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AUSTRALIAN AND NEW ZEALAND
COLLEGE OF ANAESTHETISTS

New Zealand
National Committee

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Ministry of Health
PO Box 5013
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By email: therapeuticproducts@moh.govt.nz

Dear Sir/Madam

Proposed Therapeutic Products Regulatory Scheme

The Australian and New Zealand College of Anaesthetists (ANZCA), which includes the Faculty of Pain Medicine (FPM), is responsible for the training and examination of anaesthetists and pain medicine specialists and for the standards of clinical practice in New Zealand and Australia. ANZCA's mission is to serve the community by fostering safety and high quality patient care in anaesthesia, perioperative medicine and pain medicine.

ANZCA appreciates the opportunity to provide feedback on the proposed regulatory scheme for therapeutic products in New Zealand. We acknowledge that much of the detail of the proposed scheme will be in regulations, rules and notices and that there will be further opportunity to provide feedback on proposals.

We note that there is provision on page ix of the consultation document for expert advisory committees to be set up. ANZCA believes such committees would be useful if they include the right people and are properly used, for example, to advise on new devices, drugs, and innovations. We suggest that consideration is given to establishing a permanent expert committee for anaesthesia, possibly combined with pain and intensive care medicine, with responsibility for medicines and medical devices relevant to these specialities. The 'experts' will need to be clinicians and other personnel with extensive knowledge and significant practical experience.

ANZCA has the following specific comments to make on two questions.

QC46: What do you think about the approach for the off-label use of medicines that have been approved in NZ?

The key concern we have with the exposure draft of the Bill is the proposed modified approach for the use of off-label medicines. In ANZCA's view, this part of the scheme is not well considered and, if implemented, would adversely affect patient care.

The approach does not take into consideration the unique anaesthesia context or the way in which anaesthetists practice. The proposed requirement for a special clinical needs supply authority (SCNSA) would hinder how anaesthetists (and other medical practitioners) use off-label medications. It would create a barrier to safe and timely administration of medications deemed to be the most suitable for the medical situation. A SCNSA, even tick-box, would be impossible for anaesthetists to adhere to and would potentially see them practicing outside of the law.

Anaesthetists are not prescribers in the traditional sense because administration of medication occurs simultaneously with the decision to use – or 'prescribe' - a drug. It is important, therefore, that the way in which anaesthetists practise as combined prescribers and administrators is understood, and that the realities of the operating room, ICU and emergency department environments are recognised to ensure the legislation is workable, and that unintended consequences are avoided.

Many anaesthesia and critical care medications are used off-label, both in New Zealand and internationally, for paediatric and obstetric patients. This is because there is limited or no trial data for these patient groups and other approved medicines are not available.

ANZCA believes that regulatory requirements should not prevent patients from benefitting from medications because they have not been specifically assessed in these patients, particularly when there is a long history of safety to support their use. For example, in paediatric cardiac anaesthesia and intensive care, anaesthetists use many drugs that are off-label, such as clonidine, assorted vasoconstrictors, dopamine, and antifibrinolytic agents (aprotonin); and, anaesthetists and paediatricians in neonatal intensive care units around the country, regularly use DBL fentanyl off-label. In addition, the use of off-label drugs by anaesthetists is supported by overseas use over many years and in many patients. Many medicines have been in accepted practice for decades that will never have evidence from randomised trials. Multiple papers can be found in the literature reporting/supporting their use, but this is not shown on the manufacturers' information sheets. Further, anaesthetists make decisions to use drugs off-label based on their extensive knowledge of pharmacology, pharmacokinetics and pharmacodynamics, and extrapolation to specialised patient groups particularly when other medications are not available.

The ANZCA Faculty of Pain Medicine (FPM) considers that the proposed approach for off-label use of medicines would be highly challenging in pain medicine. Many medications used for persistent pain have limited evidence of efficacy, are off-label, and are unlikely to be funded for future randomised controlled trials (RCTs). This is especially so in paediatric and adolescent persistent pain.

The idea that for a drug to be useful it must be rigidly backed by a RCT proving overall effectiveness is not a helpful framework in pain medicine (or many other areas of medicine). We refer to arguments made by Professor Andrew Moore and colleagues (in the British Medical Journal[1]) for assessing individual patient responses, recognising that no single drug will successfully treat more than a minority of patients with a painful condition; that analgesic responses are usually bimodal; and that, because success rates are low, a wide range of drugs is needed to do the best for most people, especially in complex chronic conditions.

ANZCA recommends that there is no change to the current management of off-label medications.

QC53: Do you have a view on whether DTC advertising of prescription medicines should continue to be permitted? What are the reasons for your view?

ANZCA's view on direct-to-consumer (DTC) advertising of prescription medicines aligns with the New Zealand Medical Association, the New Zealand Society of Anaesthetists, and other medical colleges in calling for advertising of prescription medicines to be prohibited.

We consider that DTC advertising of prescription medicines does not present material in a balanced or transparent way. Information provided in an advertisement is not sufficient for patients to be able to make judgments about the benefits and risks of medications appropriate to their medical conditions.

In anaesthesia and pain medicine settings, the most appropriate course of treatment should not be determined by the ability of pharmaceutical companies to inform patients about the medications

[1] Andrew Moore et al, *Expect analgesic failure; pursue analgesic success*, BMJ 2013;346:f2690.

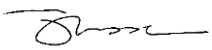
that they manufacture and sell. There is a risk that DTC advertising leads to practitioners being coerced by patients into prescribing drugs inappropriately, such as cannabis-based medications. This is also true for analgesic medications where there is limited benefit in the management of chronic pain conditions. We are also concerned that the DTC advertising of prescription medicines increases demand for psychotropic drugs and opioids to be prescribed, with the likely result of an opioid epidemic similar to that experienced in United States and Australia, and/or the potential for drug dependency problems to emerge.

In conclusion, the main points ANZCA wishes to convey are:

- That the proposal for the off-label use of medicine is not fit for purpose in the clinical settings in which anaesthetists work, or other similar medical environments such as the Emergency Department, ICU or during the emergency medical management and resuscitation of patients.
- That the proposal for the off-label use of medicines is not appropriate for pain medicine, particularly in the management of paediatric and adolescent persistent pain where is it difficult to conduct randomised control trials.
- That a more nuanced and considered approach to the management of off-label medicines is needed that does not place patient care below regulatory requirements and enables anaesthetists and pain medicine specialists to continue to provide high-quality care.
- That DTC advertising of prescription medicines should not continue to be permitted in New Zealand.

If you have any questions or would like to discuss this submission, please contact Mary Harvey (Senior Policy Adviser) in the first instance on 04 495 9780 or at mharvey@anzca.org.nz.

Yours sincerely



Dr Jennifer Woods
Chair, New Zealand National Committee