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Perspective

Medicine shortages: there are solutions! Actions to take to reduce medicine shortages

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Abstract. The aim of this paper is to propose solutions to reduce the number and frequency of medicine shortages in Australia. Some of the many factors that contribute to medicine shortages, such as manufacturers' production processes and business decisions, are outside the control of Australian stakeholders. But there are many factors that are within the control of stakeholders, including poor communication between stakeholders, incomplete and inaccurate information, unhelpful practices and attitudes of hospital tender authorities, and lack of certainty and incentives for manufacturers in relation to pharmaceutical tenders. The following strategies are designed to address these issues and achieve a significant reduction in the number and frequency of medicine shortages in Australian hospitals. They include improving communication and understanding between stakeholders, providing higher quality information on likely usage, changing practices of hospital tender authorities to better meet stakeholder requirements, and increasing incentives for manufacturers to participate in hospital tenders. The six key actions to implement the medicine shortage-reducing strategies are: (1) initiate a biannual forum for hospitals and industry; (2) establish a medicines substitutes information service operating nationally; (3) share information on likely changes to hospital usage; (4) reform stock allocation strategies; (5) introduce incentives for manufacturers; and (6) change hospital tender authority practices and policies. The first step to reduce medicine shortages is for stakeholders to think differently about the problem, and to act more collaboratively using the proposed strategies and actions, as a framework for change.

Keywords: medicine, shortages, unavailability, strategies, drugs, pharmaceuticals, tenders, substitutes.

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Introduction

The COVID-19 pandemic has amplified the recently worsening problems with the world medicine supply chain, which has led to frequent shortages of critical medicines.

Most commentary on shortages has sought to provide advice on ways to deal with shortages. The views expressed in this perspective go further by focusing on reducing the number and frequency of medicine shortages in Australia by proposing some solutions to problems. Although the focus of this paper is the hospital medicines supply chain due to the author's deeper knowledge of this sector, many of the solutions are equally applicable to the supply chain for community pharmacy medicines.

Factors contributing to shortages and strategies to address these

The medicines supply chain includes producers of raw materials, manufacturers, regulators, wholesalers and distributors, tender authorities, healthcare organisations, and patients. Shortages can be the result of a single factor or a combination of factors throughout the supply chain and of commercial and business decisions.

Some of these factors, such as manufacturing and quality problems, production delays, lack of manufacturing capacity, shortages of active pharmaceutical ingredients, and commercial and business decisions such as product range rationalisation, are outside the control of Australian stakeholders. Nevertheless, the risks to uninterrupted supply could be reduced if the Therapeutic Goods Administration (TGA) registration process required sponsors to complete a risk assessment of these factors, which would then be considered in the registration process. The same could be done for applications for listing on the Pharmaceutical Benefits Scheme (PBS). These factors could also be considered in the planned review of the National Medicines Policy, such that the policy would promote local manufacturing of medicines as a key enabler of timely access to medicines.

But there are many problems that contribute to medicine shortages that are within the control of Australian stakeholders. The following strategies are designed to reduce the impact of these problems and to address two of the central objectives of the

National Medicines Policy; that is, timely access to the medicines Australians need and maintaining a responsible and viable medicines industry. They are:

- improve communication among hospital, manufacturer and wholesaler stakeholders to increase the level of understanding of the importance of each other's processes;
- provide information on likely changes within hospitals, which will impact demand for medicines to enable manufacturers to plan production more effectively to meet anticipated demand;
- change many of the practices and attitudes of hospital tender authorities;
- increase certainty for manufacturers through commitments to purchase pre-agreed volumes;
- eliminate hoarding by hospitals stimulated by rumours of impending shortages and driven by pharmacists' desire to ensure they have sufficient stock to meet patient demand for the duration of the rumoured shortage; and
- increase incentives for manufacturers to participate in hospital tenders and to produce critical medicines.

Six key actions to implement these strategies

The following actions are recommended to implement the strategies:

(1) initiate a biannual forum for hospitals and industry (coordinated by an independent third party) where key decision-makers can meet to discuss and share the information which both need in order to increase the reliability of the medicines supply chain;
(2) supplement this forum with an annual survey of directors of pharmacy to provide information in broad terms, on planned changes in hospital casemix, occupancy, formulary, and other factors likely to impact demand to help manufacturers more effectively plan production;
(3) establish a medicines substitutes information service operating nationally, to investigate, on behalf of all hospitals, substitutes for medicines in short supply; and for products not registered in Australia, their ingredients, labelling, storage information, and transport requirements, to significantly reduce the need for individual hospitals to carry out this research into substitute medicines;
(4) reform stock allocation strategies such that in times of medicine shortages, stock is allocated by wholesalers to hospitals on the basis of each hospital's average monthly purchases of the product from the wholesaler, in order to reduce hoarding practices and ensure available stock is shared in a more equitable way;
(5) introduce incentives for manufacturers to produce and hold stock of critical medicines; and
(6) implement changes to the practices and policies of state hospital tender authorities and some private hospital tender entities, many of which currently contribute to shortages. In regard to tender activities the proposed changes include:

i. staggering the start and end dates of state pharmaceutical contracts;
ii. establishing a fixed period of two years (this duration is to accommodate changes in the market) for state pharmaceutical contracts, with one-year plus one-year extension options;
iii. inviting tenderers to offer two prices in their response to a request for tender (RFT) where the higher price would come with a guarantee of supply. This which would enable hospitals to choose between either lowest price or certainty of supply, and provide suppliers more certainty when hospitals commit to volumes. The options would be:

- Price A: a cheaper price with a 'best effort' to supply; and/or
- Price B: another price with a guarantee of supply for which a hospital would commit a specified volume for a contract period and a manufacturer would guarantee supply. This option would include a provision to vary commitments if changes to prescribing or hospital activity occur;

iv. listing the two prices at the announcement of the result of the RFT (which should be at least 6 months before the contract start date), requiring successful tenderers to ask each hospital which price option they wish to choose, and advising hospitals choosing:

- Price A option that no further action is required;
- Price B option that they would be required to enter into a contract to purchase an agreed volume of specified contract products over the first 2 years of the contract (at Price B):

v. notifying the wholesalers nominated by the hospitals of the hospitals' decisions;
vi. offering incumbent suppliers at 12 months into the first 24 months of the initial contract period and 6 months into the first 12-month extension of the contract period, the option to extend the contract by a further 12 months at the same price. If the incumbent wanted to continue but at a higher price, or they decide to withdraw the product, the state tender authority would commence the RFT process for the products affected, with a view to announcing a decision at 6 months from the end of the initial 2-year contract period;
vii. implementing different supply and penalty options for, and obligations on successful Price A and Price B tenderers and participating hospitals. These would include providing the ability for Price B hospitals to vary volume commitments with 6 months' notice based on changes to hospital prescribing patterns, casemix or activity; and
viii. providing incentives for manufacturers to establish and maintain manufacturing facilities in Australia by implementing additional weighting in the tender selection process to reward those that have a TGA-licenced manufacturing facility in Australia.

If these changes are made, there will be greater incentive for manufacturers to participate in tenders and to work more collaboratively with tender authorities and hospitals to achieve mutually beneficial outcomes.

Conclusion

Given the issues contributing to medicine shortages and outages, it is reasonable to conclude that hospitals need to find a balance between price and certainty of supply. The loss of some potential

direct savings can be offset by certainty of supply, ability to provide uninterrupted patient care, less indirect costs, and more productive pharmacy and clinical activities.

The first step to achieving a reduction in the number and frequency of medicine shortages is for stakeholders to think differently about the problem, and to act more collaboratively using the proposed strategies and actions as a framework for change.

Competing interests

The inspiration for this paper came from two case studies the author conducted to quantify the impact of medicine shortages on two major Australian teaching hospitals. The case study work was commissioned by a pharmaceutical company. The work involved in the case studies and in the production of this paper were carried out independently by the author.