may call upon solutions for Tier 1-2 incidents to also resolve Tier 3-4 incidents, such as working with wholesalers.

Tier 3-4 incidents



MSRG: Commission advice from Medical Directorate, guide NHS communications, decide on EPRR escalation.

Allocation and distribution group. Sub-group of MSRG.
Works with RPPS and DAs to move medicines between
trusts to prevent shortages arising.



ORC / EPRR: MSRG escalate to the ORC and EPRR via the NSDR Office

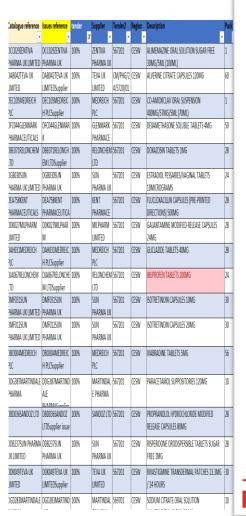


NHSE Medical Directorate: Clinical advice from NCDs, GIRFT leads, CRG chairs and Royal Colleges.

















Shortage of GLP-1 receptor agonists

Date of issue: NatPSA/2023/008/DHSC 18-Jul-23 Reference no:

This alert is for action by: All organisations involved in prescribing and dispensing GLP1-RA medicines

This is a safety critical and complex National Patient Safety Alert. Implementation should be co-ordinated by an executiv lead (or equivalent role in organisations without executive boards) and supported by clinical leaders in diabetes. GP practices, pharmacy services in all sectors, weight loss clinics, private healthcare providers, those working in the Health

Explanation of identified safety issue:

There are very limited, intermittent supplies of all glucagon-like peptide-1 receptor agonists (GLP-1 RAS) NOTE A

Supplies are not expected to stabilise to meet full market demand until at least mid-2024.

The supply issues have been caused by an increase in demand for these products for licensed and off-label indications.

The off-label use of these agents for the management of obesity is strongly discouraged. Existing stock must be conserved for use in patients with diabetes. These shortages have serious clinical implications in the management of patients with type 2 diabetes. The clinical implications include erratic blood glucose control, with the potential to increase diabetes-related complications, including the risk of future cardiovascular events and diabatic ketoacidosis

Patients established on GLP-1 RA products may not be able to access products which could result in treatment failure and/or a loss of blood glucose control. Some patients established on GLP-1 RA therapy for type 2 diabetes may need to be switched to alternative treatments including insulin. Initiating insulin therapy requires training and education alongside a potential need for enhanced glucose monitoring to ensure patients are aware of how to recognise and manage hypoglycaemic events.

Saxenda (liraglutide), a GLP-1 RA licensed for weight loss is unavailable until mid-2024.

ctions required

Actions to be completed as soon as possible. and not later than 18/10/2023

Actions for clinicians and prescribers of GLP-1 RAs until supply issues have resolved.

- Only prescribe GLP-1 RAs for their licensed
- Do not initiate new patients on GLP-1 RAs for the duration of the shortage
- Proactively identify patients established on affected GLP-1 RAs and consider prioritising for review based on the criteria set out in the clinical guidance
- i. discuss stopping treatment with patients who have not achieved treatment targets as per NICE NG28 or NICE CG189
- ii. do not switch between brands of GLP-1 RAs, including between injectable and oral forms.
- iii. do not double up a lower dose preparation where a higher dose preparation of GLP-1 RA is not available.
- iv. do not prescribe excessive quantities: limit prescribing to minimise risk to the supply chain whilst acknowledging the needs of the patient.
- Use the principles of shared decision making where an alternative agent needs to be considered, as per NICE guidelines3 and in conjunction with the clinical guidance.2,4
- Support patients to access structured education and weight management programmes where
- For type 2 diabetics; If switching a patient on to insulin, please ensure an insulin is chosen as per information on the SPS page on prescribing available insulins as not all suppliers are able to manage an uplift in demand.4

For further detail, resources and supporting materials see: Enter specific webpage provided by alert issue

For any enquiries about this alert contact: DHSCmedicinesupplyteam@dhsc.gov.uk



Department of Health & Social Care



MSN/pagy/book

Medicine Supply Notification

Generic drug name (brand name®) strength formulation Tier 2 - medium impact*

Date of issue: dd/mm/yyyyy Link: Medicines Supply Tool

Summary (add/delete as appropriate)

- Name (brand name*) strength form is out of stock until date month year.
 Alternate strengths of name (strength) form remain available and will be able to support increased
- . Alternate brand(s)/another formulation remains available. Where these are not suitable, unlicensed supplies may be sourced, lead times vary. (delete if not appropriate

Actions Required (adapt/delete as appropriate)

Where patients have insufficient supplies to last until the re-supply date, clinicians/prescribers should:

- · review patients to determine if this is still the most suitable therapy;
- · work with local pharmacy teams to understand availability of alternative strengths and issue a prescription to make up the required dose of drug name;
- . consider prescribing xxx which is able to support the market during this time, ensuring that the patient is not intolerant to any of the excipients and is counselled on the appropriate dose and volume required (see supporting information below);
- consider prescribing unlicensed products only where licensed alternatives are not appropriate Prescribers should work with local pharmacy teams to ensure orders are placed within appropriate time frames as lead times may vary (see supporting information below); and
- · if the above options are not considered appropriate, advice should be sought from specialists on

f the patient is deemed ineligible or does not consent to receive an alternative product via the SSP, clinicians can consider prescribing:

- · a suitable alternative medicine.

Supporting information (add/delete as appropriate)

Clinical Information

· Include SPS MI advice if provided

*Classification of Tiers can be found at the following link:

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SERIOUS SHORTAGE PROTOCOL (SSP)

Reference Number: SSP057

This SSP applies to the following medicine:

Name of medicine (including strength and formulation)	Estradot® (Estradiol (as hemihydrate)) 100 microgram patch	
	Pharmacists must ensure that the patient's prescriber and/or GP practice is notified when supplying a patient in accordance with this SSP. Pharmacists in Northern Ireland should note the specific guidance included in the addendum to this SSP.	
Legal category	POM	

1. Details of medication to be supplied under this SSP

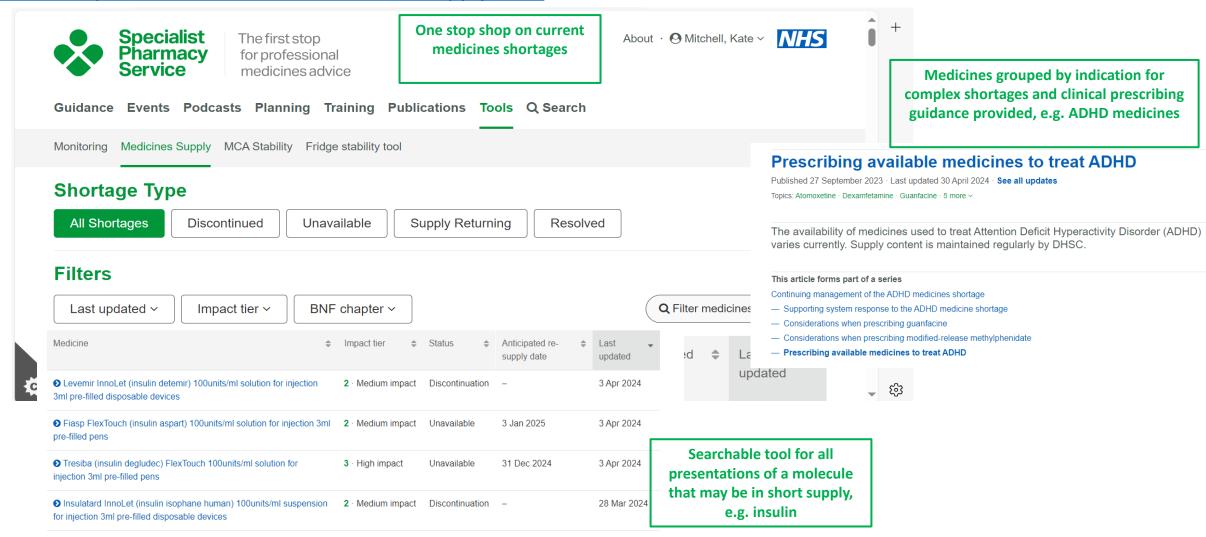
Name of medicine (including formulation and strength) to be supplied	Evorel® 100 microgram patch OR Estraderm MX® 100 microgram patch
Quantity of this formulation (if applicable)	Total quantity supplied under this protocol to be equivalent to the number of days supplied on the original prescription.
	For every Estradot® 100 microgram patch, the following quantity must be supplied in accordance with this protocol:
	1 x Evorel® 100 microgram patch



The Medicines Supply Tool



https://www.sps.nhs.uk/home/tools/medicines-supply-tool/







Steps to Manage a Supply Issue



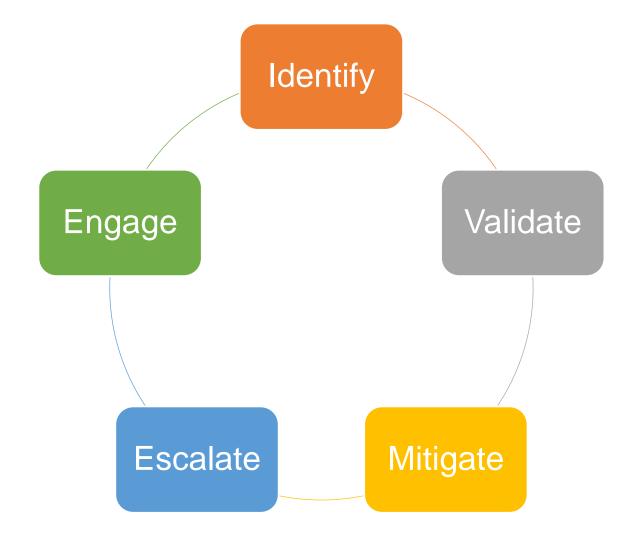
The first stop for professional medicines advice







Steps to Manage a Supply Issue





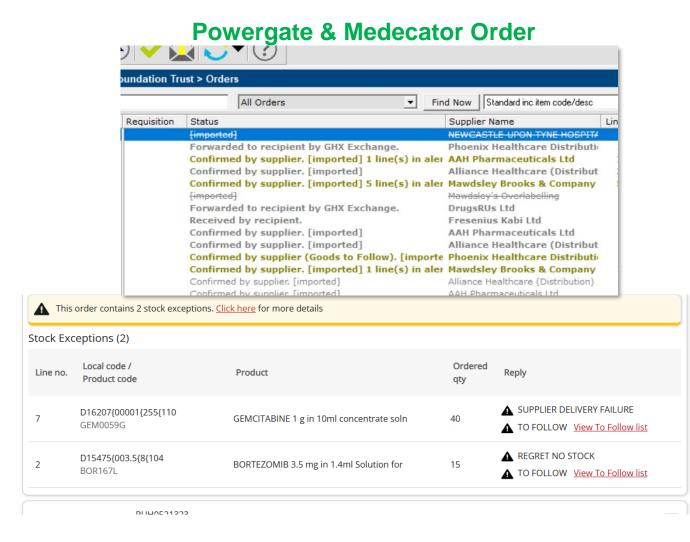


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Identification

Send orders through eCommerce platforms (Powergate or Medecator)

- Review order replies from full EDI suppliers.
- Ensure back orders are activated with your wholesalers or that you have a process for manually putting contract lines on back order.
- Robust process in place for reviewing Goods Ordered Not Received.



in specialist-pharmacy-service



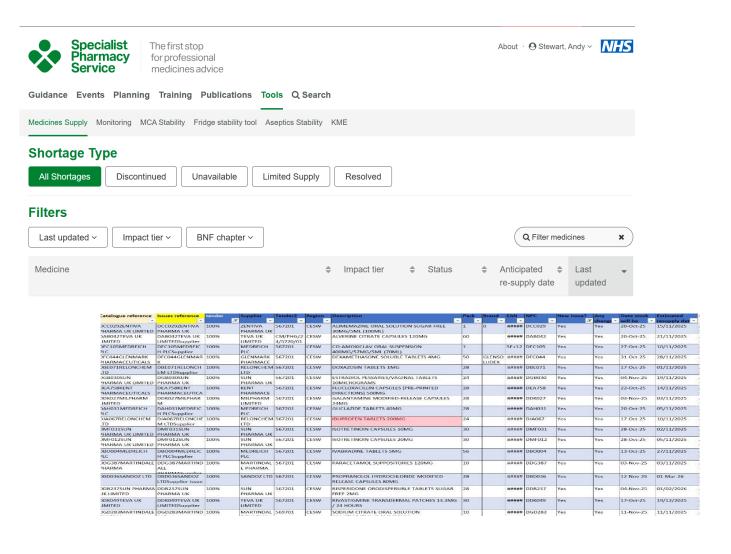


Validation

When you find an issue with a contracted line it's important to establish the scale and duration of the issue

- Review all distribution routes available for MPSC contracted line e.g. is it available from another wholesaler or direct from supplier.
- Refer to MPSC supplier issues spreadsheet (distributed fortnightly)
- Review SPS Medicines Shortages Tool

https://www.sps.nhs.uk/home/tools/medicines-supply-tool/







Validation

Manufacturer or Pharmaceutical company

- Check company website.
- Contact customer services to ascertain:
 - their stock position
 - resupply position
 - wholesaler depot restocking schedule
 - o is supply available directly from the manufacturer or via moving stock in wholesalers



Wholesalers

- Check website or portal consider searching via GTIN or EAN, PIP code or brand name.
- Contact Customer Services or account manager this could be a depot restocking issue rather than a supplier shortage.







Mitigation

Number of steps that can be taken locally to mitigate the supply issue:

- checking stock across all hospital locations
- correcting any discrepancies in the pharmacy stock control system
- checking if an alternative strength or form can be supplied from local stockholding
- sourcing non-contracted alternatives from wholesalers. Consider checking other distributors, such as direct from Alloga or Movianto.
- check <u>dm+d browser</u> for potential alternatives
- Utilise local/regional contacts e.g. via Team Channel/Chat



- check Vend on <u>Rx-Info</u>
- check availability of parallel imports from trusted suppliers







Mitigation

If an alternative can't be sourced and will result in a zero stock position escalate to your regional SPS Procurement Team to seek assistance as you may need to consider:

- Requesting mutual aid from regional or national Trusts
- Sourcing a commercial special
- Sourcing a special from an NHS Manufacturing Unit. <u>Pro-file</u> can be used for list of products
- Sourcing an imported medicine





Escalation

Regional SPS Procurement team can support through,

- having visibility of regional wholesaler stockholding via regional network
- utilising manufacturer and wholesaler contacts
- engaging with DHSC and MPSC and weekly calls
- having visibility of regional and national stockholding to support mutual aid requests

Trusts should provide key information regarding the supply issue such as medicine name, form, strength and confirm any steps already taken, information gained and urgency of request.



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Mutual Aid

Mutual aid is a form of voluntary cooperation where people support each other to meet shared needs.

NHS hospitals can transfer medicines between each other when standard supply routes can't deliver quickly enough.

The MHRA accepts that hospital pharmacies may need to obtain small quantities of medicine from other pharmacies to meet a specific patient's needs. MHRA considers the activity of mutual aid to fall within the definition of the provision of healthcare services.

In such circumstances, provided the transaction meets all the following criteria, MHRA will not deem such transactions as commercial dealing. Hospital pharmacies will not be required to hold a Wholesale Dealer's Licence (WDA(H)) if:

- the transaction takes place on an occasional basis
- the quantity supplied is small
- the supply is made on a not-for-profit basis
- the supply is not for onward wholesale distribution

Not a replacement for the normal supply chain. The main aim is to provide timely access to medicines for specific patients.





Local Management

Trusts need to have local processes in place to communicate and manage supply issues.

Some suggested approaches:

- Regular method of communicating issues e.g. weekly updates
- Host a spreadsheet on Sharepoint/Formulary webpage
- Ensure clinical engagement and ownership inside & outside of Pharmacy
- Involve Medicines Advice/Medicines Safety Officers
- Utilise and participate in regional networks

Ensure processes in place for back order management and placing of off-contract claims to mitigate financial loss from sourcing off-contract alternatives.







Further Support

- Further information on managing a potential supply issue, mutual aid can be found here:
- Navigating a potential supply issue Procurement Guidance
- <u>Mutual aid understanding best practice</u>
 <u>principles</u>
- Everything you need to know about offcontract claims

