ROYAL PHARMACEUTICAL SOCIETY

Medicines shortages: Solutions for Empty Shelves

Foreword

Medicines are a fundamental part of the majority of patients treatment. They can allow them to recover their health, manage their long-term conditions and live fulfilling and dynamic lives.

Access to medicines is something that patients and healthcare professionals have long taken for granted. Yet National Voices is increasingly hearing from its members of almost 200 health and care charities and those they advocate for, that medication shortages are affecting increasing numbers of patients.

We know that overall, the UK maintains a good supply of medicines, however for the three per cent of medicines currently in shortage the impact on patients' lives can be catastrophic.

Our members report that patients are rationing their medicines to make their supplies last, of deteriorations in health that have led to job losses or dropping out of education, of patients buying falsified medicines from the internet. This is on top of many hours wasted calling round pharmacists to track down medication and the frustration, worry and anxiety felt by those that can't access their medicines. We know from members that people often don't know where to turn for help and advice.

We are very concerned about the impact this is having on all patients, but especially those facing health inequalities. Tracking down medication and then being able to collect it, although recognisably hard for everyone, can be impossible for those that do not have access to private transport, flexible working hours or access to a phone during the day, or are digitally excluded.

As patients must go to greater lengths to obtain medicines, so do pharmacists to find and maintain a regular supply. We know that healthcare professionals, across hospitals, primary care and home delivery services, are having to spend more time dealing with medicines shortages, which can cause delays in access to medicines and takes up health professionals' time, which could be used elsewhere to support patient care. When national shortages are severe, treatment is being delayed, disrupted or patients are receiving second line treatments.

It is against this backdrop that we welcome the publication of this report from the Royal Pharmaceutical Society. It explores both the dynamics and economics of the medicines supply to the UK, but also makes sensible recommendations for collaborative action across the UK and local systems to manage shortages to help alleviate the burden placed on pharmacists and patients.

We hope that policy makers, regulators, manufacturers, the government, the NHS and local system leaders will accept the challenge these recommendations give and recognise that action is needed to make lasting change to support patients and pharmacists alike who are struggling more and more with medication shortages.

Jacob Lant
National Voices

Foreword

Over the last few years, we have seen increasing concern about medicines shortages. Pharmacists and their teams continue to express frustration about the impact this issue has on patients and healthcare teams.

All too often, valuable time is spent trying to find out where a medicine is in stock. Patients spend time running between different pharmacies. GPs spend time re-writing prescriptions for an alternative medicine when the original cannot be supplied. This can be really distressing for patients and professionally frustrating for pharmacists who want to see patients get the best care they can.

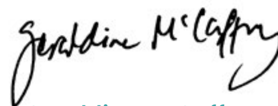
While there are significant efforts made by medicines supply teams across the UK, politicians, news agencies, charities and health professionals are concerned about the impact of shortages on patients and day-to-day practice, and ask what more can be done.

The Royal Pharmaceutical Society (RPS) set out to examine the causes of medicines shortages and help tackle their impact on patients and pharmacy practice, which has culminated in the publication of Medicines shortages: Solutions for empty shelves.

This report exposes the complexities behind shortages and offers a series of collaborative recommendations for action. It has drawn on the expertise of our advisory group, interviews with stakeholders, and RPS member experiences. We want to thank all of those involved for their time and dedication to producing this report. The rich patient insight would not have been possible without the support of National Voices and their members who ensured we heard patients' experiences.

Medicines shortages is not a new issue, but it is persistent and getting worse. There is a growing recognition that cross-sector, cross-system and cross-national collaboration is needed to help drive change to limit the impact of medicines shortages on patients and healthcare teams.

Jonathan Burton
Chair of the Scottish Pharmacy Board



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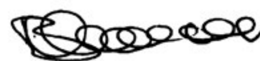
Chair of the Welsh Pharmacy Board

Tase Oputu
Chair of the English Pharmacy Board



Bruce Warner
Chair of the Advisory Group

How we worked

The three national pharmacy boards at the RPS identified medicines shortages as a key policy area that is impacting patients, pharmacy teams, clinicians and wider groups throughout the NHS. As a result, in January 2024, RPS commissioned a report into medicines shortages. This report is the culmination of extensive engagement and collaboration with patients, the pharmacy profession, wider healthcare professionals and the key local, regional and national stakeholders integral to ensure the continuity of medicines supply.

Advisory group

An independent GB-wide advisory group was formed to support the work. Members represented medicines manufacturers and wholesalers, the medicines regulator, national medicines supply teams with responsibility for medicines shortages, as well as pharmacists and pharmacy technicians from across different sectors of pharmacy practice. The group also included patient representation through National Voices, an umbrella organisation for patient groups supporting people with long-term conditions, the Royal College of GPs, and was chaired independently by Bruce Warner, former Deputy Chief Pharmaceutical Officer for England. The advisory group met four times over the duration of the project and provided independent expertise and advice to aid the development of the report and its recommendations.

Scoping review

To support the development of the report, the RPS Science and Research team completed a rapid scoping review, reviewing the evidence of the causes of medicines shortages in the UK and internationally, and to articulate the recommendations made in the literature to mitigate against them. The scoping review was used as resource to inform both the advisory group and author discussions about the scope, focus and priorities of the report.

Engagement and report development

Two online webinars were held for RPS members to share their experiences of how shortages were affecting healthcare teams delivering

direct patient care to help inform the report and recommendations. Input was also sought from the RPS hospital, community pharmacy and primary care expert advisory groups, as well as the RPS science and research committee. In addition, two specialist online engagement events were held, one with community pharmacy organisations and a second with specialist pharmacy groups (see the acknowledgements).

A dedicated medicines shortages email address, promoted widely via the RPS media team, encouraged additional feedback and communication and facilitated follow-up interviews with respondents.

In collaboration with National Voices, patient groups and patients themselves were engaged to provide feedback about the impact that medicines shortages had on patients and their families. A survey aimed at patients to gather data on the patient experience was disseminated widely with the help of patient representative bodies and received 123 responses. Similarly, a survey was distributed through patient representative bodies to gain feedback on the impact of medicines shortages on the patients they represent and the organisations themselves. Follow-up interviews were held with some of these organisations.

Following the first advisory group meeting, individual interviews with advisory group members and other key stakeholders explored the causes of medicines shortages and the mitigations and management approaches used in the UK.

After the second advisory group meeting, report chapters were drafted and circulated to the group for comment. Case studies were identified and developed based on the engagement with healthcare teams and supply chain partners.

Prior to the third advisory group meeting, key points and recommendations for action were drafted for discussion. The draft report was finalised, recommendations refined and the draft report circulated prior to the fourth and final advisory group meeting for final comment. At the same time, the final draft was circulated to all three RPS country boards and the chief pharmaceutical officers of the UK home countries.

The report was launched at the House of Commons on 27 November 2024, followed by briefing events at Holyrood on 28 November 2024 and the Senedd on 4 December 2024.

All contributions to the development of this report are listed in the acknowledgements.

Executive summary

There is growing concern about the impact of medicines shortages on patient care in the UK and around the world. While national systems have historically mitigated the impact shortages have had on patients, mounting pressures mean that further action is needed. Shortages are increasingly affecting patient care and healthcare teams, underscoring the need to invest in and strengthen the systems in place.

This report, Medicines shortages: Solutions for empty shelves, from RPS provides a comprehensive assessment of what is causing medicines shortages, their impact on patients, pharmacists and healthcare professionals, and what more can be done to mitigate and manage medicines shortages.

Impact on patients and healthcare teams

Medicines shortages impair patients' access to treatment, causing frustration, anxiety and in some case worsening health. Many patients report difficulties in obtaining the information they need about when their medicines will become available again.

The increasing burden of medicines shortages places significant pressure on healthcare professionals, especially pharmacy teams, leading to higher workloads, strained professional relationships and mental health concerns.

Medicines shortages affect other areas of the health and social care workforce, with prescribers needing to see patients multiple times, referred to them for alternative prescriptions when their regular medicines are not in stock. In hospitals, specialists see patients who cannot be treated in primary care because medicines are unavailable or in short supply.

Major drivers of medicines shortages

Medicines supply chains are global and complex, with shortages being caused by multiple, often interlinked, factors. These include manufacturing problems and less resilient supply chains more prone to disruption which have arisen due to market consolidation and cost-driven pressures.

These factors, alongside international competitive procurement practices, have limited the ability for investment in strengthening supply chains. When this is overlayed with shifts in prescribing practices and surges in demand, increasingly driven by social media, there are spikes in the use of medicines that supply chains struggle to meet.

Systemic challenges

Many NHS organisations have developed their own ways to manage shortages by the time national guidance is available, leading to duplicated efforts. Marketing Authorisation Holders are required to report expected shortages to the Department of Health and Social Care, but earlier reporting would allow systems to more effectively respond.

Community pharmacies are also struggling with an unstable economic model, potentially contributing to local shortages. Just-in-time supply chains can exacerbate supply issues, and a lack of visibility into stock levels in primary care hampers collaboration to manage shortages effectively.

Key recommendations

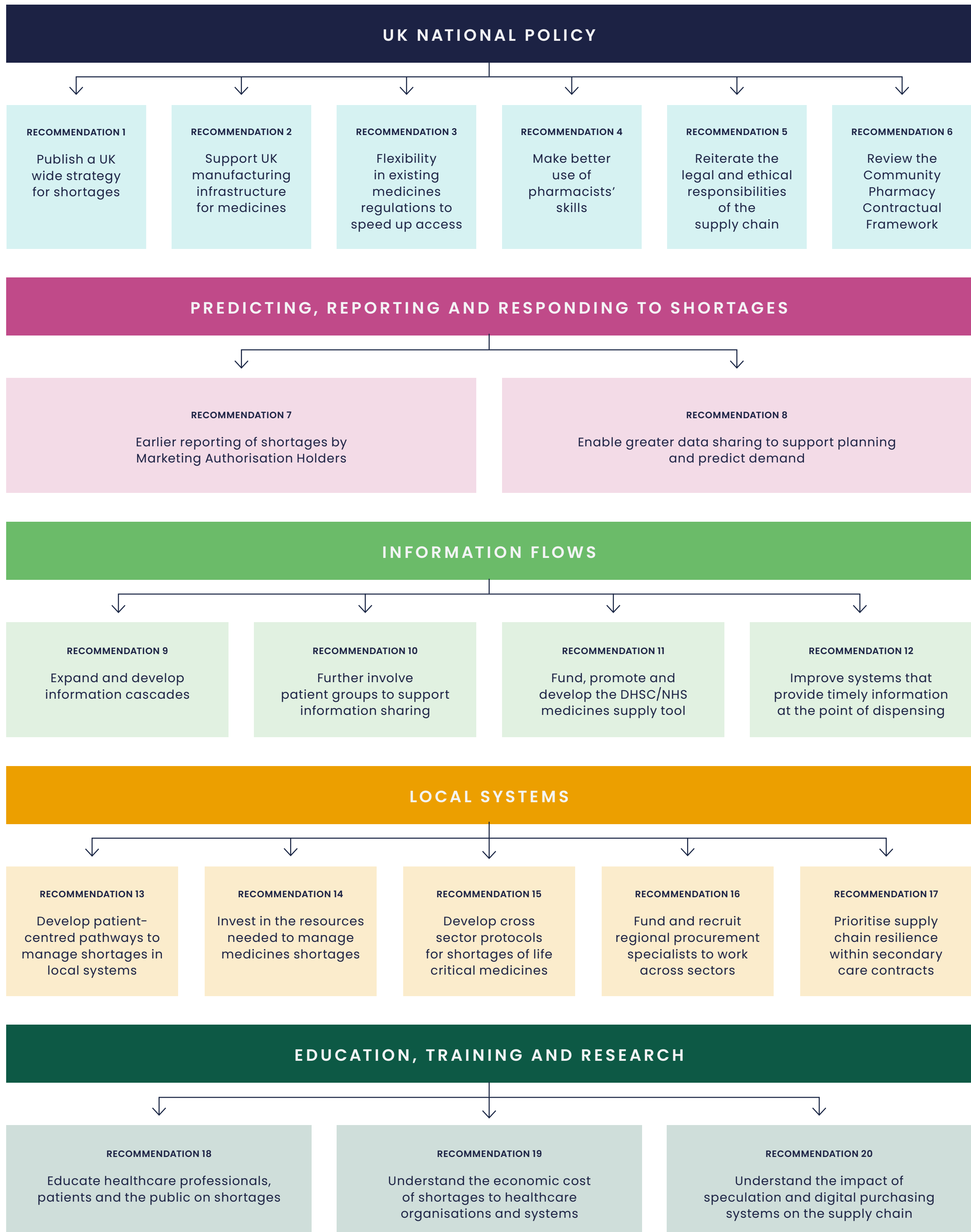
- **Publish a UK wide strategy for shortages**
  A cohesive cross-government and NHS strategy across the whole UK is needed to improve medicines supply chain resilience and medicines security.
- **Build supply chain resilience**
  NHS procurement contracts should emphasise supply chain resilience including quality measures, and ensure manufacturers have sufficient lead time to adjust production when needed. Hospitals should be supported to enforce penalties on suppliers failing to meet contract requirements.
- **Improve reporting by manufacturers**
  Better collaboration across the whole medicines supply chain is needed and improving early

reporting of shortages by manufacturers to the Department of Health and Social Care is key. Prompt notice of a supply problem allows time to act, find solutions and produce clear guidance, meaning health professionals are fully informed and patients are saved from delays and confusion that can cause distress and harm to health.

- **Improve data connectivity**
  Better demand forecasting with information shared between wholesalers, manufacturers and healthcare providers will improve coordination and mitigate shortages.
- **Enable pharmacists to amend prescriptions**
  Legislation should be changed to cut red tape and allow community pharmacists to make minor changes to prescriptions, reducing the burden on primary care services during shortages. Expansion of the role of pharmacist prescribers could also ease patient access to care.
- **Enhance systems for shortages of critical medicines**
  Cross-sector collaboration is needed for the effective management of some life-critical medicines for which there are no alternatives. All local NHS systems should have emergency protocols in place for these shortages that explore collaboration between hospital and community pharmacies.
- **Educate healthcare teams**
  More education on the causes and management of shortages would increase understanding of the issues faced, reduce professional friction and improve patient care. Expanding the use and functionality of the DHSC/NHS Medicines Supply Tool across the UK to provide real-time, easy-to-use guidance would help teams better manage shortages and communicate more effectively with patients.
- **Educate the public**
  The public should be made aware of what to do if they are unable to obtain a supply of medicine and actions to avoid that could either make shortages worse, such as hoarding, or that could be unsafe, such as buying medicines online from unregulated websites.

By implementing these recommendations, the UK can strengthen its resilience to medicines shortages, reduce the strain on healthcare teams and enable patients to get the medicines they need.

Recommendations



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Introduction

It is now widely recognised that problems in the global medicines market mean medicines shortages are increasing in many countries around the world[1,2,3,4]. In the past two years, multiple indicators have shown an increase in medicines shortages[5,6,7,8,9] at a level of complexity and scale not previously seen. High profile examples include hormone replacement therapy[10], antibiotics[11,12], medicines used to treat diabetes[13], epilepsy[14] and attention deficit hyperactivity disorder[15] (ADHD) among many others.

Despite global challenges, the UK continues to maintain access to medicines for most patients with the vast majority of over a billion prescription items in primary care alone dispensed to patients without issue[16,17].

Shortages of medicines are not new[18]; medicines supply chains are long and complex, and medicines are heavily regulated products for good reason. As a result, availability and supply issues occur for many different reasons[19]. The UK has well-established collaborative systems designed to mitigate medicines shortages and, if they do occur, to minimise the impact on patients[6]. These systems mean that, for the most part, shortages have been effectively managed and have often been invisible to the public and wider healthcare professions. This collaboration was particularly effective over the pandemic when the mitigations put in place prevented the UK from running out of medicines on the critical list of drugs needed to treat COVID-19[20] (see Case Study 4 – Managing medicines supply during the COVID-19 Pandemic In England).

However, despite only 3% of medicines reimbursed by the NHS being in shortage[21], the volume and scope of medicines shortages the UK is currently experiencing is at risk of negating the efforts of the national teams who work with supply chain partners to tackle these shortages early on. Patient charities are indicating that patients are feeling the impact of shortages on their health and in their daily life[22,23]. This level of medicines availability issues has far-reaching implications for patients and all those involved in the manufacture, sale, prescribing and supply of medicines.

There is a tangible increase in the cost of managing medicines supply problems. The Nuffield Trust estimates that the NHS in England spent £220 million more in one year (2022/23) on medicines than the same products would have

cost previously[5]. The wider impact on the system is also significant. Across secondary, primary and community care, frontline clinical teams' time is increasingly diverted away from other patient care to managing medicines shortages for their patients.

Frontline pharmacy teams are feeling the pressure of the additional work; recent reports suggest almost three-quarters of community pharmacy staff estimate spending 1–2 hours a day or more trying to obtain medicine stock or alternatives[24]. One acute hospital reported that the number of staff employed to manage shortages has increased from one person to five in the last five years; this is likely to be reflected in trusts across the country. The impact of managing shortages is also impacting prescribers across the healthcare system, with those in primary care needing to see patients referred back to them for alternative prescriptions.

In hospitals, specialists are having to see patients who cannot be treated in primary care because medicines are unavailable or in short supply. Prescribers may be asked not to initiate treatment for eligible patients as the medicine supplies are limited.

Alongside their medical and pharmacy colleagues, the wider health team also devotes considerable time to helping patients manage shortages. As well as putting additional pressure on an already stretched workforce, shortages are also leading to tensions with patients worried about not having access to the medicines they need[24] and are stabilised on.

There is a growing consensus that the medicines shortages that the UK and other countries are experiencing is becoming a 'new normal' of more frequent disruption to medicines supply[5].

Against this background, RPS, as the professional leadership body for pharmacists and pharmaceutical scientists in GB, set out to understand the challenges the UK currently faces and to identify solutions that would minimise the potential for medicines shortages to impact on patients moving forwards.

This report considers the reasons for medicines shortages and medicines availability challenges with a focus on why shortages may be on the rise (Chapter 1) and highlights the impact that this new level of shortages is having on patients and healthcare professionals (Chapter 2). It then looks at how the UK mitigates shortages and what else could be done (Chapter 3) and, once a medicine is in short supply, how the impact on patients can be managed and what other steps could be taken (Chapter 4). Finally (Chapter 5), the report makes some recommendations for key collaborative actions across the supply chain, the healthcare system and more widely. The report recognises that medicines shortages is a complex area that requires action on multiple fronts from a range of different organisations, healthcare professionals and patients.

Chapter 1. The reasons for medicines shortages

A medicine shortage occurs when there is an imbalance between demand for, and supply of a particular medicine (see Box 1). At one extreme, this might result in a patient being unable to obtain a supply of medicine for a prolonged period, at the other it may necessitate action somewhere in the supply chain to correct the imbalance so that the patient never experiences the shortage. Between these extremes, some prescriptions are presented for dispensing and, while the medicines are not immediately available, they can be obtained for patients within a couple of days.

Not all medicines shortages have the same potential impact on patients. They can range from medicines with a low patient impact where alternative treatment options are readily available, through to lifesaving, time-critical medicines for which there is no alternative, as occurred when adrenaline pens[25] were in short supply. The volumes in which the medicines are used are another key factor.

BOX 1
What is a medicines shortage?

For this report, we use the Organisation of Economic Cooperation and Development (OECD) definition of medicines shortages as meaning "any supply disruption or sudden change in the supply-demand equilibrium of a marketed pharmaceutical product that leads to an actual or anticipated lack of stock on the shelf for patients". This includes both temporary and permanent supply disruptions.

Within the report, we distinguish, when required, between national (often global) shortages of medicines and localised, often short-term, supply disruptions where sufficient medicines supply may exist within the UK but is not available to patients where they need it. For patients, both of these are experienced as a medicines shortage, although the causes, potential mitigations and how they are managed may be different.

Medicines shortages are complex and can be due to a combination of factors occurring independently of each other and/or compounded by one another. They are often broadly categorised as related to either supply- or demand-based issues[18]. Disruptions in the supply chain are a common cause of supply-based medicines shortages[2]. A sudden, unanticipated surge in demand during outbreaks of seasonal infections or patient demand spikes prompted by media/social media activity are examples of demand-based medicines shortages.

This report highlights some of the main supply and demand side issues that can impact on the availability of medicines and contribute to medicines shortages with a focus on where they might be contributing to current levels of disrupted supply. Where relevant, we also make the distinction between branded, single manufacturer medicines, and generic medicines or biosimilars where multiple manufacturers of the same medicines typically compete for market share.

1.1 Causes of shortages – supply-based

Supply-based issues usually impact the manufacturing process or the supply chains that transfer medicines, usually via a wholesaler or distributor to pharmacies. Disruptions can be broadly categorised as relating to:

- **1.1.1** Manufacturing and product quality challenges
- **1.1.2** Supply chain issues
- **1.1.3** Regulatory changes/challenges
- **1.1.4** Globalisation, business and commercial issues
- **1.1.5** UK position in a global market
- **1.1.6** UK medicines reimbursement

Each of these is explored in more detail below.

1.1.1 Manufacturing and product quality challenges

The reasons cited most often for medicines shortages are related to manufacturing and product quality for which there are several different causes[4]. These can be things that happen unexpectedly and are difficult to predict, such as quality issues like batch failures or out of specification laboratory results, or those that are scheduled and planned for (e.g., plant maintenance).

The availability of starting materials such as active pharmaceutical ingredients (APIs) or other products (e.g., excipients) used in the manufacture of medicines are also often cited as reasons for shortages. This is reported more for generic medicines than innovative drugs, which are more likely to use APIs manufactured in Europe[4].

While not unique to pharmaceuticals, manufacturing process issues, such as production line faults, software failures or packaging failures, can also cause shortages. Product quality issues, such as batch release failures, the identification of contaminants or unreliable quality control or data required to satisfy regulations, can lead to curtailed supply. Manufacturing plant inspections by medicines regulators (also see section 1.1.3) can also highlight quality issues where non-compliance with Good Manufacturing Practice (GMP) can result in the suspension or curtailment of manufacturing activity until corrective and preventative actions are implemented. Similar issues can be identified if there is a failure in Good Distribution Practice (GDP) by suppliers.

1.1.2 Supply chain issues

In common with the manufacture of many products, pharmaceutical manufacturers often use Just in Time (JIT) supply chains. JIT is a supply chain strategy that relies on partners to move production materials right before they are needed for production or use. As a result, inventory stockpiles are managed depending on the criticality of the medicine and anticipated fluctuations in demand. This reduces storage costs and minimises waste but, unless closely managed, can reduce resilience. JIT supply, therefore, can often mean leaner but less agile supply chains, with the provision of buffer stocks where appropriate to satisfy forecast demand and where margins allow. The amount of stock held in wholesaler warehouses and individual pharmacies has also reduced over time as JIT principles have been applied across the supply chain. This reduction in stock holding at community pharmacies can mean patients need to wait for some, or all, of their medicine supply to be ordered from wholesalers if sufficient stock is not immediately available, which may be contributing to delays in supply at the point of dispensing.

Any disruptions to supply chain logistics have the potential to impact on medicines availability. Like most countries, the UK relies on complex global transportation networks to import and transport a significant portion of medicines. Distribution logistical issues are regularly referred to as one of the causes of medicines shortages[4,18,19,28]. This can include quality issues identified as a result of GDP inspections, such as the failure of cold chain storage[29]. It can also include difficulties encountered during the delivery process (e.g., issues or failures with vehicles, maintenance of railways/roads, delivery route diversions, strikes/staffing, port and shipping route access problems or fuel shortages). These can relate to supply chains outside or within the UK.

The increasingly global nature of medicines supply chains has made supply chains more susceptible to unexpected global events. Global geopolitics and regional conflicts are increasingly having an impact on medicines supply. Attacks on essential shipping routes, such as those passing through the Red Sea, have disrupted the manufacturing and transportation of medicines. For generic manufacturers located in India, this has meant longer lead times for the delivery of medicines to the UK or shifting distribution from sea to higher cost air freight, which can be unaffordable for some lower-margin generic medicines[30]. In recent times, the shortage of available HGV drivers or fuel shortages in the UK has also impacted the ability to ensure that medicines supplies are in the right place for use[31].

Shortages of APIs and raw materials may be exacerbated by the structure of the pharmaceutical supply chain of a given medicine, for example, depending upon the locations of API production and medicine manufacture. Typically, these shortages are reported more frequently

with the production of generic medicines than branded single-manufacturer medicines. For generic medicines, APIs and raw materials are increasingly produced in India and China[2,32], requiring manufacturers to maintain oversight of international supply chains.

Non-UK-based production also means that the supply of medicines to the UK is at increased risk from export restrictions or from events and policies that affect operations elsewhere. This was illustrated by the COVID-19 pandemic when API production in China was suspended due to local lockdowns, and exacerbated shortages[4].

1.1.3 Regulatory changes/challenges

All medicines marketed in the UK require a market authorisation, in the UK this is issued by the UK regulator, the Medicines and Healthcare products Regulatory Agency (MHRA) (see Box 2). To make medicines, manufacturers must have a GMP certificate and obtain a manufacturer's licence. This is issued following an inspection of their products, premises and manufacturing processes by the MHRA. GMP is the minimum standard that medicine manufacturers must meet to obtain their licence[28]. If a company is found to be GMP non-compliant, this licence may be varied, suspended or revoked. Quality standards of stringent regulators around the globe work in a similar way to make sure medicines are safe and maintain a high-quality standard of supplies to patients. MHRA will inspect certain overseas manufacturers to ensure compliance with GMP standards.

In addition, to be able to distribute and supply medicines, parties in the UK supply chain must observe GDP[33]. This ensures that the medicines are consistently stored, transported and handled under suitable conditions, as required by the product specification. Organisations must comply with GDP to hold a MHRA-issued wholesale distribution authorisation. The MHRA conducts periodic inspections, based on risk assessments, to ensure that manufacturing and distribution sites comply with GMP and/or GDP.

BOX 2
Medicines Manufacturer Or Marketing Authorisation Holder

In this report we use medicines manufacturers as a general term that covers companies who either manufacture and/or manufacture and market medicines for the UK market. Medicines can be made by companies that hold the authorisation to market medicines from the medicines regulator – known as Marketing Authorisation Holders (MAHs) – and by contract manufacturing organisations that make medicines on behalf of MAHs. Where regulation relates specifically to MAHs we make that distinction.

While it is an essential step in ensuring the safety, quality and efficacy of medicines, medicines regulation or the timeliness of regulatory activities more broadly, is another cited contributing cause of medicines shortages[34,35,36].

Trade bodies and medicines manufacturers have suggested that the speed at which the UK regulatory authority is able to issue new marketing authorisations leads to delayed market access for medicines that could potentially help to mitigate medicines shortages[38,37]. Currently, expedited assessment of a new marketing authorisation application is possible to support the national management some medicines shortages in the UK (see section 3.1.3).

The COVID-19 pandemic restricted travel, so physical regulatory inspections of overseas manufacturing facilities by the MHRA and other medicines regulators were suspended. As inspections resumed, a backlog of quality issues with manufacturing sites emerged which could be leading to some of the observed shortages[39].

Differences in regulation and regulatory processes across countries can impact on medicines shortages. For example, the increasing regulatory divergence between the UK and EU following Brexit is reportedly adding to supply chain problems contributing to medicines shortages in both regions[8]. In January 2025, implementation of the Windsor Framework for supply to Northern Ireland will introduce further regulatory requirements[40]. The additional costs associated with managing more regulatory complexity can be particularly challenging for generic manufacturers where

the business model is based on high-volume production with low margins, leading to further disincentive to supply.

1.1.4 Globalisation, business and commercial issues

Business and commercial considerations inevitably impact on medicine supply. Many issues are common to all medicine manufacturers, such as energy, raw ingredient costs and general market conditions in the developed world. There are, however, some differences in the business models for generic or biosimilar multi-source manufacturers, as opposed to originator single-manufacturer medicines.

Globalisation and market conditions in the developed world have contributed to worsening medicines shortages[5]. Competitive procurement processes in developed countries have driven the price of generic medicines down, close to the marginal cost of production. This may lead to insufficient incentive for resilience-oriented manufacturing and distribution of products and could discourage suppliers from maintaining the surplus stock necessary to meet unexpected demand surges[41]. Increasing input costs (e.g., for raw ingredients[42]) combined with low prices for medicines putting downward pressure on the available profit margin, has caused some manufacturers to scale back their portfolios (in particular for generic medicines)[38,43]. At the same time, the consolidation of international manufacturing into fewer factories has complicated supply chains and left global supply more susceptible to manufacturing failures in individual production sites. For medicines supplied by a limited number of manufacturers, this creates the potential for significant impact should a manufacturing site issue occur, or a medicines manufacturer withdraws from the market.

When medicines manufacturers determine that the return on investment from a given product is too low, these products can be discontinued from the manufacturer's portfolio either globally or in low-margin countries. This puts un-forecast pressure on the other suppliers in the market or on manufacturers supplying therapeutic alternatives to that medicine to fill the demand[2,44].

1.1.5 UK position in a global market

In the context of a more commoditised, disruption-prone global market, the UK, which in 2023 represented 2.4% of the global pharmaceuticals market, competes with other developed economies for medicines supplies[44].

Consolidation of the global market for the production of generic medicines means that there are now fewer companies manufacturing generic medicines, and those that are manufacturing them rely on raw ingredients/APIs predominately from China and India. Yet these generic medicines/biosimilars account for about four out of five NHS prescriptions[44].

A recent analysis by The Nuffield Trust suggests that the UK may not be seen as an attractive commodity market and that some companies may be removing the UK from their supply chains or restricting their portfolios[5]. While not the only factor, some commentators believe Brexit may have contributed to these difficulties by lowering the value of sterling, increasing business complexity and removing the UK from EU supply chains[5]. The ongoing review of EU pharmaceutical regulation includes several potential changes to address security of medicines supply which, if enacted, will inevitably have implications for the UK[45].

While questions have been raised by the pharmaceutical industry about whether it might have an impact on the availability of medicines in the UK, consideration of the voluntary scheme for branded medicine pricing access and growth[46] is outside the scope of this report.

1.1.6 UK medicines reimbursement

The economics of medicines pricing mechanisms and reimbursement frameworks in UK primary care have been highlighted by pharmacy organisations as possible contributory factors to medicines shortages observed by patients[6].

Within the UK, reimbursements are provided to pharmacy contractors for the supply of medicines under the contractual framework agreements that exist in each of the four nations. Pharmacies purchase medicines on the open market and are reimbursed by the NHS. The NHS's medicines reimbursement prices are published in The Drug

Tariff (England and Wales), which is updated monthly[47]. There are separate tariffs for Scotland[48] and Northern Ireland[49]. If the cost of a medicine is below the listed tariff price, then the pharmacy contractor can retain the difference between the two prices – an 'allowable margin'. If the price the pharmacy contractor pays for the medicine increases, they may need to pay more than they will be reimbursed. Overall, the system is designed so that pharmacies should, in totality, achieve a fair share of margin of the medicines they supply, even if on some individual products they may pay more than they are reimbursed. If pharmacies collectively exceed a target allowable margin, then the pricing is set to 'clawback' some of these saving to the public purse. While successful in driving down medicines' prices, this model can lead to a disparity in ability to obtain an equitable share of the margin and disincentivise the sourcing of low margin products. Community pharmacy reimbursement is discussed in more detail in section 3.2.7.

In NHS hospitals in England, Scotland and Wales, about 70% of medicines used are supplied via contracted arrangement, with suppliers invited to tender at competitive rates. This approach provides greater certainty around price but is not without its drawbacks. For example, tender management is required to avoid unintentional supply disruption, especially at both the beginning and the end of tenders, and tender awards do not assure use. Secondary care tendering is discussed in more detail in section 3.2.5. (see also 1.2.3).

1.2 Causes of shortages – demand-based

Changes in demand for medicines can cause medicines shortages if manufacturers cannot revise production to meet that demand, especially at short notice. When combined with more fragile global supply chains, demand surges have more of an impact on the continuity of medicines supply than previously observed[50]. As with supply-based causes of shortages, there are several different reasons that demand-based shortages occur.

- **1.2.1** Increased prescribing demand
- **1.2.2** Increased patient-led demand
- **1.2.3** Increased manufacturing demand
- **1.2.4** Environmental demand
- **1.2.5** Demand-led stockpiling

1.2.1 Increased prescribing demand

Changes to clinical practice directed by national guidelines can increase demand. For example, updates to SIGN guidelines, NICE clinical guidelines or novel pathway developments requiring medicines can influence prescribing behaviours. This can result in shortages if implementation is done without effective planning and communication that allows time to produce sufficient supplies.

As well as changes to national prescribing guidance, local changes to prescribing patterns can potentially create demand surges. For example, the switching of patients from higher-cost medicines to better value, lower-cost (typically generic or biosimilar) medicines is used by the NHS as a way of getting the most from the medicines budget while ensuring that patients still receive effective treatment. This may have minimal impact on medicines supply if effectively managed by the system (e.g., when an originator medicine comes off patent). However, if switches are made without informing suppliers of the medicines to which the switch is being made, and allowing sufficient time for the supply chains to adjust to the changing usage, there is the potential to create demand surges, in particular if multiple localities are making the same switches simultaneously (also see section 3.2.5).

1.2.2 Increased patient-led demand

Patient behaviours can influence the medicines supply chain.

Public awareness and perception of medical conditions can substantially influence the demand for medicines. Media coverage, celebrity endorsement or public campaigns focusing on specific issues can all increase public awareness. A greater awareness of ADHD and menopause (the 'Davina' effect[51]) from media coverage has prompted patients to seek medical support and sparked rises in patient-led demand for the associated medications[52]. Social-media-fuelled demand for GLP-1 RA medicines for weight loss has also led to supply issues for people using those medicines for type 2 diabetes[53] (case study 1).

The speed with which information about medicines availability, whether true or false, spreads has

increased in the era of social media and instant communication. Patients concerned about their ability to consistently and reliably access medicines may stockpile larger quantities to protect themselves from shortages. This effect that has been observed in other environments, such as toilet paper shortages at the beginning of the pandemic[54,55].

Patients can choose to access medicines through the private sector, including purchasing medicines online from remote prescribers. The market for private medicines supply is not subject to the same fiscal and access constraints as the NHS. Therefore, greater flexibility in access and the ability to pay more for medicines may pull them from the NHS supply chains and dramatically skew the market, as seen with GLP-1 RA medications. As patient demand increases through these newer channels, this may have a knock-on impact on the traditional supply chains used by the NHS.

CASE STUDY 1

A national shortage of a therapeutic class – GLP-1 RAs

Since June 2023, there has been a national shortage of glucagon-like peptide-1 receptor agonists (GLP-1 RAs) licensed for type 2 diabetes mellitus due to an increased demand for prescriptions for type 2 diabetes but also for weight loss; initially an unlicenced (off-label) use.

The impact of this shortage has been exacerbated by a surge in patients being prescribed off-label supplies of the medicine for weight loss, which has meant that demand globally outstripped supply. Social media and celebrity endorsement are driving the demand for GLP-1 RAs for weight loss, and this has been further complicated by the number of off-label private prescriptions being issued for this use, despite national clinical guidance to the contrary.

The shortage initially led to all NHS stocks of GLP-1 RAs being reserved for people already using the medications, meaning that many people with type 2 diabetes who could have benefited from them were unable to access them.

It also meant that some patients already stabilised on a GLP-1 RA had to be switched to alternatives (such as insulin) which for some people was particularly difficult as the risk of hypoglycaemia had implications for their employment or driving licence.

In line with guidance in the National Patient Safety Alert, primary care and specialist teams stepped in to handle the shortages, many of them putting in local processes to ensure all patients with type 2 diabetes taking GLP-1 RAs were reviewed. This put an unplanned burden on primary care teams and patients, and potentially caused tension as patients stabilised on a medicine had to switch to a suboptimal alternative.

The pressure on the supply of GLP-1 RAs is easing; however, the demand is likely to remain high especially as their use in weight loss is recommended nationally. The impact on the work for NHS clinical teams, as well as NHS pharmacy teams in managing these shortages continues.

Communicating with patients throughout shortages is crucial. Diabetes UK reports an increase in the number of people contacting it for advice and an increase in media enquiries. It works to produce content to clarify the shortages situation and let people know what action to take.

1.2.3 Increased manufacturing demand

There are a variety of demand-based reasons that may require a medicines manufacturer to increase production. For example, a manufacturer exiting the market can increase the demand on the remaining producers for that medicine or the withdrawal or discontinuation of one medicine can lead to a rise in demand for any alternative medicines (including different pack sizes, formulations, strengths, etc.) with the same clinical use that remain available.

Where competitive tendering reduces the number of available suppliers in a market and a surge in demand is experienced, there may not be the capacity within the market to meet or respond to that demand[56].

When contracts are awarded by NHS organisations, the volumes required can mean manufacturers need sufficient time and notification to increase their production capacity to meet that expectation. The production lead time for many medicines

is now up to, or longer than, twenty weeks to manufacture and arrive with patients[57]. Without effective notice and forward planning, there may be shortages while production capacity is increased (see also section 3.2.5).

1.2.4 Environmental demand

A sudden increase in infection rate within a population will cause an increased demand for effective medications that cure the disease or lessen the severity of the symptoms. If this demand cannot be met by the supplying manufacturers, a shortage can occur[58]. This was illustrated during the COVID-19 pandemic; the combination of unexpectedly increased demand, as well as the suspension of API production in China due to a lockdown, meant attaining an adequate supply of medicines for COVID-19 was challenging[8]. A further example is the scarcity of antibiotics following spikes in demand[59]. For example, an unexpected increase in Strep A infections caused an increase in demand for liquid penicillin that led to a shortage over winter in 2022[60].

1.2.5 Demand-led stockpiling or hoarding

Demand-led stockpiling or hoarding across a healthcare system can exacerbate medicines shortages, particularly locally. The government restricts the export and hoarding of some medicines where there is evidence of a critical shortage, or a risk of a critical shortage, which could adversely impact UK patients[61].

As awareness of shortages spreads, hoarding may occur at various points in the supply chain, from wholesalers to pharmacies and by patients to build up personal stock buffers. In a fragile supply chain, any uncoordinated building of stock in one part of the system has the potential to remove supply from another (also see section 3.2.8).

1.3 Summary of key points of the reasons for medicines shortages

KEY POINT 1.1
The global market for medicines is under pressure, with many developed countries, not just the UK, experiencing increasing numbers of medicines shortages.

KEY POINT 1.2
Generic manufacturing, which represents 80% of medicines used in the UK, has consolidated its supply chains globally, reducing the number of manufacturing sites. The production of active pharmaceutical ingredients for generic medicines is also now predominately located in India and China. This consolidation, in combination with leaner, more disruption-prone global supply chains, has reduced the resilience of medicines supply.

KEY POINT 1.3
In general, competitive procurement in the UK and other developed economies has driven prices for generic medicines down to close to the marginal cost of production; this may be at the expense of resilience-oriented manufacturing and supply chain management.

KEY POINT 1.4
Medicines shortages are often caused by supply-side issues, such as manufacturing problems or product quality issues. Distribution and supply chain problems are another common cause, and, with the global nature of supply chains, they are more susceptible to disruptions.

KEY POINT 1.5
In a constrained market where the UK competes globally for medicines supplies, chasing lower prices may be a mixed blessing if it leads to portfolio pruning and disincentivises manufacturers from supplying or investing in manufacturing in the UK.

KEY POINT 1.6
Demand-side issues are increasingly a feature of medicines shortages, for example, unplanned/uncoordinated increases in prescribing because of changes in clinical practice, procurement processes, or patient-led demand driven through media/social media and access to private prescribers.

KEY POINT 1.7
Any building of stock or hoarding in one part of the system has the potential to disrupt supply in another. Uncoordinated activities at various points in the supply chain to build stocks or restrict flow by manufacturers, wholesalers, pharmacies and by patients, can create or exacerbate existing shortages.

Chapter 2.
Impact on patients and healthcare professionals

Chapter 1 of this report looked at some of the reasons that medicines shortages occur and why they may be becoming more frequent in the UK and more widely. This chapter considers how the increase in frequency is impacting on both patients and the frontline healthcare professionals spending increasing amounts of time managing medicines shortages for their patients.

Pharmacy teams manage medicines shortages in dialogue with other healthcare professionals and patients. To understand the impact shortages are having on the frontline of care, we spoke to RPS members, pharmacy specialist groups, regional and national teams in all UK nations involved in managing medicines shortages and medical and other healthcare professional colleagues. The first part of this chapter reflects the key themes that we have heard from this engagement.

The experiences of patients were collected with National Voices and their member organisations. We were also contacted spontaneously by other patient groups and charities concerned about the impact shortages were having on patients and patient safety. We sought to understand the experience of patients regardless of their conditions or from where they get their medicines. The second half of this chapter reflects what we heard from patients.

2.1 Impact on healthcare professionals

Managing medicines shortages is now a daily reality for all pharmacy teams in community pharmacy, primary care, hospital pharmacy, homecare services, the armed forces and others.

Community pharmacy teams describe their lack of confidence when ordering medicines, with some medicines appearing to be in stock when ordered but not arriving, others remaining out of stock indefinitely, sometimes for no apparent reason. We also heard from general practitioners and primary care pharmacists that they are experiencing supply issues daily with the medicines they want to prescribe.

In secondary and tertiary care, the number of staff involved in managing shortages is increasing and the spectrum of medicines in shortage is extending to those used in critical and emergency care. The impact is not only being felt by pharmacists and pharmacy teams but also by the wider healthcare team. This includes medical and nursing staff involved in rewriting guidelines for treatment and treatment pathways, and creating capacity to see patients to change the prescriptions that they were stabilised on. In areas of specialist care, patients are being referred back to specialist prescribers from primary care to manage medication changes.

> *"The volume of work involved in managing shortages at the levels we are seeing cannot just be absorbed into existing roles. We really need to think about redesigning the workforce to enable proactive management with dedicated resources."*
>
> **Clinical services manager**

Some of the key themes that emerged from engagement with healthcare teams are outlined below under the following headings:

- **2.1.1** Poor communication to the frontline
- **2.1.2** What is a national shortage vs a local supply disruption?
- **2.1.3** Piling pressure on already stretched workforces
- **2.1.4** Added tension in professional relationships
- **2.1.5** Impact on wellbeing and mental health of healthcare teams
- **2.1.6** The mounting cost of medicines shortages

2.1.1 Poor communication to the front line

We heard repeatedly that frontline teams are not getting the information that they need about medicines shortages quickly enough to support their patients. This may be information from manufacturers, wholesalers, the national DHSC, NHS teams or through their own local internal

communication channels. We heard that in some hospitals it can take time for information to effectively disseminate through the organisation to influence the behaviour of prescribers. Often, frontline teams are aware of and managing a medicine in shortage well before any official notifications or guidance are available.

While it is recognised that national guidance inevitably takes time and requires quality assurance processes prior to publication, the speed of information became a consistent theme across both primary and secondary care. In particular, hospital teams across the UK described the duplication of effort required across the NHS with each organisation developing their own guidelines and systems for managing shortages as a common source of frustration.

"We have all known about the Creon shortage for months and have already got plans in place. This means across the UK there has been a huge duplication of effort. When we get earlier national communication the visibility [of the shortage] increases and it is easier for us to engage across professions and with managers."

Primary care pharmacist

We also heard that underdeveloped local communication systems between pharmacy teams and prescribers can exacerbate problems for patients both in primary and secondary care. These were related to underdeveloped internal organisational communication systems within hospitals as well as within local healthcare systems. The pathway for sharing shortage information between general practice and community pharmacy was often highlighted. The result being that prescribers were often unaware of medicines being unavailable and/or potential alternatives at the point of making a prescribing decision.

2.1.2 What is a national shortage vs a local supply disruption?

Another common theme was the difficulty pharmacy teams can have in establishing the reason for a medicine's shortage. This makes it hard to communicate effectively with clinical colleagues and patients. When pharmacies are unable to obtain a supply of a medicine from their wholesalers, it can be difficult to determine if the medicine is unavailable because of a national shortage (in particular if national guidance has not been published), or if it is because of a localised supply disruption which is likely to be resolved in the shorter term.

We heard about occasions where medicines manufacturers indicate that there is sufficient stock in the country but wholesalers are unable to access supplies of the medicines locally. Shorter-term disruptions may be related to short-term logistics issues, for example, when stock is in the wrong depot, or a manufacturer missed a delivery slot to a particular warehouse.

Alternatively, purchasing behaviours may be driving local shortages, for example, when wholesalers have a sudden spike in demand for a medicine that is rumoured to be going short. Additional reasons may be related to local stockpiling of medicine in anticipation of demand or due to pharmacies inability to source medicines because central wholesaling contracting agreements restrict them to a single supplier.

"Once word gets out there could be a shortage, even if it isn't actually one the rumour creates one as pharmacies buy up supplies."

RPS member

To fill the gap in information about local shortages and to save time for pharmacy teams, we heard about the use of digital procurement platforms that track the appearance of shortages in real time using multiple data sources and medicines brokers who are connecting manufacturers/suppliers with pharmacies who need medicines[62] (this is discussed further in section 3.2.7).

2.1.3 Piling pressure on already stretched workforces

In their 2023 survey of workforce pressures, Community Pharmacy England reported that the time spent by community pharmacy teams managing shortages had doubled[63]. This picture continued into 2024 with 85% of community pharmacies reporting that their teams were spending more time than ever before managing shortages[64]. The time spent in procuring medicines at commercially viable prices and managing shortages for their patients is wrapped up in a

community pharmacy's standard contract. The current contractual framework remuneration system for community pharmacy means that it is imperative for pharmacy teams to source medicines at as competitive a price as possible so as not to lose money. Under the current fiscal environment, we heard that the amount of time pharmacy teams currently spend chasing medicines supplies is increasing. As a result, this risks diverting an already stretched pharmacy workforce away from providing the public with the clinical services that the NHS in England[65], Scotland[66] and Wales[67] are encouraging the public to use (see Figure 1).

In secondary care, we heard that specialist prescribers, including pharmacists, are also spending more time identifying and switching patients to alternative medicines taking time away from other clinical activities. To manage a medicines shortage, national guidance sometimes advises healthcare professionals to prioritise supplies for existing patients on established therapy and delay starting treatment for new patients.

As well as pulling pharmacy teams from clinical roles, more time is being spent on procurement activities, finding and managing solutions for medicines shortages, for example, the import and/or use of unlicensed medicines, requires a range of risk assessment and/or pre-purchasing checks to ensure quality and comply with regulations.

Figure 1. Impact of medicines shortages in community pharmacy

CASE STUDY 2

The daily reality of medicines shortages in primary care

I am a community pharmacist who owns a pharmacy in a rural area of Wales. Shortages of medicines have been particularly difficult in recent years. For many patients, we are their only local and accessible pharmacy, so we do whatever we can to try and source their medicines for them.

We have had problems sourcing methylphenidate for our patients with ADHD and must liaise continually with prescribers to amend prescriptions for patients to different brands or strengths of tablets.

For one specific patient, neither of the two wholesalers with which I held accounts could source methylphenidate or any viable alternatives. However, I found another that did have stock. I opened a new account with this wholesaler to enable the pharmacy to get the medicine. I have subsequently opened accounts with a further three wholesalers to increase the options for patients due to ongoing medicines supply problems. As the proprietor of the pharmacy, I can take those decisions, even though it increases our workload and has a financial cost to the pharmacy due to the terms of medicines purchase.

We still experience problems on a daily basis getting supplies of medicines which can cause anxiety for our patients and is time consuming and stressful for our pharmacy team as we constantly chase wholesalers, wait on orders and liaise with prescribers to find alternatives for patients.
Community Pharmacist owner and RPS member, Wales.

I am a GP. I was visiting a care home patient and wanted to prescribe clarithromycin suspension as the patient could not swallow. I knew there was a shortage of clarithromycin so I checked with our practice clinical pharmacist and was told 125mg/5ml was available, so I prescribed that. The care home staff went to the local pharmacy to be told it was not available. The care home told the patients' relatives who then called around other pharmacies but could not find any. They then contacted the practice to ask for an alternative.

The practice pharmacist, having thought clarithromycin was available, found an alternative medicine but then had to check with the community pharmacy to make sure it was actually available. Once a supply was confirmed, the prescription was issued and then the care home staff went back to the community pharmacist.

The net result was five people chasing around to get one prescription supplied. Care home staff, GP, practice pharmacist, patient's relatives and community pharmacists. This scenario is being repeated every day across the country.
Member, Royal College of GPs

It is not just pharmacy teams that are seeing increases in workload from medicines shortages. Of 2,000 community pharmacy team members surveyed, 60% report contacting general practices daily about supply chain issues[66]. Prescribers in general practices are regularly seeing patients referred to them by the community pharmacy for alternative prescriptions, and the practice team is spending time trying to establish what is in stock locally before they prescribe. The same is happening in secondary care with clinical teams seeing patients referred back to them from primary care or reviewing patients and pathways as medicines become unavailable.

"There have always been shortages but there is a sea change of difference in the number now. I deal every day with a medicines shortage. I used to be able to hold the medicines in shortage in my head but not anymore, there is way too much going on."

General Practitioner

Pharmacists described the anxiety that the shortages had created in their patients, and how this anxiety had sometimes been directed at them and their teams with verbal and physical abuse. In a 2023 RPS survey, 41% of pharmacists reported verbal or physical abuse from the public[68].

2.1.4 Added tension in professional relationships

We heard that medicines shortages are often viewed as a pharmacy issue by healthcare teams with little appreciation of the wider context in which shortages occur. Professional tensions are added

to by the lack of clear and timely information about medicines shortages, differences in availability of medicines nationally and locally, limited information about the anticipated resupply of a medicine locally, and a lack of information and understanding of the root causes of medicines shortages.

Tensions and frustrations have been described to us across both primary and secondary care. We have heard of increasing frustration between GP practices and community pharmacies and also between hospital clinical multidisciplinary teams and the pharmacy department. In addition, we heard of conflict in the management of patients requiring more specialist treatment being stuck between general practice and secondary care specialists.

This was cited for shortages of ADHD medications, where there was limited specialist capacity in hospitals to meet the demand created by the shortages, and limited confidence in general practice to alter consultant-initiated therapies. Ultimately this was most acutely faced by patients, many of them children and adolescents, unable to obtain supplies of medicines on which they relied to help them function on a day-to-day basis.

Several also described the challenges with returning patients to their original medications when supplies return, with both reluctance from prescribers and patients to switch back for fear that shortages may occur again, which can leave patients on sub-optimal therapy for longer.

2.1.5 Impact on wellbeing and mental health of healthcare teams

The increased pressure on pharmacy workload resulting from the additional time needed to manage shortages has been well documented in workforce pressure surveys[66]. During our engagement events we also heard about the toll this is taking on the wellbeing and mental health. Pharmacists told us that they feel personally responsible when patients are unable to get the treatments that they need. We also heard about the pressure they sometimes feel from colleagues unable to understand how it is possible for critical medicines to not be available.

Research from the RPS and Pharmacist Support 2024 workforce wellbeing survey of over 6,500 pharmacists and pharmacy technicians found that in the last 12 months over half reported that medicines shortages directly impacted on their own wellbeing and/or workload. With 40% of respondents suggesting that patients had been put at risk because of shortages[69].

"With the alteplase shortage, sometimes I would go to bed worrying about not being able to thrombolise stroke patients coming through the door." (See Case Study 7)

Clinical services pharmacist

The impact on wellness and mental health is not limited to pharmacy teams, with prescribers, including medical and nursing teams also feeling personally responsible for being unable to prescribe the medicines that patients need[70,71]. The impact on the wider healthcare team should not be underestimated, for example, we heard from dieticians who, due to shortages of pancreatic enzyme therapies, were struggling to support the increased demand being placed on their services.

We heard from pharmacists in secondary care facing challenging ethical and moral decisions about which patients should be provided with the limited medicines that they were able to obtain. Decisions such as these about medicine allocation have been described as 'tragic choices' which recognise the significant psychological distress for the clinicians involved[72,73,74], (see Case Study 3).

CASE STUDY 3
Olanzapine shortages

From October 2023, difficulties in sourcing and intermittent supplies of olanzapine depot injections proved extremely challenging for mental health teams looking after forensic patients and for the patients themselves. Forensic patients are detained under the Mental Health Act and treated as in-patients when there are concerns about mental health needs and levels of risk to self and others. The aim is to look after people in the least restricted environment possible and support them to recover and return back to the community in a safe and supported way.

Olanzapine given as a slow-release depot injection monthly is typically used to manage symptoms of schizophrenia such as hallucinations, delusions, and disordered thinking. It is used in forensic settings to help people recover and return to the community. Depot injections of olanzapine are also essential for patients once in the community to help them remain stable.

National medicines supply teams cascaded a Medicines Supply Notification about the shortage along with a concurrent entry on the DHSC/NHS Medicines Supply Tool (see Box 7). Local pharmacy teams, working with their clinical colleagues, introduced a range of solutions to manage the shortage. These included moving stock around the country to ensure patients continued to receive their dose of medication on time and delaying starting olanzapine for new patients to conserve supplies for those already on established treatment, in line with clinical advice from national teams.

As a last resort when shortages were severe, vials of olanzapine were split so that two patients could be treated with one vial. A process that added an increased risk of error in medicine dosing as nursing teams were unfamiliar with the process.

Pharmacy and clinical teams spent significant amounts of time looking for supplies of olanzapine and managing patients unable to be effectively treated. As well as pulling them away from seeing other patients, this has taken its toll on clinical teams aware that their decisions may lead to deteriorations in their patient's mental state, for example, readmission to forensic settings, assaults on other patients or staff, and general decline in function which has likely delayed their discharge.

2.1.6 The mounting cost of medicines shortages

As well as the pharmacy, medical, nursing and wider healthcare workforces spending more time managing medicines shortages and foregoing other clinical work, we heard about cost pressures both in hospital and in primary care related to medicines spend. While the direct costs of supplying alternative medicines can be quantified, the system costs involved in managing shortages are often not and need to be captured[43,75]. These costs include the lost opportunity to see other patients, time spent setting up and managing shortage processes, extending waiting lists for treatment, reversing medicine management plans once a medicine returns to stock, re-designing care pathways for an alternative medication, managing the complexities of unlicensed or imported medicines that may be used as alternatives. One example shared was how the limited access to medicines used to support imaging and diagnostics could increase waiting lists, delay access to a timely diagnosis and ultimately in some cases lead to further disease progression.

> *"We have always had and managed shortages but now they are at the level where we are seeing that it can't easily be done. It is impacting clinical care and we need to consider delaying patients coming in for treatment."*
>
> **Chief Pharmacist, NHS Trust**

We heard in secondary care about an increase in admissions for patients unable to self-manage in primary care that require outpatient appointments. In primary care, this included additional pressure for GP appointments to make prescription changes or reduced availability of appointment for patients with practice pharmacists pulled into managing shortages. Working with colleagues in secondary care we identified a series of wider implications and costs to the system of managing medication shortages (see Figure 2).

Figure 2.

Additional costs of managing medicines shortages in secondary care

2.2 Impact on patients

Patient charities and the media are increasingly sounding the alarm about medicines shortages and the significant impact these have on patients across a range of different conditions[54,76,77].

Charities working with patients have reported troubling increases in helpline calls associated with particular shortages. Epilepsy Action reported five times as many calls in early 2024 as a year earlier, associated with worrying shortages of the key medications carbamazepine, sodium valproate and lamotrigine[78]. ADHD UK reports that for many patients, ADHD medicines have been out of stock since the NHS issued a patient safety alert[15] in September 2023. Add to these the well-publicised shortages of hormone replacement therapy, GLP-1 RAs for type two diabetes[55] and pancreatic enzyme replacement therapies (PERT) for people with pancreatic insufficiency[79,80] among many others, and a worrying picture for these patients is emerging.

In partnership with National Voices, RPS engaged with patients and charities, bodies and organisations that represent them. Our research highlights the difficulties patients are experiencing accessing medicines, the lengths they are forced to go to, and the anxiety medicines shortages are causing for them and their families. These findings are in tune with feedback from patient representative bodies and are outlined below under the following headings:

- **2.2.1** Shortages are widespread and affect patients multiple times
- **2.2.2** Patients and their families are exploring many avenues to source medicines
- **2.2.3** A confusing situation for patients who need more help
- **2.2.4** Patients and families are feeling the strain

2.2.1 Shortages are widespread and affect patients multiple times

We asked the 123 patients responding to our survey from across the UK if they had *"experienced shortages with your medicines in the previous year?"* and, if so, the name of the medicine that they had struggled to source. Their responses highlighted over 80 different medicines in more than 30 therapeutic areas. We also asked how often they had problems getting that medicine. Over a 12-month period, almost 90% of patients responding to the survey reported they had trouble sourcing a particular medicine more than once, with nearly half having problems on more than four separate occasions (see Figure 3).

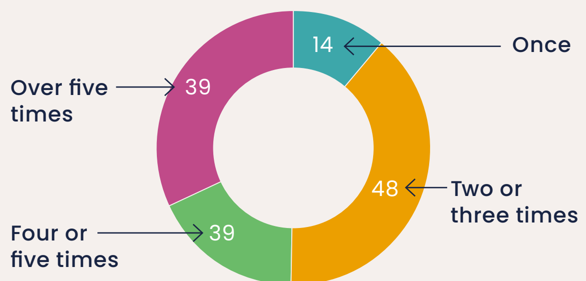
"It has been a constant worry never knowing each time I get a prescription if I will be able to obtain my medication, I have to go sparingly with it in the event I cannot get any."

Patient Quote

Figure 3.

Patient survey response

How often have you had problems getting this medicine/these medicines from a pharmacy in the last year? (Please select one option)



These findings are reflected by other patient surveys. Healthwatch found 42% of 1,650 patients had experienced problems sourcing medicines from pharmacies in the previous 12 months[78]. Charities supporting people with epilepsy and Parkinson's found 70% of respondents to their survey said they had problems getting their medicines over the past year[23]. Market researcher Opinium found that 49% of over 2,000 representative adults surveyed reported struggles receiving their prescription medicine due to medicines shortages[81].

In August 2024, data from the Office for National Statistics found that 20% of adults in England had problems getting an NHS prescription at a pharmacy in the previous 28 days[9]. However, of those patients, 40% had the problem resolved the same or the next day, 36% three to four days later

and the remainder six days or longer. This indicates that some of the issues patients are reporting obtaining medicines may be due to localised supply disruptions rather than active national shortages (see section 2.1.2).

2.2.2 Patients and their families are exploring many avenues to source medicines.

Patients surveyed during our research reported having to undertake multiple steps to try to get the medicines they needed; 51% reported they needed to return to the prescriber for a new prescription, 35% had to telephone multiple pharmacies to try to find their medicines and 41% visited multiple pharmacies in search of medication. Similarly, research conducted by the epilepsy and Parkinson's charities found more than half (55%) of respondents needed to visit multiple pharmacies before getting their medication[23].

This aligns with what we have heard from patient charities, which report patients spending hours on the phone to pharmacies to find supplies of their medicines or driving long distances to collect medicines from places where they may be available. Similarly, they also report patients returning to GPs to get new prescriptions issued for alternative medicines.

The need for such measures has the potential to exacerbate existing inequalities. The flexibility needed to call pharmacies or collect prescriptions in work hours may not be available to all. Patients without the means and access to necessary transport may be disadvantaged, as could those in rural populations with alternative pharmacies located greater distances away. In communities where English is not the first language, or for patients who are marginalised in society, this could exacerbate the inequalities that exist, particularly where patients are seeking access to medicines from pharmacies outside their local community.

My toddler had croup and developed very strained breathing so, being a Sunday, we called 111 and were sent to an out of hours GP based in a hospital. They prescribed steroids and told us we needed to start them straight away. We were told by the GP we couldn't get them from the hospital pharmacy because we had the wrong colour prescription.

After driving to one pharmacy, we were told the medication wasn't available and there was a shortage. We then called, or drove to, another seven pharmacies, none of whom had the medicine in stock. We were, however, told by one pharmacy that they had it in a slightly different form and that we would need to return to the GP to get a new prescription if we wanted that one. Three hours had gone by at this point.

Aware my toddlers breathing could potentially worsen and that we'd been advised to start the steroids immediately, I was quite concerned. I called the hospital and luckily, we just caught the GP whose shift was finishing at noon. We had to drive back to the hospital, collect the new prescription and travel back to the pharmacy to get his medication.

I was very fortunate that I have a car, a phone with credit, English is my first language, could pay the hospital parking fees (twice) and could do this three-hour trip without having to bring several other children with me. Many do not have these privileges. It's a huge safety and equity issue. And I was actually able to get the medication eventually that day, many others seem to be facing issues that are leaving them without their prescriptions for weeks.

Patient experience shared via the Patient Safety Learning hub, www.pslhub.org

As well as looking to access medicines from community pharmacies that they would not normally visit, patients may explore other options as they become increasingly frustrated. Our data shows 24% of respondents who had difficulty getting their medicines then tried to do so online, with 20% successfully obtaining a supply.

Online pharmacies registered with the General Pharmaceutical Council (GPhC) can and do provide a viable alternative for patients to access medicines. However, we heard concerning reports about the increasing numbers of websites that appear to the public to be reputable pharmacies providing medicines but are not registered with the GPhC. These unregulated websites often specifically target those medicines that are in shortage. These illegal sites come with the risk that patients may be accessing medicines that are

outside of a rigorous, quality-controlled supply chain and may be unauthorised and/or falsified.

This has led patient charities and others to issue warnings and advice to patients considering this option[82].

Access to medicines online requires both the means to access the internet, and digital literacy. In April 2024 data from the Good Things Foundation revealed the reality of digital exclusion and the digital divide that exists within the UK. The data highlight that 8.5 million people lack basic digital skills, 2.4 million households cannot afford their mobile phone contract and 1.5 million have no smartphone, tablet or laptop. In relation to Health, 33% of those offline say it's difficult to interact with NHS services[83].

2.2.3 A confusing situation for patients who need more help

We have described above the amount of time pharmacy and the wider healthcare team are spending dealing with medicines shortages and heard of the lengths that these teams are having to go to get medicines for their patients.

Despite this, our research showed that over 50% of patients felt they didn't get enough help from healthcare professionals when they couldn't get the medicines they needed. When asked what would have been helpful to them one theme within the responses was more consistency in how medicines shortages are handled, with patients having varied experiences on how the healthcare system and professionals dealt with their specific shortage.

The overwhelming common thread aligns closely to what we heard from healthcare professionals, namely communication of information about stock availability. Patient responses consistently suggest the need for not only better communication but timely communication. Specifically requested was information for patients about when their medication is likely to be available again and what they should do while it is out of stock.

Some patients also highlighted the need for a system where they could see which pharmacies had stock of the medicine they need, avoiding the necessity to contact or visit multiple pharmacies (this is discussed further in section 4.2.5).

"What would help is a U.K. wide database showing stock by pharmacy location. So you could search easily rather than manually contacting each store."

Patient

2.2.4 Patients and families are feeling the strain

Understandably for patients trying to access medicines that may be essential for their physical and mental wellbeing, this causes inconvenience, stress and anxiety.

We asked patients about the impact medicines shortages were having on them and their families. Almost 70% of patients described feeling anxious, stressed, frustrated or similar when trying to source prescribed medicines in short supply, with some describing how they experience these types of symptoms from the moment they request a new prescription. Almost 20% of respondents described a worsening of symptoms or an impact on their health as a result of having to go without regular medicines. Some described rationing the supply of the medicines to conserve supplies. It is not only the patients themselves who are being impacted, with family members and carers helping to find medicines or feeling the strain of their loved one's health being impacted by shortages.

Patient charities have also reported on the impact of medicines shortages on patients. Epilepsy and Parkinson's charities found nearly 40% of respondents with epilepsy reported having seizures induced by having to switch or skip doses of medication, and 36% of respondents with Parkinson's reported their symptoms worsening[84]. In December 2023, an ADHD survey of over 2,000 patients reported that medicines shortages had negative impacts on patients work, education and personal relationships[85].

"I spend hours chasing my epilepsy medications. I get my medications monthly on repeat prescription but because of the medication shortages I never know whether they will be in stock. I found one pharmacy that had my medication but they were the other side of London so I had to jump in a cab and pay £60 to pick up my prescription. It's a lot of money but if I don't have my medication, I will have a seizure. The stress of not knowing whether I can get my medication can also induce seizures. The number of seizures I have had in the last six or seven months has rocketed."

Person Living with Epilepsy

2.3 Summary of key points from healthcare professional and patient engagement

KEY POINT 2.1

Medicines shortages are impacting frontline healthcare teams and patients in both hospitals and community settings. They are impacting professional relationships and the mental health and wellness of healthcare teams.

KEY POINT 2.2

Healthcare teams reported that local systems and processes for managing and communicating medicines shortages are not sufficiently developed to address the scale of shortages they are now experiencing.

KEY POINT 2.3

Healthcare teams spend significant time finding solutions for patients experiencing a medicine shortage but, despite their efforts, the volume and scope of shortages now being faced daily on the frontline of care continues to impact patients.

KEY POINT 2.4

Healthcare teams point to the need for more timely national guidance that can support local implementation for the management of country-wide, long-term or critical medicines shortages. This would minimise the duplication of effort where local NHS organisations all develop their own responses before national guidance arrives.

KEY POINT 2.5

Within the UK, some patients may be experiencing an 'apparent' medicine shortage linked to localised or system-level factors, rather than a 'real' national shortage of a medicine. For example, Just in Time procurement and reduced stock holdings in community pharmacies can require patients to wait for medicines while they are ordered from wholesalers.

KEY POINT 2.6

Interviews with stakeholders highlighted that shortages, or the potential for shortages in the market, may drive unhelpful wholesaling and purchasing activity. More work is necessary to establish the extent to which this is happening in practice and how it can be mitigated.

KEY POINT 2.7

The cost to the system of medicines shortages needs to be better understood in terms of the opportunity for care lost, as well as the increased workload of healthcare teams and the cost of alternative treatments. There is a need to expand the research base about the impact and cost of shortages beyond the cost of medicines to account for the wider system costs.

KEY POINT 2.8

More patient charities are sounding the alarm about the burden medicines shortages are placing on the patients that they represent. As patients face additional hurdles to access medicines this has the potential to exacerbate existing health inequalities.

KEY POINT 2.9

Medicines shortages take a toll on patients' mental health. Patients report feeling frustrated, worried and anxious when they can't access their medicines, and some report rationing what they take to conserve supplies.

KEY POINT 2.10

Despite all the help that pharmacy and healthcare teams are providing, our research showed that half of patients feel that they do not get enough help when their medicines are not available. The need for better, more timely communication when there are problems obtaining medicines was often highlighted.

Chapter 3. Mitigating against medicines shortages

Chapters 1 and 2 explored the causes of medicines shortages with a focus on what may be responsible for the observed increases, and the impact they have on both patients and healthcare professionals. This chapter considers what currently happens in the UK to mitigate shortages and considers what more could be done.

To mitigate medicines shortages, there are a range of long-standing national and local systems in place[86]. These systems mean that, even in this time of unprecedented supply challenges, the majority of potential or actual medicines shortages are managed by the healthcare system nationally (see Box 4) and locally (with the active support of supply chain partners) with minimal impact on patients.

3.1 How are we currently mitigating shortages?

This chapter now looks at how the UK currently mitigates shortages under the following headings:

- **3.1.1** UK national policy
- **3.1.2** Early proactive national management
- **3.1.3** Regulatory approaches to mitigate against potential shortages
- **3.1.4** Supply and distribution mitigations in the medicines supply chain

3.1.1 UK national policy

Increases in medicines shortages are affecting countries globally, the extent of shortages and the potential impact on patients is now a significant cause for concern and has led to countries beginning to identify/implement policies and measures to increase the resilience of their medicine supplies[87,88] (see Box 3). Many countries have adopted and published specific strategies to address and manage shortages. Work to improve the resilience of medicines supply in the UK is underway, however this has not been pulled together into a single strategy across government departments and NHS in all nations.

The DHSC states that: *"resilience of UK supply chains is a key priority, and DHSC and NHS England are committed to helping to build long term supply chain resilience for medicines. We are continually learning and seeking to improve the way we work to both manage and help prevent supply issues and avoid shortages. Together with the NHS, DHSC has developed a range of potential interventions and is collaborating with partners across the medicines supply chain to consider what could be developed to optimally strengthen the resilience of the supply chain so more medicine supply issues can be prevented."*

The current Government Life Sciences Vision (2021)[89] aims to strengthen the UK's position in the global life sciences economy with a strong focus on innovation. The vision strongly supports companies researching and investing in new and innovative medicines. However, there has been criticism that it does not address the UK manufacturing of generic and biosimilar medicines. Similar criticisms have been levelled at Innovate UK's Transforming Medicines Manufacturing programme[90]. It has also been suggested that the lack of support for the generics/biosimilar industry at a national policy level means that opportunities to develop a UK manufacturing base with the flexibility to support the UK with acute supply challenges has been missed[38].

The new Life Sciences Innovative Manufacturing Fund[91] enables UK registered businesses to apply for funding for life science manufacturing capital investment projects which help increase UK health resilience. This large, multi-year fund open to generic manufacturers and overseen by the Office for Life Sciences offers the potential to support UK manufacturing infrastructure.

UK policy and NHS commissioning has been very effective in driving down the prices paid by the NHS for medicines to some of the lowest in the developed world. This has been achieved through a combination of market-driven approaches and negotiations and is widely regarded as positive for the public purse. However, as highlighted in Chapter 1, *Causes of medicines shortages*,

concerns are being raised by medicines manufacturers that the primary focus on pushing down the cost of generic medicines means that, globally, the UK may be a less attractive place to supply medicines when output is constrained.

In April 2024, a Critical Imports Council[92] made up of industry leaders with expertise from business, academia and government was set up to advise on securing resilience in supply chains for items critical to the UK's economic prosperity, national security and essential services. Medicines are identified as critical products, and the group has representatives from both the on- and off-patent pharmaceutical industries. This group may offer some wider policy recommendation regarding medicines security, although following the 2024 general election, the commitment to this group is unclear.

BOX 3

What are other countries doing at a policy level to mitigate shortages?

The UK is not alone in experiencing an increase in medicines shortages. Medicines shortages are increasing in countries around the world[93,94,95]. Examples of what other countries are doing at a policy level to address shortages include:

European Union – EU guidance on monitoring supply and addressing medicines shortages was updated in 2023. This includes initiatives such as:

- Creating a Critical Medicines Alliance to develop coordinated action at the EU level against shortages of medicines
- The development of an EU critical medicines list (coordinated by the European Medicines Agency)
- Boosting EU innovation and manufacturing capacity of critical medicines and ingredients
- Developing a common strategic approach to medicines stockpiling across the EU.

USA – In 2024, the federal government awarded $14 million to an API innovation centre to fund API production in the USA. This follows on from wider government contracts aimed at reshoring medicines production. The FDA has created a Drug Shortage Assistance Award to provide public recognition to manufacturers who have demonstrated a commitment to preventing or alleviating drug shortages of medically necessary drugs[96].

France – In 2022, the French regulator increased the financial penalties that they can impose on companies that don't maintain adequate safety stocks of essential medicines[97]. In 2023, the French government presented a plan to re-shore the production of essential medicines[98], bringing production of 50 critical medicines back to France.

Australia – In 2024, the Therapeutic Goods Administration carried out a supply chain review to understand the impact on the systems and ways to address them[99].

3.1.2 Early proactive national management

In the UK, there are long standing systems that aim to mitigate shortages impacting patients managed by the DHSC and NHS national supply teams (see Box 4 – The national teams managing medicines shortages). These systems are central to the UKs approach to mitigating shortages of medicines early and were particularly effective in managing medicines supply during the COVID-19 pandemic (see Case Study 4).

BOX 4
The national teams managing medicines shortages

Nationally, the Department of Health and Social Care (DHSC) is responsible for the continuity of the supply of medicines into the UK. A DHSC medicines supply team manages shortages on a day-to-day basis. They work closely on supply issues with the MHRA, NHS Specialist Pharmacy Services and the Medicines Procurement and Supply Chain (MPSC) team in NHS England which is responsible for the procurement of secondary care medicines on its frameworks and the management of supply issues for those medicines on a day-to-day basis. The DHSC and MPSC also work closely with the devolved nations through National Procurement Scotland, NHS Wales Shared Services Partnership and the Northern Ireland Regional Pharmaceutical Procurement Service.

In addition, a Medicines Shortages Response Group (made up of clinicians, and representatives of DHSC, MHRA, NHS England and the wider NHS in England, Scotland and Wales and chaired by the head of the NHS Specialist Pharmacy Service) provides support for the management of significant supply problems. Chapter 4: *Managing shortages once they occur,* discusses more about the work of the Medicines Shortages Response Group.

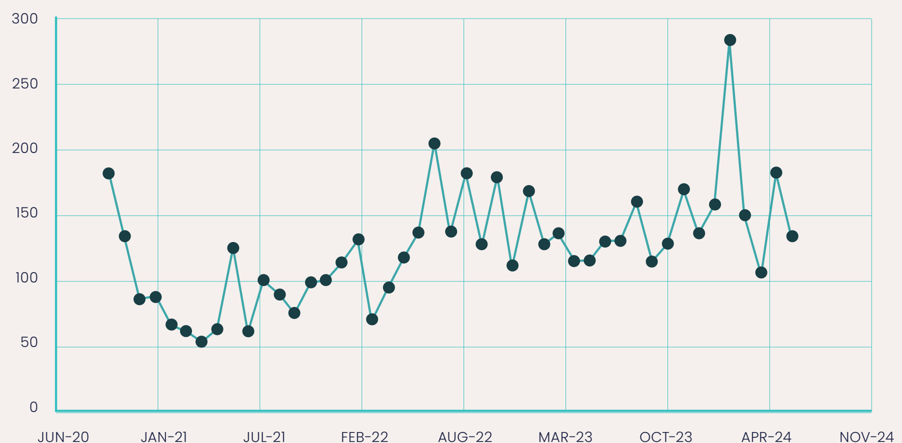
Early notification of supply disruptions is central to minimising any impact on patients. The earlier the national teams responsible for managing shortages are aware of potential supply disruptions, the sooner measures can be put in place to ensure that the impact on patients is minimised.

The national DHSC and NHSE medicines supply teams (and their equivalents in Wales, Scotland and Northern Ireland) have an ongoing dialogue with Marketing Authorisation Holders on product availability that helps to mitigate potential medicines shortages. In addition, holders of marketing authorisations are required to give six-months' notice of potential medicine shortages, discontinuations or updates on current medicine supply issues[100]. Since 2020[a], the DHSC has placed increased emphasis on Marketing Authorisation Holders to report supply issues by replacing its previous reporting system with the Discontinuations and Shortages (DaSH) portal which enables electronic notifications directly to the DHSC medicines supply team. As shown in Figure 4, the use of the portal has increased over time and has been a significant improvement in the process used to identify and respond to potential medicines shortages more rapidly. While these represent reported supply issues, not all notifications will lead to a supply issues. The vast majority will have no impact on patients due to the efforts of the national teams.

Marketing Authorisation Holders can be subject to fines if they fail to provide sufficient notification[101]. This penalty has not been used in practice, and its critics point to that fact that often, manufacturing problems or demand surges cannot be predicted six months ahead of time. This is discussed further in section 3.2.1.

Figure 4. Additional costs of managing medicines shortages in secondary care

Source:
The data is sourced from the DaSH portal and is a count of supply issue notifications by the date they were added to the portal by the Marketing Authorisation Holders (MAHs). Data captures all supply notifications for the UK market. Notifications are reported at an individual medicine level. MAHs can notify DHSC multiple times if the situation doesn't improve, therefore there may be multiple notifications of supply issues with a single product[101].



[a] Through legislation enacted in 2021, it became mandatory for Marketing Authorisation Holders to report supply issues, prior to that date it was voluntary.

BOX 5

The four tiers of medicines shortages

Tier 1: Likely to carry low patient safety risk. Management options should result in patients being maintained on the same licensed medicine.

Tier 2: Likely to carry moderate to high patient safety risk. Requires more intense management options than tier 1 issues.

Tier 3: Likely to carry high patient safety risk and/or high operational burden that requires system-wide action.

Tier 4: Carries very high patient safety risk and requires system-wide action at a national level. This may include additional support from outside the health system.

Once DHSC is aware of a potential medicines shortage, either through Marketing Authorisation Holders reporting or other sources, for example, from the MHRA, the NHS, NHS bodies across the devolved nations, medicines wholesalers, healthcare providers, healthcare professionals, patient groups and/or communication directly from the public, supply problems are risk assessed and classified into one of four tiers according to their potential impact on patients and/or the complexity of operational management[88] (see Box 5).

The response to anticipated or identified medicines supply problems can then include a range of measures depending on the severity and scale of the specific supply problem and involve national supply teams working with a wide range of stakeholders, depending on the issue, including patient groups[87].

Shortage mitigation options coordinated by national supply teams can include:

- Direct liaison with medicines manufacturers
- Working with the MHRA to identify potential regulatory flexibilities (see section 3.1.3)
- Contact with alternative suppliers and wholesalers to secure additional supplies and to manage existing stocks
- Contact with medicines importers to identify potential sources of medicines and expedite import processes, including potentially arranging unlicensed imports
- Working closely with specialist clinicians to ensure that the guidance and actions, including suggested alternatives, are safe and appropriate.

CASE STUDY 4

Managing medicines supply during the COVID-19 Pandemic In England

This case study sets out how NHS England and Improvement (now NHS England and referred to as NHSE throughout) and DHSC worked with key clinical and industry partners to ensure continuity of supply of priority supportive medicines to patients with COVID-19. The case study shows how successful medicines supply resilience is enabled through clinical expertise and guidance, clear intra- and inter-agency governance mechanisms, access to and analysis of demand and supply data, supplier engagement, commercial management and knowledge and coordination of supply chains at a national level.

Understanding clinical need to inform supply chain resilience

A National Clinical Group (NCG), comprising senior specialist clinicians and specialist pharmacists was set up to develop priority medicines lists for critical care, end-of-life care and antibiotics, including preferred presentations and first- and second-line alternatives. This list was used to inform:

- An assessment of any possible issues in the medicine supply chain for these medicines so that NHSE could work to increase stock visibility in the NHS and wider supply chain and engage with industry to secure additional volumes of priority products
- A regular assessment of supply for these medicines
- DHSC procurement for the COVID-19 medicines stockpile, which was established to mitigate the risk of insufficient supplies during future waves of the disease.

Demand modelling and supply tracking

NHSE developed a COVID-19 priority medicines supply assessment model which was central to the successful management of medicines. It provided

an early warning system that estimated potential shortages over a three-month period for the medicines identified by the NCG and was informed by a bespoke data collection from suppliers and wholesalers covering stockholding and expected deliveries. It supported DHSC and NHSE medicines analysis, allowing actions to conserve supplies, prioritise products for commercial procurement by DHSC and its partners and allocate to the NHS based on patient caseload, informed by clinical guidance.

Clear governance structures to support effective decision making to inform shortage management activities
A COVID-19-specific Allocation and Distribution Group (ADG) – chaired by the Head of the Specialist Pharmacy Service (SPS) – was set up and members included pharmacy, procurement and analyst leads from across NHSE, DHSC, SPS and the devolved nations. It operated under the remit of the clinically chaired, cross-organisational Medicines Shortage Response Group (MSRG). ADG drew on the modelling to provide regular updates on the current supply position, any anticipated issues and planned mitigations. Where necessary, ADG made recommendations to MSRG on action to take. This included regional and national allocation of business-as-usual supply (e.g., for atracurium and rocuronium) with key involvement from SPS regional pharmacy procurement specialists, including mutual aid, issuance of clinical guidance and supply notifications and/or release of stockpile products.

System engagement
It was important for healthcare professionals and wider stakeholders in the system to be kept abreast of changes to medicine supply positions and clinical guidance via a number of written and online collaboration channels. For example, medicines supply notifications (e.g., for noradrenaline in April 2020) and supply disruption notices (e.g., for methylprednisolone in January 2021), webinars held by the Chief Pharmaceutical Officer for England and the medicines optimisation FutureNHS platform.

3.1.3 Regulatory approaches to mitigate against potential shortages

Once a potential supply disruption is identified, close working by DHSC, national NHS supply teams where relevant, medicines manufacturers and wholesalers with the MHRA can also identify a range of regulatory measures that may help mitigate shortages[52] (see Box 6 – Regulatory approaches to mitigate against shortages).

During the COVID-19 pandemic, additional regulatory flexibility was used, for example, to enable the movement of stock around the UK to prevent shortages and the reuse of patients unused medicines in hospices and care homes. Many of these regulatory flexibilities finished after the pandemic, returning supply to the primary marketing authorisation routes.

The regulatory flexibilities used during the COVID-19 pandemic may not be appropriate for current medicines shortages. However, it may be possible through collaborative working in times of acute national medicines shortages to utilise other regulatory flexibilities. For example, enabling medicines manufacturers to reactivate dormant market authorisations more rapidly so they could potentially supply medicines in acute shortage.

In addition to flexing regulatory approaches when a potential or actual shortage has been identified, international recognition agreements for GMP inspections and Marketing Authorisations facilitate the sharing of information and allow reliance on approvals granted by competent authorities in specified countries. This aids compliance assessments and accelerates the approval process[103].

BOX 6

Regulatory approaches to mitigate against shortages

- **Expedited assessments.** New applications for marketing authorisations and product variations can be fast tracked if there is compelling evidence of benefit in a public health emergency or if there is a shortage of supply of an essential medicine that has been verified by the DHSC.
- **Batch specific variation applications.** Medicines manufacturers can request a single or small number of batches of product be released outside of the usual conditions of the marketing authorisation; there may be the possibility to expedite applications to help maintain supply[104].
- **Temporary exemptions to labelling requirements.** Marketing Authorisation Holders can apply for a temporary exemption to supply packs intended for another country to GB or Northern Ireland (NI) to mitigate supply disruptions.
- **Importation of licensed medicines.** Licensed medicines may be imported to an alternative authorised site under quarantine with appropriate quality controls while testing concludes
- **Unlicensed medicines.** Medicines manufacturers and wholesalers can apply to import unlicensed medicines for the UK market to meet a patient's individual needs.

3.1.4 Supply and distribution mitigations in the medicines supply chain

At each stage of the supply chain for medicines, organisations holding supplies of medicines, whether medicines manufacturers, wholesalers or individual pharmacies, have the potential to impact on the availability of medicines to patients. Both manufacturers and wholesalers licensed to trade in the UK have a legal duty to ensure that UK patient needs are met[105]. At the same time, pharmacists and dispensing doctors have professional and ethical obligations to ensure the needs of patients are always put first.

When supplies of medicines are disrupted, behaviours in the supply chain can either help or exacerbate the problem of shortages. Guidance from 2013 highlights *Best Practice for Ensuring the Efficient Supply and Distribution of Medicines to Patients* for organisations to help reduce the impact of supply disruptions[106]. This guidance needs reviewing in light of the changing nature and increase prevalence of high impact medicines shortages.

As highlighted in Chapter 1, in the interests of efficiency, organisations typically utilise just-in-time processes that support lean stockholdings. Where there are disruptions of medicines supply, the drive towards efficiency and lower cost products needs to be balanced against supply resilience and the potential impact of shortages on patients.

Within the supply chain, there are several ways shortages can be mitigated, these are highlighted below.

Stock availability information

The ability to mitigate against medicines shortages in secondary care is aided by the availability of data on stockholding that can be accessed at a local, regional or national level and allows for coordinated activities by NHS procurement teams and supply chain partners to ensure that medicines are available for patients and managed to address demand as equitably as possible see section 4.1.2.

By contrast, in primary care, there are upward of 11,000 community pharmacies across the UK who are independent contractors to the NHS purchasing their own stocks of medicines and using different digital systems. As a result, there is no accessible visibility of stock beyond the wholesale level (including what stock is available at individual community pharmacies) that allows for coordinated mitigation activities in primary care.

The use of capping

When medicines are in short supply, limits or quotas can be used to help ensure an equitable distribution of stock to hospitals and community pharmacies around the country[106]. Wholesalers, and in some circumstances medicines manufacturers, can cap supply to individual pharmacies to maintain some visibility of available

stock and reduce the risk of 'down-stream' hoarding. Our engagement highlighted that the speed at which caps or quotas are introduced, their responsiveness to changes in availability and the processes they require those dispensing the medicines to complete may benefit from streamlining (see Figure 1).

The use of contracts

In secondary care, approximately 70% of medicines in England, Scotland and Wales are supplied to the NHS through contracts that require tenders with suppliers managed by the relevant NHS purchasing authority. To improve the resilience of the supply chain, NHSE frameworks require suppliers to hold eight weeks of buffer stock in the event of a shortage to allow the NHS time to put measures in place to reduce the impact on patients. Although evidence suggests that this requirement is not consistently met[106].

In addition, non-supply penalties in contracts incentivise medicines manufacturers to find an alternative in a shortage situation. If the supplier is out of stock for over two weeks and the hospital is required to purchase the medicine at a higher price, there are penalties in contract terms and conditions requiring manufacturers to pay the difference in cost. In practice, trusts may not have the resources necessary to always make use of penalty clauses to maximise the contractual levers available to them or be able to use these levers to mitigate shortage risks.

Contracts are also used for clinical homecare services provided to patients in their own homes rather than in hospitals. Shortages of these medicines can be complex to manage, and contracts need to enable flexibility when shortages do occur (see Case Study 5).

CASE STUDY 5

Managing a Shortage of A Homecare Medicine –Abatacept

Over half a million people with chronic conditions in England depend upon medicines which, along with any necessary help to administer them, are delivered to their homes. These types of services are called 'clinical homecare medicines services' and replace care that would previously have been supplied in hospital[107].

Homecare medicines are typically specialist and high-cost medicines, and while they were primarily branded medicines produced by one pharmaceutical company, an increasing number are now generic medicines or biosimilars produced by a range of manufacturers.

Broadly speaking, manufacturers of homecare medicines are reimbursed for their medicines by the NHS via the private homecare provider company, the homecare delivery element is carried out by private homecare companies. The cost of homecare may be wrapped up in the reimbursement price that a manufacturer gets from the NHS, or there may be a separate service fee. The nature of the homecare market (specialist medicines and complex contracting arrangements) makes the management of medicines supply and subsequent shortages complex.

A recent shortage of a Bristol Myers Squibb medicine (Orencia-abatacept) provided through clinical homecare services as pre-filled pens for patients to inject subcutaneously for rheumatoid arthritis highlights this complexity[108].

The pre-filled pens were out of stock from June 2024, but the company was able to supply powder concentrate for infusion however not all homecare providers had the capacity to support intravenous infusion at home despite additional funding from the manufacturer. For hospitals working with homecare providers unable to provide home infusion, hospital appointments had to be arranged for all their patients. Homecare providers also had to identify sufficient nursing resources to provide home infusions and contact all their patients proactively to counsel them on the changes to their treatment and schedule appointments at home. Managing this medicines shortage for hospitals and homecare providers took considerable resources.

The added complexity in the homecare sector means that the need for early communication from manufacturers about potential shortages is critical to enable hospitals and homecare providers time to respond to alternative clinical pathways for their patients. As more homecare medicines become available, resilience in

the medicines supply chain needs to be considered in contracts for medicines delivered through homecare and procurement needs to enable flexibility when shortages do occur. In addition, where there are shortages, homecare infrastructure needs to be agile, particularly around the digital management of prescriptions.

Wholesalers

A wholesale distribution authorisation is needed from the MHRA to wholesale medicines in the UK. There are approximately 1800 wholesale distribution authorisations in the UK. An authorisation is the same regardless of the type of wholesaling activity an organisation (of whatever size) undertakes. The MHRA is responsible for inspecting authorisation holders to ensure that they comply with Good Distribution Practice.

Approximately ten wholesalers supply 98% of medicines to the NHS[109]. Of those medicines, 70% are provided by three 'full-service wholesalers'[110,111,112] who carry 25,000 individual product lines[113]. The other wholesalers supplying the NHS are often referred to as short-line wholesalers who typically provide around 2,000–6,000 product lines, short-line wholesalers vary considerably in size and scope of activity. There can also be trading between wholesalers, which adds additional complexity to the market.

Some wholesalers work with government, regulators and other supply chain partners to help identify, prevent and mitigate shortages whether caused by supply disruptions, demand increases or a combination of these factors (see Case Study 6). This communication between wholesalers and the NHS nationally and locally is key to help inform the mitigations and management actions needed to ensure that patients have a continuing supply of medicines.

CASE STUDY 6
How national wholesalers mitigate medicines shortages

A typical national wholesale distributor operates around 15 distribution centres across the four nations of the UK, this allows twice daily deliveries to be made to most pharmacies, hospitals and dispensing doctors across the country. Each national wholesaler picks and delivers many million packs of medicines every week.

Wholesale distributors operate a system of 'hub and satellite' depots with a network of three or four hub sites – larger, highly automated distribution centres holding around 25,000 individual products and local satellite sites holding a smaller product range but having access to the hub site stock range. Stock and orders are transferred between hub and satellite sites daily, sometimes overnight. This network maximises equitable access to stock for all customers across the UK, minimising local stock differences.

National wholesalers use advanced enterprise resource planning (ERP) systems, to manage stock inventory, algorithms, some with Artificial Intelligence support, identify and forecast demand changes, increasing orders automatically or with human intervention. These systems take account of seasonal and other demand changes. The ERP system generates daily reports of products in shortage and at risk of shortage.

Each wholesaler has a national replenishment team that works to understand and mitigate any stock issues identified by the ERP system. These teams have close working relationships with their supply chain partners, and each wholesaler has supplies from around 1,500 unique suppliers. These suppliers range from large and small manufacturers, parallel importers, medicines brokers and many others. Wholesalers have regular meetings and other interactions with their suppliers to understand availability and lead times, this allows wholesalers to buy stock from another supplier in the event of one supplier having reduced availability. In times of shortage, wholesalers often meet daily with their manufacturer counterparts, and then wholesalers and their suppliers will work together to plan and prioritise shipments of products in shortage or at risk of shortage.

In the event of significant and protracted product shortages, wholesalers use order capping on specific products to try to ensure that stock is equitably distributed. The systems can cap per order and/or time period and ensure that supplies are appropriate to the scale, licensing and operation of the pharmacy.

For generic medicines, wholesalers hold many different manufacturers' stock and operate cascade systems so that the pharmacy does not have to reorder if their first choice is not available.

In the case of protracted shortages, wholesalers work together with the DHSC and regulators to maximise supply, this may include intelligence sharing, reporting stock levels to DHSC, agreeing stock management strategies, prioritising supplies to specific sectors and increasing stock levels of alternative products. Also, in collaboration with manufacturers and regulators, products from other markets are imported on a batch-specific release basis.

Many wholesalers import medicines from the EU and further afield to supply as unlicenced medicines in the UK where the UK version is in shortage.

Community pharmacies and other primary care contractors

Contractors in primary care (including community pharmacies and dispensing doctors) can range from single pharmacist owners to local chains with several pharmacies, up to large national chains, and everything in between. Community pharmacies follow an agreement to provide services for the NHS (see section 1.1.6). As private entities, community pharmacies procure their medicine stocks independently through contracts and agreements with wholesalers, manufacturers or buying groups. The community pharmacy network in the UK helps to mitigate shortages by using all the wholesalers available to them to source medicines for their patients.

In addition to supplying medicines directly to patients, some pharmacy organisations, appliance contractors and dispensing doctors have MHRA wholesale distribution authorisations. Some use the licence to supply medicines to other pharmacies in their group, others have a wholesaling arm of their business that trades in medicine to supply other pharmacies, leveraging their combined buying power[114] (see wholesalers above).

3.2 What more can be done?

While the mitigations outlined above are currently in place in the UK, there is always more that could be done. This section highlights additional measures that could be taken to strengthen the current response to medicines shortages under the following headings. These measures were identified during the development of this report from the rapid scoping review, through discussions with advisory group members and wider stakeholder engagement (see How we worked and Acknowledgements).

- **3.2.1** Consistent, timely communication from manufacturers
- **3.2.2** Identify early warning signs sooner
- **3.2.3** Interrogate data to predict demand
- **3.2.4** Smooth out demand spikes proactively
- **3.2.5** Consider value and supply resilience in purchasing, procurement and national policy
- **3.2.6** Improve resilience by strengthening UK manufacturing
- **3.2.7** Community pharmacy reimbursement for medicines
- **3.2.8** Working with wholesalers

3.2.1 Consistent, timely communication from manufacturers

Medicines manufacturers and wholesalers have legal obligations regarding maintaining appropriate and continued supply of medicines[115] and should therefore have visibility of their supply chains and receive information, for example, from contract manufacturers, about issues in a timely manner so that they can take early action and put contingency plans into action. Maintaining compliance with their regulatory obligations across all good practice quality guidelines and regulations (GxP)[b] supports this obligation.

The speed and transparency with which Marketing Authorisation Holders report potential shortages through the Discontinuations and Shortages (DaSH) portal has been repeatedly highlighted as key to putting in timely national measures to mitigate shortages and reduce the impact on patients.

[b] GxP is a general term used to describe the quality guidelines and regulations applied in the pharmaceutical industry. Examples of GxPs include: Good Manufacturing Practice (GMP), Good Laboratory Practice (GLP), Good Distribution Practice (GDP) and Good Clinical Practice (GCP).

Where a Marketing Authorisation Holder is aware of a potential issue with supply, this needs to be communicated at the earliest possible opportunity and an ongoing dialogue maintained to enable effective mitigations. The DHSC confirmed that some Marketing Authorisation Holders were very proactive in alerting them to the risk of shortages, but this was not universal.

While there is a need to be mindful of the commercial sensitivities that medicines authorisation holders face when reporting a potential shortage, for those who consistently fail to report shortages of medicines, action should be taken in line with the requirements and obligations of their marketing authorisations.

Marketing Authorisation Holders are required to report medicines supply issues six months ahead of time with a penalty for non-reporting, although that penalty has, to date, not been used. There may be valid reasons why communication ahead of a supply issue is not possible; manufacturing problems and demand surges can be inherently unpredictable, making such communication impractical. Given the importance of early reporting by marketing authorisation holders, a revised model for reporting and for penalties may be required. A performance management approach which encourages faster information when shortages could or do occur, and potentially penalises Marketing Authorisation Holders who repeatedly fail to report/provide ongoing information could be explored. In secondary care, the tender award system also provides a mechanism to encourage faster reporting (also see section 3.2.3).

3.2.2 Identify warning signs earlier

In an environment where disrupted supply chains are more common, recognising warning signs earlier could help to identify, and potentially head off the impact of shortages on patients. It is early communication from marketing authorisation holders, who have the principle responsibility for the supply chain for their products to the point of sale, that will allow for the collaborative action necessary to mitigate shortages most effectively.

Use of technology

In secondary care, there is national visibility of stock levels across hospitals and so there is potential to use that data more proactively to anticipate shortages and further manage demand (see section 3.2.4). However, NHS teams must be supported and resourced adequately to maximise this system's potential.

While currently there is no accessible national or local visibility of stock in wholesalers and/or community pharmacies/dispensing doctors, exploring how IT systems might be developed and connected to enable this could provide opportunities to use data in a more proactive way. In particular, this could help inform the management of specific products when local shortages occur.

Tools have been developed that use the data provided by manufacturers globally which help to provide anticipatory warning of potential shortages based on demand and patterns of supply that exist in other countries in Europe. Some European national competent authorities have invested in these systems to help their healthcare systems mitigate the shortages that they are experiencing. As these tools develop, they need to be examined as to their applicability to the UK and their potential to support UK systems.

As well as wholesalers investing in stock management systems, some hospitals have also invested heavily in staff and the development of inventory and stock management systems to give them insight into emerging issues, and so enable local management strategies to be put in place. Sharing good practice in the use of technology will help other organisations to improve their systems (see Case Study 7).

CASE STUDY 7

Greater Glasgow and Clyde Pharmacy Distribution Centre

In Greater Glasgow and Clyde, a single high-tech pharmacy distribution centre procures and replenishes ward and site pharmacy stocks for all hospitals and community clinics. The procurement team report to the deputy director of acute services who is part of a single system pharmacy team that includes, primary care, community pharmacy and governance all reporting to a director of pharmacy.

Over the last five years, the team in the pharmacy distribution centre managing medicines shortages has grown from one pharmacy technician to a team of five: three pharmacy technicians and two pharmacy support workers. This is in response to the general increase in shortages and the rise in critical and specialist drug shortages.

The output from the pharmacy distribution centre is over 100,000 packs per week, operating on a lean stock holding of six to eight days which means that supply issues need to be anticipated and managed quickly.

Data from the stockholding system is used proactively to mitigate against shortages supported by specialist pharmacy data analysts. The analysts generate a suite of reports, refined over years, to give an insight into usage and are able to predict pinch points so that proactive action can be taken. For example, a daily report looks at usage of the top 300 lines and applies a traffic light system to highlight when stocks might be running low based on usage patterns. Red traffic lights trigger an action to review. Another report highlights products moving faster than usual to identify early usage trends, as well as slow-moving products to identify the risk of medicines going out of date and to avoid over ordering. Every six/eight weeks, stock holding and triggers for reordering stock is reviewed against current issues and predicted demand.

When potential issues are flagged, the procurement team have access to near real-time wholesaler data from the three largest full-service wholesalers, allowing them to proactively interrogate that data and react accordingly. Two monthly meetings with wholesalers are used for two-way feedback.

More data is generated through the customer service portal where issues are logged (via a ticket) and can provide an audit trail that allows for the early identification of potential shortages.

Insights from hospital clinical teams are gathered via a weekly drop-in virtual meeting allowing pharmacy clinicians to highlight potential changes to clinical practice that may impact on demand or highlight any concerns.

Use of local intelligence

During our engagement, we heard that frontline pharmacy teams in hospitals and community pharmacies are picking up the warning signs of shortages weeks or months before national guidance is issued. There may be reasons for this. In some cases, a delay in announcing a national shortage may be necessary to enable management plans to be put in place. In other cases, the national system may be less sensitive than frontline intelligence. Whatever the reason for the time lag, finding practical measures to improve insights from the frontline and enable national teams to take earlier action could be developed.

Encouraging frontline teams to report shortages to national teams through established routes is a key part of shortage mitigation. In community pharmacy and primary care, medicines supply issues can be reported directly to Community Pharmacy England[116]/Scotland[117]/Wales[118] using online forms. With a workforce already under pressure, enabling more intuitive reporting of potential issues, such as through an integrated platform within their ordering systems as opposed to through a web-based form may support faster access to local intelligence.

3.2.3 Interrogate data to predict demand

A data-driven NHS needs to, at its core business, predict demand for medicines to feedback to manufacturers and wholesalers. Product-usage data could be mined more intelligently to feed back up supply chains to manufacturers. More

accurate demand prediction would also help to inform the work of the teams who manage supply shortages centrally.

Quotas used in hospitals to mitigate a shortage are often based on historic stock issue data from pharmacy stores rather than predicted usage based on what has been prescribed to patients. The implementation of Electronic Prescribing and Medicines Administration (ePMA) systems across hospitals open up innovative opportunities to interface electronic prescribing and reporting systems with stock holding, and to use anticipatory demand. This would mean using predictive analytics to look at what is being prescribed for patients that have been admitted to the wards, what is being stocked (already available on a ward) and hence what volume of medicines a hospital will need to maintain that supply for a given period of time. Where national quotas are used this would enable more accurate demand prediction based on patient demand (prescription increase or increase in patient numbers).

As more and more hospitals adopt electronic prescribing systems, there should be systems in place within trusts to help ensure that prescribers on the wards receive alerts and information about the local supply issues at the point of prescribing. This has significant value in mitigating acute issues on the wards.

3.2.4 Smooth out demand spikes proactively

Proactively recognising and planning for the impact that changes in demand will have on medicines supply is a helpful tool in mitigating against shortages. While demand-side pressures have always existed, the need to plan for them in a more structured way is becoming increasingly important as supply-chain issues become more prevalent.

When updating clinical guidance NHS organisations (and clinician leaders) need to consider the impact that changes in treatment guidelines may have on the availability of medicines supply associated with that guidance. We heard that clinical decision makers often don't consider the availability of medicines to meet the demand when implementing local polices and guidelines. It is important that the pharmacy team are closely involved in guideline development to act as a liaison to the supply chain and help to mitigate the impact of such changes. There is a need for clinicians and healthcare managers to be supported further to understand the supply chain and their impact upon it (also see section 4.2.6).

3.2.5 Consider value of supply resilience in purchasing, procurement and national policy

Increasing the emphasis on the value of supply resilience is a way to help mitigate shortages. For example, using incentives when procuring NHS secondary care and/or homecare medicines that reward supply chain resilience quality measures such as good manufacturing compliance records and encourage early reporting of supply disruptions. At the same time, support could be provided for secondary care to use contractual penalties and terms to penalise for disrupted supply.

As highlighted in section 1.2, unplanned increases in demand can lead to medicines shortages. Ideally the tender process in secondary care should work in a way that minimises supply disruptions across the lifecycle of the tender. Allowing appropriate lead times for manufacturers who are awarded contracts to increase their production capacity would help alleviate some of the acute local shortages that have been reported. Similarly, managing transitions between tenders can help pinch points when moving from one supplier to another, like destocking by one supplier before the other supplier is ready to supply.

When making decisions to switch medicines to generic alternatives (in primary care or for non-contracted hospital medicines) the balance between cost savings in local NHS organisations and the availability of medicines across a wider national or regional footprint should be considered. Direct medication cost alone should not be the only factor, as savings on paper at a local level may not equate to a real saving when a local system/national view is taken and the costs of managing shortages are considered. For example, whilst generic medicines are often the most cost-effective way of prescribing, manufacturers can reduce the price of their 'branded generic' product to one that is cheaper than the equivalent generic product. This is done to promote medicines switches and increase market share of the branded generic product[119]. While branded generics may save costs on local prescribing budgets in the short

term, they can increase the burden on prescribers, pharmacists and patients if they become subject to shortage because when a generic medicine is prescribed by brand name, pharmacists cannot automatically supply an alternative generic medicine that may be available.

At a national policy level, the impact of the low prices paid for generic medicines should be evaluated in relation to the availability of product lines in the UK[43]. This is particularly important for older, low-volume generic medicines where there are limited manufacturers or, in some cases, only one manufacturer. We have heard from patient groups about the difficulties patients have obtaining older generic medicines on which they are dependent, especially when these are low priced complex molecules that may be loss making for manufacturers[76,120]. In these cases, strategic considerations at a national policy level are needed to protect supply for these patient groups. More generally, pricing policy needs to ensure a consistent incentive across different product lines and over time, to minimise the risk that some product lines are unprofitable and being subsidised by others, which makes the former vulnerable to market exit or unappealing for market entry.

3.2.6 Support UK medicines manufacturing capacity

Overall, 25% of generic medicines used in the UK are manufactured in the UK, the remainder are manufactured in the EU (25%), India (30%) and the rest of the world (20%)[121].

Ensuring that the UK maintains and expands its current commercial medicines manufacturing capability could help mitigate medicines shortages caused by global supply chain disruptions or demand surges as it may be possible to manufacture extra supplies of medicine in the UK[122]. This includes having the capacity to ramp up national production should a crisis occur[123]. This would be in line with other developed countries who are looking to improve national medicines manufacturing capacity and responsiveness to mitigate against critical medicines shortages. As described above, UK national policy levers could support this (see also section 3.1.1).

At the same time, many hospitals in the UK have manufacturing and aseptic facilities. To help address some of the supply chain challenges with medicines, it's been proposed that existing NHS facilities assist with manufacturing medicines that are in shortage. Nationally reviewing hospital manufacturing capacity could form part of a strategy to support the resilience of the UK supply chain, especially where the current commercial environment in the UK is not sufficient to incentivise commercial manufacturers to supply products. Five 'pathfinder' aseptic hubs initially planned to open across England by 2027 with a view to developing a network of regional hubs that will potentially produce high-volume products on an industrial scale present an opportunity to explore this approach further.

3.2.7 Community pharmacy reimbursement for medicines

The community pharmacy funding agreements and their associated terms and conditions determine how community pharmacies, as independent contractors to the NHS are renumerated for the medicines that they supply to patients (see section 1.1.3). These agreements and frameworks are complex in their construction, being a collection of different provisions that work together to ensure patients get their medicines, while enabling efficient purchasing of medicines for the NHS and helping to support a dynamic market for medicines supply. Separate agreements exist for England[124], Wales[125], Scotland[126] and Northern Ireland[127].

However, medicines reimbursement and the economics of the community pharmacy markets has been highlighted by community pharmacy organisations as a significant factor in increasing financial pressure on community pharmacies[128,129]. There have been calls for a review of medicines supply and pricing, including a review of how much pharmacies can earn from medicines purchasing[130]. These concerns for the financial viability of the community pharmacy sector were reflected during our engagement with community pharmacists and more widely from wholesalers and manufacturers[131].

NHS Regulations require that, with some exceptions, pharmacies must dispense prescriptions presented and do so with reasonable promptness. The reimbursement arrangements aim to reimburse community pharmacy contractors 'as a

sector' the cost of the medicines purchase *plus* the allowed medicine margin, although that does not mean that each individual contractor will dispense every single item at a profit. The medicine margin survey monitors this to ensure at least the allowed margin above purchase costs is delivered overall, recognising that there will be 'winners and losers' at individual contractor level.

Recognising that due to changing market dynamics, pharmacies may need to purchase medicines at a loss (i.e., for more than they will be reimbursed by the NHS) a temporary monthly price concession[132] is used. Price concessions act as a safeguard so that if purchase prices for the average pharmacy increases above the Drug Tariff price, increased reimbursement prices can be granted in month. This can be for medicines in shortage, where the increased demand on a limited supply drives up prices. However, if a product has been awarded a price concession that does not automatically mean it is linked to a shortage. This mechanism, negotiated between Community Pharmacy England[c] and Community Pharmacy Scotland with their respective Departments of Health allows pharmacies to recover those costs, but price concessions are not always granted.

We heard during our engagement that the use of price concessions and the system's responsiveness to price changes needs to be evaluated to establish how effective the pricing system is in mitigating the impact of price volatility on community pharmacies. We also heard anecdotally that a price concession, or potential for one may be acting as a perverse incentive that can in some cases worsen local shortages. Further work would be needed to establish the extent to which this is happening.

As digital systems pervade the procurement space community pharmacy contractors are turning to technology-enabled cascade purchasing systems to shop around for competitive medicines prices. Many systems can be configured to reduce dispensing at a loss by enabling purchases of only those medicines available at, or below, the listed Drug Tariff prices. This does not mean that the medicine is not purchased elsewhere but time and effort is then required potentially causing delay to the patient. We heard that the use of cascade purchasing systems may be having a wider impact on wholesalers' ability to forecast demand and the accuracy of stockholding. This needs to be better understood in the context of medicines shortages.

3.2.8 Working with wholesalers

Mitigating medicines shortages works most effectively when the system collaborates. This was seen during the COVID-19 pandemic when the UK full-service wholesalers assisted DHSC/NHSE by sharing up-to-date information with the Government and the NHS on medicines stock levels within UK suppliers (see Case Study 4). While this was predominately in secondary care, this collaboration could be built on to develop systems in both primary and secondary care to mitigate against national shortages, particularly for medicines that are considered by the UK to be critical.

We heard during our engagement that there is often minimal communication between wholesalers and community pharmacies about the specific reason for a medicine being out of stock, and, importantly for patients, when the medicine may be back in stock. This can make it difficult for community pharmacy teams to distinguish between supply disruptions and national shortages (see section 2.1.2).

Investment in wholesaler and community pharmacy IT systems to provide more granularity of communication, in particular about re-stock dates, would help pharmacists to advise their patients and enable more consistent communication. Recognising that for such a system to work, manufacturers would also have to supply suitable information to the wholesalers. While improving communication of information across the supply chain was generally deemed positive, it was noted that such communications can lead to inappropriate and detrimental behaviours, intentional or otherwise, by some in the supply chain. For example, stock piling medications in anticipation of a shortage, which in turn may exacerbate the shortage.

Wholesale dealers authorisations are also held by some hospitals to support their manufacturing activity and may, in some cases, enable them to import medicines as required. These flexibilities

[c] Community Pharmacy Wales, Community Pharmacy Northern Ireland adopt the prices published by DHSC in England.

could potentially be used by hospitals to support supply in a local system when medicines are in national shortage (see section 4.2.2).

3.3 Summary of key points for mitigating medicines shortages – with a focus on what more could be done

KEY POINT 3.1

The UK has long-standing arrangements for mitigating medicines shortages. The DHSC medicines supply team and national NHS supply teams work closely with the MHRA, manufacturers and wholesalers to put in measures that prevent many reported shortages impacting patients.

KEY POINT 3.2

The reporting and ongoing provision of information about medicines shortages by manufacturers is critical in ensuring effective mitigations. More needs to be done to ensure all Marketing Authorisation Holders report shortages at the earliest possible opportunity.

KEY POINT 3.3

Marketing Authorisation Holders and wholesalers also have an obligation to maintain the appropriate and continued supply of medicines. Ensuring compliance with good practice quality guidelines and regulations and maintaining supply chain visibility with appropriate contingency plans in place will support this obligation.

KEY POINT 3.4

Developed economies are increasingly pursuing policy approaches to secure their medicines supplies in the context of more disruption-prone global supply chains. The UK needs to continue to look closely at national policy levers that can be used to mitigate against medicines shortages.

KEY POINT 3.5

UK-based manufacturers currently supply a quarter of the generic medicines that the NHS uses. In common with other developed economies, the UK should consider how UK-based medicines manufacturing can support UK patients when medicines are in shortage; this includes both commercial manufacturers and NHS hospital-based manufacturing units. The Life Sciences Innovation Manufacturing Fund may offer one potential lever.

KEY POINT 3.6

In collaboration with the MHRA, regulatory flexibilities are already used to mitigate medicines shortages. There may be scope to develop these flexibilities further if medicines are in acute national shortage, recognising that medicines regulation cannot be undermined. For example, enabling medicines manufacturers to reactivate dormant market authorisations more rapidly so they could potentially supply medicines in acute shortage.

KEY POINT 3.7

To mitigate shortages, medicines procured through contracts with the NHS for hospital and homecare services should continue to have more weight on supply resilience. Measures that could be considered include secondary care tender criteria that reward good supply history and quality measures, such as, manufacturing compliance and quality assurance, and mark down poor past performance. Tender management should also support supply resilience by providing sufficient lead time for manufacturers to increase production.

KEY POINT 3.8

At the same time, hospitals should create the capability and infrastructure to hold suppliers to account locally using the penalties that already exist in standard contracts where medicines manufacturers fail to supply medicines.

KEY POINT 3.9

System approaches that view medicines in the round to encourage consideration of the implications of cost savings on supply chains are needed. For example, at a local level, switching to branded generics may achieve short-term savings but can be a particular problem when medicines go into shortage; prescribing unbranded generics avoids this problem.

KEY POINT 3.10

Low prices for older, low-volume generic medicines can make losses for medicines manufacturers; these generics may require strategic considerations at a national policy level to protect supply for patients.

KEY POINT 3.11

Improved data connectivity and more proactive approaches to predicting demand, both nationally and in the local NHS, have potential mitigate shortages. This information could be shared with manufacturers and wholesalers to enable effective planning.

KEY POINT 3.12
Similarly, improved supply chain visibility/data connectivity could enable suppliers and wholesalers to share information on medicines in shortage, such as stockholding and expected delivery dates, that would enable national teams to more proactively manage the medicines supply chain and increase resilience.

KEY POINT 3.13
Community pharmacies mitigate the impact of shortages on patients by purchasing medicines from across wholesale networks for which they are subsequently reimbursed. The economics of supply in community pharmacy is destabilising the community pharmacy network and potentially contributing to medicines shortages. Considering the dynamic market that exists today, the community pharmacy contract needs review.

KEY POINT 3.14
Community pharmacies are using automated purchasing platforms to source medicines from across the wholesale network, the impact of the widespread use of these systems on the medicines market and wholesalers' ability to forecast demand, and the accuracy of stockholding needs to be better understood in the context of medicines shortages.

KEY POINT 3.15
There is currently no visibility of medicines stock held in primary care. This lack of visibility makes it difficult to mitigate against shortages in a coordinated way, as is done in secondary care.

KEY POINT 3.16
The data available to community pharmacies from wholesalers through their ordering systems is limited. Using these IT systems to improve the granularity of information provided to community pharmacies would enable community pharmacists to provide more consistent information to patients about when their medicine will be in stock; recognising such systems may not be straightforward to develop.

KEY POINT 3.17
There are occasions when the DHSC and manufacturers report that there is sufficient stock of a given medicine in the country, however, community pharmacies are unable to either source stock or obtain it in a financially sustainable way. More work needs to be done to understand the root causes of these local supply disruptions.

Chapter 4. Managing shortages once they occur

The previous chapter explored how the UK mitigates medicines shortages with the support of supply chain partners. This chapter looks at when shortages do occur how they are actively managed to minimise the impact on patients. It also looks at what else could be done to reduce the impact of shortages on patients.

4.1 HOW ARE WE MANAGING SHORTAGES CURRENTLY?

This chapter looks at how the UK currently manages shortages nationally and by sectors of practice.

- **4.1.1** National support for managing shortages
- **4.1.2** Managing shortages in secondary care
- **4.1.3** Managing shortages in primary care

4.1.1 National support for managing shortages

When the DHSC Medicines Supply Team/NHSE Medicines Procurement and Supply Chain Team (see Box 4) is alerted to potential or actual medicines shortages the shortage is risk assessed (see Box 5). The medicines supply team then work with a wide range of relevant stakeholders to put in place steps to mitigate against and manage each individual shortage.

As highlighted in Chapter 3, the Medicines Shortage Response Group (MSRG) supports the national teams. All tier 3 and 4 medicines shortages are escalated to MSRG and generally briefed to ministers before being communicated more widely. MSRG can also provide advice on tier 2 shortages if considered necessary or when requested. Advice and support on the clinical implications of a shortage is sought from the NHS Specialist Pharmacy Service[133,91] and other clinical experts and stakeholders.

Summaries of all current shortages and actions that the NHS needs to take are uploaded by the DHSC medicines supply team or the NHSE medicines procurement and supply chain (MPSC) team onto the DHSC/NHS Medicines Supply Tool which is hosted by the NHS Specialist Pharmacy Service[135] (see Box 7 – DHSC/NHS Medicines Supply Tool). In addition, shortages may be communicated (although not exclusively) by the following routes:

- **Tier 1 shortages:** Not routinely communicated, however, options could be Online Medicines Supply Tool; NHSE MPSC fortnightly generics supply issues report distributed to all regional pharmacy procurement specialists and local procurement leads in secondary care in England; email to regional pharmacy procurement specialists
- **Tier 2 shortages:** Communications may be issued via a medicines safety notification which can be disseminated to primary and/or secondary care via various routes including the NHSE National Operations Centre and NHS mail. Tier 2 issues will also be reported on the DHSC/NHS Medicines Supply Tool and MPSC fortnightly generics supply issue report as will tier 1 issues (England)
- **Tier 3 shortages:** These are escalated to the Medicines Shortage Response Group, which will decide whether to issue a: National Patient Safety Alert, where the criteria are met[134], to the NHS via the MHRA Central Alerting System (CAS). Tier 3 medicines safety notifications can be disseminated to primary and/or secondary care via various routes including the NHSE National Operations Centre and NHS mail and include, where MSRG agrees, the use of the CAS mailing list with an email and a link to the Online Medicines Supply Tool
- **Tier 4 shortages:** Communications issued via a National Patient Safety Alert, where the criteria are met, to the NHS via the MHRA CAS. Additional supportive and targeted communications may be required as signed off by the senior responsible officer.

These information cascades provide the health system with notification of the shortage and seek to inform prescribers and clinicians of the approaches to be taken to help mitigate the impact on patients.

BOX 7
DHSC/NHS Medicines Supply Tool – developed and hosted by SPS

Summaries of all current medicines shortages and actions that the NHS needs to take are uploaded by the DHSC Medicines Supply Team or NHS England pharmacy and supply chain team onto the medicines supply tool which is developed and hosted by the NHS Specialist Pharmacy Service (SPS) on their website *sps.nhs.uk.*

The tool provides up-to-date information on supply issues, including a list of current and recently resolved supply issues, the anticipated duration of the issues, suggested management actions, advice on alternative medicines and clinical advice, where appropriate, as well as contact details for queries.

Content for the medicines supply tool is provided by DHSC and NHSE, and with NHS SPS, all three organisations work together to make technical improvements and improve useability to the tool. The tool is used across England, Scotland and Wales.

For the purpose of this report, we refer to the tool as the DHSC/NHS Medicines Supply Tool.

4.1.2 Managing shortages in secondary care

As highlighted earlier, the visibility of stock holdings across hospitals is a valuable tool to help mitigate and manage medicines shortages.

In England, a regional network of NHS Specialist Pharmacy Service (SPS) pharmacy procurement specialists has some visibility of the stock available in hospital pharmacies and this regional network helps to manage shortages (see Case Study 8). In cases where supply is being actively managed across the country, for example, through stock allocations from wholesalers to hospital pharmacies, the NHS SPS pharmacy procurement specialists identify and verify usage figures for NHS trusts in their regions and assess how long their stocks are likely to last.

In NHS Wales, there is a single supplier for hospital pharmacy stock management systems, which allows stock visibility across the whole of Wales for stock kept in any hospital pharmacy. This is utilised by the local procurement teams in critical situations to obtain stock under mutual aid when possible.

In NHS Scotland, a dedicated national procurement team advise and coordinate supply issues and stock allocations, utilising a stockholding database used by all hospitals.

In exceptional cases where there is a public health need, hospitals are permitted to transfer medicines they hold to another hospital. This is an exception to wholesale regulations and has regulatory constraints[135]. During the COVID-19 pandemic, this exception was used for some medicines in short supply and became known as 'mutual aid'. It was also used to help manage the recent alteplase shortage (see Case Study 7). The practice has been flagged as a potential way that medicines shortages could be managed in secondary care, and potentially extended to community pharmacies[136]. Currently, regulatory constraints and the fact that it is a resource intensive process limit its use.

For medicines purchased on contracts for secondary care there is scope for suppliers in one region to supply other regions where products are in shortage (with the appropriate assurances that manufacturers won't be contractually penalised).

In Scotland, best practice standards for managing medicines shortages in secondary care stress the importance of collaboration between health boards and directors of pharmacy sharing stock to minimise the impact of shortages on patients[137].

CASE STUDY 8

Managing a national shortage of a critical care medicine – alteplase (In England)

In August 2022, a National Patient Safety Alert was issued to the NHS through the CAS alert system to state that the availability of alteplase would be restricted with no improvement expected until early 2023.

Alteplase is licenced for several indications and was, at the time, the only treatment available for the thrombolytic treatment of acute stroke. Boehringer Ingelheim had restricted supply of alteplase injection, due to a global manufacturing capacity constraint and alerted the DHSC medicines supply team. Boehringer and the DHSC partnered with a system of allocations designed to maintain essential supply for patients. The regional pharmacy procurement specialists worked closely with the hospital pharmacy procurement teams and liaised with the Boehringer Ingelheim project team to ensure sufficient stock was available on a monthly basis.

The National Patient Safety Alert requested that alteplase be conserved for patients with acute ischaemic stroke, given the lack of an alternative and the significant risk of harm without treatment. It requested that alternative therapeutic options to alteplase be considered in the other conditions for which alteplase was licensed.

Hospital pharmacy teams responding to the National Patient Safety Alert had to coordinate both the local operational management of a prolonged shortage of a critical medicine for stroke and the shift away from alteplase to alternative treatments for the other conditions for which alteplase was used.

Nationally, alteplase was allocated for use in stroke patients by specialist pharmacy procurement leads, based on historic usage and visibility of stock levels in hospital pharmacies through the software also used in the COVID-19 pandemic. Trusts at risk of running out of alteplase could contact their regional specialist pharmacy procurement leads who could direct them to hospitals with supplies who could provide some of that stock to them through 'mutual aid'. In some cases, the NHS specialist pharmacy services regional procurement leads were able to secure additional supply directly from Boehringer Ingelheim. The shortage situation lasted longer than the original National Patient Safety Alert projected, carrying on into 2024, and so collaborative arrangements to ensure supply for patients remained in place over this period.

National Patient Safety Alerts trigger review by trust risk teams and have a designated lead consultant with oversight, however the operational management of medicines shortages generally falls to pharmacy teams. The critical nature of the alteplase shortage, with its knock-on effect on multiple clinical areas and the potential impact on patients, put considerable pressure on pharmacy teams.

In light of the current level of shortages and the breadth of medicines these shortages now impact, including critical medicines, hospitals will be reviewing their processes. Forums sharing the learnings from any review of the management of the alteplase shortages would benefit the system.

This particular example applied equally to the other UK countries and was managed in a similar coordinated way, with all key stakeholders working closely to ensure optimal use of the allocated stock to support patient care in a fair and transparent manner.

4.1.3 Managing shortages in primary care

In primary care, the DHSC shares information out about medicines shortages and, where relevant, the management of individual shortages via email cascades to defined distribution groups. Community pharmacists and primary care pharmacists should receive all national medicine supply notifications and patient safety alerts and act on any specific guidance they contain. However, feedback received from engagement suggests that pharmacists do not always receive these notifications.

Where there is a severe medicines shortage, a serious shortage protocol (SSP) may be issued[138] (see Box 8). Once issued community pharmacists can supply an alternative product in line with the protocol.

BOX 8
Serious Shortage Protocols

Community pharmacists can supply prescription only medicines that are affected by shortages through a Serious Shortage Protocol (SSP), rather than what was originally specified on the prescription[140].

SSPs were brought about through changes made in 2019 to the Human Medicines Regulations 2012 and subsequent modifications to the NHS regulations in Wales[139] England[140] Scotland[141] and Northern Ireland[142].

When the Government deems that there is, or may be, a serious shortage of a medicine or appliance then they may decide to issue an SSP.

When issued an SSP will specify an alternative product or quantity that may be supplied by the community pharmacy and the dates for which the SSP is valid. This may be an alternative strength or formulation of a medicines in shortage or could be a generic or therapeutic alternative of the medicines.

Pharmacists must gain patient consent to make the change and must exercise their professional skill and judgment to be satisfied that the alternative product or quantity is reasonable and appropriate for the patient.

Pharmacists must endorse the prescriptions correctly and input the correct information to ensure that the change is accurately recorded to ensure accurate payment for the medicines supplied.

SSPs are a potential way to help pharmacies to manage any serious shortages of medicines that may occur, without needing to refer patients back to prescribers.

If a community pharmacy is unable to obtain a medicine, the community pharmacy team may try to facilitate patient access in various ways, such as contacting medicines suppliers directly for an update and to check how supplies can be obtained. They may check whether other local pharmacies have stock of the product, although there are no formal mechanisms to do this. If stock is available at another pharmacy, they may arrange for the patient to collect the stock from that pharmacy or get the stock transferred if possible (generally at their own expense). If these approaches don't work, then pharmacists liaise with prescribers about alternative brands, strengths, formulations and medicines that are available and may be clinically appropriate for the patient. This often requires a new prescription to be sent to the pharmacy and creates considerable work for the pharmacy team and the prescriber (see Chapter 2).

4.2 What more can be done?

This section highlights additional measures that could be taken to strengthen the management of medicines shortages. These measures were identified during the development of this report from the rapid scoping review, through discussions with advisory group members and wider stakeholder engagement (see How we worked) and are split into six sections that cover systems and processes from the national to the local level.

- **4.2.1** Do things once nationally where possible
- **4.2.2** More local collaboration across sectors
- **4.2.3** Put systems in place between general practice and community pharmacy
- **4.2.4** Enable community pharmacists to make substitutions
- **4.2.5** Improve communication with patients, patient groups, the public and the media
- **4.2.6** Raise awareness about shortages with all healthcare professionals

4.2.1 Do things once nationally where possible

As highlighted in section 2.1.1, where there is a national medicine shortage but national guidance on how it should be managed does not appear fast enough, the duplication of effort across the NHS is considerable[138]. In the absence of national guidance, hospital and primary care clinical and pharmacy teams develop their own guidance and strategies to manage the shortage in their local healthcare environment.

Understandably, the development of national guidance requires due consideration and significant quality assurance, which takes time.

However, the volume and scope of shortages the UK is now experiencing suggests that there is a need to review the timeliness and resourcing of national systems.

The need for rapid national guidance is particularly important for life-critical medicines for which there is no alternative for patients, as was the case with the alteplase shortage in secondary care (see Case Study 8 – Managing a national shortage of a critical care medicine – alteplase). More recently, the shortage of pancreatic enzyme replacement therapy (see Box 11) has highlighted that when, despite all mitigations, patients are unable to obtain life-critical medicines, rapid national guidance is needed that can be quickly implemented by teams on the ground.

The DHSC/NHS Medicines Supply Tool (see Box 7) provides a single accessible source of information on medicines shortages for the NHS and can be used across the UK. It also provides clinical guidance agreed nationally for managing shortages to support pharmacy teams and clinicians with their planning. This resource is widely used by pharmacy teams in secondary care and by primary care pharmacy teams, although it is currently less utilised by community pharmacists (see Case Study 10) and prescribers. The utility of the tool has been limited by the speed at which shortages and the guidance to manage them appears and the ease at which it can be accessed.

"Because the SPS [NHS] medicines supply tool runs a couple of weeks behind, we maintain our own spreadsheet on shortages. We have already developed clinical plans by the time the DHSC guidance arrives."

Chief Pharmacist

As the 'single source of truth' on shortages, the use of the DHSC/NHS Medicines Supply Tool could be developed and promoted to encourage its use across the NHS. The potential to increase its utility could be explored as part of any national review. This might include digital updates when there are changes to shortages or when medicines are no longer in shortage, and the potential to link the data contained within the tool to general practice systems to provide prescribers with information on shortages and alternatives in real time (see section 4.2.3). Ease of accessibility could be reviewed and an app-based format considered to support busy practitioners. It could also be used to help distinguish between local supply disruptions and national long-term shortages, with functionality enabled to provide proactive alerts to healthcare teams.

4.2.2 More local collaboration across sectors

There is an appetite in local health geographies (integrated care systems/health boards) to look for solutions to medicines shortages that involves collaboration across sectors.

Sharing information across sectors about shortages that have an impact in hospitals and primary care and collaborating to identify where stocks of medicines are located across a geographic area is one way that organisations can work together. In addition, further development of the DHSC/NHS Medicines Supply Tool (see Box 7) would enable reliable information about shortages to be shared as rapidly as possible to all sectors.

In England, the NHS Specialist Pharmacy Service (SPS) regional network of procurement specialists currently support trusts in its region with procurement and medicines supply issues. National Procurement Scotland, NHS Wales Shared Services Partnership and the Northern Ireland Regional Pharmaceutical Procurement Service support their hospitals with procurement issues. Extending these services to provide more cross-sector support could be considered. Linking community pharmacy leads in local health geographies with hospital teams or regional procurement leads to share information is one way of facilitating greater collaboration.

Regulations and commercial models around the supply of medicines, in particular wholesale dealer regulations, can make the sharing of medicines across sectors (and within sectors) complex. There may, however, be some medicines and some situations where collaboration is possible in the best interests of patients or a work around that enables patients to access medicines can be developed. We heard of examples from within systems where secondary care trusts had worked with community pharmacies in primary care to

provide information and access to medicines that are in shortage. These examples could be developed and shared more widely and/or regulations changed to facilitate this.

We heard that for cross-sector, high-impact national medicines shortages, local health systems (integrated care systems/health boards) are currently being reactive in their responses rather than being proactive in their readiness to address supply constraints. Local continuity plans should be developed to manage high-impact national medicines shortages that support the equitable distribution of medicines to patients. This should include provision to consolidate available stock into designated locations across the local health system if necessary (see Case Study 9).

CASE STUDY 9

Reserve pharmacy model for critical national medicines shortages – NHS Dorset ICB

Dorset ICB has in place an assessment tool for the impact of medicines shortages across its population, based on the DHSC medicines shortage impact tiers. For critical shortages, a local escalation pathway is in place and the ICB develops an appropriate system response. This includes the use of a reserve pharmacy model that enables equitable access for patients across Dorset for medicines in national shortage that have been escalated to this pathway.

For the recent pancreatic enzyme replacement therapy (PERT) shortages expected to last until 2026 this has involved using the reserve pharmacy model initially in two outpatient hospital pharmacies. Patients unable to obtain a supply of PERT from their local community pharmacy can access a supply at one of the hospital pharmacies which are located at different sides of the county.

While initially based in hospitals, the reserve pharmacies will transition to four community pharmacies, two pharmacies supplying face-to-face and two providing remote supply to patients unable to travel. This will give patients in Dorset access to supplies of PERT over the period that the medicine is in shortage, after which the reserve pharmacy pathway will be stood down.

Patients will be contacted via email and text messages to alert them to the new pathway. The ICB pharmacy team has worked closely with hospital pharmacy teams and community pharmacies to enable the reserve pharmacy model to function effectively and ensure that any regulatory and operational barriers have been overcome.

While the ICB pathway is in place, a hospital with a wholesale dealers authorisation is importing PERT and supplying the reserve pharmacies. This arrangement will cease once the pathway is stepped down. The ICB is covering the transport costs of the PERT to the reserve pharmacies.

This model has the potential to be used for other life-critical medicines shortages as needed across the population of Dorset.

Such a system would require national or regional oversight to ensure patients in all localities benefit from these systems. Equally, the provision of mutual aid (see section 4.1.2) through hospitals could be further explored, identifying opportunities to make the process less burdensome and the potential to allow for small transfers of stock to community pharmacies considered in times of critical shortage. While the operational, logistical and regulatory complexities need further consideration, these options may benefit from greater exploration. For example, the supply of aseptic products prepared under a section 10 exemption can be used only within a single hospital trust in England[143]. There may be scope to improve the resilience of aseptic product supply within a local system by allowing the ICB to be the designated authority rather than the hospital trust. This would better support mutual aid from one trust to another in a local system in times of need.

4.2.3 Put systems in place between general practice and community pharmacy

In primary care, proactive liaison between primary care pharmacists working at a local system level and/or in general practice, and local community pharmacies about the availability of medicines is needed to avoid patients being prescribed medicines which are unavailable. Active collaboration will help to avoid patients

being bounced between general practice and community pharmacies.

Community pharmacists, primary care pharmacy teams and GP practices are establishing local communication processes to facilitate the prompt resolution of issues. For example, WhatsApp groups of local pharmacies provide a practical way to find medicines for patients (see Case Study 10) and IT systems are being used to enable more efficient communication between GPs and community pharmacists (see Box 9).

BOX 9
Speeding Up Communication about Medicines Shortages

Community pharmacies and GP practices are streamlining their digital communication by using software solutions[144] that enable direct, digital, two-way communication between community pharmacists and GPs to resolve medicines supply issues more rapidly. Community pharmacies can communicate, for example, what items are out of stock, what alternative is in stock (where appropriate) and how long the DHSC/NHS Medicines Supply Tool (see Box 7) states the item is out of stock for, with the benefit of a full audit trail of all communication. This rapid, digital communication can avoid patients having to go back to GP surgeries and community pharmacists having to make multiple phone calls.

Examples of other local primary care solutions developed to better manage shortages and save time for healthcare professionals and patients are highlighted in Box 10.

BOX 10
Examples of local solutions to help manage shortages

- Community pharmacists asking patients to go back to general practice because they cannot supply a medicine, letting prescribers know (where appropriate) what they are able to supply as an alternative (via a form). This avoids the prescriber choosing an alternative that is also in shortage
- Practice receptionists being trained about initial advice to give to patients unable to get a supply of medicines
- Patients prescribed a medicine in shortage not having their prescription sent to a particular pharmacy but being given a code, so that only when the pharmacy confirms that they have a supply is the prescription downloaded from the NHS spine (England and Wales). This avoids delays for patients having to have their prescription transferred
- A community health trust using the flexibility of having nurse prescribers to change prescriptions quickly for patients

The RPS has published a guide to managing medicines shortages in community pharmacy that gives practical tips for community pharmacy teams[145].

Electronic prescribing systems can be used to alert prescribers that a medicine is in shortage and avoid patients being given a prescription that cannot be supplied. We heard examples of technology solutions that already exist that are embedded into prescribing systems that inform prescribers of shortages at the point of prescribing. These help to guide prescribers in their decisions and allow the rapid access to information to switch large groups of patients if required.

However, putting things on and off the alert software also means the system is always running on a lag. A nationally developed and integrated data feed to support prescribing systems could be a powerful tool to manage the workload created by shortages on the system. The ability to link the information from the DHSC/NHS Medicines Supply Tool (see Box 7) directly into GP systems as a single source of information on shortages could be invested in and explored[135].

CASE STUDY 10

Local collaboration to understand and manage shortages – Black Country ICB

In the Black Country, all four localities have set up WhatsApp groups that include community and practice-based pharmacists. The WhatsApp groups are being used to identify where stock is available within each locality. If a patient is not willing to go, or cannot go, to wherever there is stock available for them, the pharmacies arrange for a delivery driver to collect the stock from one pharmacy to bring it to another for the patient. The cost of delivery services is not funded and must be absorbed by the community pharmacy; this may be unsustainable in the longer term. When medicines are in shortage, the practice-based pharmacists use the group to find out which pharmacy has the stock their patient requires, and then gives the patient the choice to go to that pharmacy.

The WhatsApp groups have been used to understand in more depth how medicines shortages are being managed locally and the impact on pharmacy teams, GP workload and patients.

When asked, less than 5% of community pharmacists across the WhatsApp group were aware of, had signed up for, or knew about the DHSC/NHS Medicines Supply Tool on the Specialist Pharmacy Service website (*sps.nhs.uk*). When the benefits and features of the medicines supply tool were explained, nine out of ten pharmacists said they would sign up to join. This led to training events across the ICB to raise the profile of the medicines supply tool.

A lack of reporting by community pharmacies to Community Pharmacy England (on their shortages form) was also found, with pharmacies reporting that it was burdensome to complete and that they did not feel that reporting made any difference.

Community pharmacists and GP practices were asked about the impact that medicines shortages were having on their workload. Community pharmacies were asked to log, for one week, the time spent sourcing stock or alternatives; they reported spending 1–2 hours a day on phone calls to patients, to GP practices, to wholesalers, on a local WhatsApp group and time spent organising and collecting stock. When GP practices were asked to do the same task, they also reported spending between 1–2 hours a day changing prescriptions, looking up what the alternative medicines are, checking with the GP, checking if any pharmacy has the stock, reassuring patients, etc.

Occasionally pharmacists reported that pressure on time, resources and capacity to locate a supply of a particular medicine meant that once they had exhausted these options, they had to return the prescription to the patient.

Pharmacists also reported the use of cascade purchasing systems which only purchase a medicine if it is below the drug tariff price. In these cases, the patient is advised the medicine is out of stock or can't be obtained and a change made to the prescription via the GP, or another pharmacy found.

The challenge of the 'panic buy' was highlighted. When a medicine is in shortage or expected to be in shortage, pharmacists will stock alternatives to protect their patients; for example, atorvastatin 40 mg tablets go out of stock, which then results in the 10 mg and 20 mg strength going out of stock.

When asked about patient impact, several pharmacists commented how confused patients were when their medicines kept changing, and the anxiety they felt due to being told something was out of stock. Some patients reported going without taking their medicines for several days.

This case study describes what the ICB observed over several weeks as local coping mechanisms from pharmacies and practices for the current stock shortages issue, it is not endorsing whether this process is the correct process or not. Measures need to be taken to reduce the number of stock shortages so that pharmacies and general practices are not being impacted by this volume of increased workload.

4.2.4 Enable community pharmacists to make substitutions

When a medicine is out of stock in a community pharmacy, pharmacists can substitute alternative formulations, strengths or quantities of a medicine only if an SPP (see Box 8) is in place. Without an SSP in place, patients need a new prescription even for minor changes. This causes delay and increased administrative burden for patients who often have to return to the prescriber to access the new prescription, and impacts on the workload of the general practice.

It has long been proposed that regulations be amended to allow community pharmacists to make minor amendments to prescriptions, which is routine for pharmacists in secondary care. The current RPS medicines shortages policy proposes that changes to legislation allow for pharmacists to use their professional and clinical judgement (in consultation with the patient) to make minor amendments to prescriptions where medicines are in shortage[146]. This move is supported by patient advocates, most recently Healthwatch in its research on what people want from pharmacy[79].

The case for legislative changes to allow minor amendments has also been made by the Health Select Committee report into pharmacy[16] which recommended that *"regulations are updated within three months to allow pharmacists in community settings to make dose and formulation substitutions for out-of-stock items, subject to the safeguards set out in the Royal Pharmaceutical Society's Medicines Shortage Policy"*. On generic substitution, the committee, *"recommend the introduction of generic substitution, which should follow a government consultation focusing on how best this policy could be implemented to ensure patient safety and avoid the potential for unintended impacts on the supply chain."*

The reforms to the initial education and training of pharmacists mean that from 2026 all newly qualified pharmacists will have the ability to prescribe. This, when coupled with over a quarter of existing pharmacists qualified to prescribe, means that it will quickly become more common for a pharmacy to operate with a prescriber than without. Organisations, professional bodies and regulators should consider where pharmacist prescribers can use their prescribing qualification to help manage the impact of medicines shortages on patients, and develop pathways to enable this role. Patients also need to understand the skills of pharmacists to be confident that they are receiving the best care and the right prescription.

4.2.5 Improve communication with patients, patient groups, the public and the media

The current systems mean that while medicines shortages have always occurred, most remained under the public radar, managed in the background by national teams, local pharmacy teams and prescribers. However, as medicines shortages have increased, so have the number of patients impacted and the level of public awareness and concern about the potential for shortages in general. This is reflected by the increase in media stories and questions in parliament about shortages.

Against this backdrop, the need for effective, consistent communication with patients, the public and the media about medicines shortages that is appropriately staged to avoid inadvertently creating demand surges or panic should be a priority.

Communicating with patients about individual shortages

Best practice principles on gathering information to inform communication and information sharing with patients about medicines shortages are available[147]. The principles emphasise the importance of having correct and consistent information on shortages to share with patients.

As highlighted earlier, not all medicines shortages are the same, it is particularly important to know whether the shortage is due to technical long-term reasons, such as a national or global supply issue, or if it comes from other factors (e.g., a temporary wholesaler delivery delay, the need for a pharmacy to order more stock, commercial constraints or misinformation in the media). Crucially, understanding when supply will return to normal is key along with advice for patients about what to do in the meantime.

Using the DHSC/NHS Medicines Supply Tool, accessible by all healthcare professionals in the UK (*sps.nhs.uk*), will provide a consistent source of

information and advice to use to communicate with their patients. In addition, there are national sources of information aimed at patients that can be used to help communicate about medicines shortages in general to aid communication with patients and present clear and consistent messages[148].

Patient groups know the specific concerns of the populations they represent. They understand the people they advocate for and what level of transparency and knowledge they would want on medicines shortages. Working with patient groups on communication for patients will raise awareness of shortages in general and the systems that the UK already has in place to mitigate and manage them. In addition, where there is a specific medicine shortage, patient groups can help to ensure accurate and up-to-date information is communicated to patients about steps they can take when one of their medicines is in shortage. In addition, patient groups may have helplines that can provide additional support directly to patients (see Box 11).

BOX 11

Patient group Support for Medicines Shortages: Pancreatic Enzyme Replacement Therapy

The pancreas normally makes enzymes that help to digest food. Some people cannot make these enzymes and so need to take PERT to replace the enzymes that the pancreas would normally make. Without PERT, patients will begin to experience symptoms which can impact on their ability to live normal lives including weight loss and malnutrition. It can also impact some patients' ability to access other treatments for their condition or compromise the efficiency of other crucial treatments. Supplies of PERT have been in shortage since 2023 and are not expected to return to normal levels until at least 2026. There is no clinical alternative for PERT and so the current shortages are causing significant stress and worry for those affected.

Patients affected are those with cystic fibrosis, neuroendocrine cancer, pancreatic cancer, and pancreatitis. Pancreatic Cancer UK[149] and The Cystic Fibrosis Trust[150] are supporting the patients that they represent with regular updates about the situation, advice on what to do if they are affected by supply problems and support for people experiencing symptoms. Both organisations are liaising with clinicians, manufacturers of PERT and the DHSC to ensure the most up-to-date guidance and information is available to patients.

In addition, The Cystic Fibrosis Trust has a helpline for patients and a Creon hub on its website. Recognising the lengths people have to go to obtain supplies, sometimes having to travel large distances to hospitals and alternative pharmacies. There is also financial support for people on low incomes unable to afford to travel. The Cystic Fibrosis Trust is also asking patients to share the real-time experiences and impact of the shortage through a survey. Pancreatic Cancer UK have help pages on their website, along with a free support line staffed by specialist nurses to provide support for people experiencing symptoms as a result of not having access to PERT (they do not provide advice on accessing supplies)

For people with pancreatitis and neuroendocrine cancer, Guts UK[151] and Neuroendocrine Cancer UK[152] are also proving support[153].

When medicines are in acute shortage, the benefit of a 'medicines stock checker' for patients to enable them to see which pharmacies have stock of their medicine has been highlighted by patients, healthcare professionals and other stakeholders[154]. One national pharmacy chain has already introduced a prescription stock checker that allows patients to check by postcode which of its branches has stock of a given medicine[155]. Other countries, such as Sweden, have variations of these systems[156]. While this works for a large, multiple-branch pharmacy, the challenges of introducing such a system across the diverse UK community pharmacy network are considerable. Community pharmacies are independent contractors with a variety of different IT systems that would need to interface with any digital solution. Stock availability can change rapidly, in particular with lean stock holding and frequent deliveries from multiple wholesalers. For a community pharmacy to maintain up-to-date information, they will require time and resources. For the 97% of medicines without supply issues investing in such a system would have limited benefit. The appetite for sharing potentially commercially sensitive information and

the risk of exacerbating health inequalities through digital exclusion would also need consideration. If there is a desire to explore such a system, the focus could be on those medicines in national shortage and allowing community pharmacies to choose to share their stock levels through a trusted platform, such as the NHS App, being one approach.

Communicating with the public in general

The speed at which information or misinformation spreads about medicines has increased dramatically in recent years, driven by digital media and social media in particular. This not only drives patient demand for medicines, as in the case of hormone replacement therapy and GLP-1s, but can also spread concern about medicines shortages, whether actual or unfounded. National pharmacy and healthcare organisations managing shortages need to be alert to information vacuums about the availability of medicines where rumours and false narratives can quickly take hold. More could be done nationally through collaboration between these organisations to help dispel the false narratives and myths that emerge.

Accurate and consistent communication with the public about medicines shortages and their causes in general, as well as updated communication about individual medicines shortages when they occur is needed[16]. Everyone in the supply chain, including patients and the public, have a responsibility. It is important to stress the actions to avoid that make shortages worse, such as panic buying and stockpiling, as well as raising awareness about the potential risks in sourcing medicines from unregulated online sources which may be unsafe or illegal.

4.2.6 Raise awareness about shortages with all healthcare professionals

The rise in the number of medicines shortages is impacting on the work of all healthcare professionals. However, there is little awareness outside of pharmacy teams about the reasons for shortages and the measures that everyone needs to take to manage them. This includes the actions that healthcare professionals need to avoid, such as uncoordinated prescribing of alternatives, or encouraging their patients to hoard medicines, as well as actions that help manage the shortage, such as prescribing smaller quantities or using alternative formulations until supply returns to normal.

Pharmacy teams need to communicate with their colleagues, including private prescribers, about shortages, including highlighting some of the common misconceptions about why they occur to enable all healthcare professionals to communicate more consistently with patients. This includes reminding prescribers in private practice of their ethical responsibilities, particularly in relation to the off-label prescribing of medicines that are in shortage.

Education and training resources, access to the DHSC/NHS Medicines Supply Tool (*sps.nhs.uk*) should be available and promoted to all prescribers. This should include raising awareness about how current reporting systems for medicines shortages work.

Encouraging appropriate and effective prescribing of medicines is another way to mitigate against shortages by avoiding over prescribing and deprescribing medicines where appropriate[157,158].

4.3 Summary of key points for managing shortages once they occur – with a focus on what more can be done

KEY POINT 4.1
National systems have, for the most part, mitigated and managed the majority of potential and actual medicines shortages in the UK with minimal impact on patients. However, the current volume and scope of medicines shortages are in danger of negating the efforts of the national teams and supply chain partners who focus on tackling these shortages early on.

KEY POINT 4.2
In light of the increases in high impact medicines shortages, which are being seen in many developed economies, a review of the UK national systems for mitigating and managing them, including their resourcing, could identify opportunities for improvement or areas requiring additional investment.

KEY POINT 4.3

More timely guidance from national teams to support the management of national, long-term or critical medicines shortages would avoid the duplication of effort happening currently across the local NHS and increase the consistency of support patients are receiving. Recognising that this also requires more timely reporting by marketing authorisation holders.

KEY POINT 4.4

Rapid national guidance is particularly important for life critical medicines for which there is no alternative. While the local NHS has responsibility for implementing national guidance, there is a case for more national oversight of local implementation to ensure all patients have safe and equitable access to these medicines.

KEY POINT 4.5

At the same time, the local NHS needs to adapt to the increase in volume and scope of medicines shortages through review and development of their processes. To ensure for example that local teams are aware of when national guidance is issued, have defined communication channels, and systems and processes to inform prescribers and patients when supplies return to normal.

KEY POINT 4.6

Unless appropriately managed, shortages of medicines have the potential to exacerbate health inequalities. Teams managing shortages need to recognise and address this in their management strategies.

KEY POINT 4.7

Collaboration across sectors can potentially be used to help manage medicines shortages. While regulations and commercial barriers can limit collaboration, more work could be done to identify how sectors could work together to support patients. For example, in England NHS specialist pharmacy services have a regional network of procurement specialists that support hospitals in their regions with procurement and medicines supply issues, developing and funding a service to provide more cross sector support should be considered.

KEY POINT 4.8

Community pharmacy and general practice need to urgently develop patient-centred ways of working together to communicate about shortages and find alternatives for their patients. This is already happening locally, however regional facilitation with good practice shared widely would be of benefit.

KEY POINT 4.9

Changing legislation to allow community pharmacists to make minor changes to prescriptions, in the way that their colleagues in hospital pharmacy already do, would help patients and alleviate some of the pressure on primary care services that is caused by medicines shortages.

KEY POINT 4.10

Embracing the opportunities presented by pharmacists qualifying as prescribers will also help to reduce the impact of medicines shortage on patients.

KEY POINT 4.11

The DHSC/NHS Medicines Supply Tool already provides the NHS with guidance about medicines shortages. Use of the tool, available on the SPS website (*sps.nhs.uk*), has been limited by the speed at which it is updated, lack of awareness of how it can be used (in particular in community pharmacy) and the ease with which healthcare professionals can access it. The tool could be promoted more widely across all sectors of pharmacy and to other prescribers.

KEY POINT 4.12

The functionality of the DHSC/NHS Medicines Supply Tool could be reviewed and potentially further developed so that the NHS can make better use of it as a single source of accessible, consistent, accurate and rapidly updated guidance for healthcare teams. This might include whether it could be integrated into GP prescribing systems, used to distinguish between local supply disruptions and national long-term shortages, and functionality enabled to provide proactive alerts to healthcare teams and an app-based format.

KEY POINT 4.13

Consistent and accurate communication with patients, patient groups, the public and the media about medicines shortages and their causes is increasingly important to avoid unnecessary stress and anxiety for patients.

KEY POINT 4.14

Information cascades to patient groups. The role they play in disseminating information to patients and supporting patients experiencing acute national shortages could be further developed.

KEY POINT 4.15

Pharmacists, pharmacy technicians and the wider pharmacy team need more education and training about the causes of shortages, and how to manage them. This should include how to discuss shortages with patients and the wider public including what to do if they are unable to obtain a supply and actions to avoid that could either make shortages worse, such as, stockpiling, or that could be unsafe, such as buying medicines online from unregulated websites.

KEY POINT 4.16

There is an important distinction between an actual national shortage of a medicine and a temporary supply chain disruption; both of which patients can experience as a shortage. Healthcare professionals should be informed and have the skills to make the distinction between the two when communicating with patients.

Chapter 5. Conclusions and Recommendations

This report has reviewed the causes of medicines shortages with a focus on why the UK, like many developed nations, is seeing an increase in the number and scope of these shortages. It has identified global factors linked to the medicines market and disruptions in medicines supply chains, as well as UK-specific factors.

The report looked at how the UK currently mitigates and manages medicines shortages. The UK already has well established systems to mitigate medicines shortages, coordinated by the DHSC medicines supply team in collaboration with manufacturers, wholesalers, the MHRA and NHS supply teams in each of the devolved nations. There are well established systems to provide guidance to the local NHS about how to manage medicines shortages and minimise the impact on patients, including clinical guidance where necessary. These collaborative systems, and the concerted effort of all those who contribute to them, prevent many potential shortages impacting on patients and minimise the impact of those that do.

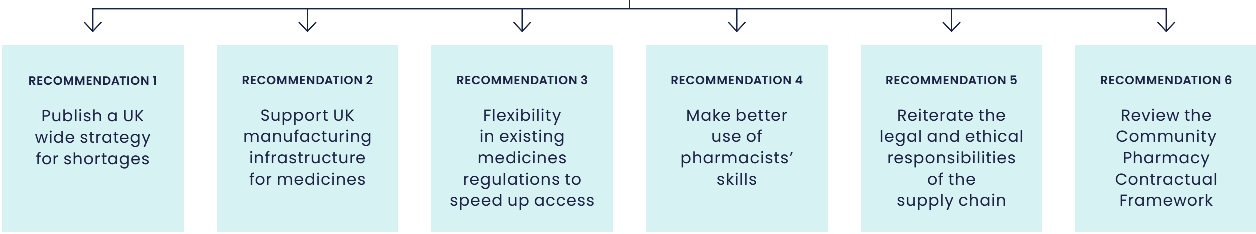
However, the report also looked at the impact that medicines shortages are having on patients and healthcare professionals. Despite the fact that less than 3% of medicines in the UK are in shortage, it is clear that the increase in number and scope of shortages the UK is now experiencing is putting considerable pressure on the front line of care at a level not previously seen. Despite all the efforts of healthcare teams, some patients are going without medicines and chasing medicines from pharmacy to pharmacy daily. We heard from patients, charities and professionals about the devastating impact that these shortages can have on people's lives.

More needs to be done to further strengthen and develop the UK's systems to mitigate and manage shortages to respond to the new levels of supply disruption. At the same time, the wider issue of medicines supply security needs to be addressed, considering the changes to global supply chains, global policy on resilience building measures and the UK internal medicines market. It is against this backdrop that this report makes recommendations for collaborative action to help reduce the impact of medicines shortages on patients in five broad areas: UK national policy; predicting, reporting and responding to shortages; information flows; local systems; and education, training and research.

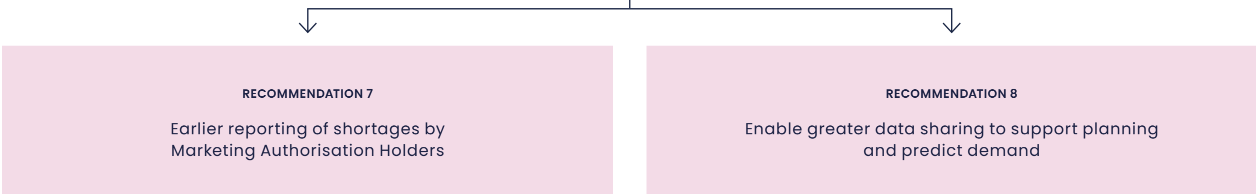
While the focus of this report will inevitably be on the recommendations for collaborative action, the report contains additional insights and learnings that will be of immediate use to pharmacy and healthcare teams currently managing medicines shortages.

The RPS, in collaboration with partners, will review the implementation of the recommendations in this report in twelve months to establish the extent of progress made.

UK NATIONAL POLICY

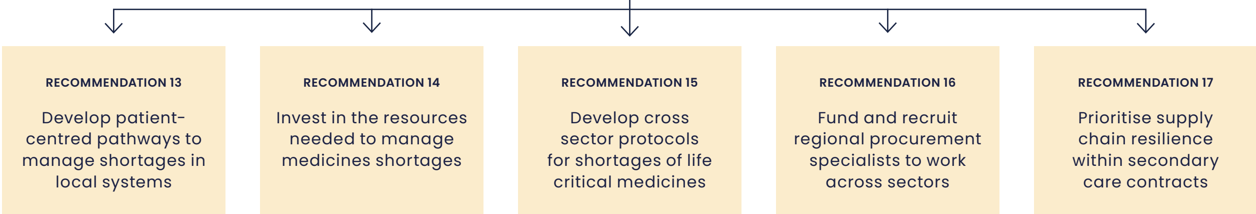


PREDICTING, REPORTING AND RESPONDING TO SHORTAGES



INFORMATION FLOWS

LOCAL SYSTEMS



EDUCATION, TRAINING AND RESEARCH

RECOMMENDATIONS

UK NATIONAL POLICY

Recommendation 1

Publish a UK-wide strategy for shortages

The UK government should develop a cohesive cross-government and NHS strategy to improve medicines supply chain resilience and medicines security in the context of changing pharmaceutical market dynamics and the ongoing increases in medicines shortages globally. The strategy should incorporate current national policy, ongoing work and existing measures, and create greater alignment in managing shortages across primary and secondary care. See key points in Chapter 1 and sections 2.1.2, 3.1.1 and 4.1.1.

Recommendation 2

Support UK manufacturing infrastructure for medicines

The Government should boost UK medicines manufacturing infrastructure, in both commercial and NHS manufacturing units – particularly generic manufacturing, which accounts for 80% of medicines prescribed in the NHS. UK manufacturing infrastructure offers the potential for a more rapid response from manufacturers to help mitigate acute national medicines shortages. See sections 3.1.1, 3.2.6 and key points 3.4 and 3.5.

Recommendation 3

Flexibility in existing medicines regulations to speed up access

Building on the learning applied during the COVID-19 pandemic, existing and potential regulatory flexibilities should be explored with the MHRA. Recognising that nothing should be done to undermine the purpose of regulation, timely opportunities to flexibly use existing regulations in acute supply challenges associated with national shortages should be identified. For example, enabling medicines manufacturers to reactivate dormant market authorisations more rapidly so they could potentially supply medicines in acute shortage. See sections 1.1.3, 3.1.3, Box 6 and key point 3.6.

Recommendation 4

Make better use of pharmacists' skills

The Government should enact legislation to enable community pharmacists to make minor amendments to prescriptions in line with existing hospital practice, RPS policy and the recommendation of the Health and Social Care Select Committee report into pharmacy. Organisations, professional bodies and regulators should identify where pharmacist prescribers can use their prescribing qualification to help manage the impact of medicines shortages on patients and develop pathways to enable this role. See section 4.2.4 and key points 4.9 and 4.10.

Recommendation 5

Reiterate the legal and ethical responsibilities of the supply chain

Organisations and professionals in all parts of the supply chain, from manufacturers to wholesalers, pharmacists and prescribers, should understand their responsibilities to patients to enable appropriate, equitable and ethical access to medicines. The 2013 guidance published by the Department of Health Supply Chain Forum – Best practice for ensuring the efficient supply and distribution of medicines across the supply chain (2013) – should be refreshed (or an equivalent developed) and re-promoted to reinforce the behaviours expected in all parts of the supply chain. See sections 1.2.5, 3.1.4 and key point 1.7.

Recommendation 6

Review the community pharmacy contractual framework

The community pharmacy contract in each of the UK nations should be reviewed to ensure that, while acknowledging a pharmacists professional and contractual responsibilities, it minimises the risk of individual contractors incurring a potential loss on the purchase of medicines and supports a stable supply of medicines to patients. See sections 1.1.6, 3.2.7 and key point 3.13.

PREDICTING, REPORTING AND RESPONDING TO SHORTAGES

Recommendation 7

Earlier reporting of shortages by Marketing Authorisation Holders

Timely and accurate information on supply disruptions and shortages should be provided by medicines manufacturers. Marketing Authorisation Holders should work with DHSC to find ways to improve the reporting of medicines shortages and the provision of ongoing information to help mitigate shortages, with a focus on early and consistent information sharing. Developing a more meaningful performance management approach to reporting that promotes good practice, distinguishes between planned and unexpected shortages and actively penalises repeated poor performance would facilitate this. See sections 3.1.2, 3.2.1 and key point 3.2.

Recommendation 8

Enable greater data sharing to support planning and predict demand

The NHS and manufacturers/wholesalers should proactively collaborate to share data, for example, NHS data that enable manufacturers/wholesalers to better predict demand for their products and manufacturer/wholesaler supply chain data that enable the NHS/DHSC to proactively manage the medicines supply chain to minimise disruption and increase resilience of supply. See sections 3.2.1, 3.2.3, 3.2.4, Case Study 4 and key points 3.11 and 3.12.

INFORMATION FLOWS

Recommendation 9

Expand and develop information cascades

Information cascades about medicines shortages from DHSC and relevant NHS national medicines supply teams to the wider healthcare system should be reviewed to ensure that they are reaching the right people at the right time. All organisations that cascade or need to act upon information about national shortages should review and develop systems to ensure that information is cascaded to and accessed by those that need it. Equally, healthcare professionals should be aware of their responsibility to access this information and act promptly. See section 2.1.1 and key point 2.4, sections 4.1.1, 4.2.1 and key point 4.5.

Recommendation 10

Further Involve patient groups to support information sharing

Patient groups should be a fundamental part of information cascades to facilitate the appropriate sharing of consistent and accurate information to patients. This will enable patient groups to provide support for patients experiencing acute national shortages of their medicines. See sections 2.2.3, 4.2.5, Box 11 and key point 4.14.

Recommendation 11

Fund, promote and develop the DHSC/NHS Medicines Supply Tool

The DHSC/NHS medicines supply tool hosted on the SPS website (sps.nhs.uk). should be the single source of accessible, consistent, accurate and rapidly updated information about medicines shortages for healthcare teams across the UK. As well as promoting the current tool more widely to healthcare teams, its utility should be increased. There should be funding for the integration of the tool into prescribing systems to alert prescribers to shortages and enable alternatives to be prescribed in real time to provide proactive updates, for example, when medicines are no longer in shortage, and to developing an app-based format to enable easier access to the information. See section 4.2.1, Box 7, key point 4.11 and 4.12.

Recommendation 12

Improve systems that provide timely information at the point of dispensing

Wholesaler and community pharmacy IT systems should be developed to provide resupply dates for medicines out of stock to enable more meaningful communication with patients and help pharmacists to more rapidly distinguish short-term supply disruptions from national shortages. This is only possible with the provision of accurate and timely information from medicines manufacturers. See section 3.2.8 and key point 3.16.

LOCAL SYSTEMS

Recommendation 13

Develop patient-centred pathways to manage shortages in local systems

Continuity planning in local systems should account for the resources required for healthcare teams to manage medicines shortages. Local systems should have protocols for the management of a medicines shortage that works across a locality, particularly between GP surgeries and community pharmacies, to ensure that they continue to minimise the impact of shortages on patients and do not exacerbate health inequalities. See sections 4.2.3 and key points 2.8, 4.5, 4.6 and 4.8.

Recommendation 14

Invest in the resources needed to manage medicines shortages

NHS organisations should review whether they have sufficient resources in pharmacy teams to mitigate and manage medicines shortages. Any investment required needs to be weighed against the opportunity costs of healthcare teams managing a shortage and the impact on patients' health outcomes and quality of life, not just the cost of alternative medicines. See sections 2.1.3, 2.1.6 and key point 2.7.

Recommendation 15

Develop cross-sector protocols for shortages of life-critical medicines

Cross-sector emergency protocols for life-critical medicines where patients have no alternative treatment should be developed. This will require collaborative working across local systems and the use of regulatory flexibility to allow medicines to flow between primary and secondary care. There should be national/regional oversight to ensure this happens. See section 4.2.2, Case Study 9 and key point 4.4.

Recommendation 16

Fund and recruit regional procurement specialists to work across sectors

In England, NHS specialist pharmacy services' regional network of procurement specialists should be funded to work with ICBs to facilitate the development of cross-sector approaches to acute medicines shortages. In Wales, Scotland and Northern Ireland, equivalent arrangement should be established. See section 4.2.2, Case Study 9 and key point 4.7.

Recommendation 17

Prioritise supply chain resilience within secondary care contracts

Supply chain resilience measures and management of lead times should be further developed and incentivised in awarding secondary care and homecare contracts, which should be proactively managed with suppliers to minimise avoidable causes of supply disruptions. See sections 1.1.6, 1.2.3, 3.1.4 (the use of contracts), 3.2.5 and key points 3.7 and 3.8.

Recommendation 18

Educate healthcare professionals, patients and the public on shortages

Joint education programmes for healthcare professionals should be developed to support wider understanding of how UK systems operate end-to-end to mitigate and manage medicines shortages, and highlight common misconceptions about their causes and how to manage them. This will improve transparency and understanding across the supply chain and improve opportunities for shared education and training. All pharmacy teams and students should be trained in where to find accurate information about medicines shortages, and in how to have proactive, informed and supportive conversations with individual patients and the wider public regarding medicines shortages. See sections 4.2.5, 4.2.6, and key points 4.13, 4.15 and 4.16.

Recommendation 19

Understand the economic cost of shortages to healthcare organisations and systems

The research base on the costs of medicines shortages should be developed to inform resourcing decisions and underpin investment in resources and the implementation of quality improvement programmes. This should include not just the cost of alternative medicines but the wider costs to the healthcare systems and the clinical impact on patients in terms of their health outcomes and quality of life. See section 2.1.6 and key point 2.7.

Recommendation 20

Understand the impact of speculation and digital purchasing systems on the supply chain

Further work needs to be done to understand the extent to which speculation exists within wholesale and medicines brokering activities and the extent to which the use of automated purchasing platforms is disrupting demand prediction and purchasing patterns. These factors have the potential to confuse the issue of medicines shortages locally. See section 2.1.2 and key point 2.6, section 3.2.7 and key point 3.14.

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ROYAL PHARMACEUTICAL SOCIETY

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