



An Annual Review of Drug Shortages Managed by the MMUH Pharmacy Department

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INTRODUCTION

"A shortage of a medicinal product for human or veterinary use occurs when supply does not meet demand at a national level" European Medicines Agency (EMA), 2019

"A shortage occurs when the supply of a medicinal product is inadequate to meet the needs of patients" Health Product Regulatory Authority (HPRA), 2018

Note: Logistical reasons leading to regional medicine supply disruption are not considered shortages as per the definitions above.

Drug shortages can adversely affect drug therapy, compromise or delay medical procedures, result in medication errors and ultimately cause patient harm. Drug shortages also have financial consequences for hospitals, the state and patients.

In response to increasing drug shortages nationally, the HPRA established the Drug Shortage Framework in 2018.¹

The causes for drug shortages are complex and can occur at a variety of points throughout the drug supply chain.



In the MMUH, the Medicines Information (MI) service collaborates with dispensary, clinical and other colleagues to manage drug shortages. In 2019 drug shortages represented 17% of MI service workload in contrast to 9% in 2018, prompting a review of drug shortage management in the Pharmacy Department.

AIM To review the nature and impact of drug shortages managed by the MMUH Pharmacy Department in 2019.

METHODS

Shortages are logged on MiDatabank with 'shortage' as a keyword. Relevant 2019 enquiries were identified

Details for each shortage were collected, categorised and analysed on Microsoft Excel

The procedure for managing drug shortages in MMUH was reviewed

RESULTS AND DISCUSSION

The Pharmacy Department managed **403 drug shortages** in 2019.

How were drug shortages identified?

- Drug shortages were mainly communicated by the HPRA (46%), the wholesaler (28%) or the manufacturer (22%).
- Other sources of information included Health Service Executive (HSE) distribution lists, other pharmacy colleagues and UK platforms.

What drugs experienced shortages?

- Drug shortages spanned a wide range of therapeutic classes (Figure 1).
- The active ingredients associated with the most drug shortages were morphine (n=13), tinzaparin (n=10), losartan (n=9), fentanyl (n=7), venlafaxine (n=7) and betamethasone (n=7).

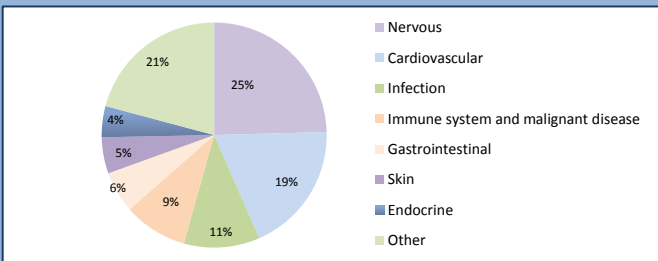


Figure 1. Drug shortages according to BNF Therapeutic Class

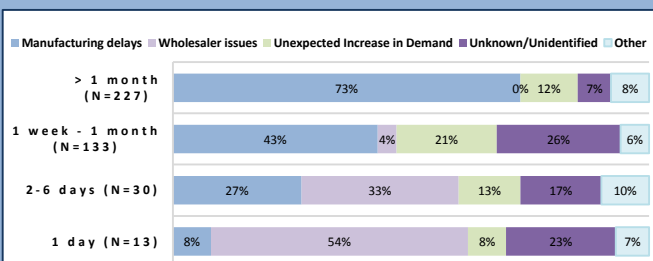


Figure 2. Drug shortage duration with associated causes

What was the nature of drug shortages?

Figure 2 identifies drug shortage duration with associated reasons for drug shortages. The majority of drug shortages lasted > 1 month (56%) mostly due to manufacturing delays or an unexpected increase in product demand.

How were drug shortages managed?

- Figure 3 details the purchasing strategies to resolve the shortages. In the majority of cases no purchasing action was taken as there was sufficient stock to cover the shortage duration (n=141; 81%), or because no alternative option was available (n=33; 19%). Where no purchasing action was available, strategies for managing the shortage included immediate stock rationing, using a therapeutic alternative and/or communicating the shortage outside the department.
- Apart from purchasing reactions, 18% (n=72) of drug shortages required at least one further follow-up action. Further actions needed were hospital-wide communication (13%), stock rationing (9%) and/or protocol amendments (3%). Drug shortages requiring follow up mainly concerned drugs of critical nature (e.g. antimicrobials, fentanyl, morphine, lorazepam, magnesium sulfate). Five drug shortages (lorazepam, ranitidine, moxifloxacin) required all three follow-up actions.
- 5% (n=22) of drug shortages were due to wholesaler issues. These shortages were generally not concerning as there was sufficient stock to cover the expected shortage duration. In four cases immediate action was needed (two cases required hospital-wide communication and two other cases required immediate stock rationing). Wholesaler shortages do not fall under the accepted European or national definition of true drug shortages, however, MMUH experience is that these shortages can require similar assessment and treatment as true shortages.
- In January 2020, 21% of drug shortages identified in 2019 were ongoing.

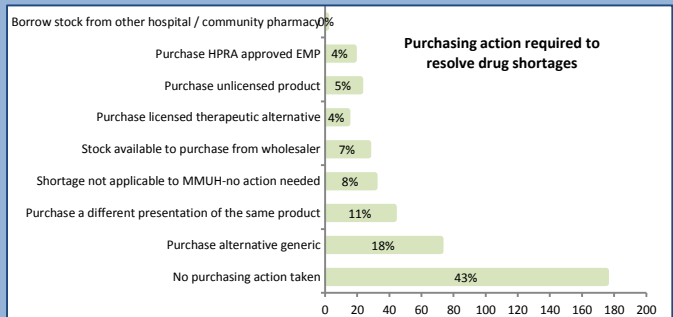


Figure 3. Purchasing action required to resolve drug shortages

In light of the increasing number of drug shortages encountered in 2019, the Pharmacy Department processes on managing drug shortages were reviewed and streamlined. The current process provides a step-wise approach to the management of a drug shortage with individual Pharmacy Department members roles and responsibilities clearly defined.

CONCLUSION

Drug shortages are a challenging part of pharmacy service delivery with a significant impact on daily operations. Greater collaboration amongst all stakeholders is needed in Ireland to enable Pharmacy Departments to appropriately assess the impact of drug shortages and make practical decisions to ensure continuity of drug supply for their patients.