FPM
Faculty of Pain Medicine
ANZCA

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Australian and New Zealand
College of Anaesthetists

22 July 2026

The Senate Standing Committee on Community Affairs
Legislation Committee
C/o Ms Fattimah Imtoual, Committee Secretary

Email it to Community.Affairs.Sen@aph.gov.au

Re: Therapeutic Goods Amendment (Medicines Shortages And Other Measures) Bill 2026 and the Therapeutic Goods (Charges) Amendment Bill 2026

Thank you for your email of 3rd July 2026 inviting commentary from the Faculty of Pain Medicine (FPM) on the proposed *Therapeutic Goods Amendment (Medicines Shortages And Other Measures) Bill 2026* and the *Therapeutic Goods (Charges) Amendment Bill 2026*. FPM's main concern relates to medicines shortages and discontinuations. Our commentary will focus on this specific area.

The original Australian therapeutic Goods Act 1989 was a detailed piece of legislation relating to appropriate safety and monitoring requirements for the provision of therapeutic goods, particularly prescribed medications, in Australia. Patient safety was obviously a high-level concern of this document. High standards were expected of pharmaceutical suppliers wishing to sell their products in the Australian market.

The medicines market has changed greatly since the 1989 legislation. In particular, the number of pharmaceutical products supplied to the Australian market has increased substantially. This has, inevitably, seen pharmaceutical companies tending to concentrate on the most lucrative opportunities for product placement together with a process of ongoing evaluation of products with lower returns. It seems that this has resulted in some pressures to discontinue medication in circumstances where higher returns might be found elsewhere.

In the field of pain medicine, this has seen some commercial decisions being made that have, in our opinion, not prioritised patient welfare. These problems became especially prominent with respect to a number of opioid medications used in both pain medicine and palliative care through the period 2021 – 2023. In some instances, the time period between announcement of discontinuation of a product and its subsequent complete loss from prescribing availability was below 6 months. Additionally, some of these preparations were well suited to particular niche areas of pain medicine and palliative care and there were no easy substitutions.

This whole environment caused great difficulties for many prescribers and their patients. It undoubtedly resulted in unnecessary clinical complications and separate legal difficulties, noting the strictly limited provisions under which Schedule 8 medications are made available to patients in Australia.

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The FPM Dean wrote to Minister Butler in August 2024 outlining the nature of these problems.

A very recent example of a similar problem arose earlier this month when a pharmaceutical company, Indivior, announced that it was withdrawing a product, Sublocade, from 31 December 2026. Sublocade is an important product that has improved the management of persons seeking assistance with opioid addiction. Alternative agents can be used, but for many people who have found great difficulty in finding a medication that suits them well in this area, loss of access to Sublocade will be a significant challenge. In this case, the company has withdrawn the medication with 6 months' notice for what appear to be purely commercial reasons.

The proposed medicines shortages bill does address a number of our earlier concerns. The early warning of discontinuation is a major improvement although we remain concerned that inclusion of the clause "*as soon as practicable if circumstances prevent this*" may be too easy to circumvent.

We are also concerned that the proposed amendments impose no obligation on medication suppliers to either maintain supply or to arrange access to replacement products. The amendments therefore regulate the notification of market withdrawal, but not the responsibilities associated with market withdrawal.

A broader concern persists; specifically, noting that in international terms Australia is a relatively small but wealthy market, we consider that more substantive obligations should be demanded of multinational pharmaceutical companies regarding long-term supply security. In this respect, the proposed amendments do fulfil criteria for an effective notification scheme but do not address more significant concerns relating to obligations for continuity of supply.

In the earlier correspondence to Minister Butler, FPM highlighted that manufacturers of motor vehicles are expected to support products after sale by maintaining the availability of parts over a prolonged period, even when production of the vehicles themselves has been discontinued. Comparable statutory obligations do not presently exist for suppliers of essential medicines and this raises an important question: specifically, should companies that market essential medicines owe a statutory duty of continuous supply to Australian patients?

In this respect, whilst the proposed requirement for 12 months' advanced notification of supply discontinuation is a major improvement over the previous legislation, we must respectfully point out that notification is not the same as accepting responsibility. In our opinion a logical further step would be to advocate for reform, introducing obligations for sponsors of new or critical medicines to the Australian market to develop transition plans or continuity arrangements before permanent market withdrawal. Adding this amendment would highlight the fact that if pharmaceutical companies wish to access the Australian market, they must also assume an ongoing obligation to Australian patients.

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Additionally, the Faculty recommends that sponsors of medicines included on the Medicines Watch List, together with any other medicines designated by the Minister as being of critical clinical importance, should be required to develop and implement an approved continuity-of-supply or transition plan before permanent withdrawal from the Australian market.

We understand that our recommendations would represent important changes to the 1989 act, which had a much narrower focus on the standards that pharmaceutical companies should meet. Nevertheless, we feel that these are reasonable amendments which would find favour with the great majority of the Australian public, particularly those who are potentially at risk of harm through interruption of the supply of vital medications.

Regards

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