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Te Whare Tohu o
Te Hau Whakaora

16 June 2025

PHARMAC

By email: tenderconsult@pharmac.govt.nz

Consultation on possible brand changes through the annual tender.

About the Australian and New Zealand College of Anaesthetists (ANZCA)

ANZCA, which includes the Faculty of Pain Medicine and Chapter of Perioperative Medicine, is the leading authority on anaesthesia, pain medicine and perioperative medicine. It is the professional organisation responsible for postgraduate training programs of anaesthetists and specialist pain medicine physicians, and for setting the standards of clinical practice throughout Australia and Aotearoa New Zealand. Our collective membership comprises 9649 fellows and trainees in anaesthesia and pain medicine, of which about 1300 work in Aotearoa New Zealand. ANZCA is committed to upholding Te Tiriti o Waitangi in the provision of competent, culturally safe care, and to promoting best practice and ongoing continuous improvement in a high-quality health system.

Consultation

Thank you for the opportunity to comment on possible brand changes. We have consulted with members of ANZCA's New Zealand National Committee, Faculty of Pain Medicine, Anaesthesia Quality Improvement New Zealand Network, Clinical Directors Network and Director of Professional Affairs (New Zealand). Their feedback and recommendations on specific anaesthetic and pain medicines is provided below, followed by some general principles to ensure safety. We also bring your attention to the ongoing issue with section 29 medicines.

Anaesthesia and Pain Medicines

ANZCA confirms that the listed medicines listed below are widely used:

- Glycopyrronium
- Heparin
- Noradrenaline
- Rocuronium bromide Injection 10 mg per ml, 5ml
- Dexamethasone
- Droperidol Injection 2.5 mg per ml, 1 ml
- Methadone hydrochloride Tab 5 mg
- Metoclopramide hydrochloride Inj 5 mg per ml, 2 ml.

We recommend that you:

1. Widen access to /ensure supply of:
    - **Aprepitant** as new class of antiemetic. Aprepitant is a new class of antiemetic. Currently, it is available for highly emetogenic chemotherapy, but not for those with a history of post-operative nausea and vomiting (PONV). It is highly efficacious when compared to existing therapy. It has the advantage of being a perioral prophylactic medicine with a long half life. There is potential for health system cost savings.

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- **Carbetocin -** a long acting subcutaneous injection form of the uteriotonic medicine syntocinon. This one injection therapy is effective and reduces the need for IV infusion pumps and extra giving sets.

- **Cisatracurium** a low-cost non-depolarising muscle relaxant (NDMR) for cases where allergic reaction has been a problem. It is currently sourced via named patient pharmac application, at the expense of time and cost to individual anaesthetists.

- **Buprenorphine** sub lingual and patch – access to these low cost and effective medicines is limited. This atypical opioid offers added benefit over conventional opioid medication. At managed doses, it is significantly safer and less likely to cause opioid related side effects. While the general recommendation for persistent pain is to avoid opioids, there are moves internationally to use atypical opioids when other options are unsuccessful. The recent US veterans hospital network advice - "*For patients receiving daily opioids for the treatment of chronic pain, we suggest the use of buprenorphine instead of full agonist opioids due to lower risk of overdose and misuse.*"

- **Duloxetine** - is a low cost selective noradrenergic reuptake inhibitor which is licensed for use in the treatment of Diabetic Peripheral Neuropathic Pain (DPNP) Fibromyalgia (FM) (1.4) and Chronic Musculoskeletal Pain. It is the standard of care internationally for neuropathic pain. We don't have an easy to use alternative in this class.

- **Tapentadol** immediate and sustained release (IR/SR) is another atypical opioid. It was reverse engineered from tramadol. It doesn't have the serotoninergic side effects or change to seizure threshold. Tapentadol pharmacological effect is not dependent on difficult to predict medication metabolism. This medication is now off patent and is relatively affordable.

2. Take particular care with packaging, concentration and other requirements for the following drugs where errors may have serious consequences.

    - **Glycopyrronium**
    - **Heparin**
    - **Noradrenaline**
    - **Rocuronium**

3. Note that **Dexamethasone** needs to be free of additives for use in joints and nerve blocks

General principles for medications and brand changes include:

- Clear labelling in English ensuring that the font and size is legible, without having to use a magnifying glass.
- Any colour on the label or ampoule needs to be distinctive – this is especially important for the drugs listed under point 2 above.
- The size and shape of vial or ampoule needs to be consistent with current formulations
- Our preference is for glass ampoules rather than plastic as they offer greater protection against certain chemicals.
- Giving considering to storage and shelf life
- Avoiding changes of concentration of from current formulations

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Note that brand changes, alternative packaging and changes of concentration, need to be well-signalled by other means additional to email notification and updating the website.

Section 29

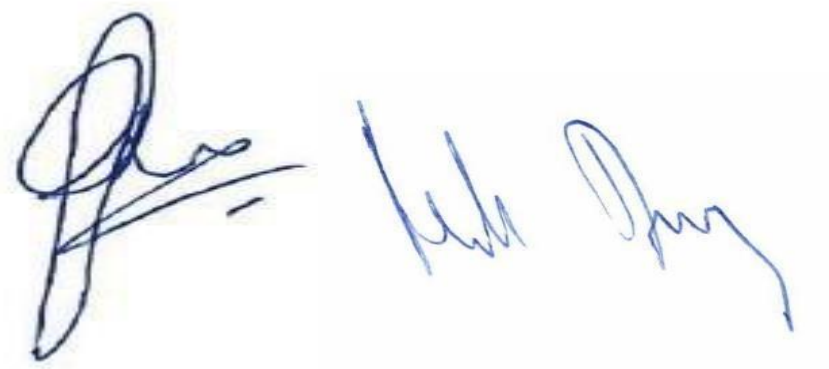
A general problem with changing to a different drug even if the active component stays the same arises if the new drug is not approved and therefore must be given as a S29 drug. S29 bypasses the Medsafe approval process by allowing the use of unapproved medicine which have more potential for harm than approved medicines, as they have not been assessed for safety, quality or efficacy in Aotearoa New Zealand.

Prescribers and dispensers are responsible for the medicines they prescribe, supply and dispense, but have limited ability to assess the medicine. Moreover, s29 requires adherence to time-consuming requirements such as documenting the patient's permission for each drug.

An additional pathway for approval of new medications is being sought with the recent Medicines Amendment Bill Medsafe and the implications for this have not been satisfactorily scoped. Nor does the bill address the problem of the rapidly increasing number of s29 medications which is becoming unmanageable on several levels. As per ANZCA's submission to the Health Committee, to improve access and safety and reduce onerous bureaucracy, ANZCA strongly recommends that work on separating the requirements for routine 'replacement' medicines that make up the bulk of unapproved medicines from the high-risk drugs that require more oversight is expedited.

Thank you again for alerting us to this consultation. We hope the above is useful.

Nāku noa, nā



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