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A Guide to Managing Medicines Supply and Shortages

NHS England and NHS Improvement



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Purpose

This document has been developed jointly by the Department of Health and Social Care (DHSC) and NHS England and NHS Improvement (NHSE&I) to detail the national, regional and local management and escalation processes and communication routes for medicines supply issues.

This guide supports NHS teams and professionals who have responsibility for reporting a medicine supply issue, as well as those teams and professionals who need to take action when a shortage arises.

Context

The production of medicines is complex and highly regulated. Materials and processes must meet rigorous safety and quality standards. In such a global supply chain, problems can arise for various reasons including manufacturing issues, access to raw ingredients, batch failures and regulatory intervention.

Occasionally sudden changes in prescribing practice, particularly if implemented across several regions or nationally, can cause supply problems. Companies will have forecasted production based on expected demand several months in advance and will be unlikely to have significant reserves of products if not alerted well in advance.

All of this means that some supply problems with medicines will always happen and require national management as well as local collaboration across the DHSC, the NHS and by prescribers across the health service to help mitigate the risk affecting patients.

Background

The DHSC is responsible for the continuity of supply of medicines and manufacturers have a legal requirement to inform DHSC of any supply problems. DHSC works closely with NHSE&I, the Medicines and Healthcare products Regulatory Agency (MHRA), the wider NHS, pharmaceutical companies, wholesalers and others in the supply chain to ensure consistency of supply of medicines.

The escalation and management of medicines shortages, including dissemination of information to primary and secondary care organisations, is vital in ensuring continuity of supply and in ensuring patients receive the treatment and medication required.

All organisations involved in the national management of shortages must always be mindful of the commercial and competitive nature of the pharmaceutical industry and ensure that information exchanged is handled sensitively and shared appropriately. It is in everyone's interest that companies are not deterred from providing information that is essential to the management and mitigation of medicines supply issues.

Scope

This guide provides information on the role and responsibilities of the following organisations and teams in managing medicines shortages:

Chapter 1: National Processes

- DHSC Medicines Supply Team
- NHSE&I Commercial Medicines Unit
- NHSE&I Patient Safety Team
- NHSE&I Community Pharmacy Commissioning Team
- Medicines and Healthcare products Regulatory Agency (MHRA)
- Medicines Shortage Response Group

Chapter 2: Secondary Care Processes

- The Specialist Pharmacy Service
- Collaborative Purchasing Organisations
- NHS Trust Pharmacy Teams

Chapter 3: Primary Care Processes

- Primary Care Contractors
- NHSE&I Commissioning Teams
- Clinical Commissioning Groups (CCGs)

This guide covers all national, secondary care and primary care processes for managing medicines shortages in the NHS in England. The processes apply to all types of medicines used in the NHS, though additional processes for managing shortages may be required for vaccines, clinical trials, general sales list medicines and specials. These additional processes are outside the scope of this document.

The management, escalation and communication processes for non-medicines shortages in the NHS, including those non-medicines which are prescribed, are not within the scope of this document.

DHSC regularly shares information about high impact and critical medicine shortages with the devolved administrations to support management of medicines supply issues across the UK. Although devolved administrations are not directly within the scope, this document will include some information on DHSC's information sharing with the devolved administrations.

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Chapter 1: National Processes

1 Chapter Overview

1.1 Overview

- 1.1.1 The Department of Health and Social Care (DHSC) has overall responsibility for ensuring the continuity of the supply of medicines to the NHS in England. Working closely with DHSC, the Commercial Medicines Unit in NHS England and NHS Improvement (NHSE&I) is responsible for coordinating operational management of supply problems for medicines procured for hospitals on Commercial Medicines Unit frameworks.
- 1.1.2 The Medicines Shortage Response Group has been established to support the DHSC Medicines Supply Team and the NHSE&I Commercial Medicines Unit with managing and escalating high impact and critical medicines shortages.
- 1.1.3 This chapter sets out the national processes for management and escalation of medicines supply issues, including the roles of the national bodies, the different options available to manage supply issues depending on their severity and scale, and the drafting and sign-off of communications for medicines supply issues to healthcare professionals and procurement teams in the NHS.

2 Role of National Teams and Bodies

2.1 DHSC Medicine Supply Team

- 2.1.1 This team of pharmacists and pharmacy technicians is responsible for the day to day management of medicine supply issues across primary and secondary care, including shortages and discontinuations.
- 2.1.2 To manage medicine supply issues, the team works closely with NHSE&I, the Medicines and Healthcare products Regulatory Agency (MHRA), the pharmaceutical industry, the Specialist Pharmacy Service and others operating in the supply chain to help prevent shortages and to ensure risks to patients are minimised when shortages do arise. The team also works with wholesalers and national pharmacy representative organisations to manage medicines supply issues as required.
- 2.1.3 The team regularly shares information about high impact and critical medicine shortages with the devolved administrations to support management of medicines supply issues across the UK.

2.2 NHSE&I Commercial Medicines Unit

- 2.2.1 This team is responsible for the management of national framework agreements for the procurement of medicines and homecare services by hospitals in England. Supply issues for products on a framework are reported directly to the team by manufacturers and suppliers or by pharmacy procurement teams. The NHSE&I Commercial Medicines Unit manage these supply issues in close collaboration with the DHSC Medicines Supply Team.
- 2.2.2 Both the NHSE&I Commercial Medicines Unit and the DHSC Medicines Supply Team also work closely with the Specialist Pharmacy Service medicines information function and the Regional Pharmacy Procurement Specialists and other stakeholders to seek their advice and support on potential management options.

2.3 NHSE&I Patient Safety Team

- 2.3.1 This team provides insight and advice in relation to potential patient safety issues that may arise from a medicine supply issue or shortage. The team can also facilitate access to specialist clinical expert advice.
- 2.3.2 The National Director of Patient Safety acts on behalf of the Medicines Shortage Response Group as the conduit for obtaining additional clinical advice on specific high-risk medicines supply issues and is also a Senior Responsible Officer for any Tier 4 supply issues. More information on Tiers and clinical advice can be found on pages 12- 13.

2.4 NHSE&I Community Pharmacy Commissioning Team

- 2.4.1 This team is responsible for commissioning of pharmaceutical services for the population of England. The team works closely with NHSE&I Regional Teams who link with contractors. All business as usual communications to community pharmacy and dispensing appliance contractors are disseminated via this team.

2.5 Medicine and Healthcare products Regulatory Agency (MHRA)

- 2.5.1 The MHRA assist the DHSC Medicines Supply Team in the management of supply issues through expediting regulatory procedures to ensure continuity of supply and providing companies with regulatory support if there is an underlying regulatory issue contributing to the supply issue.
- 2.5.2 The MHRA also liaise with the DHSC Medicines Supply Team on any likely regulatory action they propose to take in circumstances where manufacturers and suppliers do not meet Good Practice Standards- this includes Good Manufacturing Practice (GMP), Good Distribution Practice (GDP) and Good

Pharmacovigilance Standards. The MHRA notify the DHSC Medicines Supply Team of potential regulatory action and the team then undertake a risk assessment on the potential impact on supply of products from that manufacturer and, if required, develop strategies to manage the supply issue.

2.6 Medicines Shortage Response Group

2.6.1 The Medicines Shortage Response Group is a multi-disciplinary group, including clinicians, with members from across DHSC, NHSE&I and the wider NHS. The Medicines Shortage Response Group supports the DHSC Medicines Supply Team and the NHSE&I Commercial Medicines Unit with the management of supply issues that are categorised as high impact (Tier 3) or critical (Tier 4) medicines supply issues. The Medicines Shortage Response Group also provides advice on issues categorised as Tier 1 or 2 when requested. For more information on the levels used to categorise medicines supply issues see Annex A: Clinical Escalation Categories Overview Table.

2.6.2 The Medicines Shortage Response Group is an advisory body which:

- Provides oversight of medicine supply issues and support the work that the DHSC Medicines Supply Team and the NHSE&I Commercial Medicines Unit undertake to manage supply issues;
- Supports the management of medicines supply issues reported to the DHSC Medicines Supply Team and the NHSE&I Commercial Medicines Unit classified under the clinical escalation categories as Tier 3 or Tier 4. This includes:
 - Overseeing escalation to EPPR where necessary for Tier 3 and Tier 4 shortages;
 - Providing advice on communications content and dissemination;
 - Commissioning the NHSE&I Medical Directorate, via the National Director for Patient Safety, to obtain clinical advice on medicines supply issues. This advice is in addition to the information that has been provided by UK Medicines Information to DHSC Medicines Supply Team and the NHSE&I Commercial Medicines Unit.
- Advises on whether the development of a Serious Shortage Protocol would be beneficial to help mitigate a shortage and provides a recommendation to the National Medical Director and Chief Pharmaceutical Officer on this basis. The National Medical Director and Chief Pharmaceutical Officer then provide the final recommendation to Ministers.

3 Management and Escalation Process

3.1 Overview of Management and Escalation Process

3.1.1 The management and escalation of medicine supply issues follows the three steps set out in Diagram 1 below:

- Notification of the supply issue;
- Initial risk assessment; and
- Identification and implementation of management options.

3.1.2 The next three sub-sections provide more detail on these three steps.

3.2 Diagram 1 – Shortage Management Process

Shortage management processes

Notification of Issue

- Shortage regulations
- Wholesalers
- DHSC guidelines
- CMU supply issues
- MHRA
- NHS/PMSG
- DAs
- Correspondence Unit
- Patient groups
- Public



Risk Assessment

- Nature of the problem
- Duration
- Indication (licensed and unlicensed)
- Usage figures
- Market share
- Alternative products
- Clinical need
- Engagement with procurement leads
- Assign clinical tiers



Management Options

- Working with manufacturer and alternative suppliers
- Working with wholesalers in managing limited stock
- Expediting regulatory procedure
- Unlicensed imports
- Escalate to MSRG
- Commissioning clinical advice
- Issuing NHS communications
- Briefing Ministers and Press Office

3.3 Step 1: Notification of Supply Issue

Overview

3.3.1 As detailed in Diagram 1 above, the DHSC Medicines Supply Team and the NHSE&I Commercial Medicines Unit may receive notification of a supply issue through several different routes. The following three sub-sections provide more information on:

- The responsibilities of manufacturers and suppliers;
- The NHS intelligence gathering sources; and
- Other intelligence sources.

Manufacturers Notifications

3.3.2 Under Part 6 of the Health Service Products (Provision and Disclosure of Information) Regulations 2018, manufacturers are legally required to provide information to the DHSC Medicines Supply Team about availability of UK licensed medicines and about discontinuation or anticipated supply shortages. The regulations were introduced in January 2019, superseding previous voluntary arrangements.

3.3.3 These requirements ensure that the DHSC Medicines Supply Team have relevant information from manufacturers at the earliest point to help manage supply shortages and mitigate any potential impacts on patients. Marketing Authorisation Holders (“MAHs”) are expected to be fully accountable for their supply chain to the UK market and required to understand the potential impact on UK patients should supplies of their products become unavailable.

3.3.4 More information on the DHSC reporting requirements for medicine shortages and discontinuations introduced in January 2019, can be found [here](#).

3.3.5 Any Information submitted by companies as outlined in regulation 29(2) of the Health Service Products (Provision and Disclosure of Information) Regulations 2018 is commercially confidential information and treated sensitively by DHSC.

3.3.6 If a supplier is part of a Commercial Medicines Unit framework agreement, then that supplier should also notify NHSE&I Commercial Medicines Unit about anticipated supply issues and discontinuation of products. Working closely with the DHSC Medicines Supply Team, the NHSE&I Commercial Medicines Unit then investigate the issue and develop a management plan.

NHS Notifications

3.3.7 The DHSC Medicines Supply Team and the NHSE&I Commercial Medicines Unit also receive intelligence on medicines supply issues through other, more informal NHS routes. These secondary and primary care routes are detailed in Chapters 2 and 3.

Other Notifications and Intelligence

3.3.8 The DHSC Medicines Supply Team and NHSE&I Commercial Medicines Unit also receive intelligence from the following sources:

- **MHRA:** The MHRA notifies the DHSC Medicines Supply Team regarding potential regulatory issues affecting medicines that may have an impact on supply;
- **Wholesalers:** All the main wholesalers have points of contact within both the DHSC Medicines Supply Team and the NHSE&I Commercial Medicines Unit and they contact these teams directly about any supply issues;
- **Homecare Providers:** Where a Homecare Provider has queries about the supply of a specific homecare medicine, these issues are escalated to the Regional Homecare lead and, if they cannot be resolved at regional level, to the National Homecare Medicines Committee. The National Homecare Medicines Committee then escalates the issue to the DHSC Medicines Supply Team and/or the NHSE&I Commercial Medicines Unit where necessary;
- **Health and Justice Providers:** Where the named Lead/Chief Health and Justice Pharmacist for a Health and Justice provider has a query or concern about the supply of a medicine, these issues are escalated to the NHSE&I Health and Justice Commissioners. Where the NHSE&I Health and Justice Commissioners are unable to resolve the issue, it is then escalated to the DHSC Medicines Supply Team;
- **Primary Care Representative Bodies:** These organisations such as the Pharmaceutical Services Negotiating Committee contact the DHSC Medicines Supply Team directly to raise any supply issues;
- **Royal Colleges and other clinical networks:** These networks may contact NHSE&I or the UK Medicines Information to raise any supply issues;
- **Patient groups:** Patient groups may notify the DHSC Medicines Supply Team or the DHSC correspondence unit of any supply issues identified;
- **Members of the public:** Supply concerns from members of the public are received through the DHSC, NHSE&I or MHRA correspondence units.

3.4 Step 2: Initial Risk Assessment

3.4.1 Once notified of an issue via any of the above routes, the DHSC Medicines Supply Team and/or the NHSE&I Commercial Medicines Unit carry out a thorough risk assessment to determine the potential impact on patients and what type of management options should be considered. The risk assessment considers several factors including:

- Nature of the problem, including the reason for the supply issue, the anticipated out of stock date and the likely resupply date
- Product
- Pack Size

- Strength
- Duration
- Potential clinical impact
- Risk issues
- Indication (licensed and unlicensed)
- Usage figures (using primary and secondary care data)
- Market share
- Alternative products available
- Clinical need / patient groups affected

3.4.2 To further assess the medicine supply issue, the DHSC Medicines Supply Team and NHSE&I Commercial Medicines Unit may also:

- Access the Rx-Info Define and Exend® systems to view NHS Trust stock levels & medicines usage data; and
- Request NHS Business Services Authority (NHS BSA) data on the number of patients likely to be affected in primary care by the medicine supply issue.

3.4.3 To support the risk assessment of a medicine supply issue and develop a management plan, the DHSC Medicines Supply Team and NHSE&I Commercial Medicines Unit may seek early advice from the Specialist Pharmacy Service medicines information function. This function provides provisional clinical advice when supply issues first become apparent to help inform the initial action plan and to brief the Medicines Shortage Response Group if appropriate.

3.4.4 As part of the assessment of a medicine supply issue, the DHSC Medicines Supply Team and/or NHSE&I Commercial Medicines Unit make an initial decision as to the severity of the medicine supply issue and which Tier the supply issue should be allocated to. The Tier allocated to a supply issue may be discussed at a Medicines Shortage Response Group meeting where required. The four Tiers are:

- **Tier 1 (low impact):** These supply issues are likely to carry low risk. Management options should result in patients being maintained on the same licensed medicine.
- **Tier 2 (medium impact):** These supply issues require more intense management options (such as using low risk therapeutic alternatives, unlicensed imports or alternative strengths or formulations), which may carry a greater risk to patients/health providers than Tier 1 issues, but which are considered safe to be implemented locally without further escalation.
- **Tier 3 (high impact):** These supply issues are more critical, with potential change in clinical practice or patient safety implications that require clinical or operational direction to the system. The response is nationally coordinated and guided and the NHS may invoke the Emergency Preparedness Resilience and Response (EPRR) function.

- **Tier 4 (critical):** These supply issues require additional support from outside the health system and trigger the use of dedicated national NHS EPRR incident processes and procedures in order to provide additional support for the management of the shortage.

3.4.5 For more information on the four clinical escalation Tiers and the characteristics used to categorise medicines, see Annex A: Clinical Escalation Categories Overview Table.

3.5 Step 3: Management Options for the Supply Issue

3.5.1 Each supply issue has specific characteristics and must be managed on an individual basis whilst adhering to the clinical escalation categories guidelines.

3.5.2 If an issue is likely to have the potential to impact on patient care, the DHSC Medicines Supply Team and the NHSE&I Commercial Medicines Unit work with manufacturers and other relevant stakeholders and consider a range of options to help mitigate and manage any issues which might include:

- Working with the MHRA to support affected companies with relevant regulatory advice and to the expedition of regulatory procedures for products deemed critical;
- Working with companies and wholesalers to manage supply of existing stocks;
- Identifying and liaising with other manufacturers to increase production of the product concerned and/or alternative medicines;
- Commissioning clinical advice from the Specialist Pharmacy Service medicines information function and national clinical experts regarding potential management options;
- Contacting importers to identify sources of product from abroad and expediting import processes;
- Setting allocations for NHS Trusts to manage current stock of a product. If this management option is being considered, the Regional Pharmacy Procurement Specialists are responsible for identifying and verifying usage figures for NHS Trusts in their regions and assessing how long these stocks are likely to last.

3.5.3 All Tier 1 and Tier 2 medicines supply issues are managed by the DHSC Medicines Supply Team and the NHSE&I Commercial Medicines Unit through the above processes. The Medicines Shortage Response Group have sight of Tier 1 and 2 supply issues but do not support the management of these unless their support is specifically requested by the DHSC Medicines Supply Team and/or the NHSE&I Commercial Medicines Unit.

3.5.4 Tier 3 and Tier 4 supply issues are escalated by the DHSC Medicines Supply Team and the NHSE&I Commercial Medicines Unit to the Medicines

Shortage Response Group who oversee management and escalation plans for these issues. This may include:

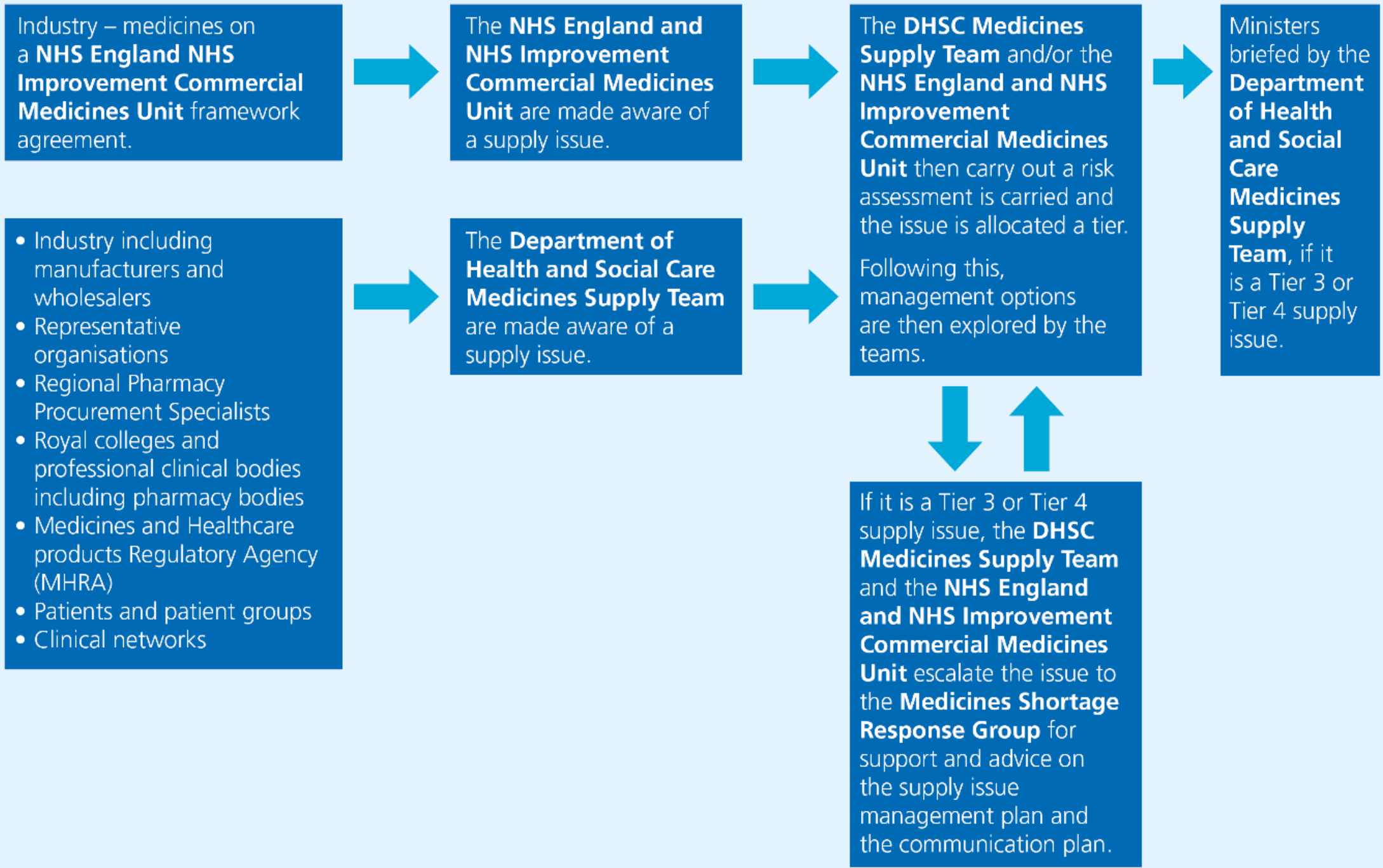
- Commissioning the NHSE&I Medical Directorate, via the National Director of Patient Safety, to follow the NHSE&I agreed processes for obtaining further clinical advice in addition to information already gathered from clinical experts including:
 - National Clinical Directors (NCDs);
 - Getting it Right First Time (GIRFT) clinical leads;
 - Clinical Reference Group (CRG) chairs; and
 - Royal Colleges and other professional bodies.

The Specialist Pharmacy Service Medicines Information function also helps draft any formal clinical advice requested by the Medicines Shortage Response Group which is then reviewed and agreed with expert clinicians as detailed in Chapter 1 of this document.

- Providing advice on the content and dissemination routes for communications to the NHS and other stakeholders including patient groups;
- Advises on whether the development of a Serious Shortage Protocol would be beneficial to help mitigate a shortage and provides a recommendation to the National Medical Director and Chief Pharmaceutical Officer on this basis. The National Medical Director and Chief Pharmaceutical Officer then provide the final recommendation to Ministers;
- Deciding when issues need to be escalated to, and de-escalated from, EPRR teams using the clinical escalation categories framework.

3.6 Diagram 2 – Escalation Routes for Supply Issues with Medicines Identified at a National Level

Escalation Routes for Supply Issue with Medicines Identified at a National Level



4 Medicines Supply Communications

4.1 General Approach

- 4.1.1 Each medicine supply issue is different, and the type of communication used depends on a number of factors such as whether the product is mainly used in primary or secondary care, the potential duration of the shortage, the availability of equivalent or similar alternatives and the criticality of the shortage in terms of impact on patients.
- 4.1.2 The DHSC Medicines Supply Team and NHSE&I Commercial Medicines Unit work closely with companies, Regional Pharmacy Procurement Specialists' and others in the supply chain in these situations to provide advice on whether to, and how best to, communicate a supply problem. This includes working with the relevant patient groups to develop tailored patient communication where needed.
- 4.1.3 The DHSC Medicines Supply Team and NHSE&I Commercial Medicines Unit are responsible for drafting communications for medicines supply issues of all Tiers of severity. Where a medicine is on a Commercial Medicines Unit framework, the NHSE&I Commercial Medicines Unit are responsible for leading and drafting the communications and the DHSC Medicines Supply Team lead on this process for all medicines not on a Commercial Medicines Unit framework.
- 4.1.4 For all Tier 3 and Tier 4 shortages, the DHSC Medicines Supply Team and the NHSE&I Commercial Medicines Unit will share the communication plan, including content and dissemination routes with the Medicines Shortage Response Group for input and advice. The Medicines Shortage Response Group Chair is responsible for signing off the final communications for Tier 3 and 4 supply issues, including Supply Disruption Alerts via the CAS system.
- 4.1.5 The DHSC Medicines Supply Team and/or the NHSE&I Commercial Medicines Unit may also request input from the Medicines Shortage Response Group on specific Tier 2 issues when the teams feel additional communication support is required. The Medicines Shortage Response Group considers who the key stakeholders are for a specific shortage and utilises existing networks where possible to disseminate information about shortages.
- 4.1.6 All Tier 2-4 medicines supply communications must:
- Include an overview of the issue including the anticipated out of stock date and latest update on resupply date;
 - Provide details on the management plan and any local actions required;
 - Provide links to any relevant clinical advice that has been commissioned;
 - Provide information on the availability of potential alternative medicines (including unlicensed imports) that have been recommended as part of the management plan;
 - Signpost to sources of further information such as clinical advice and expertise where available (e.g. for secondary care, suggesting Trusts

contact the relevant Regional Pharmacy Procurement Specialists for their region if further advice or support is needed).

- 4.1.7 The secondary and primary care communications dissemination routes for medicines supply issues are detailed in the Chapters 2 and 3 below.

4.2 Supply Disruption Alerts via the Central Alerting System (CAS)

- 4.2.1 Some shortages have the potential to have a more serious patient safety or system wide impact and therefore require prompt and proactive actions for clinicians to undertake locally. For these shortages, the use of the Central Alerting System (CAS) to issue a 'Supply Disruption Alert' to the NHS and independent and social care providers is considered by the Medicines Shortage Response Group.
- 4.2.2 Issuing a 'Supply Disruption Alert' involves publishing the alert via the [CAS website](#), which generates an email to subscribers. Email alerts are sent to those who need to take action and confirm their actions by logging into the [CAS website](#). Emails are also sent to those subscribers who have requested to receive alerts for their information.
- 4.2.3 The decision to issue a 'Supply Disruption Alert' via the CAS system would routinely be agreed and recommended by the Medicines Shortage Response Group. The NHSE&I National Director of Patient Safety is a member of this group and so has input into this discussion and decision. The NHSE&I National Director of Patient Safety will inform the NHSE&I National Medical Director of any key issues discussed at the Medicines Shortage Response Group, allowing the opportunity to intervene and influence as appropriate.
- 4.2.4 For all Tier 3 and Tier 4 supply issues, national guidance to primary and secondary care will be issued as a 'Supply Disruption Alert' by default. In exceptional circumstances, the Medicines Shortage Response Group may decide that another method of communication is more appropriate.

4.3 Diagram 3 – Dissemination Route for Supply Issues with Medicines Prescribed in Primary Care or Secondary Care

Dissemination Route for Supply Issues with a Medicine Prescribed in Primary Care or Secondary Care

The DHSC Medicines Supply Team and NHS England and NHS Improvement Commercial Medicines Unit draft communications for all medicines supply issues.

Communications will go out to the NHS and community pharmacies either via NHS England and NHS Improvement commissioning and procurement routes or via the Central Alerting System.



Tier 1 and Tier 2 Medicines Supply Issues In Primary Care

- If the supply issue is categorised as Tier 1 or 2, and is therefore less severe, the DHSC will ask NHS England and NHS Improvement to send out communications to community pharmacies, GP practices, dentists, optometrists, dispensing doctors and health and justice services where appropriate, via NHS England and NHS Improvement commissioning routes.
- The information is also sent to the national pharmacy bodies by the DHSC Medicines Supply Team.



Tier 1 and Tier 2 Medicines Supply Issues in Secondary Care

- If the supply issue is categorised as Tier 1 or 2, and is therefore less severe, information will be sent to NHS Trusts via Regional Pharmacy Procurement Specialists from the DHSC Medicines Supply Team or the NHSE&I Commercial Medicines Unit.



Tier 3 and Tier 4 Medicines Supply Issues in Primary Care and Secondary Care

- If the supply issue is more severe and categorised as a Tier 3 or Tier 4, a CAS alert will be issued.
- The Medicines Shortage Response Group signs off communications for Tier 3 and 4 issues.

Regular Updates on all Medicines Supply Issues (Tiers 1- 4)

- A monthly supply report, which provides an overview of all current supply issues is published by the DHSC Medicines Supply Team on the Specialist Pharmacy Services website for NHS registered users. It is also circulated to the relevant procurement contacts in NHS Trusts and to national representative and professional bodies including;
 - PSNC
 - PresQIPP who circulate onwards to CCGs
 - Dispensing Doctors Association
 - British Medical Association
 - Royal College of Physicians
 - Royal Pharmaceutical Society
 - Regional Pharmacy Procurement Specialists' to cascade to NHS Trusts
- The NHS England and NHS Improvement Commercial Medicines Unit supply issues report is updated and cascaded to all procurement leads at NHS Trusts in England on a fortnightly basis. It contains an update on supply issues for products on framework agreements.

Case Study: Sinemet (Co-careldopa)

Company: Merck Sharp & Dohme Limited (MSD)

Date of Shortage: September 2018- December 2018

Tier Level: Tier 2 (medium impact)

Overview of Supply Issue: After experiencing a number of manufacturing constraints for a number of Sinemet® products, a treatment for Parkinson's disease, Merck Sharp & Dohme Limited (MSD) transferred production for these products to a new site in Italy in order to improve the consistency of supply. As a result of the move some unavoidable manufacturing issues occurred which, coupled with an increase in demand for some products, led to intermittent supply gaps of some presentations of Sinemet over a number of months.

Although there are several suppliers who market generic Co-careldopa, the majority of NHS patients who take Co-careldopa, use the Sinemet® brand.

Risk Assessment: The DHSC Medicines Supply Team and the NHSE&I Commercial Medicines Unit worked together to undertake a risk assessment to determine potential impact and the management options for consideration. Although a number of generic supplies are available, and clinically Co-careldopa does not need to be prescribed by brand, the majority of prescriptions for Co-careldopa are prescribed by brand. Therefore, for patients requiring a generic Co-careldopa, a new prescription is required for the pharmacist to be able to dispense.

Management Options: The DHSC Medicines Supply Team worked with the other suppliers who were able to increase production of the generic supplies and between them were able to cover the shortfall in supply of the product.

Communications: Merck Sharp & Dohme Limited (MSD) wrote a letter to clinicians working in primary and secondary care to communicate the supply issue. The DHSC Medicine Supply Team issued communications to primary care networks and Regional Pharmacy Procurement Specialists and other secondary care contacts to cascade into their secondary care networks.

The DHSC Medicines Supply Team and Merck Sharp & Dohme Limited (MSD) also worked closely with the national patient group, Parkinson's UK, to develop tailored patient communications. Parkinson's UK then published information on their website and were able to provide reassurance and advice to patients through their helpline.

Case Study: Epanutin (Phenytoin) 30mg/5ml Oral Suspension

Company: Pfizer

Date of shortage: October 2018 – December 2018

Tier Level: Tier 3 (high impact)

Overview of Supply Issue: Pfizer, the sole supplier of Epanutin (phenytoin) 30mg/5ml oral suspension experienced global delays in manufacturing this product, as they needed to produce new batches to bring it in line with recently updated international standards.

Risk Assessment: The DHSC Medicines Supply Team and the NHSE&I Commercial Medicines Unit worked together to undertake a risk assessment to determine potential impact and the management options for consideration.

One important factor in this risk assessment was that Epanutin is used to treat epilepsy and guidance issued by the MHRA stipulates that patients taking phenytoin ideally should not be switched to a different version of the same product due to clinical differences with other products. If a switch to another product is the only option in a shortage, then this must be managed under medical supervision and may require monitoring of phenytoin serum levels.

Management Options: The DHSC Medicines Supply Team worked closely with Pfizer to explore possible options to mitigate the risk of this affecting UK patients. Pfizer had identified a product of a similar phenytoin oral suspension that they manufacture in Canada, which contained the same concentration of phenytoin as the UK presentation, under the brand name Dilantin. As the product from Canada was unlicensed for use in the UK and as some of the non-active ingredients are different, the DHSC Medicines Supply Team worked with the MHRA, NHS Quality Assurance and with Pfizer to ensure it would be safe for patients to use in the UK. Having established its safety, 2,040 packs of the Canadian Dilantin were used to cover the shortage period. UK Epanutin oral suspension went out of stock from week commencing 28th October 2018. Pfizer sourced and were able to provide Canadian Dilantin oral suspension from week commencing 4th November 2018. During this one-week period from 28th October to 4th November, Pfizer weren't in a position to offer assurances that there would be enough stock of Epanutin because they were waiting for all appropriate quality approvals for the release of batches. The DHSC Medicines Supply Team therefore explored other options including unlicensed imports from other sources and unlicensed specials which can be manufactured here in the UK. Pfizer were back in stock of the UK concentrate from the week commencing 18th November.

Through their diligent planning and market sourcing, there was only one-week shortage from week commencing 28th October where no Pfizer product was available. While the Dilantin supplies were insufficient to meet potential demand, the offer from Pfizer was constructive and could be appropriately verified by the DHSC Medicines Supply Team, the MHRA and NHS Quality Assurance.

Continued next page

As a Tier 3 shortage, the management plan of this shortage was discussed and agreed at the Medicines Shortage Response Group. Dr Bruce Warner, Chair of the Medicine Shortage Response Group, said:

“We explored a number of options to manage this shortage and ensured patient safety was taken into account. Although there was additional stock of a very similar product produced in Canada, the quantities would not have been enough to meet the demand in the UK. The Medicines Shortage Response Group sought further clinical advice from the British Paediatric Neurology Association and the Association of British Neurologists and we were able to advise clinicians to switch patients to other unlicensed versions of phenytoin subject to these patients being carefully managed and monitored until Epanutin oral suspension was back in stock.”

Communications: Healthcare professionals in primary and secondary care, including GPs, were alerted to the shortage via the MHRA’s Central Alerting System and a supply disruption alert. Patients were contacted by their GP and the DHSC Medicines Supply Team also worked closely with the Epilepsy Society, Epilepsy Action and Young Epilepsy so that they could offer support and share information with patients.

Chapter 2: Managing Medicines Supply and Shortages in Secondary Care

5 Chapter Overview

5.1 Overview

- 5.1.1 Local management of medicines supply disruptions in secondary care is led by the Pharmacy Teams in NHS Trusts and Collaborative Purchasing Organisations with support and escalation where required to the relevant Regional Pharmacy Procurement Specialist who work as part of the Specialist Pharmacy Service.
- 5.1.2 NHS Trust Chief Pharmacists are responsible for ensuring that a documented process for responding to medicines supply disruptions is in place led by the NHS Trust Pharmacy Procurement Teams.
- 5.1.3 This chapter will provide information on the regional and local processes for medicines shortages management and escalation and the dissemination routes for medicines supply communications in secondary care. This includes detailing the role of the Specialist Pharmacy Service, the Collaborative Purchasing Organisations and NHS Trust Pharmacy Teams.

6 The Specialist Pharmacy Service

6.1 Background

- 6.1.1 The Specialist Pharmacy Service is an NHSE&I commissioned service that supports the NHS nationally and regionally by providing a network of Regional Pharmacy Procurement Specialists. The four functions of the Specialist Pharmacy Service are located across England in the regions and provide specialist advice on:
- Medicines procurement;
 - Pharmaceutical quality assurance;
 - Medicines information; and
 - Medicines use and safety.
- 6.1.2 The medicines procurement function of the Specialist Pharmacy Service works with the DHSC Medicines Supply Team, NHSE&I Commercial Medicines Unit and individual NHS Trusts on the management of medicines supply. Regional Pharmacy Procurement Specialists' work within the Specialist Pharmacy Service regional structure to coordinate and support the national, regional and local management of medicine supply issues as detailed in the section below.

6.1.3 The Specialist Pharmacy Service medicines information function supports the DHSC Medicines Supply Team and the NHSE&I Commercial Medicines Unit by providing provisional clinical advice when supply issues first become apparent to help inform the initial action plan and to brief the Medicines Shortage Response Group if appropriate. The Specialist Pharmacy Service Medicines information function also helps draft any formal clinical advice requested by the Medicines Shortage Response Group which is then reviewed and agreed with expert clinicians as detailed in Chapter 1 of this document.

6.2 Specialist Pharmacy Service Medicines Supply and Shortage Management Functions

6.2.1 Upon being notified of a medicine supply issue by either the DHSC Medicines Supply Team, the NHSE&I Commercial Medicines Unit, an NHS Trust Pharmacy Procurement Team, or a Collaborative Purchasing Organisation, the Regional Pharmacy Procurement Specialists undertakes a supportive and facilitative role with the relevant Pharmacy Procurement Team or relevant Collaborative Purchasing Organisations to ensure continuity of supply is maintained. Support from the Regional Pharmacy Procurement Specialist may include:

- using the Rx-Info Define® and Exend® systems and information from the NHS Trust Pharmacy Procurement Teams to identify NHS Trust stock levels and usage trends for the product across the region and create an overall regional picture;
- assessing wholesaler or supplier stock positions; and
- looking at possible clinical alternatives.

6.2.2 Various management actions may then be taken, including:

- Supporting the redistribution of stock between NHS Trusts where required (available via NHSE&I accessed Rx-Info Define® and Exend® stock data);
- Where allocations have been introduced by the DHSC Medicines Supply Team or the NHSE&I Commercial Medicines Unit, to manage stock of a product, supporting NHS Trusts to manage within these allocations and assisting NHS Trusts where specific clinical need or patient demand cannot be met within the allocation;
- If directed by the DHSC Medicines Supply Team or the NHSE&I Commercial Medicines Unit, developing and sharing guidance on best practice for local management of a particular shortage.

6.2.3 The Regional Pharmacy Procurement Specialists also work with the NHS Trust Pharmacy Procurement Teams and Collaborative Purchasing Organisations to ensure that any additional relevant stakeholders in the

health sector are informed of shortages and management plans where necessary.

- 6.2.4 If after examining all the above factors and considering local management options, the Regional Pharmacy Procurement Specialist is still concerned about the supply issue or feels it is unable to be managed and mitigated locally, they are responsible for escalating or re-escalating the supply disruption issue to the DHSC Medicines Supply Team and/or the NHSE&I Commercial Medicines Unit for advice and/or supply management.

7 Collaborative Purchasing Organisations

7.1 Background

- 7.1.1 There are nine recognised Collaborative Purchasing Organisations for Pharmacy Products and Services in England. They manage the procurement of some pharmacy products and services not managed through NHSE&I framework agreements. These products and services include; contrast media, medical gases, fibrin sealants, radio-pharmaceuticals and compounding services, including dose branded chemotherapy.
- 7.1.2 The Collaborative Purchasing Organisation is the contracting authority of these medicines and services, and undertakes a formal legal procurement exercise, naming all NHS organisations that participate in their contracts. The Collaborative Purchasing Organisation leads on all aspects of supplier engagement and management during the life of the contract.

7.2 Collaborative Purchasing Organisations Medicines Supply and Shortage Management Functions

- 7.2.1 In the event of a service or supply failure, NHS Trust Pharmacy Procurement Teams are expected to contact the Collaborative Purchasing Organisation in the first instance. The Collaborative Purchasing Organisation then investigate the nature of the service or supply disruption with the contracted supplier.
- 7.2.2 The Collaborative Purchasing Organisation should establish if alternative suppliers/providers on their contract(s) are able to support the acute NHS Trusts. For instance, this might be an alternative importer or specials manufacturer, or an alternative service provider as with homecare or commercial compounder.
- 7.2.3 In the event that a broader market wide service or supply disruption might be emerging, the Collaborative Purchasing Organisation is responsible for escalating concerns to the appropriate Regional Pharmacy Procurement Specialists for advice and support.

8 NHS Trust Pharmacy Teams

8.1 NHS Trust Chief Pharmacist Medicines Supply and Shortage Management Functions

8.1.1 The Chief Pharmacists of NHS Trusts are responsible for overseeing the NHS Trust Pharmacy Team's local response to and management of medicines supply issues. This includes ensuring that a collaborative approach is taken which considers regional and national supply need as well as ensuring continuity of local supply. The Chief Pharmacist must take a leadership role in ensuring individual organisations work with national processes and escalate supply issues where needed.

8.2 Overview of NHS Trust Pharmacy Procurement Teams

8.2.1 NHS Trust Pharmacy Procurement Teams are supported by Clinical Pharmacy Services and are responsible for managing any supply disruptions in their Trust in accordance with local policy and for working closely with Regional Pharmacy Procurement Specialists. As some NHS Trusts supply medicines locally and internally to other NHS organisations such as Mental Health Trusts and Community Trusts, the team are also responsible for managing any supply disruptions experienced by these organisations.

8.2.2 The teams have responsibility for NHS Trust level communications to relevant clinicians and ensuring that that local risk register reporting and management is undertaken to ensure that clinicians are aware of the issue and the management plan. The teams should also ensure that medicines governance systems are used for high impact or critical medicines shortages. Most supply disruptions are resolved locally with an NHS Trust.

8.3 NHS Trust Pharmacy Procurement Teams Medicines Supply and Shortage Management Functions

8.3.1 When a medicine supply disruption is identified by an NHS Trust Pharmacy Procurement Team for a product that is procured and managed by the Collaborative Purchasing Organisation, the team contact the Collaborative Purchasing Organisation in the first instance.

8.3.2 For all other identified medicines supply issues, the NHS Trust Pharmacy Procurement Team should first check all known sources, such as wholesalers and suppliers, for information about current supply issues and should undertake steps to manage the shortage locally. As part of this process, Pharmacy Procurement Teams should consult:

- The medicines shortages update documents from the DHSC Medicines Supply Team;
- The NHSE&I Commercial Medicines Unit supply issues fortnightly spreadsheet;

- The Rx-Info Define® and Exend® medicines shortage system;
- All other recent communications on medicines shortages from national teams;
- The [Specialist Pharmacy Service website](#).

8.3.3 For more information on the NHS Trust Pharmacy Procurement Teams local processes for managing supply disruptions locally, see *Annex B: Checklist for use by NHS Trust Pharmacy Procurement Teams*.

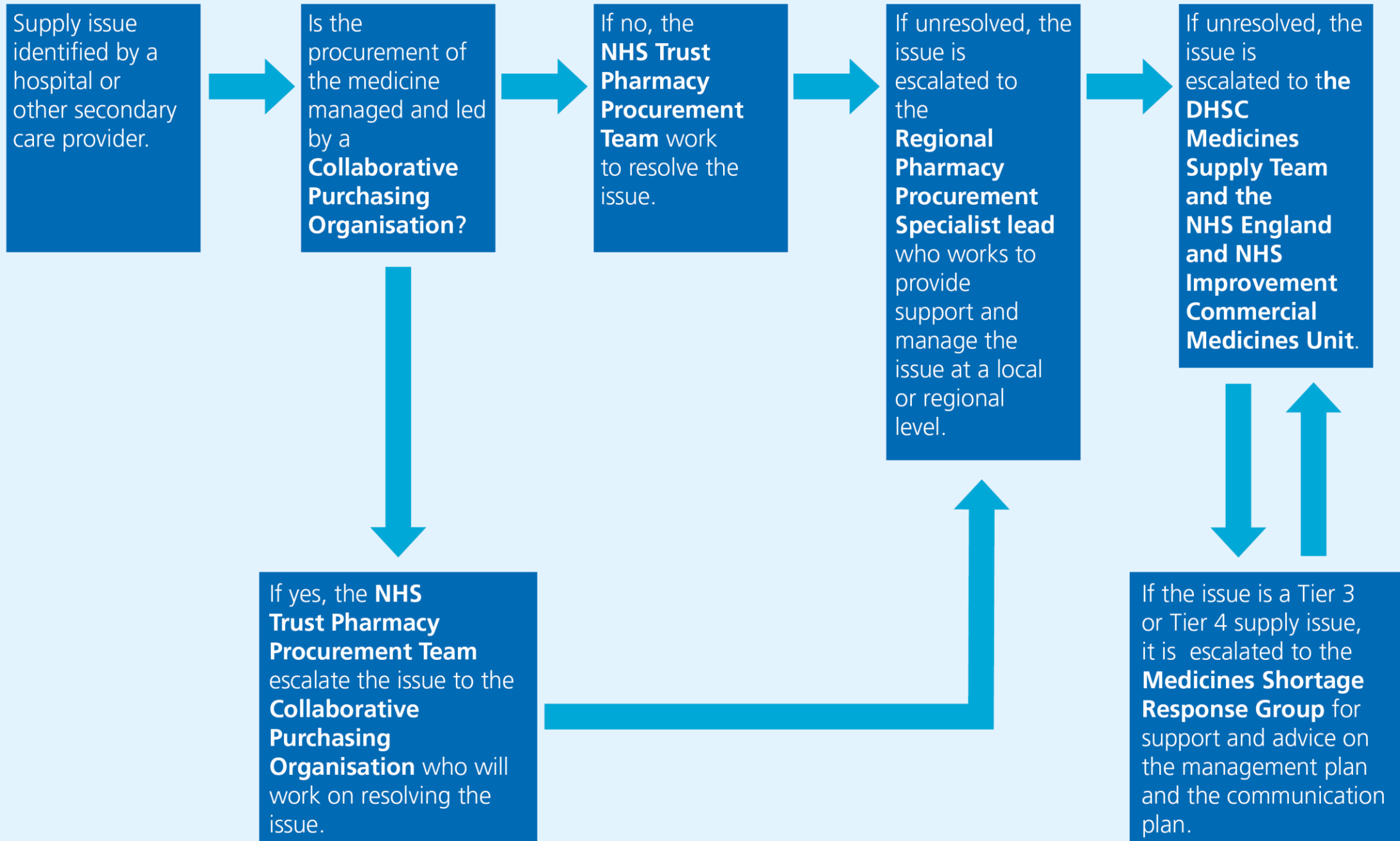
8.4 NHS Trust Pharmacy Procurement Teams Medicines Supply and Shortage Escalation Functions

8.4.1 It is recognised that local capacity to investigate and manage supply disruptions is variable, but it is important that the local action recommended in section 8.3 is taken to avoid premature escalation and to enable resolution of most supply issues locally.

8.4.2 Only if after using the checklist and reviewing all immediately available information resources the medicine supply issue has not been satisfactorily resolved, should the Pharmacy Procurement Team escalate the issue to the relevant Regional Pharmacy Procurement Specialist in their region.

8.5 Diagram 4 – Escalation Route for Medicines Supply Issues Identified Locally in Secondary Care

Escalation Route for Supply Issues Identified Locally in Secondary Care



9 Dissemination of Communications in Secondary Care

9.1 Overview of Dissemination of Communications in Secondary Care

- 9.1.1 The Medicines Supply Communications section (section 4) details the national drafting and sign-off processes, including general principles on content.
- 9.1.2 The format and dissemination routes for these communication routes in secondary care are dependent on the severity of the supply issue or shortage and are detailed in the below sections.

9.2 Low Impact Medicine Supply Issues (Tier 1)

- 9.2.1 The NHSE&I Commercial Medicines Unit supply issues report is updated and cascaded to all procurement leads at NHS Trusts in England on a fortnightly basis.
- 9.2.2 The monthly DHSC Medicines Supply Team supply report summary is circulated to Regional Pharmacy Procurement Specialists' to cascade to relevant contacts in NHS Trusts and is also uploaded to the [Specialist Pharmacy Service website](#) which all NHS staff can register to access.
- 9.2.3 For low impact shortages, other communication routes are unlikely to be required in between these monthly supply report summaries.

9.3 Medium Impact Medicine Supply Issues (Tier 2)

- 9.3.1 Where further communication is required to support a medicine supply issue, email communication with comprehensive management plans are sent from the NHSE&I Commercial Medicines Unit or the DHSC Medicines Supply Team to Regional Pharmacy Procurement Specialists' to cascade to secondary care networks. A template has been developed for these Tier 2 medicines supply issues communications (See Annex C). The template will be used for all Tier 2 shortage communications, unless considered inappropriate by the DHSC Medicines Supply Team or NHSE&I Commercial Medicines Unit.
- 9.3.2 Other groups who routinely receive these communications include the Devolved Administrations and private hospital networks. Any additional stakeholders relevant to the specific medicine supply issue also receive communications.

9.4 High- Critical Impact Medicine Supply Issues (Tier 3 and 4)

- 9.4.1 For all Tier 3 and Tier 4 supply issues, national guidance to secondary care will be issued as a 'Supply Disruption Alert' via the Central Alerting System

(CAS) by default unless, in exceptional circumstances, the Medicines Shortage Response Group decides that another method of communication would be more appropriate.

- 9.4.2 This provides assurance that all stakeholders have received and acted on a management plan for a medicine supply issue.

Case Study: Sodium Chloride 0.9% IV fluid

Company: Baxter Healthcare Ltd

Date of Shortage: August 2018 – February 2019

Tier Level: Tier 2 (medium impact)

Overview of Supply Issue: In August 2018 the healthcare company Baxter reported an issue with their production of IV fluid bags. Baxter alerted the DHSC Medicines Supply Team after a utility failure at their manufacturing facility which meant that they needed to discard a large volume of stock which did not pass quality tests following the disruption. The situation was exacerbated by unprecedented increases in orders, due to the hot weather.

Risk Assessment: The DHSC Medicines Supply Team and the NHSE&I Commercial Medicines Unit worked together to undertake a risk assessment to determine potential impact and the management options for consideration. Sodium Chloride bags are used in hospitals for patients that need re-hydration or need their medication administered through an IV drip. 27,000 1 litre bags of IV fluid are needed for NHS Trusts in England every day. Other suppliers of Sodium Chloride 0.9% were contacted but they were unable to produce enough additional stock to meet the demand at short notice.

Management Plan: Following further discussion with the DHSC Medicines Supply Team and the NHSE&I Commercial Medicines Unit, Baxter were able to source stock from their production sites in the United States (US). It was imported into the UK as an unlicensed product. To support hospitals using the US product, the NHSE&I Commercial Medicines Unit requested that a national quality and risk assessment of the imported product be undertaken by a Quality Assurance specialist.

The Principal Pharmacist in the DHSC Medicines Supply Team, Sarah McAleer, explains: “As the product from the US was not licensed for the UK, the DHSC Medicine Supply Team worked closely with the MHRA and Baxter to ensure that the paperwork was in place for the product to be imported. When there is a shortage of a medicine we often work with companies, the MHRA and clinicians to investigate the benefit of importing an unlicensed drug from abroad to help ensure continuity of supply for patients”.

Communications: To mitigate the risk in using this unlicensed stock, the DHSC Medicines Supply Team and NHSE&I Commercial Medicines Unit together with Baxter ensured that clinical materials were disseminated to support correct and safe use of this alternative stock. These materials included a poster to display in hospital wards showing the differences between the bags of fluid, and healthcare professional FAQs were also distributed. This information was disseminated to secondary care networks including private hospital networks and the devolved nations for cascading.

NHSE&I Commercial Medicines Unit sent communications on the supply issue and management plan to Regional Pharmacy Procurement Specialists and other secondary care contacts to cascade into their secondary care networks.

Case Study: Phenylephrine 1mg in 10ml (0.1mg /ml) Injection

Company: Martindale

Date of Shortage: July – August 2019

Tier Level: Tier 2 (medium impact)

Overview of Supply Issue: Phenylephrine is used in NHS Trusts to treat hypotension during spinal, epidural and general anaesthesia. Martindale are the sole supplier of Phenylephrine 1mg in 10ml injection and supply the product under a national procurement framework agreement with the NHSE&I Commercial Medicines Unit. Martindale reported a quality issue with their packaging to the DHSC Medicines Supply Team and the NHSE&I Commercial Medicine Unit in July 2019 which led to the product being unavailable for 6 weeks.

Risk Assessment: The DHSC Medicines Supply Team and the NHSE&I Commercial Medicines Unit worked together to undertake a risk assessment to determine potential impact and the management options for consideration. One factor taken into account during the risk assessment was that Martindale is the sole supplier of Phenylephrine 1mg in 10ml (0.1mg /ml) ampoules to NHS Trusts in England.

Management Plan: The NHSE&I Commercial Medicines Unit undertook two actions:1) Approached other suppliers of Phenylephrine to find other supply sources. Only Advanz (Mercury) stated they could support the supply issue and provide a higher strength product (phenylephrine injection 10mg/ml). As dilution of the product would be required to provide a ready to administer low strength solution, a patient safety risk was identified when substituting these low strength products with a higher strength product.

2) Worked closely with the Royal College of Anaesthetists to investigate alternative products that might be used by hospitals during this out of stock period. The Royal College suggested the use of Metaraminol which is licensed for the same indications as Phenylephrine and advised that this would require a change in clinical practice and update of all relevant local pathways and clinical guidance. Following these actions, secondary care NHS Trusts were therefore instructed to assign a lead anaesthetist as the risk owner, perform a risk assessment and to choose to use either the higher strength Phenylephrine or Metaraminol.

Communications: The communication plan was agreed at the Medicines Shortage Response Group. Working with NHSE&I's Patient Safety Team and the UK Medicines Information service, national advice was drafted by the NHSE&I Commercial Medicines Unit and disseminated to Regional Pharmacy Procurement Specialists and cascaded to secondary care networks. Jane Kelly, the Principle Pharmacist in NHSE&I's Commercial Medicines Unit said: *"This supply issue needed very careful management at a local level by an identified lead anaesthetist, in conjunction with the NHS Trust's Medication Safety Officer. Working within the national advice issued by the NHSE&I Commercial Medicines Unit, each NHS Trust developed their own local management plan including a risk assessment of the management options taken by the NHS Trust"*.

Chapter 3: Managing Medicines Supply and Shortages in Primary Care

10 Chapter Overview

10.1 Overview

- 10.1.1 Community pharmacies and dispensing doctors dispense over a billion prescription items a year and deal with medicines supply issues on a daily basis. They work closely with wholesalers and suppliers to support patients to receive the medicines they need in a timely manner. In situations where supplies cannot be obtained, they work with patients and prescribers to ensure patients receive suitable alternatives on an individual patient basis.
- 10.1.2 This chapter will focus on the management of supply issues for medicines that are prescribed and dispensed in primary care. This includes prescribing and administration by GPs, nurse prescribers, dentists, optometrists and pharmacists and also dispensing by community pharmacies and dispensing doctors. It will also cover the communication dissemination routes that exist to support notification and management of a shortage.

11 Management

11.1 Primary Care Contractors

- 11.1.1 In the event of supply issues, primary care contractors such as community pharmacies and dispensing doctors manage the issue at an individual patient level.
- 11.1.2 Methods used to manage supply issues locally in order of preference are as follows:
- Check NHS.net emails or the [Specialist Pharmacy Service website](#) to see if the issue has already been communicated by the DHSC Medicines Supply Team and, if so, check:
 - The proposed management plan and share information with local prescribers and patients as appropriate;
 - Whether there is a Serious Shortage Protocol in place. If there is, further information can be found on the [Business Services Authority Serious Shortage Protocol webpage](#). Where a Serious Shortage Protocol has been issued, community pharmacies and dispensers are expected to supply in line with the Serious Shortage Protocol and facilitate patient access in line with the protocol and in accordance with the terms of service;
 - If the shortage is not listed on the [Specialist Pharmacy Service website](#), primary care contractors should report the issue via the [Pharmaceutical Services Negotiating Committee website](#) who will report the issue to the DHSC Medicines Supply Team.

- Liaise with medicine wholesalers to check information on the availability resupply dates.
- If specific demand management processes have been put in place at wholesaler level, such as prescription validation management, the necessary processes will need to be undertaken by primary care contractors to obtain stock.
- Consider contacting medicines suppliers directly for an update and to check how supplies can be obtained. In some cases, suppliers may be able to supply direct.
- Check whether other pharmacies locally have stock of the product. If stock is available at another pharmacy, either arrange for the patient to collect the stock from that pharmacy or get the stock transferred.
- Liaise with prescribers regarding alternative brands, strengths formulations and medicines that are available and may be clinically appropriate for the individual and arrange a new prescription to be sent to the pharmacy.

11.1.3 In all cases of medicines supply issues, community pharmacies should endeavour to communicate any supply issues and relevant information about resupply dates and the proposed management plan clearly with patients. They should also undertake counselling to support affected patients where possible.

12 Intelligence Gathering from Primary Care

12.1 Sources of Intelligence

12.1.1 Intelligence gathering from primary care is supplementary to formal reporting by manufacturers and close working relationships with wholesalers and collaborative purchasing organisations which ensure that the DHSC Medicines Supply Team are aware of supply issues and are developing managements plans as detailed in Chapter 1. Where at all possible, these mitigations mean that the impact of any supply issues do not interrupt clinical practice and patient provision.

12.1.2 Any additional soft intelligence received could come from:

- **Representative organisations** such as the National Pharmacy Association or the BMA Dispensing Doctors Association who also receive intelligence on medicines supply issues and may provide this information to the DHSC Medicines Supply Team to support with identifying issues and informing the management plans. This is not a formal reporting process as representative organisations have no legal requirement to provide this information.
- **The Pharmaceutical Services Negotiating Committee** who formally collect and provide monthly data on medicines that cannot be obtained at the Drug Tariff price also collate information on shortages. Community pharmacies should notify the Pharmaceutical Services Negotiating Committee [via the website](#) of any medicines supply issues that they

become aware of that are not on the [Specialist Pharmacy Service website](#). The Pharmaceutical Services Negotiating Committee will then notify the DHSC Medicines Supply Team.

- **NHS operational intelligence sources**, including NHSE&I Local Professional Networks, Clinical Commissioning Groups, NHSE&I Commissioning Teams and others who provide intelligence on medicines supply issues to the NHSE&I Central Pharmacy Commissioning Team. This is then reported by the team to the DHSC Medicines Supply Team.
- **Other trusted sources** who have national coverage and link into the DHSC Medicines Supply Team providing soft intelligence. They are an established network of pharmacists or buyers who work for community pharmacies, to obtain timely market intelligence on potential and actual supply issues.

13 Dissemination of Communications in Primary Care

13.1 Overview of Dissemination of Communications in Primary Care

- 13.1.1 The Medicines Supply Communications section (Section 4) detail the national drafting and sign-off processes, including general principles on content.
- 13.1.2 The format and dissemination routes for these communication routes in primary care are dependent on the severity of the supply issue or shortage and are detailed in the below sections.

13.2 Low Impact Medicine Supply Issues (Tier 1)

- 13.2.1 Monthly supply report summaries provide an overview of all current supply issues and shortages and are circulated to the below groups:
- Primary care networks including the Pharmaceutical Services Negotiating Committee and PresQIPP who circulate onwards to CCGs, Dispensing Doctors Association, the British Medical Association;
 - Royal College of Physicians and Royal Pharmaceutical Society;
 - Lead Pharmacists and Government Departments in the Devolved Administrations;
 - Uploaded onto the [Specialist Pharmacy Service website](#), which all users with an nhs.net email account can register to access.
- 13.2.2 For low impact shortages, other communication routes are unlikely to be required in between these monthly supply report summaries.

13.3 Medium Impact Medicine Supply Issues (Tier 2)

In addition to the routes used for low impact shortages, where wider communications about specific medicine shortages and their associated management are required for primary care, NHSE&I commissioning routes and NHS mail addresses are used to cascade communications to:

- The NHSE&I Central Community Pharmacy Commissioning Team who will send the communications out via their Pharmacy Contract Managers in Regional teams to all community pharmacies on the NHSE&I pharmaceutical list. They will also copy in:
 - NHSE&I Regional Chief Pharmacists;
 - The Pharmaceutical Advisers Group for onward circulation to CCG Medicines Optimisation Leads;
 - The Pharmaceutical Services Negotiating Committee for onward circulation to Local Pharmaceutical Committees, the Company Chemist Association, Head Offices of Multiples, the National Pharmacy Association and the Association of Independent Multiples;
 - NHSE&I Pharmacy Local Professional Network Chairs, NHSE&I Controlled Drug Accountable Officers.
- The NHSE&I Primary Care Commissioning Team who will send the communications to all GPs, Dentists and Optometrists and copy others as required.

13.3.1 Any additional stakeholders relevant to the specific medicine supply issue, such as Royal Colleges and Patient Groups, also receive communications

13.3.2 A template has been developed for Tier 2 medicines supply issues communications (See Annex C). The template will be used for all Tier 2 shortage communications, unless considered inappropriate by the DHSC Medicines Supply Team or NHSE&I Commercial Medicines Unit.

13.4 High- Critical Impact Medicine Supply Issues (Tier 3 and 4)

13.4.1 For all Tier 3 and Tier 4 supply issues, national guidance to primary care will be issued as a 'Supply Disruption Alert' via the Central Alerting System (CAS) by default unless, in exceptional circumstances, the Medicines Shortage Response Group decides that another method of communication would be more appropriate.

13.4.2 This provides assurance that all stakeholders have received the 'Supply Disruption Alert'. Primary care contractors have a contractual requirement to implement 'Supply Disruption Alerts'.

Case Study: Adrenaline (Epinephrine) 1 mg/ml (1:1000) Solution for Injection

Company: Martindale

Date of Shortage: May 2019 – June 2019

Tier Level: Tier 1 (low impact)

Overview of Supply Issue: Martindale, a company who produce adrenaline for the NHS, notified the DHSC Medicines Supply Team of an issue with some of their batches of adrenaline which is used to treat severe allergic reactions and anaphylactic shock. This drug is required to be kept in emergency crash kits in a range of different health care settings.

Martindale were able to resolve their manufacturing issue and their product was back in stock within a few weeks.

Risk Assessment: The DHSC Medicines Supply Team and NHSE&I Commercial Medicines Unit worked together to undertake a risk assessment to determine potential impact and the management options for consideration.

Management Plan: Limited Martindale stock was available, but this was sufficient to cover forecasted volumes to primary care. Other suppliers were contacted to ascertain if they could provide additional stock to meet patient need. Two suppliers, Hameln and Advanz Pharma (Mercury), agreed to provide additional supply of the product and NHS Trusts were signposted to Hameln or Advanz Pharma (Mercury) adrenaline 1:1000 injection stock.

Communications: During the brief shortage of supply of the Martindale product, the DHSC Medicines Supply Team included information on this supply issue in their monthly supply report which is cascaded to primary and secondary care networks. NHS organisations were advised that, although the Martindale brand of product was out of stock, they would be able to order adrenaline from the other suppliers.

Case Study: Diamorphine 5mg Injection

Company: Accord and Wockhardt

Date of Shortage: May – August 2019

Tier Level: Tier 3 (high impact)

Overview of Supply Issue: Diamorphine is used to treat severe pain associated with surgery, heart attack, or a terminal illness. It is also used for labour pain, the relief of shortness of breath in serious heart conditions and a small number of patients may receive diamorphine to manage heroin addiction.

There are currently two suppliers of diamorphine injection in the UK- Accord and Wockhardt. Both companies reported that they would be out of stock of the 5mg injection from May until August 2019 due to manufacturing issues.

Risk Assessment: The DHSC Medicines Supply Team and the NHSE&I Commercial Medicines Unit worked together to undertake a risk assessment to determine potential impact and the management options for consideration.

Management Plan: The NHSE&I Commercial Medicines Unit worked with Accord and Wockhardt to identify whether they had sufficient diamorphine 10mg injection to cover the 5mg shortfall. They also contacted other suppliers of alternative opioids to identify how much alternative product would be available and one supplier was able to provide additional stocks of morphine 10mg injections to help cover the shortfall of diamorphine.

As a Tier 3 shortage, the management plan of this shortage was discussed and agreed at the Medicines Shortage Response Group and the following actions were agreed:

Both Accord and Wockhardt had sufficient stocks of diamorphine 5mg injection to cover forecasted use in primary care, private hospitals, hospices and substance misuse treatment centres.

NHS Trusts were advised to use morphine 10mg injection where possible as there was insufficient stock of other alternatives to support full forecasted demand. Clinical and procurement experts advised that it was easier to manage this shortage in secondary care where engagement and support to clinical staff and patients was less complicated. Restrictions were put in place at wholesalers to support this.

Sarah McAleer, Principal Pharmacist, DHSC said on the management of the shortage: *“The UK is unique in that it is the only country that routinely uses diamorphine which meant that for this shortage, imports weren’t available from elsewhere in Europe.”*

Communications: NHSE&I Commercial Medicines Unit sent communications to Regional Pharmacy Procurement Specialists and other secondary care contacts to cascade into their secondary care networks.* This was supported by UK Medicines Information Service who [updated their clinical guidance](#) on the Specialist Pharmacy Service website.

**To note, for all Tier 3 and Tier 4 supply issues, national guidance will now be issued as a supply disruption alert*

Appendix

Annex A: Clinical Escalation Categories Overview Table

Tier	Definition	Characteristics	Potential Response
Tier 1 – Low Impact	Likely to carry low risk. Management options should result in patients being maintained on the same licensed medicine.	<ul style="list-style-type: none"> Supply problems with a short-expected duration (up to one month), and where temporary supply controls are expected to manage available stock. Companies have low market shares and the supply issue is unlikely to cause any disruption. Other suppliers of the same medicine are able to pick up the demand and meet the full supply gap. 	<ul style="list-style-type: none"> Business as Usual Managed locally
Tier 2 – Medium Impact	Require more intense management options, which may carry a greater risk to patients/health providers than Tier one issues, but which is considered safe to be implemented locally without further escalation.	<ul style="list-style-type: none"> Therapeutic alternatives are available, and Specialist Pharmacy Service medicines information 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. An alternative strength/suitable formulation of the same medicine is sufficient to meet the supply gaps but further clinical advice is required to help manage the switch. 	<ul style="list-style-type: none"> Communication to all stakeholders, signposting to alternatives and providing supporting information, as required.
Tier 3 – High Impact	Considered more critical than Tier two issues, with potential patient safety implications that may require clinical advice to the system.	<ul style="list-style-type: none"> 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 over to a therapeutic alternative requires monitoring. The patient group affected is likely to be considered a vulnerable population such as neonates, paediatrics or people with learning disabilities, or because of issues such as disease, age, social circumstance or access to services. 	<ul style="list-style-type: none"> The use of a 'serious shortage protocol'. The provision of additional clinical advice to the NHS. Requesting the consideration of exceptional regulatory measures by the MHRA (for example, the extension of product expiry dates). Issuing a 'Supply Disruption Alert' to the NHS via the Central Alerting System (CAS).
Tier 4 – Critical Impact	Cannot be resolved as a Tier three – high impact' shortage, and which requires additional support from outside the health system.	<ul style="list-style-type: none"> A supply gap remains (and no viable therapeutic alternatives exist) following the exhaustion of supply and clinical management plans at previous Tiers 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. 	<ul style="list-style-type: none"> EPRR triggered – including priority links with other agencies outside the health system, and additional project management or communications support. Clear links and command and control mechanism established between the Medicines Shortage Response Group, EPRR functions at both NHSE and DHSC. Issuing a 'Supply Disruption Alert' to the NHS via the Central Alerting System (CAS)

Annex B: Checklist for use by NHS Trust Pharmacy Procurement Teams

Verification of Secondary Care Medicines Shortage

Section 1 Product details	
Product:	Date:
Strength:	Pack size
Form:	
<p>Section 2 The NHSE&I Commercial Medicines Unit oversees and supports management of all medicine shortages on NHSE&I Commercial Medicines Unit frameworks.</p> <p>The NHSE&I Commercial Medicines Unit Supplier Issues spreadsheet – distributed fortnightly and managed by the NHSE&I Commercial Medicines Unit.</p> <p>(Available on the Specialist Pharmacy Service website August 2019; expected to be available on the NHS England website and via Rx-Info Define and Exend systems by end September 2019)</p>	
Does the product have a NHSE&I Commercial Medicines Unit code - NPC number:	y/n
If yes check the NHSE&I Commercial Medicines Unit list (If no go to section 3)	y/n
Is the product actively managed by the NHSE&I Commercial Medicines Unit?	y/n
If no go to section 5 to check for alternative suppliers.	y/n
Adherence to product specific NHSE&I Commercial Medicines Unit advice is essential to maintain a controlled supply – can the advice be followed?	y/n
<p>If no, ensure all supply routes have been checked, record details and inform your Regional Pharmacy Procurement Specialist.</p> <p>Go to section 5 to source an alternative.</p>	
<p>Section 3 DHSC Supply Issues Update for Primary and Secondary Care – distributed monthly and managed by the DHSC Medicines Supply Team (Available on the Specialist Pharmacy Service website; expected to be available on the NHS England website and via Rx-Info Define and Exend systems.)</p> <p><i>The DHSC Medicines Supply Team and the NHSE&I Commercial Medicines Unit work very closely together to do everything possible to support management and mitigation of shortages of medicines whether procured through NHSE&I Commercial Medicines Unit- managed frameworks by acute and mental health providers or sourced by community pharmacists for dispensing to patients in the community.</i></p>	
Is the product on the DHSC shortages list? (If no go to section 4)	y/n
Can the advice be followed?	y/n

If no, ensure all supply routes have been checked, record details and inform your regional procurement specialist. Go to section 5 to source an alternative.			
Section 4 Collaborative Purchasing Organisations , examples include East of England, North of England, LPP			
Is the product on contract with a purchasing organisation?		y/n	
Has the purchasing organisation contacted trusts regarding the shortage?		y/n	
Is the Regional Pharmacy Procurement Specialist aware? Check for any communication and follow advice if applicable.		y/n	
If no, record details and inform your Regional Pharmacy Procurement Specialist.			
Section 5 Medicine NOT reported on the NHSE&I Commercial Medicines Unit or DHSC supply issues updates and no information available from purchasing hub. Check wholesalers and distributors for stock			
<input type="checkbox"/>	AAH	<input type="checkbox"/>	Alloga
<input type="checkbox"/>	Alliance	<input type="checkbox"/>	Movianto
<input type="checkbox"/>	Mawdsleys	<input type="checkbox"/>	TPS
<input type="checkbox"/>	Phoenix	<input type="checkbox"/>	Other distributors
<input type="checkbox"/>	Other	<input type="checkbox"/>	Manufacturer
Consider alternative			
<input type="checkbox"/>	Pack	<input type="checkbox"/>	Review where stock is stored - can ward stock be utilised?
<input type="checkbox"/>	Strength	<input type="checkbox"/>	Consider risk assessment for alternative
<input type="checkbox"/>	Has the dm&d website been reviewed for possible alternatives https://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/dictionary-medicines-and-devices-dmd	<input type="checkbox"/>	If the product is a special has NHS Profile been reviewed for possible alternatives? http://www.pro-file.nhs.uk/

Annex C: Template for Communicating Medicines Supply Issues



Department
of Health &
Social Care



Medicine Supply Notification

TITLE (FONT: Arial 14)

Tier (FONT: Arial 12) Tier 2 – medium impact*

Date of issue: (FONT: Arial 12)

Summary

- Summary of Issue – no more than 2-3 bullet points (FONT: Arial 11)
- Include the following: Anticipated resolution date: XX/XXX/XXXX (FONT: Arial 11)

Actions Required

- All actions to be included here and if applicable these can be separated out to what we are asking prescribers or pharmacists or others to do. (FONT: Arial 11).
- Separate text boxes can be used if required to highlight actions for different healthcare professionals.

Supporting Information

- This should include any information to supplement actions from above including where to find further information to help manage the issue. No more than 2-3 bullets (FONT: Arial 11)

Enquiries

Insert email address for either DHSC Medicine Supply Team or NHSE&I Commercial Medicines Unit or Regional Procurement Specialists (this will depend on which organisation is disseminating the information) (FONT: Arial 11)

