Pharmacy and Prescribing Department

Procedure for managing medicine shortages

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Version number: 1

Date of Authorisation: August 2019

Date of review: July 2021

Document Development Coversheet

Date	Group/Individual	Outcome	Changes updated
May 19	Discussion with pharmacy managers and Directors of Pharmacy	Document updated	MMcF
Jul 19	APC	Document supported	
August 19	Discussion with ADTC	Document approved	

PROCEDURE FOR MANAGING MEDICINE SHORTAGES IN SHETLAND.

1. BACKGROUND TO THE PROCEDURE

Medicine shortages are an everyday occurrence in the UK. The number of lines in short supply is increasing. This situation is not directly related to the exit from the European Union, The NHS in Scotland can experience shortages of up to 80 medicines of varying impact at any one time unrelated to the exit from Europe. However the situation is likely to get worse for a time around the date of exit.

Medicines shortages can occur at a local, regional, national, European or global level and can affect some or all dispensing settings, including community and hospital pharmacy, dispensing doctors and home care. Managing these shortages, which includes trying to source stock, identifying alternative medicines and arranging for prescriptions to be updated to legally permit supply of alternatives are a routine part of NHS activity. However, it creates a workload burden through the additional time spent attempting to source medicines and to identify and risk assess suitable alternatives. Shortages can also affect patient care.

There is a need for a clear local process, nationally the Medicine Shortages Short life working group have made a number of recommendations, many of which are directly applicable to local Health Boards. This has necessitated the development of this procedure.

The procedure has concentrated on local responsibilities. The clinical engagement required in developing shortage protocols is a national matter is not described here. Similarly the arrangements around stockpiling medicines are also considered at a national level.

2. DEFINED ROLES IN MANAGING MEDICINE SHORTAGES

Pharmacy and Medicines Division of the Scottish Government have defined the following roles in managing medicine shortages in Scotland, but there is also a requirement to specify roles locally. Clearly defined and agreed pharmacy roles for the management of medicine shortages are important to ensure that resilience is optimized and responsibilities are clear. A summary of the roles of the different organisations in relation to shortages was developed collaboratively by a Medicines Shortages Short Life Working Group. The roles of other professions will be further defined below as appropriate.

Department of Health and Social Care (DHSC)

The DHSC lead in relation to:

- coordinating the UK Administrations to manage medicines shortages, by convening the UK Medicines Shortages Resources Group (MSRG).
- liaison with the UK medicines supply chain and industry representative bodies (branded and generic medicines).
- the management of the essential medicines buffer stockpile.

Scottish Government (SG)

The SG Pharmacy and Medicines Division leads in relation to:

- liaison with the DHSC and the other Devolved Administrations (DAs) through the UK MSRG.

- convening MSRG (SCO) to ensure that decisions are taken about the management of shortages in Scotland.
- further to decisions of MSRG (SCO), determine the content and initiate the delivery of communications, and any associated supporting materials, to NHS 24, NHS Inform, National Services Scotland (NSS), NHS Scotland, GPs and community pharmacists.
- issuing general information about medicine shortages to the public.
- working with Community Pharmacy Scotland and NSS to ensure concessionary pricing arrangements are in place for Part 7 items.
- ensuring alignment and liaison with Scottish Government resilience arrangements and health communications.

National Services Scotland (NSS) – National Procurement (NP)

NSS NP leads in relation to:

- acting as the central point for documenting, disseminating and revising decisions of MSRG (SCO) and connected information to Health Boards and Community Pharmacy Scotland as well as across NSS, including Public Health and Intelligence Service and Practitioner Services.

- For medicines listed on current NHS contracts/frameworks:
    - ensuring the tender process for medicines is robust and emphasizes requirement for effective communication relating to medicine shortages.
    - acting as the central point for updates from suppliers contracted with NHS Scotland.
    - supporting the sourcing of alternative medicines for health boards.
    - working with Health Boards and manufacturers to support restricted allocation of medicines in the event of a severe shortage, in conformity with a decision of MRSG (SCO).
    - informing SG, MSRG (SCO) and DHSC Commercial Medicines Unit (CMU) of level 2,3 and 4 medicine shortages. See Appendix 1

- for medicines not listed on current contracts/frameworks:
    - working with Health Boards, manufacturers and Community Pharmacy Scotland to manage restricted allocation of medicines in the event of a severe shortage, in conformity with a decision of MRSG (SCO).
    - informing SG, MSRG (SCO) and DHSC Commercial Medicines Unit (CMU) of level 2,3 and 4 medicine shortages. (See Annex 1)

National Services Scotland (NSS) – Public Health and Intelligence Service (PHIS)

NSS PHIS lead in relation to:

- providing intelligence to SG on pricing, availability and usage of medicines.
- supporting modelling activities and impact assessment where product substitution is considered.
- liaising with Community Pharmacy Scotland and SG on concession pricing arrangements.

National Services Scotland (NSS) – Practitioner Services (PS)

NSS PS lead in relation to:

- publishing decisions of MSRG (SCO).
- liaising with PHIS, Community Pharmacy Scotland and SG to ensure pricing files reflect any concession pricing arrangements.

Community Pharmacy Scotland (CPS)

CPS lead in relation to:

- undertaking intelligence gathering on medicine shortages.
- collating information on all medicine shortages, including Part 7, non-Part 7 and branded medicines, experienced by community pharmacists.
- sharing collated information on shortages with NSS.
- liaising with NSS PHIS and SG on concession pricing arrangements.
- ensuring the delivery of decisions of MSRG (SCO) and connected information to community pharmacists.

Community pharmacists and pharmacy technicians

Community pharmacists and pharmacy technicians lead in relation to:

- adhering to the principles of the Best Practice Standards for Managing Medicine Shortages in Primary Care in Scotland.
- ensuring all medicine shortages, including Part 7, non-Part 7 and branded medicines, are reported to CPS using the shortage app or the on-line shortage reporter on the CPS website.
- taking responsibility for resolving each medicine shortage using a person-centred approach and in a timely manner in line with current pharmaceutical services regulations and guidance.
- minimising any additional workload by fully utilising the flexibilities to electronically endorse prescriptions where the shortage necessitates a change in the strength, dose and/or brand substitution in line with the endorsing guidance and pricing rules issued by Community Pharmacy Scotland for any strength, dose and/or brand substitution rather than requesting a new prescription.
- communicating information relating to medicine shortages and the potential impact/impact to patients and their carers' and their relevant healthcare professionals.
- managing available stock including restricted supplies and alternative medicines.

Shetland Health Board

In Shetland it is also necessary to define roles.

Directors of Pharmacy, Chris Nicolson leads in relation to:

- ensuring the delivery of decisions of MSRG (SCO) and connected information to persons with a need to know.
- management of medicine supply within the Health Board.
- ensuring written policies are in place that support systems for the management of medicines shortages which adhere to the principles of the Best Practice Standards for Managing Medicine Shortages in Primary and Secondary Care in Scotland.
- reporting level 2, 3 and 4 shortages to MSRG (SCO) and NSS NP. (See Appendix 1)

NHS Shetland Gilbert Bain Hospital

Principal Pharmacist, Mary MacFarlane will lead in secondary care lead in relation to:

- adhering to local policies that support systems for the management of medicines shortages, for example policies for the use of unlicensed medicines.
- ensuring all medicine shortages are documented appropriately at a local level. See Section 3.
- identifying options to mitigate the effects of a medicine shortage locally.
- communicating information relating to medicine shortages and the potential impact/impact to patients and their carers', healthcare professionals and any other relevant persons e.g. finance.
- managing available stock including restricted supplies, alternative products etc.
- informing the DoP of medicine shortages for onward cascade to the SG and MSRG (SCO) and DHSC.

Procurement Officer Dawid Niesciur is responsible for:

- sourcing an alternative medicine including risk and escalating to the Principal pharmacist for assessing any alternatives and completion of appropriate form(s) required for governance purposes. See Appendix 3 and 4
- managing the off-contract claim process in relation to medicines unavailable and currently listed on a national contract/framework
- liaising with National procurement in the event of impending shortages.

Shetland Health Board (primary care)

Pharmacy leads in primary care, including the Prescribing Advisors (Anthony McDavitt) is responsible for:

- adhering to local policies that support systems for the management of medicines shortages, for example policies for the use of unlicensed medicines.
- ensuring all medicine shortages are documented appropriately. See Section 3
- providing advice on options to mitigate the effects of a medicine shortage locally.
- communicating information relating to medicine shortages and the potential impact/impact including alternative products to patients and their carers', healthcare professionals and any other relevant person.
- informing their DoP of medicine shortages for onward cascade to the SG and MSRG (SCO) and DHSC

3. THE LOCAL PROCEDURE

MANAGING SHORTAGES IN THE GILBERT BAIN HOSPITAL

At Health Board level, risk assessments are undertaken to determine possible actions including escalation of the issue to National Procurement (NP). These risk assessments are not typically documented. Given the volume of reports of shortages received by NP, full investigation of reported supply disruption is only undertaken if there is evidence to suggest the shortage will have a significant impact. A similar approach is taken by the DHSC Commercial Medicines Unit (CMU) who prioritise investigation of a supply problem where the medicine is an injectable or where the manufacturer supplies a number of regions of England with a re-supply date of greater than one month.

NP link with a named purchasing lead/team at each Health Board, in Shetland this is Dawid Niesciur. If the medicine shortage is a contract line and the Shetland Board cannot source from the contracted company, they should contact NP immediately and NP will work with the supplier to resolve the issue. For generic medicines, the contract requires the supplier to source an alternative to supply to Boards or accept Board 'off-contract claims' for the difference in cost under an agreed national process. If there are no direct alternatives, NP will alert DHSC. If the medicines shortage is a non-contract line, Boards will try to source an alternative and should share the findings with other Boards, although this does not always happen. If there are no direct alternatives or there is a significant issue, NP will alert DHSC.

When a medicine shortage is impending the procurement officer will contact clinical pharmacy staff to make the necessary arrangements with senior clinicians. This may also involve developing a communication plan for GPs and patients.

MANAGING MEDICINE SHORTAGES IN PRIMARY CARE

Scope

A National Short Life Working Group on Medicine Shortages was set up in July 2016 to identify what more could be done to improve and strengthen the existing management and monitoring processes of medicine shortages in primary care. These draft standards are the output from those discussions.

Overarching Principles

i. Whilst the guiding principle must be that appropriate medicines should be available for all patients, pharmacy professionals should ensure that no action is taken within a GP practice or community pharmacy which could exacerbate a medicines shortage within the wider NHS, for example issuing prescriptions for larger quantities or more prescriptions than normal, stockpiling medicines or ordering more stock than required to meet normal demand.

ii. Where there is insufficient stock to meet the needs of all patients, Health Boards should work collaboratively to ensure that priority is given to patients with the greatest clinical need.

iii. Health Boards should seek to work on a collaborative basis to minimise duplication of effort, for example on risk assessments, procurement alternatives and production of clinical advice.

iv. Whoever provides the initial information on a medicine shortage, be it the Department of Health and Social Care, NHS National Procurement, the Medicine

Shortages Response Group or the pharmaceutical industry, this should be provided in a timely manner, with as much supporting information as possible, to allow Boards to take appropriate action to mitigate any effects on patient safety.

In addition the following standards should apply:

v. The Director of Pharmacy for the Health Board is responsible for taking a leadership role in ensuring that there are strategies, procedures and, working with the Chief Executive, ensure that sufficient staff resource in place for effective management of medicines shortages within the Board.

vi. This Health Board procedure for managing medicines shortages covers all settings where the Board issues advice on shortages.

vii. The log of shortages (see Appendix 3) should include details of the shortage, decisions taken, alternatives used and any new safeguards which have been introduced for all settings.

The Health Boards Primary Care Pharmacy Team

i. Shortages will be identified from various sources which the Shetland primary care pharmacy team can amend for local needs e.g. local treatment choices.

ii. A risk assessment should be conducted to evaluate the potential effect of the shortage in primary care. This assessment should be documented (see Appendix 4) and take account of:

- The estimated duration of the shortage
- Estimate of usage from prescribing data
- The availability of suitable alternative products
- The potential risk to patients
- Assessment of financial impact of shortage

iii. In Shetland this work will be done jointly with pharmacists in Secondary Care to ensure guidance is consistent and to avoid duplication of effort. If the alternative medicine involves the use of an unlicensed product, then Shetland will follow the guidance in MHRA Guidance Note 14 and local process.

iv. There should be engagement with relevant clinical stakeholders to agree and support implementation of management strategies, for example the doctor for the specialty(s) that use the medicine in short supply.

v. Not all shortages will require further action, but where the risk assessment supports further work on a long term/critical shortage, the time period the shortage will cover should be estimated.

vi. Where limited stock leads to a restriction being placed on the use of a medicine, then this restriction should be discussed with the Health Board Medical Director, Clinical Director with start and review dates, and should be communicated immediately to all relevant staff. Communication of these restrictions is essential for ensuring patient safety and preventing medication errors.

vii. NHS Greater Glasgow and Clyde, National Procurement and ISD provide intelligence on shortages to all Health Boards. Working with the local medicines procurement officer and using the Prescribing Points bulletin and direct communication, shortages will be communicated to relevant staff including GP practices and Community Pharmacies All relevant information about shortages is held in the knowledge hub nationally.

viii. If any training, clinical advice or patient counselling is necessary as a result of the use of the alternative medicine, this information should be co-ordinated in a prompt and effective manner.

ix. Patients/carers should be consulted when a medicine shortage is likely to delay or compromise care or where it leads to a change in medication regimen.

x. The resolution of a medicines shortage should be communicated to relevant staff at the weekly communications meeting and consideration should be given to lessons learned and future actions.

Recommendations for Community Pharmacists and Pharmacy Technicians

i. Pharmacists and pharmacy technicians should adhere to the overarching principles above and Best Practice Standards for Managing Medicine Shortages in Primary Care in Scotland sumarised below.

ii. Following an initial assessment, all potential shortages (including Part 7, non-Part 7 and branded medicines) should be reported to Community Pharmacy Scotland (CPS) using the shortage app or the on-line shortage reporter on the CPS website. Pharmacists and pharmacy technicians should consult available resources.

iii. In the event of an acute shortage, and where none of the wholesalers or depots has a supply, community pharmacies should consider borrowing from another pharmacy or the hospital pharmacy see Appendix 2. Patients can be directed to another pharmacy which has stock.

iv. Amendments to the medication supplied can be made by fully utilising the flexibilities to electronically endorse prescriptions where the shortage necessitates a change in the strength, dose and/or brand substitution in line with the endorsing guidance and pricing rules issued by CPS for any strength, dose and/or brand substitution rather than requesting a new prescription.

v. Pharmacists and pharmacy technicians should communicate information relating to medicine shortages and the potential impact/impact, including any changes to medication, to patients and their carers' and their relevant healthcare professionals. Communications to the GP practices can be done using the Pharmacy Care Record (PCR) S-BAR tool or by telephone.

vi. Pharmacists and pharmacy technicians should take responsibility for resolving each medicine shortage using a person-centred approach and in a timely manner in line with current pharmaceutical services regulations and guidance. This includes taking advice from their local health board into account when selecting an alternative for the patient however supplying the alternative should not delay the supply to the patient if required before the recommended alternative can be obtained.

vii. Pharmacists and pharmacy technicians should manage available stock including restricted supplies and alternative medicines. Stockpiling medicines or ordering more

stock than required to meet normal demand can exacerbate a medicines shortage within the wider NHS and should be avoided.

4. Recommendations for GP practices including dispensing practices and Out of Hours service.

i. GP practices, including dispensing practices, and out of hours service providers should report any potential shortages to the Shetland Primary Care Pharmacy Team

ii. Prescribers should refer to national or local advice when selecting an alternative to prescribe. Alternatives many change over time due to limited stock.

iii. Issuing prescriptions for larger quantities or prescriptions more frequently than normal, stockpiling medicines or ordering more stock than required to meet normal demand can exacerbate a medicines shortage within the wider NHS and should be avoided.

iv. Community pharmacists will have a limited ability to supply an alternative medicine without requiring a change to a prescription. GPs should issue a new prescription in the event that:

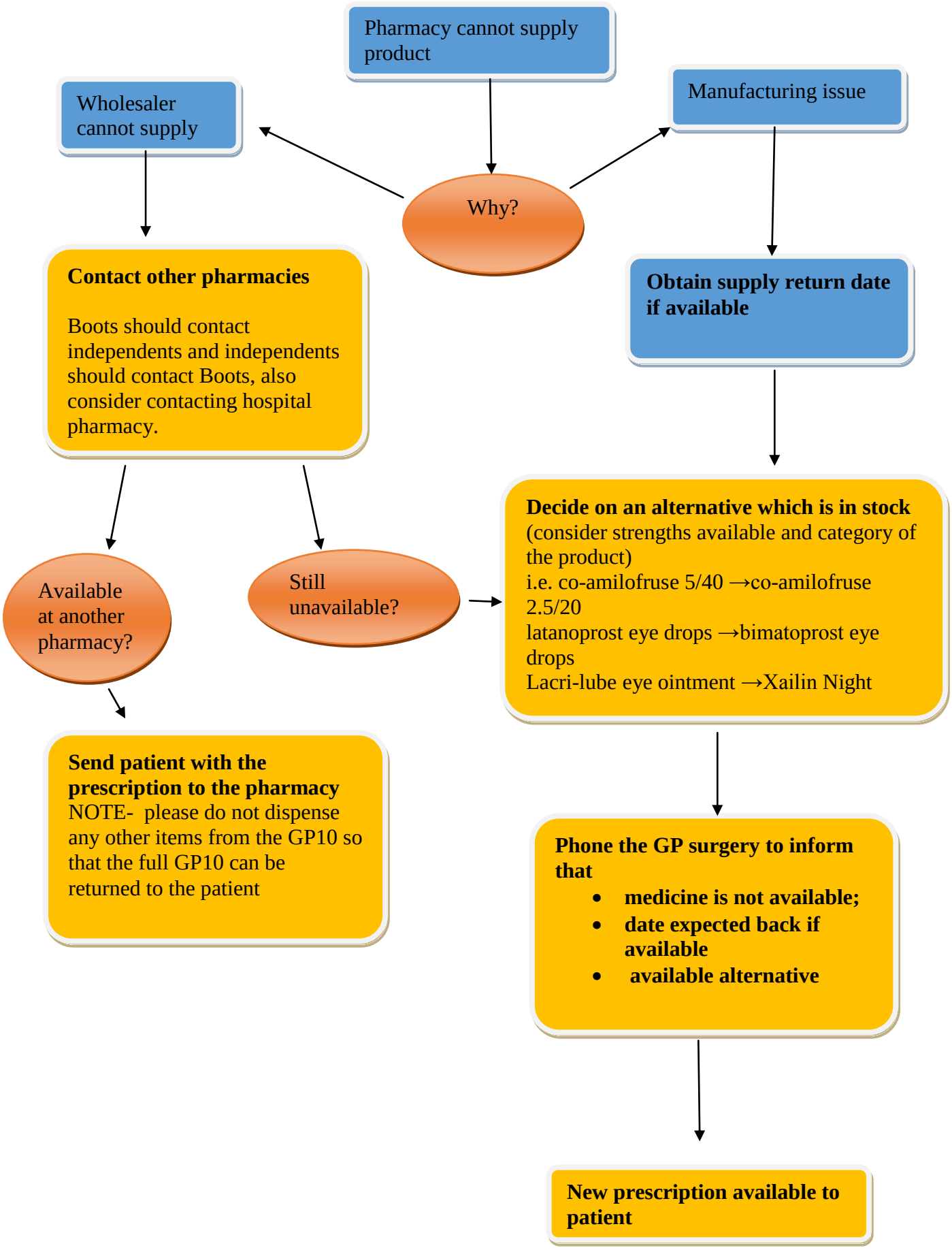
- A community pharmacist does not have access to all the information to make a substitution;
- there is a clinical decision required to select an alternative medicine; and
- for Schedule 2 and 3 controlled drugs.

v. GPs and practice staff should communicate information relating to medicine shortages and the potential impact/impact, including any changes to medication, to patients and their carers' and their relevant healthcare professionals.

Appendix 1 medicine shortage levels

LEVEL	DESCRIPTION	POTENTIAL RESPONSES
Level one (low impact)	Supply problem with a short duration **(up to one month**) where immediately available measures are expected to be sufficient and there is minimal additional management requirement.	Business as usual. Response likely to involve using the same medicine. • Alternative strength/formulation available to meet demand, potentially from other suppliers.
Level two (medium impact)	Supply problem where alternatives in the same therapeutic class are available but which may require some management such as switching to those alternatives, which may include unlicensed medicines. Level two shortages also include level one shortages that continue for more than a month.	Business as usual. Response not likely to require a change in the class of medicine. • Alternative strength/formulation available but clinical advice is required to help manage the switch. • Alternative medicine in the same therapeutic class. • Unlicensed alternatives may be used.
Level three (high impact)	Supply problems where there are limited or no alternatives in the same therapeutic class and which require significant management, 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 life saving conditions such as anaphylaxis or involving patient groups considered as vulnerable, such as neonates, paediatrics or people with learning disabilities.	Serious shortage situation. Response likely to require a change in the class of medicine. • Alternative therapeutic class of medicine available. • The use of a 'serious shortage protocol'. • Additional clinical advice. • Exceptional MHRA regulatory measures. • Issuing a 'Supply Disruption Alert' to the NHS via the Central Alerting System (CAS).
Level four (critical impact)	Supply problems where there is no viable therapeutic alternative 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. • Non-medicine support provided to patients. • National Resilience procedures potentially activated – including links with agencies outside NHS. Additional project management or communications support may be required.

Appendix 2 Medicines Shortage Flow chart



Appendix 3 : Log of Shortages

Date	Medicine	Form	Strength	Date for return to stock	Added by	Actions to mitigate position	Alternatives available	Affects 1°/2°care	Other comments	Date resolved	Closed by
Example											
20/05/2019	Diamorphine	inj	5mg	mid June 19	MM	n/a	10mg good availability				

Appendix 4 : Risk Assessment for Medicine Shortage

Risk Assessment for Medicine Shortage		Date:
Medicine	Form	Strength
Manufacturer	Pack Size	
Usual Supplier(s)		
Expected date for return to stock		

Alternatives	Availability	Action taken if no alternatives

Risk to Patients	Clinician(s) informed (identify)

Financial impact

Name Signature Date Pharmacist name Pharmacist signature Date

Review/resolution date
Outcome