



**ANZCA**  
FPM

June 30, 2020

Committee Secretary  
Joint Standing Committee on Foreign Affairs, Defence and Trade  
PO Box 6021  
Parliament House  
Canberra ACT 2600

Dear Committee members

### Anaesthetic medicine supply chains and PPE in Australia

The Australian and New Zealand College of Anaesthetists (ANZCA), including the Faculty of Pain Medicine (FPM), is committed to the highest standards of clinical practice in the fields of anaesthesia, perioperative medicine and pain medicine. As one of the largest medical colleges in Australia, ANZCA is responsible for the postgraduate training programs of anaesthetists and specialist pain medicine physicians, in addition to promoting best practice and ongoing continuous improvement that contributes to a high quality health system.

ANZCA appreciates the opportunity to make a submission to the *Inquiry into the implications of the COVID-19 pandemic for Australia's foreign affairs, defence and trade*. Our intention is to highlight the risks associated with anaesthetic medicine supply chains and sourcing of personal protective equipment (PPE) that were present prior to, and further exacerbated by, the COVID-19 pandemic.

#### Background

Medicine shortages are a relatively common occurrence in Australia and the Therapeutic Goods Administration (TGA) works swiftly to identify, monitor and mitigate such events. In most instances, if the shortage is expected to be prolonged, a substitute agent may be granted by the TGA under Section 19A of the *Therapeutic Goods Administration Act 1989*. This system has proven to be effective, however it requires adequate time and functioning of accessible global supply chains, with these preconditions not being met during the onset of the COVID-19 pandemic. Anaesthetic medicines are particularly exposed in light of the time required to have off-label anaesthetic medicines, such as sedatives, approved under the *Act*.

ANZCA acknowledges the proactive work being undertaken by the TGA in assessing the issue of medicine shortages, highlighted by the formation of the Medicine Shortages Working Party. Even prior to the COVID-19 pandemic, the issue of medicine shortages was becoming increasingly common with the TGA estimating that in 2019 there was a 290% increase in the total number of shortage notifications reported compared with 2018.<sup>1</sup>

#### Anaesthetic medicines

The manufacturing of anaesthetic medicines in Australia is minimal with the majority of agents imported. The usual process is for an overseas supplier or manufacturer to be sponsored by a private company which has established operations in Australia in order to have a product that is manufactured overseas approved for use. Although details regarding the sponsoring company and supplying company are readily available, often the country of manufacture is not explicitly stated. This can create uncertainty and acts to constrain the ability of industry to effectively engage with government agencies and suppliers to address supply chain disruptions. This issue is further compounded at times such as COVID-19 where a manufacturer may make decisions and/or

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<sup>1</sup> <https://www.tga.gov.au/sites/default/files/medicine-shortages-report-first-12-months-mandatory-reporting-scheme.pdf>

renege on orders of products to redirect to other countries. It creates an opaque policy setting that limits supply modelling and ultimately affects the provision of anaesthetic services.

As the authority responsible for education, training, setting of standards and the promotion of safety and quality of anaesthesia and pain medicine, ANZCA is often the first point of contact for anaesthetists and specialist pain medicine physicians when shortages arise. However our ability to provide advice and guidance to address medicine shortages is constrained by the lack of detail within publicly accessible supply chain information. The need for greater transparency, particularly for industry stakeholders, is critical to facilitating collaborative efforts in addressing shortages among the tertiary, private and public sectors.

### **COVID-19 disruptions**

The COVID-19 pandemic has exacerbated a wide array for disruptions for the supply of anaesthetic agents, with prolonged disruptions presenting a potential threat to the continuity and stability for the provision of anaesthetic services. As of May 2020, the TGA Medicine Shortages Information Initiative database listed 13 critical shortages for sedatives and neuromuscular blockers which are vital to the provision of anaesthesia, such as dantrolene, propofol, cisatracurium, suxamethonium, rocuronium, fentanyl and atracurium. Most of these shortages relate to manufacturing, commercial reasons and unexpected increases in demand.<sup>2</sup>

As a binational college, we are also alert to the situation in New Zealand, where the New Zealand Pharmaceutical Management Agency (PHARMAC) has notified ANZCA of disruptions to the supply of key medicines in the provision of anaesthesia including propofol, fentanyl and suxamethonium.<sup>3</sup> As in Australia, there are concerns pertaining to supply chain integrity surrounding these medicine shortages.

In normal circumstances these shortages can be addressed given adequate lead time. However the COVID-19 pandemic has highlighted that in the event of a crisis, which significantly disrupts Australia's access and engagement in global supply chains, there is a potential threat to the continuity and quality of health service provision in Australia. The over-reliance on international medicine supply chains was evident prior to, and continues to be exacerbated by, the COVID-19 pandemic and disruption to international trade.

The production of the majority of anaesthetic medicines outside of Australia will continue to pose a risk to the continuity of care for anaesthesia during future pandemics and crises. We recognise that solving this issue is complex and would be happy to provide further input to the Medicines Shortages Working Party.

During the early stages of the COVID-19 pandemic, the issue of PPE quickly became a major concern for anaesthetists in Australia. The lack of clarity regarding procurement, supply levels and appropriate use of PPE fuelled significant anxiety among anaesthetists who contacted the college during this time. We received reports of experiences with sourcing PPE, describing instances of anaesthetists personally purchase N95/P2 respirators from retailers such as Bunnings Warehouse because their hospital supplies were inadequate or access to PPE was limited by hospital administration.

The depletion of local PPE stocks was addressed by the rapid approval process put in place by the TGA. Subsequently, it emerged that non-compliant PPE products were being marketed and a number of examples of fake and faulty PPE products being available were reported.

N95/P2 respirators require formal fit-testing to comply with the Australian and New Zealand standard AS/NZS 1715:2009 and the Australian Government infection prevention and control guidelines. Fit-testing ensures that the respirator is able to be properly fitted to the anatomical

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<sup>2</sup> Collected from information pertaining to anaesthetic agents contained within the TGA Medicine Shortages Information Initiative. [apps.tga.gov.au/prod/MSI/search](https://apps.tga.gov.au/prod/MSI/search)

<sup>3</sup> [www.pharmac.govt.nz/information-for/enquiries/propofol/](https://www.pharmac.govt.nz/information-for/enquiries/propofol/)  
[www.pharmac.govt.nz/information-for/enquiries/fentanyl-injection-supply-issue/](https://www.pharmac.govt.nz/information-for/enquiries/fentanyl-injection-supply-issue/)  
[www.pharmac.govt.nz/information-for/enquiries/suxamethonium-supply-issue/](https://www.pharmac.govt.nz/information-for/enquiries/suxamethonium-supply-issue/)

features of the wearer. Disrupted and unpredictable supply chains have meant that some healthcare workers have been using respirators that do not properly fit their face and do not provide them with the necessary protection from coronavirus infection

Although many these concerns were promptly addressed, the situation may have been worse if it were not for the effective control of the COVID-19 spread in Australia. We would like to acknowledge the significant work undertaken by the Commonwealth Government on these issue and in particular the Deputy Chief Medical Officer Dr Nick Coatsworth who engaged, and worked collaboratively with us during the COVID-19 pandemic

In summary, ANZCA would like to highlight the following;

- Shortages of critical medicines were exacerbated by the COVID-19 pandemic and Australia has a heavily reliance on overseas suppliers to fill these gaps. The significant disruption to global supply chains caused by the COVID-19 pandemic exposed our sovereign vulnerability in the supply of critical medicines.
- The unclear and poor transparency of information regarding procurement chains and supply levels at both a national and jurisdictional level have fuelled significant angst among healthcare workers during the COVID-19 pandemic.
- Rapid responses to boost the supply of PPE need to ensure that health care workers can access appropriate and effective products and must be balanced against the risk of non-compliant products entering the market.

ANZCA recognises that addressing issue of medicine shortages, PPE supply and healthcare system preparedness is a multifaceted challenge. While long-term solutions are challenging, they are vital to ensuring the Australian healthcare sector can provide the continuity of care and service provision that forms the foundation for our reputation as global leaders in healthcare provision. Thank you for considering these issues and we hope to have the opportunity to continuing to work with government towards resolving these.

Yours sincerely



**Nigel Fidgeon**  
Chief Executive Officer