

### Medicine Shortages

A medicine shortage is defined as when the total supply of a medication is inadequate to meet the current or projected demand at patient level. Medicine shortages present ongoing challenges across NHS Scotland, and some have the potential to impact significantly on patient care.

The Royal Pharmaceutical Society released a report [Medicines Shortages: Solutions for Empty Shelves](#) which outlines the reasons for medicines shortages, impact on patients and health care professionals and recommendations for managing shortages.

The 'Medicines Shortage Response Group (Scotland)' (MSRG) developed a set of standards to improve the management and monitoring of shortages in Primary Care, and the MSRG shortage Classifications (Levels) are included in Appendix 2. Further information can be found here: <https://www.gov.scot/news/update-on-medicine-supplies/>

This guideline outlines the roles and responsibilities of the Medicines Guidance Team and other relevant stakeholders to facilitate timeous communication, analysis and action when a medicine shortage occurs in NHS Lanarkshire.

### Role of the Medicines Guidance team

The role of the Medicines Guidance Team is to receive and coordinate a response in relation to published medicine shortages.

1. Monitor sources of shortage information – more information can be found in Appendix 2
2. Complete a Medicines Shortage Impact Assessment where appropriate (see below)
3. Complete the Lanarkshire Medicines Shortages Group Risk Assessment Tool where appropriate (see below) to assist the group with information gathering and decision-making
4. Assemble and Chair the Lanarkshire Medicines Shortages Group where required
5. Co-ordinate changes to the NHS Lanarkshire formulary and ScriptSwitch messages in response to a shortage where required including disablement of messages once shortage has resolved.
6. Publish shortages and supporting information to the agreed platform which can be accessed by all clinicians and other stakeholders in NHS Lanarkshire
7. Disseminate primary care prescribing data on shortages to locality senior pharmacists to support local management of shortages
8. Have oversight and update and amend as appropriate, shortages processes across Lanarkshire
9. Report on the impact of shortages bi-annually into the Area Drugs & Therapeutics Committee (ADTC) and Partnership Medicines Management Board (PMMB)

Whilst the Medicines Guidance Team will undertake the steps above, all NHSL clinicians/prescribers will have responsibility for regularly checking the agreed platform (suggested weekly checks).

## Management of Medicines Shortages within NHS Lanarkshire

### Level 1 & 2 Shortages

The steps below will be actioned by the Medicines Guidance Team within 7 calendar days of the shortage being published.

1. Identify the shortage using the sources listed in Appendix 2 and confirm it is a Level/Tier 1 or 2
2. Check the initial duration of the shortage;
  - a. If less than 4 weeks, publish the shortage on the agreed platform with no additional actions
  - b. If the duration of the shortage changes over time and increases to over 4 weeks, complete Step 3 onwards
3. If the shortage duration is to last longer than 4 weeks, run a PRISMS search to determine prescribing within primary care over a 12-month period
4. Use the PRISMS data and the information contained on the shortages notice to complete the shortage impact assessment form and save in 'medicines shortages information' folder in R-drive
5. Utilise the information above to determine if the shortage can be managed by the Medicines Guidance Team or if stakeholder input is required. This depends on:
  - a. Amount of prescribing in NHS Lanarkshire
  - b. Duration of shortage
  - c. Availability and suitability of alternative medications
    - i. Can they support uplift in demand?
    - ii. Are they in the same drug class?
    - iii. Do they require additional monitoring?
    - iv. Are they licensed?
  - d. Does this shortage affect any special patient groups, e.g. paediatrics?
  - e. Is the medicine mainly prescribed in primary care, secondary care or both?
6. If the shortage can be managed by the Medicines Guidance Team:
  - a. Publish the shortage on the agreed platform
  - b. Send PRISMS data to primary care locality senior pharmacists for awareness
  - c. Add a ScriptSwitch message where appropriate
  - d. Add a note or change to the formulary where appropriate
  - e. Report any shortages considered to have a medium, high or very high clinical or financial risk to the AMB/ PMMB via Lead Pharmacist Prescribing Quality & Efficiency
  - f. Update the Shortages Action Log and Risk Register

If it cannot be managed by the Medicines Guidance Team, please follow the steps below for the level 3 shortages.

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## Management of Medicines Shortages within NHS Lanarkshire

### Level 3 Shortages

The steps below will be actioned by the Medicines Guidance Team within 48 hours of the shortage being published

1. Identify the shortage using the sources listed in Appendix 2 and confirm it is a Level/Tier 3
2. Use the PRISMS data and the information contained on the shortages notice to complete the shortage impact assessment form
3. Utilise the information above to determine if the shortage can be managed by the Medicines Guidance Team or if stakeholder input is required; If it can be managed by the Medicines Guidance Team, please follow step 6 from the level 1&2 shortages process above
4. If it cannot be managed by the Medicines Guidance Team, a member of the team will complete the Lanarkshire Medicines Shortages Group (LMSG) Risk Assessment tool and assemble the LMSG
5. If the shortage can be managed by the LMSG, follow Step 6 from the level 1 & 2 shortage process ensuring to include any actions agreed by the LMSG
6. If the LMSG cannot manage the shortage, then it will be escalated to the Director of Pharmacy and Medical Director for a decision regarding ongoing management. Please note any escalation to the Director of Pharmacy and Medical Director should include clear recommendation of action using available information.

### Level 4 Shortages

Identify the shortage using the sources listed in Appendix 2 and confirm it is a Level/Tier 4. Within 24 hours of the shortage being published, escalate to the Director of Pharmacy and Medical Director for a decision regarding ongoing management.

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## Management of Medicines Shortages within NHS Lanarkshire

### Lanarkshire Medicines Shortages Group (LMSG)

The Lanarkshire Medicines Shortages Group (LMSG) will act as a focus group for the management of shortage responses where the shortage can no longer be managed by the Medicines Guidance Team or where pan-Lanarkshire actions are required.

The LMSG will:

1. Act as the route of escalation for medicines shortages which are broader than management within an individual healthcare sector, requiring a coordinated response across NHS Lanarkshire.
2. Work with pharmacy/medical colleagues across NHS Lanarkshire and national contacts within National Procurement (NP) and other relevant stakeholders to manage shortages, minimising the need for further escalation.

Examples of the activities to be undertaken in managing a shortage will include:

- a) Keeping notes of LMSG meetings relating to identified medicines shortages (including actions and resolution information).
- b) Assessing the significance of shortage/urgency required regarding alternative stock/advice and classify a shortage using the categories in Appendix 4b.
- c) Sourcing and risk assessment of alternative medicines (e.g. alternative pack size, strength, unlicensed product) using the risk assessment tool to record the impact of identified medicines shortages within NHS Lanarkshire.
- d) Submitting a medicines information enquiry via [Medicines.Information@lanarkshire.scot.nhs.uk](mailto:Medicines.Information@lanarkshire.scot.nhs.uk) if required
- e) Communicating confirmed medicines shortages to all relevant stakeholders through established routes.
- f) Collaborating with key departments on management of specific medicines shortage when required.
- g) Escalating when required, e.g. to manage limited stocks of medicines, by prioritising use of limited stocks to particular patient groups, or, where significant clinical or patient impact is envisaged, the LMSG will escalate to the Director of Pharmacy and Medical Director for a decision regarding ongoing management.

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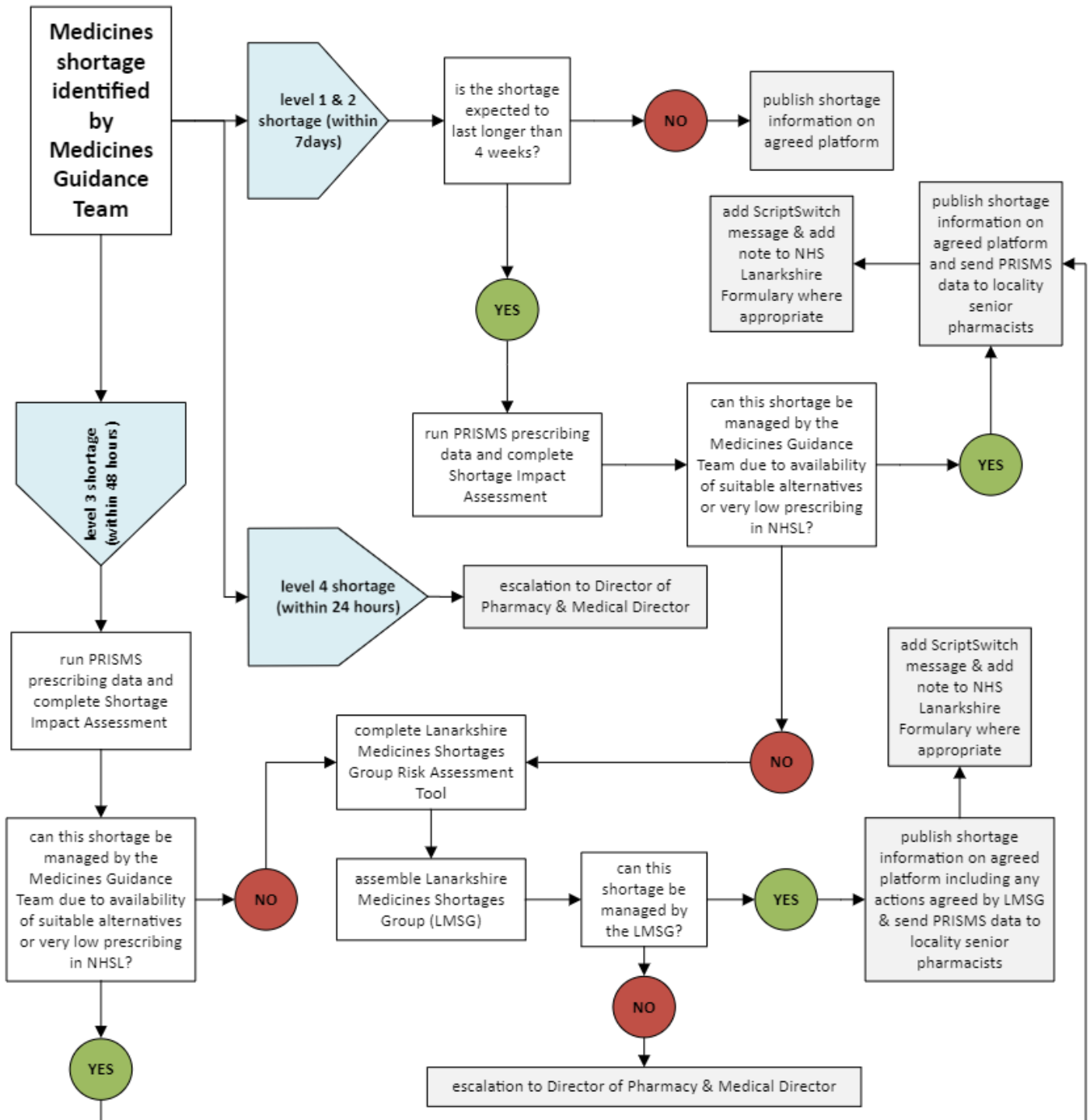
LMSG Membership*	Role & Responsibility
Advanced Pharmacist Medicines Guidance (on behalf of the Medicines Guidance Team)	Chair, completion of LMSG Risk assessment tool & collator of notes from LMSG meetings
Central Prescribing Adviser	Represent primary care locality teams and co-ordinate any information dissemination to locality lead pharmacists
Lead Pharmacist Prescribing Quality and Efficiency	To asses impact on prescribing spend and PQES service
Lead Pharmacist Advanced Clinical Services	To asses impact on pharmacotherapy service
Lead Pharmacist for Community Pharmacy	Represent community pharmacy and co-ordinate any information dissemination to community pharmacy
Representative from each hospital site: could include Head of Pharmacy, Clinical Manager, Dispensary Manager or Procurement Lead	Represent hospital pharmacy and co-ordinate any information dissemination to hospital pharmacy sites. To allow planning for ordering alternatives and provide info on secondary care stock levels
Secondary care specialist (where applicable)	To provide expert advice if required
Secondary care pharmacist for a speciality (where required)	To provide expert advice if required
Primary care link pharmacist for a speciality (where applicable)	To provide advice if required
Locality Lead GP representative	To asses impact on GP service

*\*Deputies should be nominated where the named members cannot attend*

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# Management of Medicines Shortages within NHS Lanarkshire

## Overview of Shortages Process



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## Management of Medicines Shortages within NHS Lanarkshire

### Appendix 1 - Governance information for Guidance document

<b>Lead Author(s):</b>	Medicines Guidance Team
<b>Endorsing Body:</b>	ADTC
<b>Version Number:</b>	V3
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<b>Responsible Person (if different from lead author)</b>	

CONSULTATION AND DISTRIBUTION RECORD	
<b>Contributing Author / Authors</b>	Adapted with permission from 'NHS Grampian Guidance For The Management Of Medicine Shortages Within NHS Grampian'
<b>Consultation Process / Stakeholders:</b>	<ul style="list-style-type: none"> <li>• Heads of Pharmacy at Hairmyers, Monklands and Wishaw</li> <li>• Primary care central prescribing team</li> <li>• Dr Chris Deighan - Executive Medical Director</li> <li>• Graeme Bryson – Director of Pharmacy</li> </ul>
<b>Distribution</b>	ADTC

CHANGE RECORD			
Date	Lead Author	Change	Version No.
31/01/2025	Medicines Policy and Guidance Team	<ul style="list-style-type: none"> <li>• Updated process with flowchart</li> <li>• Creation of the Lanarkshire Medicines Shortages Group</li> <li>• Updated impact assessment tool</li> <li>• Inclusion of Lanarkshire Primary Care Technician Stock Query Process</li> <li>• Move to hosting shortages information on right decision site rather than weekly shortages bulletin</li> </ul>	3

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### Appendix 2 - Medicines Shortages Response Group (SCOTLAND) - CLASSIFICATION OF MEDICINE SHORTAGES

<https://www.nss.nhs.scot/pharmacy-services/pharmacy-prescriptions/medicines-supply-alert-notice/>

LEVEL	DESCRIPTION	POTENTIAL RESPONSES
<b>Level one (low impact)</b>	Supply problem with a short duration ( <b>up to one month</b> ) where immediately available <u>measures are expected to be sufficient</u> and there is minimal additional management requirement.	Business as usual. Response likely to involve using the same medicine. <ul style="list-style-type: none"> <li>Alternative strength/formulation available to meet demand, potentially from other suppliers.</li> </ul>
<b>Level two (medium impact)</b>	Supply problem where <u>alternatives in the same therapeutic class are available but which may require some management</u> such as switching to those alternatives, which may include unlicensed medicines.	Business as usual. Response not likely to require a change in the class of medicine. <ul style="list-style-type: none"> <li>Alternative strength/formulation available but clinical advice is required to help manage the switch.</li> <li>Alternative medicine in the same therapeutic class.</li> <li>Unlicensed alternatives may be used.</li> <li>Issuing a Medicine Supply Alert Notice.</li> </ul>
<b>Level three (high impact)</b>	Supply problems where there are <u>limited or no alternatives in the same therapeutic class and which require significant management</u> , potentially including changes in clinical practice or operational direction or that have patient safety implications.  Level three shortages also include level two shortages for medicines used in <u>life saving conditions</u> such as anaphylaxis or involving <u>patient groups considered as vulnerable</u> , such as neonates, paediatrics or people with learning disabilities.	Serious shortage situation. Response likely to require a change in the class of medicine. <ul style="list-style-type: none"> <li>Alternative therapeutic class of medicine available.</li> <li>The use of a 'serious shortage protocol'.</li> <li>Additional clinical advice.</li> <li>Exceptional MHRA regulatory measures.</li> <li>Issuing a Medicine Supply Alert Notice.</li> </ul>
<b>Level four (critical impact)</b>	Supply problems where there is <u>no viable therapeutic alternative</u> and where responses may also require support from outside the health system and / or which trigger the use of national resilience structures.	Very serious shortage situation. Wider burden on NHS and public sector. <ul style="list-style-type: none"> <li>Non-medicine support provided to patients.</li> <li>National Resilience procedures potentially activated – including links with agencies outside NHS. Additional project management or communications support may be required.</li> <li>Issuing a Medicine Supply Alert Notice.</li> </ul>

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## Management of Medicines Shortages within NHS Lanarkshire

### Appendix 3 - Sources of Shortages Information

The sources of shortages include but are not limited to:

- NHS Scotland Publications: <https://www.publications.scot.nhs.uk/>
- [Specialist Pharmacy Service Medicines Supply Tool](https://www.sps.nhs.uk/home/tools/medicines-supply-tool/): <https://www.sps.nhs.uk/home/tools/medicines-supply-tool/> (requires a log in)
- NHS Scotland Acute Medicine Shortages Group (via subscription)
- NICE Medicines Awareness Service (via email subscription)

#### Note

Medicines Supply Alert Notices (MSANs) are provided by the Scottish Government and classify shortages as 'Levels'.

Medicine Supply Notifications (MSNs) are provided by the Department of Health and Social Care from NHS England and classify shortages as 'Tiers'.

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### Appendix 4a - Shortages Impact Assessment

<b>Date of Impact Assessment</b>			
<b>Medicine name</b>			
<b>MSAN/MSN number</b>			
<b>Shortage Level/Tier</b>			
<b>Estimated duration of shortage</b>			
<b>Primary care items dispensed in last 12 months</b>			
<b>Quantity dispensed in last 12 months</b>			
<b>Prescribed in which localities in last 12 months</b>			
<b>Cost of OOS product</b>			
<b>Cost of alternative product</b>			
<b>Estimated financial impact over 12months</b>			
<b>Clinical risk</b>	Likelihood	Impact	Risk Level
<b>Financial risk</b>	Likelihood	Impact	Risk level
<b>Has the Medicines Shortages Group been consulted?</b>			
<b>Actions/decisions/monitoring</b>			
<b>ScriptSwitch message required?</b>			
<b>Formulary update required?</b>			
<b>Form completed by</b>			

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### Appendix 4b - NHS Lanarkshire Risk Matrix for Shortages

Likelihood			
Score	Chance of Occurrence		
1	Rare	0-15%	Hard to imagine this event happening- will only happen in exceptional circumstance
2	Unlikely	15-35%	Not expected to occur but might- unlikely to happen
3	Possible	35-60%	May occur-reasonable chance of occurring.
4	Likely	60-80%	More likely to occur than not.
5	Almost Certain	80-100%	Hard to imagine this event not happening

Impact		Category	
Score	Description	Business	Clinical
1.	Negligible	Financial impact <£10k Minimal impact no operational disruption	No obvious harm to patient/public
2.	Minor	Financial impact £10k-£100k Minor impact on service provision	Short term disruption to service with minor impact on delivery of service to patients
3.	Moderate	Financial impact £100k-£250k	Some disruption in service with unacceptable impact on delivery of services to patients/public
4.	Major	Financial impact £250k-£1000k Significant impact on service provision	Sustained loss of service which has serious impact on delivery of services to patients/public (resulting in major contingency plans being invoked)
5.	Catastrophic	Financial Impact of >£1000K Total failure in service provision	Incident leading to death or permanent damage to patient

		Impact				
		1	2	3	4	5
Likelihood	5	M	H	H	VH	VH
	4	L	M	H	VH	VH
	3	L	M	M	H	H
	2	L	M	M	M	H
	1	L	L	L	M	M

The classifications below should be used as a guide, with ultimate decisions for classification sitting with the LMSG where they are managing the shortage.

Level	Description	Potential Responses
VH	These supply issues will require additional support from outside the health system and will trigger the use of dedicated national processes and procedures in order to provide additional support for the management of the shortage.	Very serious shortage situation with wider burden on NHS and public sector. Non-medicine support provided to patients. National Resilience procedures potentially activated – including links with agencies outside NHS.
H	These supply issues will be more critical, with potential change in clinical practice or patient safety implications that require clinical or operational direction to the system. The response will be nationally coordinated and guided.	Serious shortage situation. Response likely to require a change in the class of medicine. Use of a 'serious shortage protocol'. Additional clinical advice required. Exceptional MHRA regulatory
M	Greater risk to patients/health providers than Level 1 issues but considered safe to be implemented at without further escalation. May require using therapeutic alternatives, unlicensed specials, unlicensed imports or alternative strengths or formulations.	Business as usual. Response not likely to require a change in the class of medicine. Use of alternative strength/formulation available but clinical advice is required to help manage the switch.
L	Likely to carry low risk and management should result in patients being maintained on the same licensed medicine.	Business as usual. Response likely to involve using the same medicine with alternative strength/formulation available

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## Management of Medicines Shortages within NHS Lanarkshire

### Appendix 5 - Lanarkshire Medicines Shortages Group Risk Assessment Tool

details of shortage	
medications affected (strength, form, manufacturer etc)	
official documentation relating to the shortage (MSN, MSAN etc)	
operational assessment	
anticipated duration of shortage / re-supply date	
stock in hand and will this cover the shortage (hospital sites only)	
stock levels of potential alternatives and ability to support uplift in demand	
therapeutic assessment	
Patient numbers and prescribing data in last 12months (PIS and PRISMS)	
potential alternatives inc drug class route dose etc	
details of off label alternatives	
any special patient groups impacted (eg paed, pregnant women etc)	
do potential alternatives have excipients or allergens which should be considered relevant (e.g. alcohol, propylene glycol, sorbitol, gelatine, sulphites, benzoates, latex etc)	
are there likely to be any additional monitoring requirements	
technical issues with alternatives (e.g. route of admin, compatibility, aseptic preparations etc)	
other considerations	
who will require official communication/notification of the shortage	
estimation financial impact over 12months	
governance considerations	
Is there need for a Medicines Information enquiry?	

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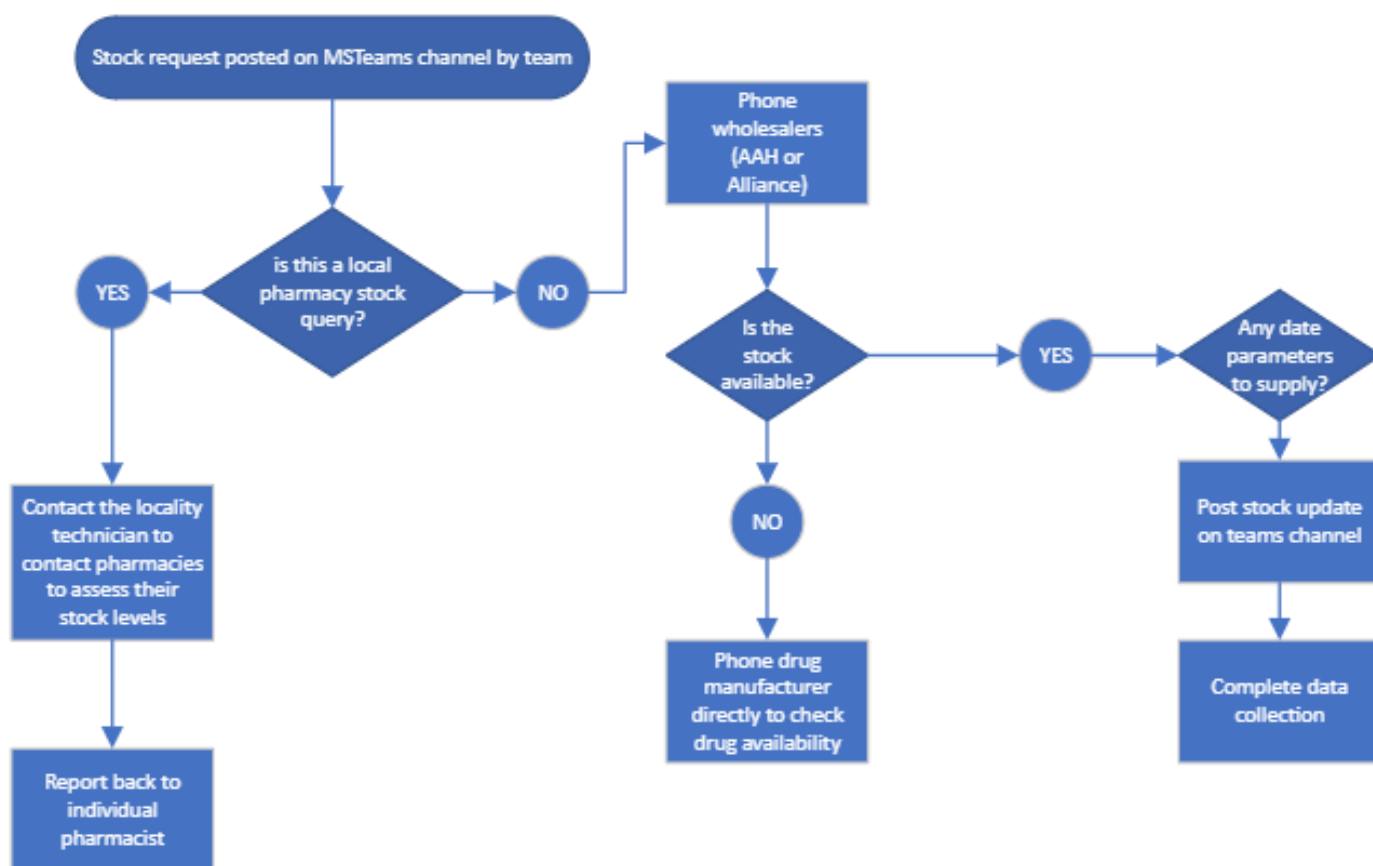
## Management of Medicines Shortages within NHS Lanarkshire

### Appendix 6 - Lanarkshire Primary Care Technician Stock Query Process

NHSL have established a centralised process to deal with stock queries relating to national stock issues. The aim is to minimise duplication of work across the localities and be able to centralise the efforts to answer an increasing number of stock queries. A Microsoft teams channel has been established that is monitored by a technician where by any stock queries relating to national issues, can be posted and answered.

This channel is available to all in the team and is monitored five days per week.

\*Note - local stock availability questions are dealt with by each individual localities



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