

Research Briefing

1 May 2024

By Claire Duddy

# Medicines shortages



## Summary

- 1 Medicines shortages in the UK
- 2 UK Government response to medicines shortages
- 3 Calls for reform of medicines shortages management

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## Summary

Pharmacies in the UK dispense millions of prescription items each year. Since 2021 there have been reports of increasing supply problems affecting medicines. Recent media coverage has highlighted shortages of medicines used to treat diabetes, attention deficit hyperactivity disorder (ADHD) and epilepsy, as well as hormone replacement therapy (HRT) and others.

This briefing provides information on the causes and consequences of medicines shortages in the UK and internationally, and the UK Government's approach to address supply problems.

## Causes and consequences of medicines shortages

Supply chains for medicines are long and complex and [shortages can be caused by multiple factors](#). These include manufacturing or distribution problems and increased demand for medicines. Commentators have also drawn attention to [the effects of wider geopolitical factors](#), including the conflict in Ukraine, the Covid-19 pandemic and Brexit.

Pharmacists and patient organisations have drawn attention to [the impact of medicines shortages on patients](#), who may struggle to access medicines and sometimes have to switch to alternative drugs. Community Pharmacy England, which represents community pharmacies, has also reported that [medicines supply and pricing issues are “severe” financial pressures](#) on pharmacy staff and businesses.

## Government response to medicines shortages

The government has described medicines shortages as [“an ongoing issue that the Department \[of Health and Social Care\] has been managing for many years”](#).

The Department of Health and Social Care and NHS England have published [guidance on the management of medicines supply and shortages](#), which outlines the processes followed and options available to the government to address supply disruption. These include:

- issuing [serious shortage protocols](#), which enable pharmacists to provide specific alternatives to scarce medicines

- taking regulatory action to [approve new medicines or, in exceptional circumstances, extend medicine expiry dates](#)
- [restricting medicines exports](#)
- offering pharmacies [price concessions](#), to help pharmacies to cover the cost of NHS prescriptions.

## Potential reforms to manage medicines shortages

Organisations representing pharmacists have called for reforms to the systems used to manage medicines shortages. Community Pharmacy England has called for “[a strategic Government review of medicine supply and pricing](#)” that focuses on supply chain functioning.

Appeals for reform centre on calls for pharmacists to be able to [amend prescriptions to provide alternatives](#) to patients when medicines are out of stock, and on [changes to current medicines pricing systems](#).

## 1

## Medicines shortages in the UK

In the 2022 to 2023 financial year, 1.37 billion prescription items were dispensed in the community in England, Scotland and Wales, at a cost of £12.3 billion.<sup>1</sup> In Northern Ireland in 2023, 45.2 million items were dispensed, at a cost of £504 million.<sup>2</sup> Reports of supply problems affecting medicines have increased since 2021, and recent media coverage has highlighted the issue of medicines shortages.<sup>3</sup>

Under the [Health Service Products \(Provision and Disclosure of Information\) Regulations 2018](#), medicines manufacturers and suppliers are obliged to record and share information with the Department of Health and Social Care (DHSC) about the discontinuation of any medicine, or any anticipated shortages that will directly affect patients.<sup>4</sup>

In January 2024, the Pharmaceutical Journal reported a 67% increase in reports from pharmaceutical manufacturers about potential medicines shortages between 2021 and 2023.<sup>5</sup> Data obtained by the Pharmaceutical Journal through a freedom of information (FOI) request showed that the DHSC had received an average of 137 notifications each month in 2023.<sup>6</sup> Similar data obtained through FOI requests was published by the Nuffield Trust in April 2024.<sup>7</sup> This showed both increased rates of notifications about supply disruptions and an increase in the number of alerts issued to hospitals and general practitioners (GPs) about shortages likely to affect patient care.<sup>8</sup>

In November 2023, the British Generic Manufacturers Association (BGMA), a trade body representing generic medicine manufacturers, reported that medicines supply problems have reached record highs.<sup>9</sup> According to the

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<sup>1</sup> NHS Business Services Authority, [Prescription Cost Analysis – England – 2023-23](#), 8 June 2023; Public Health Scotland, [Dispenser payments and prescription cost analysis Financial year 2022 to 2023](#), 19 September 2023; Welsh Government, [Primary care prescriptions: April 2022 to March 2023](#), 22 November 2023

<sup>2</sup> HSC Business Services Organisation, [Prescription Cost Analysis – PCA 2023](#), 29 February 2024

<sup>3</sup> PQ 17245 [on: [Drugs](#)] 5 March 2024; “[Is YOUR prescription at risk of running out? As pharmacists warn of stocks running low, the definitive guide to the drugs affected](#)”, Daily Mail, 18 January 2024; “[The Guardian view on medicine shortages: a global issue for which Britain needs a plan](#)”, The Guardian, 21 January 2024

<sup>4</sup> [The Health Service Products \(Provision and Disclosure of Information\) Regulations 2018, pt 6](#)

<sup>5</sup> Carolyn Wickware, [Medicines shortages reported to government increase by almost 70% since 2021](#), Pharmaceutical Journal, 6 March 2024

<sup>6</sup> Carolyn Wickware, [Medicines shortages reported to government increase by almost 70% since 2021](#), Pharmaceutical Journal, 6 March 2024

<sup>7</sup> Mark Dayan and others, [The future for health after Brexit](#), 18 April 2024

<sup>8</sup> Mark Dayan and others, [The future for health after Brexit](#), 18 April 2024

<sup>9</sup> Jacqui Wise, [Record number of drugs hit by supply problems, trade body warns](#), British Medical Journal, Vol 383, 7 November 2023

BGMA, there was [a 100% increase in shortages of medicines](#) between January 2022 and January 2024. The BGMA publishes a monthly summary of numbers of supply issues affecting generic medicines in England on their [supply issues dashboard](#).<sup>10</sup>

Supply problems have affected a wide range of medicines, including hormone replacement therapy (HRT), antibiotics, medicines used to treat diabetes and attention deficit hyperactivity disorder (ADHD) and many others.

## 1.1

### What causes medicines shortages?

Medicines supply chains are long and complex, and both the manufacture and supply of medicines are rigorously regulated.<sup>11</sup> A recent report in the *Pharmaceutical Journal* explains that medicines shortages can have multiple causes. These include:

- manufacturing problems, including shortages of raw materials, issues with industrial capacity and flexibility, medicine recalls and product quality problems
- distribution or logistical problems, including capacity issues, international trade barriers and excessive exporting or deliberately withholding the supply of medicines (hoarding)
- discontinuation or withdrawal of medicines from the market
- increased demand for medicines and/or changing prescribing patterns, in response to changing guidance or health needs, especially where this is unanticipated. This may include the knock on effects of shortages of other medicines, leading to patients switching to other similar drugs
- changes in pricing and drug reimbursement arrangements for medicines.

<sup>12</sup>

The *Pharmaceutical Journal* also notes that wider geopolitical factors, including Brexit, the conflict in Ukraine, the Covid-19 pandemic and increased energy costs have affected medicines' manufacture and supply.<sup>13</sup>

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<sup>10</sup> Generic medicines are drugs for which patents have expired, allowing multiple manufacturers to produce and sell them. British Generic Medicines Association, [BGMA supply issues dashboard](#), January 2024

<sup>11</sup> Association of the British Pharmaceutical Industry, [Managing medicine shortages infographic](#), 3 April 2024; World Economic Forum, [Here's why some countries are experiencing medicine shortages – and what can be done to ensure supply](#), 20 February 2023

<sup>12</sup> Dawn Connelly, [Special report: the UK's medicines shortage crisis](#), *Pharmaceutical Journal*, 29 June 2023

<sup>13</sup> Dawn Connelly, [Special report: the UK's medicines shortage crisis](#), *Pharmaceutical Journal*, 29 June 2023



In April 2024, the Nuffield Trust published a research report that described global ‘fragilities’ in medicines supply chains. The report argues that Brexit has exacerbated the effects of medicines shortages in the UK, by lowering the value of sterling and introducing new regulatory and trade barriers to supply.<sup>14</sup> The government has noted that while some medicines suppliers have experienced delays at the UK border, these issues have been resolved and there is “no evidence of the EU Exit leading to sustained medicines shortages”.<sup>15</sup>

## Medicines pricing

Medicines supply problems can be caused by volatility in medicines pricing, which might come from changes in the costs of materials, manufacturing and logistics. It can also be affected by currency fluctuations (which change the prices of imports and exports) and other market forces, such as the low price of generic (non-branded) medicines compared with branded ones.

Reports from the Nuffield Trust and the Independent Commission on UK-EU Relations (an organisation that researches the impact of Brexit) have drawn attention to the effect of falls in the value of the pound.<sup>16</sup> Currency fluctuations can make imported products such as medicines more expensive and can also create incentives for suppliers to export or hoard them. A shortage of one medicine might also affect the price of other products, such as a different strength or formulation of the same medicine which could be prescribed as a substitute.

The Association of the British Pharmaceutical Industry has also noted the need to monitor the impact of the [2024 Voluntary Scheme for Branded Medicines Pricing, Access and Growth](#) on medicines supply. The scheme is an agreement between DHSC, NHS England and industry that is designed to control growth in NHS expenditure on branded medicines while ensuring a fair return to pharmaceutical manufacturers. It works by capping the growth rate of medicines sales, with sales beyond this cap subject to a levy. The Association drew attention to the risk that the scheme could lead to some branded medicines being withdrawn from the UK market where pharmaceutical companies consider that the supply of certain medicines is not ‘economically viable’.<sup>17</sup>

Similar concerns have been raised in relation to the relatively low prices of generic (non-branded) medicines in the UK. Community Pharmacy England has suggested that the UK’s “low-price environment” makes it a less attractive place for medicines manufacturers.<sup>18</sup> The potential for the prices of

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<sup>14</sup> Mark Dayan and others, [The future for health after Brexit](#), 18 April 2024

<sup>15</sup> PQ HL3538 [on [Drugs: Shortages](#)] 2 April 2024

<sup>16</sup> Independent Commission on UK-EU Relations, [Health and social care after Brexit](#), November 2023; Mark Dayan and others, [The future for health after Brexit](#), 18 April 2024

<sup>17</sup> Health and Social Care Committee, [Written evidence submitted by the ABPI. Understanding medicine shortages \(PHA0072\)](#), 5 March 2024

<sup>18</sup> Community Pharmacy England, [Briefing: Medicines Supply and Pharmacies](#) (PDF), February 2024

generic medicines to fall to the point that they are no longer profitable to produce has also been identified in the US and Europe.<sup>19</sup>

In the UK, community pharmacies buy medicines themselves and are then reimbursed for the costs of medicines that they dispense under NHS prescriptions. The [reimbursement fees for medicines](#) are set out in drug tariffs; there are three separate drug tariffs for England and Wales, Scotland, and Northern Ireland.<sup>20</sup> When medicines prices exceed the reimbursement prices listed in the drug tariffs, community pharmacies may struggle to source medicines without financial loss.

More information about the price concessions system is available in the Library briefing on [Community pharmacy in England](#).<sup>21</sup>

## Regulatory delays

Trade bodies have argued that regulatory delays can contribute to supply disruption. For example, in January 2024 the British Generic Manufacturers Association [blamed regulatory failures for medicines shortages](#). In a letter to the Guardian newspaper, the association's Chief Executive claimed that the Medicines and Healthcare products Regulatory Agency (MHRA) could take up to two-and-a-half years to approve "routine licencing changes", preventing suppliers from adding stock to the market.<sup>22</sup> Variations to licences (known as marketing authorisations) are required where there are changes to a medicines supplier's business processes or sites, for example.<sup>23</sup> The MHRA responded, stating that addressing shortages is a priority and that the regulator is working with industry to reduce timelines and improve response times.<sup>24</sup>

In evidence submitted to the [Health and Social Care Committee's Inquiry on pharmacy](#), the Association of the British Pharmaceutical Industry also drew attention to the MHRA's capacity to review licence applications:

If MHRA capacity is not addressed, it could impact the availability of certain medicines because they can't be 'placed on the market', and therefore add to the problem of shortages. It is vital that the MHRA is suitably resourced to ensure that it can offer predictable performance.<sup>25</sup>

## 1 Case study: Shortages of ADHD medicines

In September 2023, a national patient safety alert was issued in response to shortages of several medicines used to treat attention deficit hyperactivity disorder (ADHD).<sup>26</sup> The alert noted that supply disruption "is caused by a combination of manufacturing issues and an increased global demand".

Speaking to the Pharmaceutical Journal, a spokesperson for the pharmaceutical company Takeda UK (one of the main producers of ADHD medication) explained:

We have seen a significant increase in demand for ADHD medications over the past two years, which has had an ongoing impact on supply across the industry in the UK. This increase in demand, in conjunction with intermittent production challenges at one of our contract manufacturing partners, have led to disruption in our supply.<sup>27</sup>

A report in the Times newspaper noted that diagnosis of ADHD and prescriptions for medicines have steadily increased the UK. It also pointed to increased demand for the ADHD medicine Adderall in the USA and associated shortages, which may have knock-on effects for other ADHD medicines.<sup>28</sup> This report noted that Takeda had been “hit by packaging problems in its manufacturing plant” but did not provide further details.

In March 2024, the Government attributed shortages to “capacity constraints at key manufacturing sites”.<sup>29</sup> It reported that the DHSC had worked closely with industry to help resolve issues and expedite delivery of these medicines, with the aim of resolving supply issues by May 2024.

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- <sup>19</sup> [Are Generic Drugs Too Cheap for Their Own Good?](#) Bloomberg UK, 16 November 2023; Clement Francois and others, [New pricing models for generic medicines to ensure long-term sustainable competition in Europe](#), *Frontiers in Pharmacology*, Vol 14, 9 October 2023
- <sup>20</sup> For England and Wales: NHS Business Services Authority, [Drug Tariff](#), accessed 13 March 2024; for Scotland: Public Health Scotland, [Scottish Drug Tariff](#), accessed 13 March 2024; for Northern Ireland: HSC Business Services Organisation, [Drug Tariff \(Northern Ireland\)](#), March 2024
- <sup>21</sup> Commons Library research briefing CBP-9854, [Community pharmacy in England](#)
- <sup>22</sup> “[Britain’s drug shortages are caused by regulator’s failure](#)” [Letter], *The Guardian*, 31 January 2024
- <sup>23</sup> MHRA, [Apply for manufacturer or wholesaler of medicines licences - Make a change to a licence \(variation\)](#), 5 May 2023
- <sup>24</sup> “[As a medicines regulator, we are committed to ending drugs shortages](#)” [Letter], *The Guardian*, 7 February 2024
- <sup>25</sup> Health and Social Care Committee, [Written evidence submitted by the ABPI. Understanding medicine shortages \(PHA0072\)](#), 5 March 2024
- <sup>26</sup> NHS, [National Patient Safety Alert – DHSC: Shortage of methylphenidate prolonged-released capsules and tablets, lisdexamfetamine capsules and guanfacine prolonged-released tablets](#), 23 September 2023
- <sup>27</sup> Dawn Connelly, [Around 85% of patients on ADHD medication have been affected by shortages. survey indicates](#), 28 November 2023
- <sup>28</sup> Shaun Lintern, “[ADHD diagnoses are booming – but drugs are running out](#)”, *The Times*, 28 October 2023
- <sup>29</sup> PQ 19220 [on: [Attention Deficit Hyperactivity Disorder: Drugs](#)] 26 March 2024

## 1.2

## The impact of medicines shortages

### Reduced patient safety and access to medicines

In a survey of pharmacists conducted in April and May 2023, 57% of respondents indicated that they felt that medicines shortages had put patients at risk in the preceding six months.<sup>30</sup>

[Healthwatch England](#), a statutory body that represents the views of people who use health and social care services, reported in August 2023 on challenges faced by patients in accessing prescription medicines. An analysis of patient feedback highlighted the increased stress experienced by patients affected by shortages and the additional effort required to obtain medicines.<sup>31</sup>

Community Pharmacy England has also drawn attention to the impact of shortages on patients' health:

This all causes worrying delays for patients, and in worst cases it can lead to a deterioration of their health: last year [2023] we surveyed people working in pharmacies and 87% told us that their patients' health was being put at risk due to medicine supply issues.<sup>32</sup>

Patient organisations and professional bodies have also responded to medicines shortages.

In May 2022, the British Menopause Society, Royal College of General Practitioners, Royal College of Obstetricians and Gynaecologists and the Faculty of Sexual and Reproductive Healthcare issued [a joint statement about shortages of hormone replacement therapy \(HRT\)](#), highlighting the impact of supply disruption on women's health and quality of life:

The current impact of shortages of HRT products on women cannot be underestimated. HRT for many women is a lifeline which helps them to effectively manage their symptoms, and when they are unable to access it this can have a profound impact on their quality of life. Reports in the media of women having to travel across the country, or try to access products they need on the 'black market' are incredibly worrying, and action is clearly needed.<sup>33</sup>

ADHD UK is a charity that supports people affected by ADHD. Respondents to its December 2023 survey reported that medicines shortages had negative impacts on their work, education and relationships.<sup>34</sup>

<sup>30</sup> Dawn Connelly, [Special report: the UK's medicines shortage crisis](#), Pharmaceutical Journal, 29 June 2023

<sup>31</sup> Healthwatch, [Your experiences of getting prescription medication](#), 31 August 2023

<sup>32</sup> Community Pharmacy England, [NHS medicines shortages putting lives at risk](#), 15 January 2024

<sup>33</sup> British Menopause Society, [Joint BMS, FSRH, RCGP and RCOG position statement on the supply shortages of Hormone Replacement Therapy \(HRT\)](#), 6 May 2022

<sup>34</sup> ADHD UK, [Situation update: The ADHD medication crisis](#), January 2024

## 2 Information for patients affected by medicines shortages

There is no overall national guidance for patients who have been affected by medicines supply problems. Patients who are affected by shortages should contact their GP or pharmacist, or the clinician who prescribed their medicine for advice.

Some local NHS services and charities have published information and guidance for patients affected by shortages. For example, the Epilepsy Society regularly publish [information on medicine supplies](#) on their website. Patients may wish to consult the websites of charities associated with their medical condition, their local [integrated care board](#), or [Local Healthwatch](#), who may be able to provide further information.

### Increased pressures on pharmacies

Community Pharmacy England (CPE) has drawn attention to the operational and financial impact of medicines shortages on pharmacy staff and businesses. In July 2023, CPE members named instability in medicines supply as the most severe pressure facing their businesses.<sup>35</sup> In an April 2023 survey, 84% of pharmacy teams reported experiencing aggression from patients affected by medicine supply issues.<sup>36</sup>

In a statement in January 2024, CPE's Chief Executive, Janet Morrison, highlighted the additional workload created by shortages, stating that pharmacies spend an average of 11 extra hours each week tracking down medicines for patients.<sup>37</sup> She also noted that pharmacies sometimes took "huge financial risks" by purchasing medicines without knowing that they would be fully reimbursed for the costs.

Similar issues were raised by the Association of Independent Multiple Pharmacies, a trade association, in evidence provided to the Health and Social Care Committee in November 2023.<sup>38</sup> The CEO, Dr Leyla Hannbeck, noted that pharmacists and their teams "spend many hours a day trying to source medicines for their patients". She also raised the issue of medicines pricing, which could mean pharmacies pay more for medicines than the government would reimburse:

<sup>35</sup> Community Pharmacy England, [Briefing: Community Pharmacies and Medicines Supply](#) (PDF), July 2023

<sup>36</sup> Community Pharmacy England, [PSNC Briefing 009/23: Summary of the results of PSNC's 2023 Pharmacy Pressures Survey](#) (PDF), April 2023

<sup>37</sup> Community Pharmacy England, [NHS medicines shortages putting lives at risk](#), 15 January 2024

<sup>38</sup> Association of Independent Multiple Pharmacies, [Health and Social Care Committee evidence](#) (PDF), 22 November 2023

In addition, medicines costs keep rising dramatically, often without any prior warning and it takes time for the Department of Health and Social Care to give concessions to address the deficit in the price. This leaves pharmacy owners out of pocket.

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## 2 UK Government response to medicines shortages

In July 2023, the government described medicines shortages as “an ongoing issue that the Department [of Health and Social Care] has been managing for many years”.<sup>39</sup>

The Department of Health and Social Care (DHSC) is responsible for the continuity of supply of medicines in the UK. DHSC and NHS England have published [guidance on the management of medicines supply and shortages](#).<sup>40</sup>

Medicines supply problems are classified according to their likely impact. Responses to supply problems can include issuing advice to prescribers, permitting the use of alternative medicines or taking regulatory actions including speeding up the approval of new medicines or, in exceptional circumstances, extending medicine expiry dates.

More information on these processes and on calls for changes to the management of supply issues is set out below.

Ensuring continuity of medicines supply is a reserved matter, but the UK Government works closely with the devolved administrations and health services to manage supply disruptions. More information on processes and guidance in Scotland, Wales and Northern Ireland is provided in section 2.7 of this briefing.

### 2.1 The DHSC Medicines Supply Team

The DHSC Medicines Supply Team is responsible for the day-to-day management of supply issues, including shortages.<sup>41</sup> This includes the identification of supply issues, assessment of their potential impact and management of the problem.

The DHSC Medicines Supply Team works closely with the [Commercial Medicines Unit](#) in NHS England and the Medicines and Healthcare products Regulatory Agency (MHRA) to manage medicines supply problems. It shares information with the devolved administrations in Scotland, Wales and

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<sup>39</sup> PQ 194202 [on [Drugs: Shortages](#)] 14 July 2023

<sup>40</sup> Department of Health and Social Care and NHS England, [A Guide to Managing Medicines Supply and Shortages](#), 1 November 2019

<sup>41</sup> Department of Health and Social Care, [DHSC Reporting Requirements for Medicines Shortages and Discontinuations](#), 21 April 2021

Northern Ireland to help support the management of medicines supply across the UK.

In addition, the Medicines Shortages Response Group (made up of clinicians and representatives of DHSC, NHS England the wider NHS) provides support for the management of significant supply problems that are categorised as high impact or critical (known as tier 3 or 4 supply problems; see section 2.3 below).<sup>42</sup>

## 2.2 Identifying medicines supply problems

The DHSC Medicines Supply Team receive information about medicines supply from a variety of sources.

Under [Part 6 of the Health Service Products \(Provision and Disclosure of Information\) Regulations 2018](#), the marketing authorisation (licence) holder for each medicine (usually the manufacturer) must inform the DHSC when they discontinue any medicine or anticipate any shortages.<sup>43</sup> The Association of the British Pharmaceutical Industry webpage states that pharmaceutical companies “take their responsibilities very seriously and are accountable to UK regulators should supplies of their products become unavailable”.<sup>44</sup>

DHSC has published [guidance on reporting requirements for marketing authorisation holders](#).<sup>45</sup>

Pharmaceutical companies might also write directly to clinicians to inform them of supply issues, or place notices in professional/trade publications, but this is not legally required.<sup>46</sup>

DHSC also uses other sources of information about medicines supply, including the MHRA, medicines wholesalers, healthcare providers, primary care representative bodies, the medical royal colleges (professional associations of clinicians), patient groups and communication directly from the public.<sup>47</sup> Primary care staff (such as community pharmacists and GPs) can report medicines supply issues using an [online form provided by Community Pharmacy England](#).<sup>48</sup>

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<sup>42</sup> Department of Health and Social Care and NHS England, [A Guide to Managing Medicines Supply and Shortages](#), 1 November 2019

<sup>43</sup> [The Health Service Products \(Provision and Disclosure of Information\) Regulations 2018, pt 6](#)

<sup>44</sup> ABPI, [Managing medicine shortages](#), 15 January 2024

<sup>45</sup> Department of Health and Social Care, [Reporting requirements for medicine shortages and discontinuations](#), 21 April 2021

<sup>46</sup> Department of Health and Social Care and NHS England, [A Guide to Managing Medicines Supply and Shortages](#), 1 November 2019

<sup>47</sup> Department of Health and Social Care and NHS England, [A Guide to Managing Medicines Supply and Shortages](#), 1 November 2019

<sup>48</sup> Community Pharmacy England, [Shortage Reporting Form](#), no date, accessed 11 August 2023



## 2.3 Classification of medicines supply problems

Medicines supply problems are risk assessed and classified according to their potential impact into one of four ‘clinical escalation categories’, known as tiers.<sup>49</sup>

- Tier 1 (low impact) and tier 2 (medium impact) supply problems can be managed locally, using existing stock, temporary supply controls or the provision of alternative medicines.
- Tier 3 (high impact) supply problems affect medicines with no or limited alternatives, where switching between medicines is difficult or requires monitoring, or where the affected patient group are considered vulnerable.
- Tier 4 (critical) supply problems are likely to have a life-threatening impact and require the support of other agencies such as the Department for Transport or the police to manage.<sup>50</sup>

## 2.4 National management of medicines supply problems

DHSC’s response to anticipated or identified medicines supply problems can include a range of measures depending on the severity and scale of the specific supply problem. Shortage management options include:

- liaising with medicines manufacturers, alternative suppliers and wholesalers to secure additional supplies and manage existing stocks
- working with the MHRA to provide regulatory advice to affected companies and expediting regulatory procedures for medicines that are assessed as critical for patient care
- commissioning clinical advice from the NHS Specialist Pharmacy Service and national clinical experts to devise potential management options, including whether it is appropriate to recommend alternative medicines
- contacting medicines importers to identify potential sources of medicines and expediting import processes, including potentially arranging unlicensed imports

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<sup>49</sup> NECS Medicines Optimisation, [Supply Issues & Shortages – DHSC and NHSE&I Guide](#), 17 March 2020

<sup>50</sup> Department of Health and Social Care and NHS England, [A Guide to Managing Medicines Supply and Shortages](#), 1 November 2019

- allocating specific quantities of medicines to NHS trusts to manage stocks, including issuing guidance on the use of existing supplies and supporting redistribution of stock where required
- alerting prescribers and pharmacists to shortages through NHS communications.<sup>51</sup>

More detail about some specific measures and about communication about medicines supply problems is set out below.

## Serious shortage protocols (SSPs)

The government introduced serious shortage protocols (SSPs) in 2019.<sup>52</sup> The government can issue an SSP in response to a tier 2 (or higher) medicines supply problem.

### 3 Case study: SSPs for fluoxetine

In 2019 and 2020, manufacturing problems affected the supply of some formulations of the medicine [fluoxetine](#), a type of antidepressant known as a selective serotonin re-uptake inhibitor (SSRI). Fluoxetine is used in the treatment of a range of mental health conditions, including depression.

In response to these shortages, DHSC issued a series of SSPs. These allowed pharmacists to prescribe alternative formulations of fluoxetine. For example, where there were shortages of capsules, pharmacists could prescribe tablet or liquid forms of the medicine.<sup>53</sup> When certain doses were unavailable, pharmacists were able to prescribe equivalents, for example, replacing prescriptions for 40 mg capsules with an equivalent amount of 20mg capsules.<sup>54</sup>

The SSPs included additional information for prescribers, including details of the patients that should and should not be prescribed alternative formulations and advice about special considerations that apply to certain groups.

SSPs apply to individual medicines for specified time periods. They can limit the quantity of a medicine that can be dispensed or allow community pharmacists to substitute a prescribed medicine with a specific alternative.

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<sup>51</sup> Department of Health and Social Care and NHS England, [A Guide to Managing Medicines Supply and Shortages](#), 1 November 2019

<sup>52</sup> [The Human Medicines \(Amendment\) Regulations 2019](#)

<sup>53</sup> NHS Business Services Authority, [SSP01 Fluoxetine 10mg capsules](#) (PDF), 3 October 2019

<sup>54</sup> NHS Business Services Authority, [SSP09 Fluoxetine 40mg capsules](#) (PDF), 29 January 2021

If an alternative medicine is dispensed, pharmacists should inform the patient's GP that an alternative has been supplied.<sup>55</sup>

The NHS Business Services Authority publishes [information about SSPs that are currently active and expired or withdrawn SSPs](#).

In May 2021, DHSC published a one-year policy review of SSPs.<sup>56</sup> At the time of publication, a total of 12 SSPs had been issued. The review noted that DHSC was not aware of any concerns about the effect of SSPs on the medicines market or patient safety. It said that stakeholder feedback showed that “SSPs have received a largely positive reception and are viewed as being beneficial, both in managing medicines shortages and in saving time”.<sup>57</sup>

## Regulatory actions for supply disruptions

The Medicines and Healthcare products Regulatory Agency (MHRA) can take a variety of regulatory actions in response to high impact or critical medicines shortages.<sup>58</sup> These include:

- speeding up the assessment process for new medicines licences (marketing authorisations) or variations to existing licences. Variations to licences are required for administrative changes such as changes to a company's name or address, but licence holders may also seek variations where there are changes to a medicine or its intended use.
- granting temporary exemptions from medicines labelling requirements so that medicines packaged for use in another country can be used in the UK
- importing and testing batches of licensed medicines, and considering manufacturers' requests to import unlicensed medicines for the treatment of individual patients (known as 'specials')<sup>59</sup>

## Restrictions on exporting and hoarding medicines

The government can place [restrictions on the export and hoarding \(deliberately withholding the supply\) of medicines affected by shortages](#) or where there is a risk of shortages.<sup>60</sup>

Export and hoarding of medicines are prohibited when:

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<sup>55</sup> PSNC, [PSNC Briefing 023/19: Serious Shortage Protocols \(SSPs\) – a guide for community pharmacy teams](#), June 2019

<sup>56</sup> Department of Health and Social Care, [Serious shortage protocols: one-year policy review](#), 27 May 2021

<sup>57</sup> DHSC, [Serious shortage protocols: one-year policy review](#), 27 May 2021

<sup>58</sup> MHRA, [Medicines shortages: regulatory processes to manage supply disruptions](#), 23 May 2022

<sup>59</sup> MHRA, [Supply unlicensed medicinal products \(specials\)](#), 12 May 2023

<sup>60</sup> DHSC, [Export and hoarding of restricted medicines](#), 28 June 2023

- the medicine is required to meet the needs of UK patients
- the medicine is currently in critical shortage or at risk of being in critical shortage
- the export of the medicine would contribute to a critical shortage, or risk of critical shortage, of that medicine in the UK.<sup>61</sup>

Failure to comply with restrictions is considered to be a breach of [regulation 43\(2\) of the Human Medicines Regulations 2012](#), which requires medicine licence holders to ensure a continued supply of medicines to meet the needs of UK patients.<sup>62</sup>

DHSC maintains [a current list of medicines that cannot be exported from the UK or hoarded](#).<sup>63</sup>

## 4 Case study: restrictions on exports of hormone replacement therapy (HRT)

Hormone replacement therapy (HRT) is a [treatment for menopause symptoms](#).<sup>64</sup> It works by replacing the hormones oestrogen and progesterone in the body. There are a wide range of types and formulations of HRT available, including tablets, patches, gels and spray.

[Shortages of HRT medicines have been reported since 2018](#) and multiple SSPs were issued for specific products between 2021 and 2023.

In October 2019, DHSC and the MHRA imposed restrictions on the export of multiple HRT products.<sup>65</sup> The restrictions aimed to prevent medicines wholesalers from “parallel exporting”, which involves buying medicines in the UK and selling them higher prices in other countries.

Several HRT medicines remain on the list of medicines that cannot be exported or hoarded as of April 2024

## The National Supply Disruption Response

In 2020, DHSC established [the National Supply Disruption Response](#) service to address supply problems affecting medicines and a range of other clinical and non-clinical products. This service can be accessed by health and care

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<sup>61</sup> DHSC, [Export and hoarding of restricted medicines](#), 28 June 2023

<sup>62</sup> [Human Medicines Regulations 2012](#), pt 3, reg 43(2)

<sup>63</sup> DHSC and MHRA, [Medicines that you cannot export from the UK or hoard](#), 19 February 2024, accessed 7 March 2024

<sup>64</sup> NHS, [About hormone replacement therapy \(HRT\)](#), 7 February 2023

<sup>65</sup> DHSC, [New restrictions on parallel exports to tackle HRT shortages](#), 3 October 2019

providers, suppliers and research bodies across the UK that have “exhausted all other options available to them to maintain supply”.<sup>66</sup>

The National Supply Disruption Response service has access to the [Express Freight Service](#), an emergency international logistics service that can be used to ensure the continuity of medicines supply whenever there is a disruption to usual routes.<sup>67</sup>

## Local actions to address shortages

Actions to address medicines shortages may also be taken at local levels, such as by regional NHS trusts and community pharmacies. To support local responses, the Royal Pharmaceutical Society has published best-practice guidance on medicine shortages in community pharmacy (available to members of the society) and [medicine shortages in secondary care \(hospital settings\)](#) (PDF).<sup>68</sup>

The Royal Pharmaceutical Society guidance for secondary care notes that there is currently no national guidance to the NHS on managing shortages at local levels. NHS Chief Pharmacists (or equivalent roles in Scotland, Wales and Northern Ireland) are responsible for developing local strategies and procedures to manage medicines shortages. The principles for managing local shortages include that:

- local actions should not exacerbate overall shortages
- NHS trusts should work collaboratively to avoid duplication of work, including procurement and production of clinical advice, and to ensure that medicines are given to patients with the greatest clinical need

information about medicines shortages should be timely and include as much supporting information as possible.

## Price concessions

Sometimes medicines are available, but community pharmacies are unable to source them at prices at or under the reimbursement rates (paid by the NHS) set out in the drug tariffs.<sup>69</sup> In these circumstances, pharmacies can only supply medicines at a financial loss. Medicines shortages can lead to price increases, but increases in medicines prices for any reason can affect patient access to medicines whenever community pharmacies are unable to source medicines at affordable prices. To address this, DHSC can offer price

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<sup>66</sup> DHSC, [Reporting to the National Supply Disruption Response](#) (NSDR), 5 February 2024

<sup>67</sup> DHSC, [Reporting to the National Supply Disruption Response](#) (NSDR), 5 February 2024

<sup>68</sup> Royal Pharmaceutical Society, [Medicine shortages in community pharmacy](#) (subscription required), 17 January 2024; Royal Pharmaceutical Society, [Best Practice Standards for managing Medicines Shortages in Secondary Care in England](#) (PDF), no date, accessed 8 March 2024. Separate guidance for [secondary care settings in Scotland](#) (PDF) has also been published.

<sup>69</sup> Community Pharmacy England, [Price Concessions – What is a price concession?](#), 20 March 2024

concessions, which are temporary increases to the reimbursement price of a medicine that aim to ensure pharmacies can cover the costs of supplying it.<sup>70</sup>

In England, Community Pharmacy England (CPE) monitors medicines prices and community pharmacy contractors can [report pricing issues directly](#) through the CPE website. Each month, CPE submits requests for price concessions to DHSC, which conducts its own pricing research on the market. CPE can negotiate with DHSC about the level of concession offered, but DHSC makes the final decision on issuing a price concession.<sup>71</sup> Price concessions are valid until the end of the month in which they are granted. Where pricing issues persist, new price concessions must be granted each month. Section 3 below provides information on calls to reform this system.

Community Pharmacy Wales, Community Pharmacy Scotland and Community Pharmacy Northern Ireland also compile and report information on medicines pricing issues in these parts of the UK.<sup>72</sup>

## 5 Case study: Price concessions for atorvastatin

[Atorvastatin](#), a medicine used to lower blood cholesterol, is the most frequently dispensed drug in England.<sup>73</sup>

In July 2023, CPE submitted [price concession requests for atorvastatin](#), using data that showed that actual purchase prices for this medicine exceeded the reimbursement price set in the drug tariff for England and Wales.<sup>74</sup>

DHSC introduced price concessions for 10mg, 20mg, 40mg and 80mg tablets

CPE appealed to DHSC to increase the level of price concession granted for 80mg tablets, based on “an exceptionally high volume of reports from pharmacies unable to obtain Atorvastatin 80mg tablets at the published Drug Tariff price”. The price concession granted for 80mg tablets was subsequently revised upwards, from £3.45 to £3.91 for a packet of 28 tablets.<sup>75</sup>

In August and September 2023, atorvastatin price concessions were increased again to ensure that reimbursement rates for pharmacies covered costs.<sup>76</sup> The price concession was withdrawn in October 2023.<sup>77</sup>

<sup>70</sup> Community Pharmacy England, [PSNC Briefing 023/22: How the price concession system operates](#) (PDF), August 2022

<sup>71</sup> Community Pharmacy England, [Price Concessions](#), 20 March 2024

<sup>73</sup> NHS Business Services Authority, [Prescription Cost Analysis – England – 2022-23](#), 8 June 2023

<sup>74</sup> Community Pharmacy England, [July Price Concessions Update](#), 1 August 2023

<sup>75</sup> Community Pharmacy England, [Price improvement for Atorvastatin 80mg dispensed in July 2023](#), 9 August 2023

<sup>76</sup> Community Pharmacy England, [Improved Atorvastatin prices](#), 31 August 2023

<sup>77</sup> Community Pharmacy England, [October 2023 Price Concessions – Final Update](#), 31 October 2023

## 2.5

## Communication about medicines supply problems

### Low and medium impact (tiers 1 and 2)

The primary means of communication about medicines supply problems is via reports produced by the NHS England [Commercial Medicines Directorate](#) and the DHSC Medicines Supply Team.

A monthly Medicines Supply Team summary report is uploaded to the [Specialist Pharmacy Service Online Medicines Supply Tool](#) (NHS login required). This tool provides NHS staff with information about known supply problems, recommended actions to take, alternative medicines and expected resolution dates.

The DHSC report is shared with a variety of other organisations, including [Community Pharmacy England](#) and [PresQIPP](#) (a social enterprise that supports prescribing practice in the NHS). These organisations may share information further, including with local integrated care systems.

For medium impact (tier 2) supply problems, DHSC sends notifications to NHS mail addresses and commissioning organisations to reach community pharmacists, GPs, dentists, optometrists and others as needed.<sup>78</sup> It may also contact other organisations as needed, including the medical royal colleges and patient groups.<sup>79</sup>

Community Pharmacy England also publishes [medicine supply notifications for tier 2 and above](#).<sup>80</sup>

### High impact and critical (tiers 3 and 4)

From 14 February 2022, communication about high impact and critical level medicines supply problems involves [issuing a national patient safety alert](#).<sup>81</sup> Before this date, serious medicines supply issues were communicated by supply disruption alerts. In both cases, the NHS [Central Alerting System](#) is used to directly notify organisations across the health system about serious medicines supply issues.

National patient safety alerts include:

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<sup>77</sup> Community Pharmacy England, [October 2023 Price Concessions – Final Update](#), 31 October 2023

<sup>78</sup> As above

<sup>79</sup> As above

<sup>80</sup> Community Pharmacy England, [Dispensing & Supply Latest News](#), accessed 6 March 2024

<sup>81</sup> Medicines and Healthcare products Regulatory Agency, [Update from the CAS Helpdesk](#), 17 February 2022

- information on current supplies of each medicine and the anticipated resolution of shortages
- actions for clinicians and prescribers to take, including recommendations about which medicines should be prescribed, for which patients, and information about the need to identify and counsel patients on any changes to their prescriptions
- links to additional guidance and supporting information.

The DHSC Medicines Supply Team brief health and social care ministers on all tier 3 and tier 4 supply problems.

## 6 Case study: National patient safety alerts for GLP-1 receptor agonists

In July 2023 and January 2024 DHSC issued national patient safety alerts in response to ongoing shortages of a group of medicines known as glucagon-like peptide-1 receptor agonists (GLP-1 RAs).<sup>82</sup> These include the medicines semaglutide (marketed as Ozempic, Rybelsus and Wegovy), dulaglutide (Trulicity), exenatide (Byetta, Bydureon) and liraglutide (Victoza, Saxenda).

These medicines are used to [treat some patients with type 2 diabetes](#), and work by helping the body to produce more insulin and slowing down the digestion of food.<sup>83</sup> The GLP-1 RAs semaglutide (marketed as Wegovy) and liraglutide (Saxenda) are also recommended for the [management of overweight and obesity](#) for some patients.<sup>84</sup>

Increased demand and ‘off-label’ use (when medicines are [prescribed to treat a condition or group of patients not named in its existing licence](#)) of these medicines has led to shortages. The July 2023 alert notes that supplies are “limited” and “intermittent” and that they are not expected to meet market demand until mid-2024.

The alerts advise clinicians to avoid off-label prescribing and prescribing ‘excessive’ quantities of these medicines, to use alternatives in certain circumstances, and to prioritise some patients who already use these drugs

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<sup>82</sup> NHS, [National Patient Safety Alert – DHSC: Shortage of GLP-1 receptor agonists](#), 18 July 2023; NHS, [National Patient Safety Alert – DHSC: Shortage of GLP-1 receptor agonists \(GLP-1 RA\) update](#), 5 January 2024

<sup>83</sup> National Institute for Health and Care Excellence, [Type 2 diabetes in adults: management](#), 29 June 2022

<sup>84</sup> National Institute for Health and Care Excellence, [Semaglutide for managing overweight and obesity](#), 8 March 2023; National Institute for Health and Care Excellence, [Liraglutide for managing overweight and obesity](#), 9 December 2020



for medication review (for example, if the treatment does not seem to be working).

## 2.6 The Critical Imports and Supply Chains Strategy

On 17 January 2024, the government announced the publication of the [Critical Imports and Supply Chains Strategy](#).<sup>85</sup> This document sets out priorities and actions to improve the resilience of supply chains for a range of important imports, including semiconductors, critical minerals and medicines.

In relation to medicines, the strategy document notes DHSC's existing mechanisms for responding to medicines supply problems. It also notes the role of using multiple suppliers, targeted investment in domestic manufacturing and strategic procurement in strengthening the medicines supply chain.<sup>86</sup>

## 2.7 Scotland, Wales and Northern Ireland

Ensuring continuity of medicines supply is a reserved matter, but the UK Government works closely with the devolved administrations and health services to manage supply disruptions.

Information on local processes and guidance in Scotland, Wales and Northern Ireland is provided below.

### Scotland

In September 2019, the Scottish Government and Scottish Medicines Supply Response Group introduced [a new process to alert community pharmacists, Scottish health boards and other healthcare professionals](#) about medicines shortages. Medicines supply alert notices are issued by the Scottish Chief Pharmaceutical Officer and distributed to healthcare professionals and NHS services.<sup>87</sup>

Community Pharmacy Scotland has published [guidance on medicines shortages for community pharmacy services](#) (PDF), and the Royal Pharmaceutical Society has published [best practice standards for the](#)

<sup>85</sup> Department for Business and Trade, [UK critical imports and supply chains strategy](#), 17 January 2024

<sup>86</sup> Department for Business and Trade, [UK critical imports and supply chains strategy](#), 17 January 2024

<sup>87</sup> NHS National Services Scotland, [Medicines supply alert notices](#), 6 March 2024

[management of shortages in secondary care settings](#) (PDF) for hospitals in Scotland.<sup>88</sup>

## Wales

In October 2023, the Welsh Minister for Health and Social Services, Eluned Morgan, [outlined the Welsh Government's response to disruptions in medicines supply](#).<sup>89</sup> Her statement made it clear that medicines supply is a reserved matter, but emphasised that the Welsh Government work closely with DHSC to ensure continuity of medicines supply in Wales.

Community Pharmacy Wales has [published guidance on medicines shortages for professionals working in primary care settings](#) (PDF) like community pharmacies and GP surgeries.<sup>90</sup>

## Northern Ireland

In Northern Ireland, the Health and Social Care (HSC) Business Services Organisation (which provides [business support and professional services for the health and social care sector](#)) published [guidance on shortages management](#) in January 2023.<sup>91</sup> The Northern Ireland Department of Health issues medicine supply notifications in response to shortages, following similar procedures used in the rest of the UK.

### Northern Ireland Protocol

Medicines supply in Northern Ireland is affected by [the Northern Ireland Protocol](#). From 1 January 2025, medicines supplied in Northern Ireland must be approved and licenced by the MHRA.<sup>92</sup> The protocol removes the requirement for medicines in Northern Ireland to be approved by the European regulator and means that the packaging and labelling of medicines will be standardised throughout the UK. All medicines must carry a legible “UK Only” label when placed on the UK market.<sup>93</sup>

In the interim period, the [Northern Ireland MHRA Authorised Route \(NIMAR\)](#) continues to operate. NIMAR provides a route for prescription-only medicines to be supplied in Northern Ireland in compliance with UK and EU rules.<sup>94</sup> In addition, the [Centrally Authorised Products Bridging Mechanism](#) allows the supply of certain ‘innovative’ medicines (such as new cancer medicines) for

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<sup>88</sup> Community Pharmacy Scotland, [Medicines Shortages Guidance](#) (PDF), no date, accessed 13 March 2024; Royal Pharmaceutical Society and NHS Scotland, [Best Practice Standards for Managing Medicines Shortages in Secondary Care in Scotland](#) (PDF), January 2017

<sup>89</sup> Welsh Government, [Written Statement: Disruptions in the supply of medicines](#), 18 October 2023

<sup>90</sup> Community Pharmacy Wales, [Drug Shortages Briefing](#) (PDF), April 2020

<sup>91</sup> HSC Business Services Organisation, [Shortages Guidance January 2023](#), January 2023

<sup>92</sup> MHRA press release, [Windsor Framework medicines announcement](#), 9 June 2023

<sup>93</sup> MHRA, [Labelling and packaging of medicinal products for human use following agreement of the Windsor Framework](#), 11 January 2024

<sup>94</sup> MHRA, [The Northern Ireland MHRA Authorised Route \(NIMAR\)](#), 29 September 2023

up to six months, wherever the MHRA licences a product before the European regulator.<sup>95</sup>

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<sup>95</sup> MHRA, [Centrally Authorised Products \(CAPs\) Bridging Mechanism](#), 9 June 2023

## 3 Calls for reform of medicines shortages management

Organisations representing pharmacists have called for reforms to the systems used to manage medicines shortages. Community Pharmacy England has called for “a full review of the medicines supply market”.<sup>96</sup>

Appeals for reform centre on calls for pharmacists to be able to amend prescriptions, and on changes to medicines pricing and the price concessions system.

### 3.1 Pharmacists’ prescribing decisions

In July 2023, Community Pharmacy England published a briefing for MPs, which set out proposals for the government to address medicines shortages. These include two proposals that would extend pharmacists’ ability to amend prescriptions when they encounter supply disruptions:

1. Reform serious shortage protocols (SSPs), to increase flexibility and allow pharmacists to make simple changes to prescriptions without the need for SSPs or prescribers to authorise them.
2. Allow pharmacists to substitute equivalent generic medicines where prescriptions request a particular brand of medicine that is in short supply.<sup>97</sup>

The Royal Pharmaceutical Society has also called for legislative changes that would [allow pharmacists to make minor amendments to prescriptions when a medicine is out of stock](#), separate to provisions under SSPs. Under this proposal, pharmacists would be able to supply a different quantity, strength, formulation or generic version of the same medicine, in discussion with the patient. The society notes that “such substitutions are routine for pharmacists in both secondary care and general practice”.<sup>98</sup>

In January 2024, the Government indicated that it had [no plans to introduce legislative proposals of this kind](#) and would instead continue to rely on serious shortage protocols to enable pharmacists to amend prescriptions on a case by case basis. The Parliamentary Under-Secretary for Health and Social Care,

<sup>96</sup> Community Pharmacy England, [Briefing: Medicines Supply and Pharmacies](#) (PDF), February 2024

<sup>97</sup> Community Pharmacy England, [Briefing: Community Pharmacies and Medicines Supply](#) (PDF), July 2023

<sup>98</sup> Royal Pharmaceutical Society, [Medicines Shortage Policy](#). No date, accessed 13 March 2024

Andrea Leadsom, suggested that such changes could have a negative impact on patients and potentially exacerbate supply problems:

The Department has no plans to introduce legislative proposals to allow pharmacists to amend prescriptions. Allowing pharmacists to take local action to alter prescriptions could have adverse impacts on patients, because pharmacies will not know the reasons why a medicine has been prescribed, or in what particular way. Supplying an alternative without full oversight of supply issues could also create a knock-on shortage of the alternative, and could thereby have the potential to exacerbate rather than mitigate a supply problem.<sup>99</sup>

## 3.2 Medicines pricing and price concessions

Community Pharmacy England has also called on the government to:

3. Make changes to the price concessions system, to prevent community pharmacies from having to absorb increases in costs of medicines; and
4. Undertake a review of medicine supply and pricing, including reviewing the cap on how much pharmacies can earn from medicines purchases.<sup>100</sup>

In relation to price concessions, Community Pharmacy England has suggested that the current system “is longer coping” with levels of price volatility in the medicines market.<sup>101</sup> It has also repeatedly drawn attention to price concessions imposed by DHSC that are not high enough to cover the market price of medicines.<sup>102</sup>

Speaking to the Pharmaceutical Journal in 2023, [the Chief Executive of the Association of Independent Multiple Pharmacies echoed this view](#): “It’s unacceptable that the government and commissioners are refusing to reimburse pharmacy contractors their cost of acquisition of medicines at these times of operational and financial strain.”<sup>103</sup>

The National Pharmacy Association has also called [for changes to the price concessions system](#) to give pharmacies more certainty about reimbursement and pricing levels each month.<sup>104</sup> In oral evidence to the Health and Social Care Committee in November 2023, the Vice Chair of the National Pharmacy

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<sup>99</sup> PQ 14539 [on: [Pharmacy: Prescriptions](#)] 19 February 2024

<sup>100</sup> Community Pharmacy England, [Briefing: Community Pharmacies and Medicines Supply](#) (PDF), July 2023

<sup>101</sup> Community Pharmacy England, [Briefing: Community Pharmacies and Medicines Supply](#) (PDF), July 2023

<sup>102</sup> Community Pharmacy England, [Briefing: Medicines Supply and Pharmacies](#) (PDF), February 2024; Community Pharmacy England, [PSNC to seek overhaul of pricing concessions system](#), 2 September 2022

<sup>103</sup> Anna Sayburn and Carolyn Wickware, [Rising number of drug price concessions imposed on pharmacies by the government](#), 16 February 2023

<sup>104</sup> National Pharmacy Association, [Our key policy positions](#), no date, accessed 4 April 2024

Association described the uncertainties faced by pharmacies in purchasing medicines:

We do not even know what is going to be announced as a concessionary price. Throughout the whole month, we have to buy in good faith that someone somewhere will decide, “We are going to remunerate you for the medicines, at least at the price you’ve paid for them.” But we do not know that sometimes until into the following month for the previous month. If you also missed the 5th of that month for submitting your prescriptions, despite the fact that you have already bought all of those medicines at a loss, you do not get granted concessionary prices on those medicines. The whole system is broken. It needs to change.<sup>105</sup>

In March 2024, DHSC introduced changes to their approach to introducing price concessions. From 1 April 2024, the reimbursement prices for generic medicines<sup>106</sup> have been “[adjusted for underlying market prices](#)”. The information published alongside the April 2024 edition of the drug tariff for England and Wales states that price concessions in the coming months will be “constrained” to enable DHSC to make adjustments to the [medicines margin](#). The medicines margin is a fixed level of profit that community pharmacies are permitted to make each year from dispensing medicines. It is calculated as the difference between reimbursement prices and prices paid by pharmacies for medicines.<sup>107</sup> Community Pharmacy England has stated that it [strongly opposes these changes](#), outlining its concerns about the potential impact on pharmacy finances.<sup>108</sup>

As well as calls for reform of price concessions, there are wider calls for reform of community pharmacy funding. Community Pharmacy England has called for a review of the Community Pharmacy Contractual Framework, which sets out how community pharmacies in England are funded. [The Library briefing on Community pharmacy in England](#) provides more information on the current framework, including detailed information on the medicines margin and price concessions system, and calls for changes to the funding model.<sup>109</sup>

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<sup>105</sup> Health and Social Care Committee, [Oral evidence: Pharmacy, HC 140](#), 21 November 2023

<sup>106</sup> Category M medicines, for which there is more than one manufacturer, and where the medicine in question fulfils minimum spending and/or volume requirements

<sup>107</sup> NHS Business Services Authority, [Drug Tariff Part VIII – Category M prices](#), no date, accessed 4 April 2024

<sup>108</sup> Community Pharmacy England, [Government imposes Drug Tariff changes to manage margin](#), 28 March 2024

<sup>109</sup> Commons Library research briefing CBP-9854, [Community pharmacy in England](#)

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