Palliative Care Australia
Matters of life and death

Medicine shortages in Australia: Consultation on challenges and opportunities

Submission to the Therapeutic Goods Administration, March 2024

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Introduction

Palliative Care Australia (PCA) is the national peak advocacy body for palliative care. PCA represents all those who work towards high-quality palliative care for all Australians who need it. Working closely with consumers, our Member Organisations and the palliative care workforce, PCA aims to improve access to and promote palliative care.

Palliative Care Australia (PCA) thanks the Therapeutic Goods Administration (TGA) for the chance to provide input to its consultation on challenges and opportunities regarding medicine shortages in Australia.

Many of the questions in the TGA's consultation paper are less relevant for PCA. In representing the palliative care sector, PCA conveys stakeholder concerns and communicates with the sector about the availability of relevant medicines, but our role is not to resolve specific medicine shortages. Rather than address each consultation question in turn, PCA has prepared this standalone submission conveying our perspective on challenges and opportunities arising from medicines shortages affecting palliative patients and palliative care clinicians.

Challenges

Pattern of medicine discontinuations

Opioid analgesics play a crucial role in palliative care, ensuring the comfort and care of individuals with life-limiting illnesses. We would like to draw attention to the sustained shortages and discontinuations of opioid analgesic medicines in Australia. This includes recent decisions by Mundipharma to discontinue several critical opioid products (Ordine, MS Mono, Sevredol, Oxynorm) and also prior discontinuations and supply disruptions (Dilaudid, Jurnista, MS Contin Sachets).

There are other non-opioid medicines which present financial barriers for patients in community settings and which are commonly used in palliative care. These include Metoclopramide, where the two alternative products to the now discontinued Maxalon brand are not listed on the Pharmaceutical Benefits Scheme (PBS), and Midazolam, which is also not currently PBS-listed.

The growing pattern of discontinuations of essential palliative care medicines poses a significant risk to patient comfort, care, and clinical outcomes, affecting not only palliative care patients and those nearing the end of life, but also those with chronic pain, cancer, and other conditions requiring effective pain control.

Many of the medicines on the Palliative Care Schedule have been approved and in use for decades, and are well-known to be essential to the comfort and wellbeing of patients. For

that reason, various opioid analgesics are on the World Health Organisation's (WHO) Model List of Essential Medicines.[1] But because such medicines are not new or cutting-edge – and attract less of an innovation premium – they can be less commercially attractive for suppliers, and are less of a focus as we refine processes for approving new medicines. Nevertheless, threats to the supply of such medicines are clearly a matter of public interest.

Short Reporting Period

The current minimum reporting period of six months for pharmaceutical companies to inform the market of medication discontinuations has proved inadequate to avert supply disruptions and find replacements for discontinued medicines. The bureaucratic and operational processes involved in sourcing new medicines, obtaining regulatory approvals and securing PBS listing, demonstrably exceed the time available following the legislated six-month notice period.

Announcements about impending discontinuations leads to distress for patients and families while alternative medicines are assessed, even when reasonable alternatives are ultimately found and approved. As argued below, PCA believes such distress can be (at least partially) alleviated through a more proactive early warning system and a longer mandatory reporting period for suppliers who anticipate supply disruptions.

TGA Mandate

PCA would like to acknowledge and thank the TGA for its communication with stakeholders about supply issues with palliative care medicines. This ongoing dialogue has proven valuable in understanding the current landscape and disseminating accurate information.

At a time when global supply chains are challenging, we would also like to acknowledge the TGA's work to find and source temporary substitutes under Section 19A of the Therapeutic Goods Act 1989.

While the TGA has been diligent in facilitating communication and pursuing approvals under Section 19A to address supply gaps, it is important to recognise the inherent limitations in its scope. The TGA's primary functions revolve around regulatory oversight; it does not have the mandate to intervene more proactively in the market, anticipate supply risks before they emerge, or otherwise to consider changes in policy settings that would enable us to avert supply disruptions – such as encouraging local manufacturing where possible.

Engagement with the Department of Health and Aged Care

PCA has encountered challenges in engaging the Department of Health and Aged Care on matters that fall outside the TGA's scope of action.

[1] WHO 2023i. The Selection and Use of Essential Medicines 2023: Web Annex A: World Health Organisation Model List of Essential Medicines: 23rd List 2023. Geneva: World Health Organisation.

Recently the Australia and New Zealand Society of Palliative Medicine, with the support of PCA and the Society of Hospital Pharmacists of Australia, wrote to the Minister for Health raising concerns similar to those in this submission. A reply to that letter was signed by a TGA official and did not acknowledge issues beyond the TGA's mandate – underscoring the challenge for stakeholders who attempt to engage the Department to discuss broader solutions.

Attempts to initiate discussions through the recent Health Technology Assessment Review process were also unsuccessful, with the Review panel indicating that issues pertaining to medicine supply risks were out of scope for that Review.

Despite regular communication with the TGA regarding specific medicines shortages, we have not observed tangible evidence of our broader concerns being relayed to the Department of Health and Aged Care. The prevailing silence on issues beyond the TGA's control raises concerns about the effectiveness of current efforts to engage stakeholders affected by medicines shortages.

Opportunities for change

PCA's ambitions for engagement with government regarding medicines shortages extends beyond communicating with affected stakeholders about supply disruptions. We also seek meaningful dialogue with policy-makers who can address some of the long-term risks to the supply of palliative care and other essential medicines and consider whether our current systems could be adapted in response.

Improving our responses to immediate medicines shortages

In the immediate term, we propose an extension of the minimum reporting period for shortages and discontinuations of ARTG-registered medicines to no less than 12 months, specifically for medicines on the Palliative Care Schedule. We further propose a fast-track pathway for critical medicines such as opioid analgesics, along with rapid consideration and listing on the PBS for alternative opioid analgesic medicines approved for registration on the ARTG.

Anticipating future medicines shortages

We would also be keen to explore how the TGA can expand its efforts to anticipate and address supply disruptions beyond the current system of (temporary) substitutes under Section 19A. Establishing an enhanced early warning system may or may not require a change to the TGA's current mandate.

Domestic manufacture

Australia is the second largest producer globally of the raw materials for morphine.[2] It is therefore reasonable to suggest that, with the right market conditions and incentives, domestic manufacture of opioid analgesics could be commercially viable and, at the same time, mitigate the kinds of supply risks raised in this submission. Once again, PCA has not found the right forum in which to raise these issues with government, because they are clearly beyond the TGA's scope of action.

Conclusion

PCA considers the current situation a looming crisis for palliative care patients and those with chronic pain. We believe greater government intervention and systems development is needed to address a pattern of diminishing availability of palliative care medicines, perhaps supported through changes in policy settings.

We appreciate the opportunity to raise these critical issues through the TGA consultation on challenges and opportunities regarding medicines shortages.

[2] WHO 2023ii. Left behind in pain: Extent and causes of global variations in access to morphine for medical use and actions to improve safe access. Geneva: World Health Organisation.