Leicester City Clinical Commissioning Group
West Leicestershire Clinical Commissioning Group
East Leicestershire and Rutland Clinical Commissioning Group

HEALTH OVERVIEW AND SCRUTINY COMMITTEE: 15 JANUARY 2020

REPORT OF LEICESTER, LEICESTERSHIRE AND RUTLAND CLINICAL COMMISSIONING GROUPS (CCGs)

MEDICINES SHORTAGES

Purpose of report

1. The purpose of this report is to provide an overview on medicines shortages, and processes in place for the escalation and management of these shortages.

Background

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

3. Each specific medicine supply problem has its own characteristics and needs to be dealt with on a case by basis. Although some of these can have simple solutions there are others that require more complex management and monitoring.

4. Forecasting the financial impact is difficult and complex due to a number of external influences such as national designation of price changes to drugs, and unknown timeframe for shortages. Across Leicester, Leicestershire and Rutland (LLR) since 2016/17 the cost of supply issues has been in excess of £15m through increased cost for existing medicines and inflated costs when medicines return to stock *(ePACT2 data from NHS Business Services Authority).*

Reasons for drug shortages

5. The four main reasons for drug shortages are highlighted below and further detail is provided in *Appendix A*.

   a. Manufacturing problems;
   b. Supply/demand problems;
   c. Raw material availability;
   d. Regulatory.

6. Below are four examples of the most common current drug shortages including the reason for shortage and impact on patients:

a. **Ranitidine oral preparations**: This medication is used to lower stomach acid. It is currently unavailable due to a potential contaminant within all available products. Patients will require a review by their regular GP with a view to their treatment being changed to a suitable alternative.
b. **Adrenaline auto injectors:** This medication is for emergency situations where patients experience a severe allergic reaction (i.e. nut allergy). The reason for the shortage of this medication is due to the device failing to activate when used. Patient using these devices will require a change to an alternative device and re-training to go along with the new device as this may be different to current.
c. **Hormone Replacement Therapy (HRT):** These medications are primarily used for treating menopause in women and preventing osteoporosis. There has recently been a shortage of multiple HRT products due to a combination of product discontinuations and manufacturing delays which has resulted in many in-stock preparations becoming unavailable. This has caused significant impact on patients using these preparations as they require an alternative medication which is not identical to their current and at present can change each month.
d. **Diamorphine ampoules:** Diamorphine is used in end of life care to manage pain. Currently there is a shortage of two strengths of this preparation with 5mg and 10mg unavailable as a result of an ongoing issue at the individual companies manufacturing plant. The impact to patients and their families is that prescribers would be required to change the strength or the drug prescribed due to the time sensitive nature, this drug is also classed as controlled medication as such is under tighter control within community pharmacies.

7. Nationally the Department of Health and Social Care (DHSC) is responsible for the continuity of supply of medicines. The DHSC have also developed "A guide to Managing Medicines Supply and Shortages" *(see background papers below).* The DHSC guide outlines the processes and roles of national teams and bodies. This includes establishing the below groups with individual functions to support the medicines shortages, these are detailed further in appendix B:

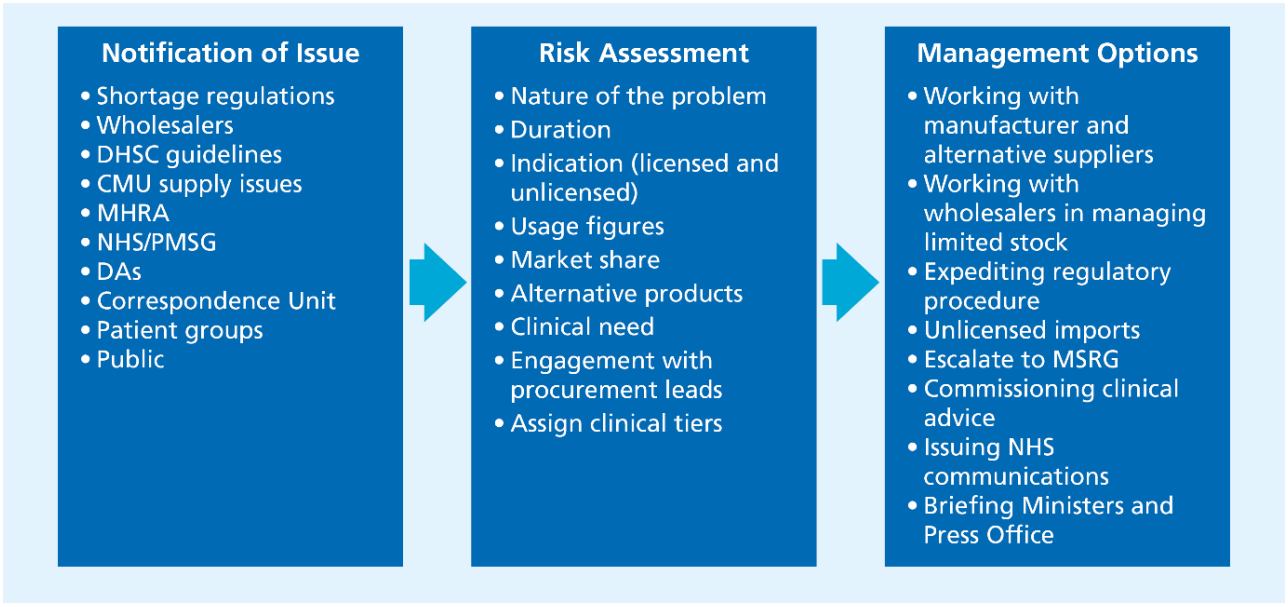
a. DHSC Medicines Supply Team;
b. NHS England and Improvement (NHSE&I) Commercial Medicines Unit;
c. NHSE&I Patient Safety Team;
d. NHSE&I Community Pharmacy Commissioning Team;
e. Medicines and Healthcare products Regulatory Agency (MHRA);
f. Medicines Shortage Response Group.

8. There is also a national management process which is followed in the situation of a shortage arising. This is provided in figure 1 below and consists of the following actions.

a. Notification: This involves the receiving of information relating to a supply issue by the DHSC medicines Supply Team predominantly from the manufacturer/supplier but can also include other intelligence sources within the health sector.
b. Risk assessment: The relevant group within the DHSC carry out a risk assessment to determine the impact to patient care. As part of this process the severity of the supply issue is determined and given a rating *(Tier 1 to 4 – Appendix B)*
c. Management options: This is how the supply issue is either resolved or if longer term how can the issue be mitigated. This can include; expediting regulatory

processes, managing supply of current stock, increased production, alternative medications to treat condition and setting allocations nationally

Figure 1: Shortage management process



9. The escalation process nationally is highlighted in figure 2 and identifies which groups within the DHSC are responsible for the various actions and at which point the supply issues are raised to Ministers.

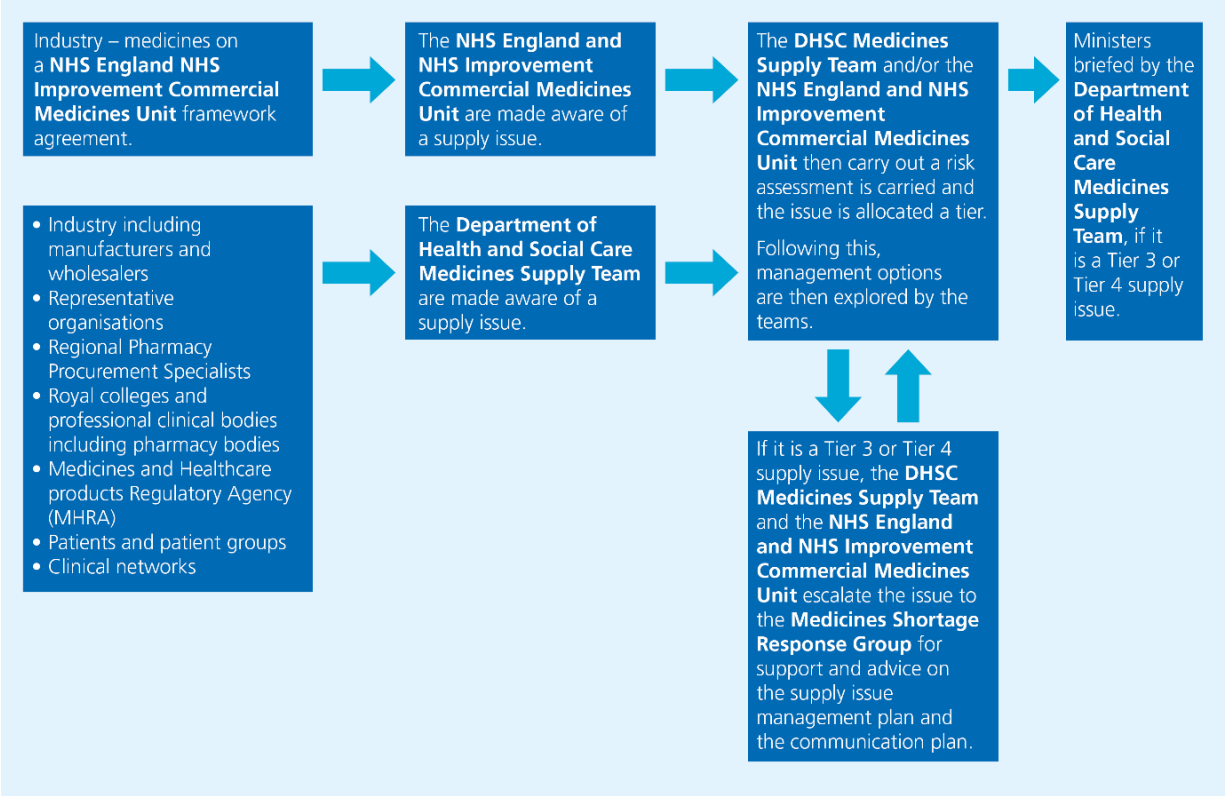
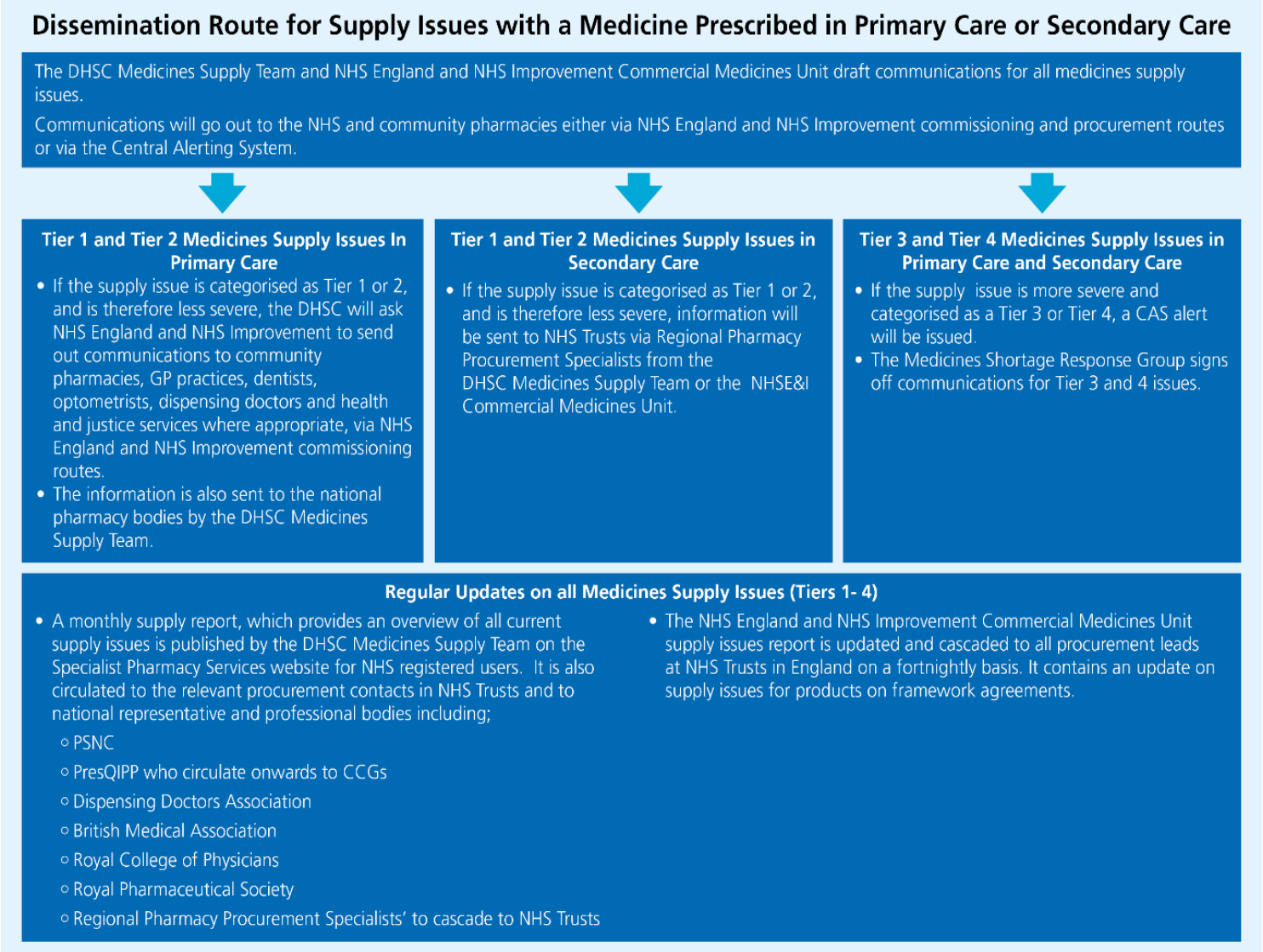


Figure 2: National Escalation Process

10. Once the medicines supply issue has been reviewed by the DHSC and assigned the relevant severity rating communications are sent out, this is dependent of the rating applied and the nature of the supply issue. The process can be seen in figure 3:

Figure 3: Communication Process



11. The communications process is managed within Primary Care with an expectation that this information and anything else relevant is communicated to patients with a management plan if necessary. Locally across Leicester, Leicestershire and Rutland information on medicines shortages is disseminated to Primary Care practices based on urgency through various different communications these include but are not limited to:

a. Biweekly newsletter to Primary care practices;
b. Monthly Medicines Quality Newsletter;
c. Through Medicines Quality presentations at Primary Care Network meetings;
d. Ad-hoc emails for more serious/urgent shortages;
e. Clinical decision software available on GP clinical systems;
f. Sharing of DHSC Supply Issues update monthly which outlines options for management.

12. The Leicester Medicines Strategy Group (LMSG) which is the local committee that makes decisions on prescribing of medicines and managing entry of new drugs and related technologies has a process endorsed by the Leicestershire health community on managing medicines supply including guidance and a checklist *(Appendix D).*

13. There is partnership working with the between clinical commissioning groups, hospital trust and local pharmaceutical committee to ensure patient care is not affected through medicines supply issues.

Proposals

14. The Medicines Optimisation teams continually monitor the changing environment on availability of medications.
15. The Medicines Optimisation teams across Leicester, Leicestershire and Rutland to continue to raise the issue of medicines shortages to the DHSC and work with stakeholders to ensure the information is disseminated to the relevant individuals in a timely manner.

Conclusions

16. Members of the committee are invited to note and comment on the content of the report and both national and local processes.

Background papers

A guide to Managing Medicines Supply and Shortages: https://www.england.nhs.uk/wp-content/uploads/2019/11/a-guide-to-managing-medicines-supply-and-shortages-2.pdf

Circulation under the Local Issues Alert Procedure

Not Applicable. Topic is nationally relevant.

Officer to Contact

Name and Job Title: Vishal Mashru, Head of Prescribing, East Leicestershire and Rutland CCG
Telephone: 0116 2957181
Email: vishal.mashru@eastleicestershireandrutlandccg.nhs.uk

List of Appendices

Appendix A: Causes of medicines supply shortages
Appendix B: Severity of Medicines Supply Issue
Appendix C: LMSG ‘Out of Stock’ Guidance and Checklist

Relevant Impact Assessments

Equality and Human Rights Implications

17. Yes, completed nationally

Crime and Disorder Implications

18. N/A

Environmental Implications

19. N/A

Partnership Working and associated issues

20. N/A

Risk Assessment

21. Yes, completed nationally.

Appendix A: Causes of medicines supply shortages

1. Manufacturing problems

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

2. Supply/demand problems

Wholesale availability and supply direct from manufacturers of branded generics

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

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

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

Quotas

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

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

3. Raw material problems

Raw material issues including shortages account for 9% of medicines shortages. Many molecules are now manufactured by only one supplier internationally, this can cause international shortages if the supply chain fails in any way, which could be due to factory issues, quality control failure or increased demand without increased production.
Availability problems arise when raw materials come from undeveloped parts of the world or where there are hostilities, animal diseases contaminate tissue used to extract raw material, climatic and other environmental changes depress the growth of plants used to extract raw material. Voluntary recalls can cause shortages, especially when a sole manufacturer's drug product dominates the market supply.

4. Regulatory

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

Appendix B: Severity of Medicines Supply Issue

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

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