REPORT OF: THE JOINT HEALTH OVERVIEW AND SCRUTINY COMMITTEE (HOSC):

Medicine Shortages:

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INTRODUCTION AND OVERVIEW

1. At its meeting on 12 September 2024, the Oxfordshire Joint Health and Overview Scrutiny Committee (HOSC) received two reports providing an update on medicine shortages; one from the BOB Integrated Care Board, and another from Oxford University Hospitals NHS Foundation Trust (OUH).

2. The Committee felt it crucial to receive an update on the causes of medicine shortages (be they international, national, or local), and the measures being taken by local partners to seek to address these shortages for Oxfordshire.

3. This item was scrutinised by HOSC given that it has a constitutional remit over all aspects of health as a whole; and this includes the availability and accessibility of medicines and residents' ability to access these. Upon commissioning this item, some of the points the Committee sought to investigate involved the following:

    - The national context of medicine shortages.
    - The reasons behind the increase in medicine shortages.
    - The extent to which medicine shortages are impacting Oxfordshire.
    - If there any particular medicines that are affected by the shortages.
    - Whether there any particular populations groups/those with specific conditions that could be most affected by the shortages.
    - Details of any impact assessments that have been conducted nationally or locally.
    - The steps being taken locally to address medicine shortages.

SUMMARY

4. The Committee would like to express thanks to Julie Dandridge (Head of Primary Care Infrastructure and Pharmacy BOB ICB), Claire Critchley (Medicines Optimisation Lead Pharmacist), David Dean (Chief Executive Officer for Community Pharmacy Thames Valley), Bhulesh Vadher (Clinical Director of Pharmacy and Medicines Management at Oxford University NHS Hospital Trust), and Rustam Rea (Consultant at Oxford University NHS Hospital Trust) and Leyla Hannbeck (CEO of the Independent Pharmacies Association) for attending this item and for answering questions from the Committee on the issue of Medicine Shortages.

5. The Head of Primary Care Infrastructure and Pharmacy highlighted the multifaceted root causes of medicine shortages and the significant impact on patients and healthcare providers. She noted the anxiety patients face when their usual medications are unavailable and the challenges for pharmacists and clinicians in managing these shortages.

6. The Committee inquired about the main complexities causing medicine shortages. They asked about the international context of manufacturing capacity and whether the impacts of this had now been addressed. The CEO of the Independent Pharmacies Association responded, explaining that global manufacturing capacity issues, dependency on raw materials from countries like China and India, and geopolitical factors contributed to the problem. She also mentioned the impact of Brexit and the UK's pricing strategies, which make it less attractive for manufacturers to supply medicines to the UK. This included the UK Vpass system which allowed a financial clawback from manufacturers and that the UK had some of the cheapest generic medicines and was therefore a less attractive market for supply. She highlighted the increased demand for certain medications, such as HRT and ADHD treatments, which exacerbated the shortages. National protocols were in place for serious medical shortages, although when alternatives were identified, these could then be in high demand and go into shortage.

7. The Committee then asked how NHS contracts and pricing strategies impacted medicine availability. The Chief Executive Officer for Community Pharmacy Thames Valley explained that the national contract for community pharmacies had remained unchanged for seven years, creating financial pressures that had led to 5 pharmacies closing every week in the UK and 15 community pharmacies closed in Oxfordshire over 5 years. He noted that the contract drove down prices, discouraging manufacturers from supplying the UK market and causing pharmacies to dispense many items at a loss.

8. The Committee sought clarification on distribution issues contributing to shortages and whether these issues were national or local in scope and what measures could be taken to address them. The Clinical Director of Pharmacy and Medicines Management at Oxford University NHS Hospital Trust explained that the distribution network itself was not the problem; rather, it was the availability of stock from wholesalers and manufacturers. He described the sophisticated systems in place within hospital pharmacies to manage stock and

share resources regionally, contrasting this with the less coordinated systems in community pharmacies. An exemplar was the regional coordination of epidurals and there were several situations were solutions had to be found.

9. The Committee asked about the impact of medicine shortages on individual patients, particularly those with conditions requiring specific medications. The Clinical Director of Pharmacy and Medicines Management at Oxford University NHS Hospital Trust provided examples of how shortages forced the use of alternative or unlicensed products, which could lead to further shortages. He emphasised the randomness of these shortages and the various factors that could cause them, such as manufacturing issues or supply chain disruptions. The CEO of the Independent Pharmacies Association explained that while national protocols, such as the serious shortages protocol, allowed pharmacists to switch medicines during shortages, high demand still led to product shortages, as seen with antibiotics and Hormone Replacement Therapy (HRT) medicines. Despite pharmacists' extensive knowledge, they were unable to make simple prescription changes without prescriber approval, which added to the workload of healthcare professionals and caused delays for patients. The CEO advocated for regulatory changes to allow pharmacists to make minor remedial prescriptions, such as substituting different dosages of the same medicine, to improve efficiency.

10. The Committee raised concerns about the impact on patients with "cliff edge" conditions where the absence of the right and timely medication could be life-threatening and so prior to Brexit had been stockpiled e.g. anti-seizure medication and insulin. The Medicines Optimisation Lead Pharmacist explained the national and local mitigations in place, including systems to manage shortages and ensure alternative medications are available. She noted that while stockpiling was not done locally, there were national reserves for critical medications. Various systems were implemented locally to address shortages, including providing information on alternative medicines, although this could lead to further shortages. Collaboration between primary and secondary care was essential, with efforts to import supplies locally when necessary. The ICB gave an example of a system-wide approach to shortages of palliative care medicines, where all doctors and nurses were aware of where they could access supply; and they agreed there was scope to extend this approach to other areas.

11. The Committee asked about the recognition of where alternatives were sub-optimal because a patient on a long-term medication was very used to taking a particular formulation e.g. elderly or someone with learning disability and where alternatives were sub-optimal because of lack of biological efficacy.

12. There was discussion of stockpiling. That across the whole system there was a discouragement of stock-piling

13. The Committee asked whether the issue of medicine shortages had impacted the workload of the clinical side of the NHS, and if this was being monitored. The Consultant at OUH highlighted the increased clinical and pharmacy

burdens due to drug shortages, which necessitated additional resources and adjustments in patient care, particularly in managing diabetes medication.

14. The Committee inquired about the global vulnerability to supply chain issues, and whether production could be brought into the UK to improve resilience. The Clinical Director of Pharmacy and Medicines Management noted that the UK's pharmaceutical industry had been offshored over the years, making it challenging to bring manufacturing back. He suggested that while it would be beneficial to increase local production, it was not entirely within the government's control as it would depend on pharma companies wishing to invest in the UK market.

15. The Committee questioned the communication and coordination efforts between Community Pharmacies to mitigate the risks associated with medicine shortages. The Chief Executive Officer for Community Pharmacy Thames Valley explained that pharmacies across BOB frequently shared stock via messaging groups to ensure patients received their medications. However, this practice added to pharmacists' workload, with each spending about a day a week locating stock. The Medicines Optimisation Lead Pharmacist described the various communication channels used to keep healthcare providers informed, including regular updates on the ICB and OUH websites and newsletters. She acknowledged the challenges of keeping information current due to the rapidly changing situation.

16. Regarding communications with the public, the ICB spoke about a campaign aimed at patients discouraging stock-piling. The Committee suggested that for some patients with long-term conditions, holding some medication stock might be considered a safe option, and it was really important that communications were contextualised for patients. The ICB were aware that some practices would prescribe for one month only, but that there was no ICB policy about that. The length of prescription should be in response to the particular condition and context for the patient. Community-based medication reviews were given as really important opportunities for medicines optimisation where it would be possible to plan the appropriate timescale for prescriptions with patients with long-term conditions.

KEY POINTS OF OBSERVATION & RECOMMENDATIONS

17. Below are some key points/themes of observation that the Committee has in relation to local impacts and the work concerning medicine shortages from this session. These observations have also been shaped from hearing about medicines shortages and impacts in other scrutiny sessions e.g. palliative care and epilepsy.

18. The Committee was acutely aware that the issue of medicines shortages was a matter of high public concern but was also complex, and these complexities were either not in the public domain or readily accessible. The Committee wished to praise local NHS leaders working on medicines for the creative way they have sought solutions and also to empathise with frontline community pharmacists and health professionals for dealing with shortages on a day-to-

day basis. Whilst the Committee made no recommendation regarding national enablers, the national and global context clearly needs to significantly improve in light of evidence at this session and national policy and media reports e.g https://www.nuffieldtrust.org.uk/news-item/patients-face-new-normal-of-medicines-shortages-as-uk-hampered-by-supply-issues-and-impact-of-eu-exit; https://www.pharmaceutical-technology.com/news/uk-charities-condemn-continued-drug-shortages/.

19. The OUH medicines lead explained that there were no problems in the past years when the UK had a strong pharmaceutical industry. Whilst it was accepted that rebuilding that may not be within the government's control, national leaders could work to improve the attractiveness to manufacturers of supplying patients in the UK and could support the sustainability of community pharmacies. Whilst the Committee has made no national recommendation, the local recommendations made requests of the ICB and providers to escalate to national policy makers the urgent need for medicines security for the UK and key enablers for this. Of particular note is the Independent Pharmacies Association (IPA) evidence that there is an urgent need for transparency regarding work to discuss the challenges with the view to solutions and that urgent mitigations include changing regulations to allow community pharmacists to make minor changes to prescriptions without having to resort back to the clinical prescriber.

20. The five key points of observation below relate to some of the local themes of discussion and have also been used to shape the recommendations made by the Committee.

Support for patients with cliff-edge conditions: In the healthcare sector, ensuring the safety and well-being of patients is paramount. Recognising and identifying patients with cliff-edge conditions (those who are at significant risk of severe health deterioration in the event of treatment disruption) is a critical aspect of patient care. Cliff-edge conditions were recognised in the lead up to Brexit as requiring special provision and are defined as medical conditions which can be immediately life-threatening if there is any interruption in treatment with a rapid and potentially irreversible deterioration in a patient's health and emergency. Common examples include but are not limited to:

- Life-threatening chronic illnesses requiring the right continuous medication (e.g., diabetes, epilepsy, asthma).
- Life-threatening acute conditions (e.g., certain types of cancers, severe infections).
- Critical post-operative or post-treatment conditions requiring constant medical support.

The Committee heard that community pharmacy teams regularly see distressed patients who cannot get hold of their medicines who need to travel from one pharmacy to another in the hope of getting hold of their

regular medicine and this was also heard in the scrutiny session that followed on epilepsy from the epilepsy clinical team. It is noted that the mental health of patients with these conditions is likely to deteriorate if they are worrying or having to travel large distances regularly to find their medicine, and that deteriorations in mental health was known in some of these conditions to worsen outcomes. This will include many that are especially vulnerable because they are not able to drive and unable to use public transport easily.

Healthcare systems and providers should do their utmost to identify patients with cliff-edge conditions. This could be through regular patient assessments and medical reviews, using electronic health records to flag high-risk patients, and through collaboration amongst specialists to ensure accurate diagnosis and treatment plans.

Furthermore, every effort should be made to maintain adequate stock levels of critical medications and supplies for those patients with cliff-edge conditions. Relevant system partners should work closely to ensure that those patients with cliff-edge conditions are swiftly and appropriately identified in the event of medicine shortages, and to have mitigations in place so as to reduce the risk of these patients experiencing harm in the event of disruptions to medicines supplies. In the absence of national enablers, it is critical that communications at a local level with patients with cliff-edge conditions about stock-piling medications are responsive to their need for enough medical supply to provide security and prevent anxieties.

Recommendation 1: *To ensure that policies are in place to recognise and identify patients with cliff-edge conditions, and to ensure that mitigations are in place to reduce the risk of harm to these patients in the event of supply disruptions.*

Coordination to mitigate risks with medicine shortages: The Committee is pleased to hear that there are various communication channels being utilised to keep healthcare providers informed, including regular updates on the ICB and OUH websites and newsletters, on updates relating to medicine shortages. It is vital that there are continued efforts not only to have open and transparent updates, but that these updates are timely given the ever-changing and rapidly developing dynamics (globally, nationally, and regionally) that could impact on medicine availability. It is also vital for there to be user-friendly avenues for regular sharing of stock information between pharmacies across the BOB footprint. This could help to ensure that risks associated with shortages in a particular locality are mitigated as much in advance as possible.

In addition, there are other potential steps that could be taken to mitigate risks including, establishing multiple supply sources to prevent dependency on a single supplier. Whilst this may not always be easy to achieve, particularly on a regional or local level, exploring such avenues could prove valuable in reducing the prospects of shortages stemming

from dependencies on single suppliers. There is also a point about regularly reviewing and updating supply chain protocols to adapt to changing circumstances.

Good coordination amongst and between system partners as well as national policymakers could help set the foundations for prompt responses to medicine shortages. The Committee urges for the development comprehensive contingency plans to address potential supply disruptions. Clear communication, coordination, and transparency can help with:

- Potentially creating emergency response teams to manage supply chain issues swiftly and efficiently.
- Developing alternative treatment plans in case of medication shortages.
- Ensuring clear communication channels with patients and their families regarding potential risks and mitigation measures.

Recommendation 2: *To ensure effective communication, coordination, and transparency within and between the local and national levels to help mitigate risks associated with medicine shortages. It is recommended that there is escalation to national levels as to the importance of national transparency with community pharmacy and patient stakeholders.*

Tackling excessive workloads: Upon commissioning this item, the Committee was keen to understand the potential impacts that medicine shortages could have on staff workload. The concern is that medicine shortages could increase additional burdens on the already substantial workloads that clinical or administrative staff are required to deal with. The Committee is concerned to hear of the increased clinical and pharmacy burdens due to drug shortages, and how this necessitated additional resources and adjustments in patient care, particularly in the management of diabetes medication.

One of the immediate impacts of medicine shortages on healthcare staff is the increase in administrative duties. Pharmacists, for instance, spend a considerable amount of time identifying alternative medications, updating electronic health records, and communicating with suppliers. The Committee heard that medicines supply issues take on average 2-3hrs per day of community pharmacy teams' time and on many occasions have led to abuse and violence against pharmacy teams.

This additional burden takes away valuable time that could be spent on other core duties, thereby reducing the overall efficiency of healthcare delivery.

When essential medications are unavailable, healthcare providers must spend additional time managing patients. This involves explaining the

situation to patients, discussing alternative treatments, and monitoring for potential side effects of substitute medications. Nurses and doctors often find themselves spending more time on each patient, which can lead to longer wait times and decreased patient throughput. Furthermore, the increased administrative and patient management duties as a result of medicine shortages could contribute to increased stress levels among healthcare staff. The constant need to find quick solutions to unforeseen problems can lead to burnout, a condition already prevalent among healthcare workers. Burnout not only affects the well-being of the staff but also compromises the quality of patient care.

Therefore, there is a need for staff to be adequately supported in the event of medicines shortages so as to help avert the prospect of staff burnout or work overload. In such contexts, consideration should be given to securing additional resource if need be so as to be able to tackle additional demands or burdens generated by medicine shortages.

Recommendation 3: *To work on reducing any prospect of additional excessive workloads on both clinical and administrative staff in the event of medicine shortages, and to provide meaningful support for staff as well as additional resource if need be for the purposes of tackling any additional demand/burdens. It is recommended that there is escalation to the national level as to the extent of workload across all health settings in the management of shortages and to seek national enablers.*

Digital database and information sharing: The prompt and accurate identification of medicine supply issues is essential for ensuring that patients receive the treatment they need. One of the key strategies to achieve this goal is the effective sharing of information and maintaining transparency among healthcare professionals. Information sharing allows healthcare providers to access up-to-date data on medicine availability, impending shortages, and alternative sources. When healthcare professionals have timely access to such information, they can make informed decisions, avoid prescribing unavailable medications, and prevent treatment disruptions. Effective communication and information sharing foster coordination among various stakeholders, including healthcare providers, pharmacists, and suppliers. This collaboration can help to ensure a cohesive approach to managing medicine supply issues, allowing for quicker responses and problem-solving.

The Committee urges system partners to explore the adoption of a digital local database to help professionals to easily identify where supply issues exist. This can serve as a centralised hub for storing and accessing information related to medicine supply. This database can include real-time data on stock levels, supply chain disruptions, and alternative suppliers, which can be easily accessed by healthcare professionals. Such a database can also enhance monitoring and reporting capabilities, allowing for the quick identification of emerging supply issues. Alerts and notifications can be set up to inform relevant parties of potential shortages, ensuring proactive measures are taken to

mitigate risks. In addition, a digital local database could open an avenue for advanced data analytics that can be employed to analyse trends, predict future supply challenges, and potentially even optimise inventory management. This predictive capability can significantly reduce the occurrence of unexpected shortages and improve overall supply chain resilience.

Furthermore, increasing transparency in medicines shortages is well recognised as critical to improvements and security of supply. The Committee was concerned about UK security of supply and the evidence about real gaps in national transparency with community pharmacy, patient and other key stakeholders. It noted that the UK is no longer part of the European Medicines Agency that provides public information on crisis preparedness and management and the work of the medicine shortages working group across Europe. Although the ICB had website information `Public Urged to Manage Prescriptions Responsibly` which urged patients to avoid stockpiling, Health Watch and the Committee members felt strongly that improved communications with the public would be a good investment to enhance transparency at a local level and empower the public to make informed decisions about their use of prescriptions.

Recommendation 4: *To continue to improve sharing of information and transparency, engaging across all health settings, including through a potential digital local database, for helping professionals to easily identify where supply issues exist. It is recommended that there is escalation to the national level on the need for; leadership on transparency with all stakeholders and the public; attracting the pharmaceutical industry to the UK market; and ensuring the sustainability of community pharmacy through improvements to the community pharmacy contract.*

Improving communication and coproduction with patients: Effective communication and coproduction with patients are crucial elements in the provision of high-quality pharmacy services and optimisation of medicines. This is especially true for patients with cliff-edge or long-term conditions, who often face unique challenges regarding the availability of medicines and the management of their health. By involving these patients in the conversation and using tools such as checklists for cliff-edge conditions and/or FAQs, pharmacies can enhance patient care, improve medication adherence, and foster a more collaborative healthcare environment. The use of medication reviews in a community-based setting might be an especially good setting for this and a good investment in prevention. Given that cliff-edge conditions refer to health issues that can suddenly worsen or escalate without timely intervention, these conditions often require immediate access to medications and close monitoring. Examples include severe asthma, epilepsy, and certain mental health disorders. Effective communication with these patients is critical to ensure they have rapid access to necessary treatments and understand their management plans.

Developing a comprehensive FAQ section can address common patient concerns and provide quick access to important information. FAQs could develop on the patient information leaflet already supplied with each medication by a pharmacy company (medication side effects, storage instructions, what to do in case of a missed dose), and include for example how to manage multiple medications, information on what to do if you have a cliff-edge condition and do not have an emergency supply, helpful signposting information. One of the most fundamental aspects of improving communication with patients is using clear and accessible language and a FAQ could help with that. FAQs in easy read for people with learning disability and different languages could save pharmacies and health professionals significant time. This resource could ideally be available both online and in printed formats within the pharmacy.

Furthermore, digital communication tools, such as email, text messaging, and patient portals and patient communication Apps for specific conditions can enhance communication with patients. These tools can be used to send reminders about medication refills, provide updates on the availability of medicines, and offer tailored checklists or educational content about managing conditions and self-care. They also allow for more immediate and convenient contact between patients and pharmacists.

Moreover, coproduction should not only inform how pharmacy services are designed/delivered, but should ideally also mean patients should be involved as active partners healthcare decisions and treatment options.

Pharmacists should be enabled to encourage patients to share their preferences and concerns regarding their treatment plans. This collaborative approach helps to tailor treatments to individual needs and increases patient satisfaction and adherence. In addition, establishing patient advisory groups can provide valuable insights into the needs and preferences of patients with cliff-edge or long-term conditions. These groups can offer feedback on pharmacy services or suggest improvements. Regular meetings and open forums for discussion can create a sense of community and partnership. The third sector is an important partner to support the NHS with co-production, helping avoidance of medical jargon and providing health information in plain language. The third sector is also well networked in respect of specific cliff-edge and long-term conditions. This ensures that patients fully understand their condition and the importance to them of their treatment and supports adherence. Liaison with Health Watch and specialist third sector health organisations for cliff-edge conditions would support a co-produced improvement.

Recommendation 5: *To work on improving communication and coproduction with patients, and involving the third-sector for those with cliff-edge or long-term conditions, regarding pharmacy services and the availability of medicines (including through the use of frequently asked questions). It is also recommended that patients are*

signposted to any support that could be available from pharmacy services and the wider voluntary sector.

Legal Implications

21. Health Scrutiny powers set out in the Health and Social Care Act 2012 and the Local Authority (Public Health, Health and Wellbeing Boards and Health Scrutiny) Regulations 2013 provide:
    - Power to scrutinise health bodies and authorities in the local area
    - Power to require members or officers of local health bodies to provide information and to attend health scrutiny meetings to answer questions
    - Duty of NHS to consult scrutiny on major service changes and provide feedback on consultations.

22. Under s. 22 (1) Local Authority (Public Health, Health and Wellbeing Boards and Health Scrutiny) Regulations 2013 'A local authority may make reports and recommendations to a responsible person on any matter it has reviewed or scrutinised'.

23. The Health and Social Care Act 2012 and the Local Authority (Public Health, Health and Wellbeing Boards and Health Scrutiny) Regulations 2013 provide that the committee may require a response from the responsible person to whom it has made the report or recommendation and that person must respond in writing within 28 days of the request.

Annex 1 – Scrutiny Response Pro Forma

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