

Surrey Heartlands advice on managing medicines stock shortages in primary care

1. Introduction

Medicines shortages are occurring more frequently in the UK, and globally, for a variety of reasons outlined later in this document. This is an ongoing issue, in both primary and secondary care, which is showing no sign of improvement in the short term. Medicines shortages cause considerable inconvenience for patients, community pharmacies and GPs, and have significant financial implications for community pharmacies and the NHS. It is important that all stakeholders work together to ensure the impact of medicines shortages on patient care is minimised, and the workload and financial implications mitigated as far as possible.

The situation is made more challenging by the volatile and unpredictable nature of the shortages. Each specific medicine supply problem has its own characteristics and needs to be dealt with on a case-by-case basis. Although some of these can have simple solutions, an increasingly large number have the potential to cause serious harm to patients. Forecasting the financial impact is difficult and complex due to a number of external influences such as national designation of price changes to drugs, and unknown timeframe for shortages.

This paper outlines some of the reasons for, and implications of medicines stock shortages, and makes some good practice recommendations to pharmacy contractors and GP practices to manage the situation.

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2. What is the pharmacy contractual requirement to supply a medicine?

Community pharmacies are required to dispense orders for NHS medicines and appliances for patients on demand, in a timely manner. There is no specific contractual requirement related to the sourcing of medicines to fulfil prescriptions.

Where the pharmacy is unable to complete supply of the NHS prescription, they are required to provide patients with a written note for any medicine which is owed and inform the patient when the medicine is expected to be available. A record of items owed should be made in the patient's medication record.

What happens when a medicine is in short supply? When there are shortages of medicines, for example, if there are manufacturing problems or a change in demand, this may result in pharmacy contractors having to dispense a generic product that is only available above the set Drug Tariff price. All drugs listed in Part VIII of the Drug Tariff are eligible for price concessions.

When a medicine shortage occurs CPE (Community Pharmacy England) is able to apply to the Department of Health and Social Care for a price concession for that particular month.

The Department of Health and Social Care can consider setting a price concession for products listed in Part VIIIA and Part VIIIB where they are only available above the set Drug Tariff reimbursement price. Pharmacy contractors will be automatically reimbursed based on the concession price rather than the Drug Tariff listed price. There is no need for any additional prescription endorsement. The list of concessionary items is listed each month and extends to both dispensing doctors and pharmacies.

Applications for a price concession is made in the month it applies to and once the price concession has been announced, it only lasts for the month in which it is granted. Where problems persist into the following month a new application is made. It is possible that a new concession will be granted by the Department of Health and Social Care for subsequent months; however, these are subject to application and are not guaranteed. The Department of Health and Social Care set price concessions using information derived from manufacturers and wholesalers.

Pharmacy contractors do not know what will be included in the list and may be disadvantaged if an item is not listed as a price concession, but the price has increased above the Drug Tariff price and will be dispensing at a loss. The list is published here:

<http://psnc.org.uk/dispensing-supply/supply-chain/generic-shortages/>

Where pharmacy contractors are unable to purchase products at the set prices, they may wish to challenge suppliers for an explanation of why their prices are so high. Where pharmacy contractors are unable to secure products at or near the concessionary price, CPE ask to receive copies of invoices for monitoring of prices. Pharmacy contractors will continue to be reimbursed the agreed Drug Tariff price for a medicine until the DOH has agreed the higher price. This means that in the interim they may be dispensing at a loss if they are unable to obtain lower cost supplies.

Further details on Price Concessions can be found in this factsheet:

<https://cpe.org.uk/briefings/psnc-briefing-023-22-how-the-price-concession-system-operates/>

3. Impact of medicines stock shortages

Some of the issues for patients, GPs and community pharmacies are summarised here:

Group	Impact
Patients	<ul style="list-style-type: none">• Breaks in treatment reported, with potential to harm patients.• Confusion caused by having a change in appearance and/or name of medicine.
Community pharmacies	<ul style="list-style-type: none">• Increased workload sourcing medication• Sourcing alternative supplies of medicines or suggesting alternative medicine to GP.• Increased workload from use of Serious Shortage Protocols to supply alternative products.• Financial cost pressure where higher cost medicine needs to be supplied and lower price paid by NHS and uncertainty if price concession will be agreed.• Impact and stress on staff from managing patient concerns and abuse due to stock shortages.
GP practices	<ul style="list-style-type: none">• Increased workload from needing to change prescriptions to alternative product.• Managing clinical risk where patient treatment is interrupted.

Financial implications for the NHS:

Medicine supply shortages have significant financial implications for the NHS. Calculated cost pressure from medicines shortages (all concessions) for financial year 2022/23 for Surrey Heartlands was £4.7 million.

4. What happens when a medicine is no longer in short supply?

When a price concession no longer applies, the drug price may return to its pre-concession price (price before the shortage). However, increasingly this is not the case, and the “Drug Tariff” price increases to near that of the “price concession” value. Under these circumstances, the additional cost pressure continues until the drug price falls, which may take several quarters. For the financial year 2022/23, these price increases cost Surrey Heartlands an additional £1.3 million and the NHS in England over £90 million.

5. What can we do locally to manage these issues?

Good communication between community pharmacy and GP practice staff can help reduce the risk of potential harm and inconvenience to patients. Simple measures such as setting up a dedicated nhs.net email address or using a messaging app such as WhatsApp to set up groups for pharmacy contractors to use to contact the GP practice or PCN, agreeing arrangements with other pharmacies, and suggesting alternatives when there are stock shortages may help improve communication and reduce the risk of potential harm to patients. See Appendix A, B C and D for more information.

6. Useful resources / weblinks

There is some information available which can be used to check if a medicine is in short supply, some of which is in the public domain, and some of which is restricted to NHS subscribers. It is important to note that these information sources are not an exhaustive and accurate list of medicines in short supply as the status of a medicine can rapidly change.

Public domain:

- **CPE:** [Manufacturer contingency arrangements](#), [Severe Shortage Protocols \(SSP's\)](#) and [reporting](#) medicines shortages not listed on the SPS website
- **US website:** <https://www.drugs.com/drug-shortages/>

NHS registered subscribers:

- **SPS:** By registering for an account with the SPS website you will be able to access the **online Medicines Supply Tool** which has the latest information on supply issues, actions to take, alternatives to use, and expected resolution dates. Content is provided by DHSC and CMU. [Register – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice](#)
- **PrescQIPP** <https://www.prescqipp.info/our-resources/data-and-analysis/strategic-activity-reports/out-of-stock-bulletins-and-intelligence/> . This includes the latest out of stock bulletin from Alliance healthcare.
- **UK Medicines Information service from Guy's and St Thomas'** produces a list for hospitals on medicines shortages being experienced by hospital pharmacy procurement specialists that is also shared with ICB medicines optimisation teams.
- **MIMS Drug Shortages Tracker for practices:**
 - MIMS publish a Drug Shortages Tracker designed to help primary care identify which products are unavailable. The table can be found here: <https://www.mims.co.uk/shortages>
 - The table lists products currently reported to be out of stock in the UK, how long the shortage is expected to last, and provides links to more detailed relevant information. A second table provides information on supply issues that have been resolved. The list is collated from a range of sources and is not exhaustive.
 - To access the tracker, you need to be registered to use MIMS on-line. Registration is via this weblink: <https://www.gponline.com/register/>.

Information for patients:

The CPE have a fact sheet for patients explaining the issues about medicines supply and why their medicines may have changed.

<https://cpe.org.uk/wp-content/uploads/2022/07/PSNC-Medicines-Supply-Information-Leaflet-July-2022.pdf>

7. Some of the causes of medicines supply shortages

Medicine shortages and reduced [availability of medicines](#) represent an increasing issue across the UK and the globe, and it has been amplified by the [COVID-19 pandemic](#).

A. Manufacturing problems

These are due to a number of different causes. Manufacturing failure; Closure/planned maintenance of the manufacturing site; Quality defect (product, packaging); Raw material unavailability; GMP non-compliance at a manufacturing site; Contamination; Unexpected increase in demand in clinical practise due to a supply shortage of a different medicinal product; Drug recall, discontinuation; Natural disaster, fire.

B. Supply/demand problems

Wholesale availability and supply direct from manufacturers of branded generics

Over recent years, contractors have continued to experience difficulties in obtaining certain branded medicines. At the heart of the problem are changes in the European import and export market. A weak Pound and strong Euro have reduced the benefits from using parallel imported products; increasing the demand for UK medicines both from UK pharmacies and internationally.

This is a complex issue - there is no easy solution. It is not possible to prevent the export of UK medicines as this would be contrary to trade laws. Increasing manufacturing output could be one solution but there are generally long lag times for changing manufacturing production plans to increase output and an argument used by some manufacturers is that this won't resolve the problem, and simply lead to an increase in the volume of stock exported.

Secondly with responsibility for prescribing costs and patient safety, some ICBs encourage the prescribing of, and switching patients to, specific branded medicines or 'branded' generics. On occasions the branded product, subject to hugely increased demand will be out of stock with the manufacturer. The more ICBs using the product the more likelihood of this happening.

Substantial long-term increases in a medicines usage can also mean that demand outstrips supply until the manufacturing increases to long term to meet the demand. The Department of Health and Social Care (DHSC) says demand for HRT has risen 38% in the past seven years which has contributed to the recent supply shortages.

Quotas

UK law permits manufacturers to manage supplies in order to ensure a fair distribution. Some manufacturers have introduced quotas to better manage the supply of UK medicines to ensure patient access, however where stock hasn't been allocated correctly by the manufacturer or managed appropriately by the wholesaler, problems arise. The allocation of quotas must be sophisticated enough to cope with reasonable fluctuations in demand such as changes in prescribing practice, changes in the number of pharmacy customers that wholesalers have and changes in access to the product from other sources including the availability of parallel imports.

Some manufacturers ask pharmacies to provide evidence of patient demand before releasing stocks. This is usually in the form of requesting anonymised copies of prescriptions. This places an administrative burden on pharmacies and presents confidentiality issues.

C. Raw material problems

Raw material issues including shortages account for 9% of medicines shortages. Many molecules are now manufactured by only one supplier internationally, this can cause international shortages if the supply chain fails in any way, which could be due to factory issues, quality control failure or increased demand without increased production.

Availability problems arise when raw materials come from undeveloped parts of the world or where there are hostilities, animal diseases contaminate tissue used to extract raw material, climatic and other environmental changes depress the growth of plants used to extract raw material. Voluntary recalls can cause shortages, especially when a sole manufacturer's drug product dominates the market supply.

D. Regulatory

The role of the MHRA is to protect and promote public health and to protect patients against ineffective or harmful drugs. This results in a gatekeeper function and obliges the MHRA to apply stringent standards of assessment and to deny marketing authorisation, where deemed necessary. Failure to meet these standards can cause withdrawal of a medication hence causing shortages. When a product is suspected or known to be faulty, the MHRA immediately works with manufacturers and wholesalers on the most appropriate and timely action to take. Sometimes this means a product has to be recalled and taken out of the supply chain.

Appendix A: Managing medicines stock shortages – good practice recommendations for Primary Care

Guiding Principles:

- Medicines should be supplied in a timely manner. The aim of all parties should be that, under normal circumstances, pharmacies should receive medicines within one working day. This guidance is relevant to prescribers, pharmacists and dispensing doctors.
- Good communication and working together can help reduce inconvenience and potential harm to patients.

Recommendations to community pharmacies & dispensing doctors

- All pharmacies should have contingency arrangements in place to source supply where stock is unobtainable from wholesalers.
- Where stock is unavailable from the first-line wholesaler, reasonable steps are to be taken to obtain the medicines in question from an alternative wholesaler where possible. Confirm all pack size and other strengths of the product are unavailable.
- Put in place where possible a reciprocal arrangement with neighbouring pharmacies to help meet urgent patient needs.
- Manufacturers contingency arrangements are available on the CPE website, <http://cpe.org.uk/dispensing-supply/supply-chain/manufacture-contingency-arrangements/>
- Pharmacies should have access to a current contact list for manufacturers.
- By having a good relationship with GP practices and regular communication, the pharmacy should keep the practice up to date on any stock issues. Use of a dedicated email nhs.net address or messaging app eg WhatsApp group is advised. Attending practice meetings where possible will further enable effective communication and troubleshooting for long term out of stock or discontinued items.
- When making recommendations to GPs, pharmacists should have a list of suitable alternatives so that the GP can make a more efficient informed decision. (Follow process in **Appendices B and C**).
- Be vigilant of any changes, so that patients can be counselled appropriately so they are aware of how to take any new medicines correctly. Use the New Medicines Service where appropriate for patients.

Recommendations to GP practices:

- Having strong communication links, flexibility and good relationships with pharmacies would ensure that any issue can be addressed quickly so that the patient does not suffer.
- Consider setting up a dedicated secure email address or messaging app eg WhatsApp group to which community pharmacies can send shortages information and having an agreed communications sheet/log.
- Consider having posters to advise patients to request their prescription in good time.

- Inviting your local pharmacist(s) and the PCN Community Pharmacy Lead to practice meetings where possible would enable the pharmacist to communicate any stock issues as well as facilitate joint discussions on how to overcome these (e.g alternatives) and build relationships.
- If having to change medication, take into account, formulations, doses, monitoring and the impact this may have on the patient as well as ensuring any quantities that need amendment so as to synchronise with the patient's other medication. It is also vital to note if a change needs to be made temporarily, if put on Repeats.

(Appendix D)

- Where possible an alternate drug from the formulary should be used.
- In cases where only a branded equivalent is available, pharmacy contractors may request a prescription for the brand to ensure reimbursement is in accordance with the product supplied. There is no requirement for the pharmacy to dispense a branded product against a generic prescription when the price of the branded product is above the Drug Tariff or the price concession price.
- If a change is made, this can be highlighted on the prescription so that the pharmacy has an opportunity to counsel the patient. (If using EPS, the 'notes to dispenser' function can be used so that the pharmacy can see the message)
- For repeat dispensing, changes can be made to EPS repeat dispensing to cancel any remaining prescriptions and issue a new one.

Appendix B: Out of stock Guidance for Pharmacists/Dispensing Practices

In order to ensure patients have access to their medicines with reasonable promptness (within one working day under normal circumstances) and to fulfil the requirements of the Pharmacy Contract Essential Service “*Dispensing*”, the Surrey Heartlands Medicines Optimisation Board advises that the following actions are taken, in the order listed, when an out of stock situation occurs in your particular pharmacy.

1

Assess the need (discussion with the patient)

- ☐ The patient has sufficient supply at home
- ☐ The patient is no longer using this medication
- ☐ The patient has been to _____ number of pharmacies to try to obtain this medication and has not been able to.
- ☐ The patient has never used this medicine
- ☐ Other/more details:



2

- Re-order via another wholesaler if you have one.
- Confirm all pack sizes of the product are unavailable through main supplier and then with another wholesaler again.
- Contact manufacturer to verify if stock shortage genuinely “Manufacturer cannot supply (MCS)”/ “Supply Chain Failure (SCF)” and expected due date if applicable.



3

- If part of a chain of pharmacies, contact other local branches in your company to see if they are holding stock.
- Contact other local pharmacies (other chains, independents, dispensing Doctors) to see if they have or are able to obtain stock.
- If another local pharmacy has stock either give the prescription back to the patient or return EPS Rx to spine and give patient token.
- Contact the manufacturer to see if they can send stock directly to your pharmacy.



4

- ONLY at this stage contact the prescriber to discuss potential alternative preparations. Include all relevant details including expected resupply date if known, as in Appendix C.

Appendix C:

Details to include in communication to GP practice

- Patient name, address and Date of Birth
- NHS number
- Medication – name, strength and form
- Reason for shortage if known
- Expected resupply date if known
- Recommended alternative - name, strength and form
- Pharmacist and pharmacy contact details

Send via secure NHS mail.

Appendix D: Out of stock Guidance for GPs

In order to ensure patients have access to their medicines with reasonable promptness (within one working day under normal circumstances) the Surrey Heartlands Medicines Optimisation Board advises that the following actions are taken, in the order listed, when an out of stock situation occurs for your particular patient.

1

- When a request for medication change is received from a community pharmacy by NHS mail.



2

If the drug is either discontinued or no longer recommended, consider:

- Does the person need the medication?
- Change the medication.

If the drug is in temporary short supply, consider:

- Following the community pharmacy recommendations



3

Changing medication

- Take into account formulations, doses, monitoring and the impact this may have on the patient.
- Amend quantities to synchronise with the patient's other medication.
- Prescribe the alternative (where possible an alternate drug from the formulary should be used) on ACUTE initially as per new drug guidelines.
- If putting on Repeat set ALERT on PMR to note that the change needs to be made temporarily until original of old medication is available.



4

Communication with Community Pharmacy

- If a change is made, this can be highlighted on the prescription so that the pharmacy has an opportunity to counsel the patient. (If using EPS, the 'notes to dispenser' function can be used so that the pharmacy can see the message).
- For repeat dispensing, changes can be made to EPS repeat dispensing to cancel remaining prescriptions and issue a new one. For paper prescriptions, this would need to be manually removed by the pharmacy and a new batch issued by the GP.