



## Medicine shortages: Implications for the Australian healthcare system

Betty B. Chaar

Department of Pharmacy, University of Sydney

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### EDITORIAL

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Please cite this paper as: Chaar BB. Medicine shortages: Implications for the Australian healthcare system AMJ 2014, 7, 3, 161-163. <http://doi.org/10.21767/AMJ.2014.1943>

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#### Corresponding Author:

Dr Betty B. Chaar Room  
S242- Bldg A15 Faculty  
of Pharmacy  
The University of Sydney NSW 2006  
Email: [betty.chaar@sydney.edu.au](mailto:betty.chaar@sydney.edu.au)

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Shortages in medicine supply are usually associated with the now well-known representation of impoverished, underdeveloped countries suffering famine, episodes of vast epidemics, and accounts of immeasurable morbidity and mortality. However, it has become alarmingly clear that medicine shortages are now occurring in the most developed countries in the world and for several reasons.<sup>1</sup> Media headlines describe severe shortages and high costs of workarounds, impact on patient safety, and many other outcomes resulting from lack of access to necessary medicines.

In a country such as Australia, “the lucky country”, it is difficult to imagine our healthcare system suffering shortages of medicines. Unimaginable some would think. However, the reality is that medicine shortages are indeed creeping into our system, with the potential to cause havoc, as already observed in several other developed countries.<sup>2</sup> The medical profession simply cannot function without medicines and medicinal products, particularly those pertinent to specialist areas of practice where there may be only limited choices of treatment or workarounds if and when necessary. Medicine shortages will be an ongoing topic of interest as issues evolve and hopefully, we in Australia begin to develop preventative and mitigating measures to avoid the consequences of having our heads in the sand.

### Background

In June 2013, the International Pharmaceutical Federation (FIP) held an inaugural International Summit on Medicine Shortages in Toronto, Canada.<sup>3</sup> It was attended by representatives from governments around the globe, healthcare practitioners and professional bodies, the pharmaceutical industry, and patients. The aim of the Summit was to provide a forum to discuss the causes and impacts of medicine shortages, and to offer solutions to address the global issue using a multi-stakeholder approach. It was an intriguing forum, in which I personally learnt much about the profound impact and worldwide scope of the problem, and the manner in which some countries have attempted to mitigate the inevitable issues associated with medicine shortages in the clinical setting.

The causes of medicine shortages are many and varied, in some cases coincidentally overlapping, which makes for a complex, difficult-to-resolve problem in health care.<sup>4,5</sup> The majority of shortages appear to be caused by lack of raw materials, and/or reliance on one source of these raw materials (for example, from India or China), which can be hazardous. It is often the case that the source cannot cope with higher than usual demand, as the world relentlessly intensifies its medicinal needs.

Often products become no longer financially viable to the manufacturer (in particular orphan drugs and generics), and consequently are simply discontinued, frequently with little or no warning. Other shortages have been due to stringent clampdowns by health authorities on quality assurance at the manufacturing level. The need to close down some plants for repair or maintenance has in some cases ironically caused widespread disruption of supply and harm to consumers. The Sandoz plant in Canada is a critical example. In early 2012 Sandoz announced it had to scale back production of several medicines, including analgesics, antibiotics, and anaesthetics, after quality control assessment by the FDA found the factory fell short of standards of production. Exacerbating the situation, a fire erupted in the factory, rendering continuation of manufacturing almost impossible. The subsequent nationwide shortages in medicines such as injectable opioids



used in palliative care triggered much distress to patients and healthcare providers alike. There were major disruptions to elective surgery, cancer treatments, and countless patients left without treatment options across the nation. Canadians paid a heavy price.

Changes in patterns of demand can also affect supply of medicines. For example, a sharp increase in demand for Penicillin G in Australian hospitals for a certain period, led to rationalisation of this product, as the only provider was unable to meet the sudden surge in demand. Similarly, in Brazil, the increasing demand for benznidazole (used to treat Chagas disease) could not be met by the sole world manufacturer (which is state owned) and resulted in medicine shortages. For whatever reason changes occur, the manufacturer may have little time to adjust its manufacturing capacity to meet the increase in demand.

Medicine shortages may also be attributed to purchasing capabilities, tender processes, the global financial crisis, corruption, natural disasters, pandemics, and the emergence of the “grey market” (i.e. where unscrupulous dealers exploit shortages by providing the market with previously stockpiled products at exorbitant prices, thereby exacerbating and exploiting the issue). There are several other reasons for medicine shortages, some of which remain unknown, or beyond the scope of this editorial, but the reasons listed briefly here give the reader an indication of the many complexities entangled in the supply of medicines around the world.

Characteristics of medicine shortages also vary greatly from country to country. There is a lack of reliable information at a global level, but most active shortages are in antimicrobials, chemotherapy, cardiovascular medicines, central nervous system medicines, and nutritional supplements. Injectables have been particularly prone to shortages, due to manufacturing issues.

In some countries the problem has been longstanding; the US, for example, has had a track record of medicine shortages for more than a decade, according to the representative of the American Society of Health-System Pharmacists (ASHP). In 2001 (although shortages had started to appear earlier), as a result of the implications on practice, the ASHP started reporting medicine shortages on a national level, and in the first year reported 120 medicines in short supply, with an average of 70 new reports yearly since then. The University of Utah Drug Information Center reported an increase in the number of new shortages from 58 to 88 in 2002–2007, to 267 in 2011, and 204 in 2012.

In Canada there has also been a relatively longstanding problem with medicine supply. The national medicine shortages reporting system ([www.drugshortages.ca](http://www.drugshortages.ca)) listed approximately 300 products in short supply as of June 2013. In Europe, 346 hospitals were surveyed by the European Association of Hospital Pharmacists and found 98.8 per cent of participating hospitals experienced shortages over the past 12 months, while 63 per cent reported that problems associated with shortages occur at least weekly.

The impact of medicine shortages can be substantial on a number of levels. Primarily, a significant degree of patient care can be compromised as a result of medicine shortages. There is a plethora of evidence to support this claim. Medicine shortages can result in delayed or unavailable treatment, or a change to an alternative (often less effective) regimen may be necessary. And there are safety implications to consider, including errors incurred as a result of administering alternative treatments with which some healthcare professionals are unfamiliar. Adverse patient outcomes have resulted. Medicine shortages can therefore result in deterioration of the patient’s condition, hospitalisation, and even death.<sup>6</sup> There is evidence that at least 15 deaths in the US could be attributed to shortages in 2010–2011.

Dr Cecil Wilson, president of the World Medical Association (WMA), represented the perspective of physicians worldwide at the Summit. He spoke about the widespread issue of shortages in medicine supplies and the challenging implications on decision-making, impact on patient care, and the crucial role of government bodies. There are often painful decisions to be made by physicians.<sup>7</sup> Some circumstances have required medical doctors to reluctantly prioritise among their patients for limited medicinal resources (those who could not survive without treatment versus those who could be delayed or have treatment cancelled). Dr Wilson emphasised the urgency to work on both prevention and mitigation of medicine shortages.

The Summit concluded with six major recommendations, which may be useful for healthcare systems around the world to take into consideration:

1. To advance transparency and increase communication between all stakeholders on existing shortages, each country should establish a publicly accessible means of providing information that is: timely, as complete as possible, focused on current



shortages and their causes, expected duration and action(s) taken. This may involve Ministry of Health, Medicines Regulatory Authority, professional bodies and/or, industry trade associations and other stakeholders.

2. A global process to determine a list of critical or vulnerable products should be developed. This would be executed by a multilateral organisation within the United Nations structure.
3. All procurers of medicines are urged to move towards active procurement processes that assure the continuity of supply of quality medicines. Elements of high-quality active procurement processes would include:
  - i. improved quantification (e.g. forecasting);
  - ii. direct communication between procurement agencies and manufacturers regarding sustainable capacity to supply;
  - iii. deliberated and considered approaches tailored to the specific situation for each product (long-term, short-term, split contracts, etc.);
  - iv. responsible pricing that values quality;
  - v. meaningful, binding, contracting.
4. All countries are encouraged to remove unnecessary variability of regulatory practices within and between countries.
5. All countries are encouraged to establish a national body charged with gathering and sharing information about demand for and supply of medicines within their jurisdiction. This body could also develop an ethical framework for decision-making relating to resource allocation at times of scarcity. This body could also coordinate the dissemination of information about the national available stock.
6. All countries are encouraged to develop evidence-based risk mitigation strategies, which might include strategic buffer stocks and stockpiles, contingency planning, pandemic planning, and capacity redundancy appropriate to their national needs.

Australian authorities have yet to develop any policy or initiative to address the ever-increasing incidence of medicine shortages in hospitals and pharmacies reported around the country.

## Conclusion

In Australia we are privileged to have the opportunity to benefit from the insight and hindsight of those who have

already suffered and continue to suffer consequences of medicine shortages. There are lessons to be learned and warnings to be heeded. However, to date, this topic has been under-scrutinised in Australia, despite disquieting warning signals appearing on our radar.

I recently received a report dated 30 October 2013, listing no less than 78 medicines in short supply in a hospital in NSW. Some medicines on the list were provided with alternatives, such as brand products or generics, or pertinent information such as being listed on the Special Access Scheme (SAS). The question is: if this is a report from just one hospital in NSW, what else is happening in Australia?

Other questions that spring to mind are: What is being done about medicine shortages at the Commonwealth government level or State departments of health levels? What plans are in place? What preventative measures are there to avert the risk of medicine shortages in Australia? Looking at other countries' experiences, surely it is time for some serious consideration of our options. A good place to start would be to adopt at least some or all of the above-mentioned recommendations.

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