16 April 2019

Sheila Swan
Principal Advisor
Ministry of Health
Email: therapeuticproducts@moh.govt.nz

Dear Sheila,

Re: Therapeutic Products Regulatory Scheme Consultation

The New Zealand Society of Anaesthetists (NZSA) welcomes the opportunity to make a submission on the above Ministry of Health consultation. We have attached the submitter profile as requested.

About the New Zealand Society of Anaesthetists
The NZSA is a professional medical education society which represents over 650 medical anaesthetists in New Zealand. Our members include specialist anaesthetists in public and private practice, and trainee anaesthetists. We facilitate and promote education and research into anaesthesia and advocate for the professional interests of our members and the safety of their patients. As an advocacy organisation we also develop submissions, work collaboratively with key stakeholders, and foster networks of anaesthetists. The NZSA, established in 1948, has strong global connections and is a member of the Society of the World Federation of Societies of Anaesthesiologists (WFSA).

Overview
The NZSA supports the Government's rationale for the new legislation as it seeks to provide stronger assurance to the public on the efficacy and safety of therapeutic products. This is integral to the delivery of safe, quality healthcare as therapeutic products have risks and benefits, and the potential for serious harm. We support the key objectives of "flexible, durable, up-to-date and easy to use" legislation and the overall principles outlined in the consultation document. It is sensible to work towards future proofing legislation and regulations for therapeutic products to keep pace with international regulatory practice and emerging technologies, including broadening the scope of these products to medical devices and therapeutic products yet to be developed. We note that the Ministry of Health will be working on regulation of natural products, which is essential, as part of a separate process.

The NZSA submission focuses on specific aspects of the proposed new legislation which have a direct and potentially far reaching impact on anaesthetic practice, particularly relating to medicines, prescribing, unapproved drugs, labelling, and controlled drugs.

Health practitioner prescribing and regulatory authorities
Under the new scheme a health practitioner's authority to prescribe would be established in, and bounded by, the person's scope of practice. Regulation around prescribing would be passed entirely onto the Regulatory Authorities (RAs), such as the Medical Council of New Zealand, the Nursing Council, etc. RAs will determine if prescribing is within the scope of practice and what can be prescribed. The Health Practitioners Competence Assurance Act 2003 will be amended to specify that scopes of practice may include the authority to prescribe, subject to the approval of the Minister of Health. The new scheme proposes the Minister of Health will have the ability to direct RA's to change the scope of practice if they feel it is not being safely managed. The current levels of prescribing (authorised, delegated and designated) will be removed.

The only category in which a medical practitioner will be the sole person allowed to initiate a prescription is for non-approved medicines e.g. novel chemotherapeutic agents.

Following on from the above, RA's will be able to decide on the medications being used within a scope of practice. There is potential for conflicts of interest with the widening of pharmacopeia being under the domain of the RA's and we need reassurance that controls are in place to ensure standards of safe practice are maintained. While the final authority will lie with the Minister of Health, this change has the potential to result in patient harm as the Minister will only be able to restrict prescribing after harm occurs and there is evidence of poor management by the RA.

Competency framework for prescribing
We strongly recommend that due to proposed prescribing changes and the increased complexity of prescribing regimes for patients, that New Zealand develop a single prescribing competency framework, to provide guidance on the key principles and parameters to be followed by *all* prescribers. As the formal Framework developed in the UK for prescribing (2016) outlines in its introduction: "This increase in complexity means that besides developing and maintaining prescribing competency for individual conditions, prescribers have the challenge of keeping up to date with new medicines as they come onto the market and being aware of the potential for interaction between medicines in patients with multiple co-morbidities."[1] The Framework can be also used to provide the basis for ongoing continuing education and development, and revalidation, informing the development of education curricula and relevant accreditation of prescribing programmes for all prescribing professions.

There is a reference included in the Pharmacy Action Plan (p. 32) for the Ministry of Health to review the legislation and prescribing framework, including consideration of different models for prescribing, in different contexts and by a range of health professionals. We would like to see progress made on this.

Restrictions on anaesthesia medications
Anaesthesia is a specific activity within medicine with an inherent high risk of harm and the drugs used in anaesthesia often have a very narrow therapeutic window with the potential for

[1] A Competency Framework for all Prescribers, Royal Pharmaceutical Society, UK, July 2016

harm ever present. Anaesthesia medication should not be simply be added to the prescription list.

We strongly urge that there should be a list of medicines deemed highly dangerous that can only be prescribed by certain practitioners. The use of controlled, dangerous drugs, such as those used in anaesthesia, and as defined in the Misuse of Drugs Act, should be restricted to practitioners with a very well-defined scope of practice. For example, there are no regulations on who can administer Propofol as it is only classified as a prescription drug. Our Anaesthesia College Guidelines define this in their Professional Statement 09 Guidelines on Sedation and/or Analgesia for Diagnostic and Interventional Medical, Dental or Surgical Procedures[2] which outlines the minimum requirements for sedation however it is not in regulation. Muscle relaxants are another medication that should be administered only under extremely specific circumstances.

Modified approach to unapproved and off-label medicines
Under the new legislation it is proposed that all health practitioner prescribers will be authorised to issue a Special Clinical Needs Supply Authority (SCNSA) to prescribe off-label use of medicines that have been approved in New Zealand (on the proviso the medicine is covered by their scope of practice). In relation to unapproved medicines, it is proposed to continue as per current legislation to limit the ability to issue a SCNSA for unapproved products to medical practitioners.

Regarding the latter point however, we are concerned that unapproved medicines will be able to be prescribed by a non-medical prescriber after they are prescribed by a doctor once. As stated in s62: “Once a SCNSA has been issued, any health practitioner prescriber would be able to prescribe that unapproved medicine for that patient (as long as it is within their scope of practice).” In effect, this means that the doctor takes on the added risk of unapproved use as there could be circumstances where the health practitioner continues to prescribe the drug after it should have been stopped, or in doses or routes that are inappropriate. At this point the original medical practitioner loses control over how, when, how much and why the medication continues to be prescribed but nonetheless shoulders the responsibility for prescribing those drugs in the first place (with the added risk that comes with non-approved drugs). If a patient experiences an adverse event while taking an unapproved medicine, or a medicine prescribed for an unapproved use, the responsibility, and liability, will rest with the medical practitioner.

Also, Anaesthetists need to know how a SCNSA will work in the operating room as we frequently use ‘section 29’ medications. A study undertaken in New Zealand found that two thirds of respondents administer Section 29 medications every few weeks.[3] We often also use approved medications in an ‘off-label’ fashion, for example, propofol is approved for use in non-pregnant adults, but is not approved for use in paediatric or obstetric patients. This is an omission based on the populations from which the safety data were derived for gaining

[2] http://www.anzca.edu.au/documents/ps09-2014-guidelines-on-sedation-and-or-analgesia

[3] A survey of the use of unapproved medicines in anaesthesia practice in New Zealand
Julian, K A, Stapelberg, F, *Anaesthesia and Intensive Care;* Jan 2008; 36, 1; ProQuest

approval by Medsafe. Propofol remains the most popular induction and only infusion agent used for general anaesthesia across all patient populations in New Zealand, but this use is technically 'off-label' in paediatrics and obstetrics.

Additionally, when approved drugs are sourced from non-approved manufacturers, despite having a proven safety record in New Zealand and/or overseas, they are placed on the Section 29 list as being non-approved. This is often because the process for obtaining approval for drugs is viewed as costly. We would like to see a process whereby older medications with proven safety records have another route that enables a simplified approval process, rather than being categorised section 29.

Establishing a national anaesthesia essential drugs list

While drug shortages are increasingly common, the specialty of anaesthesia is particularly vulnerable. This is due to dependence on sterile injectable drugs with limited shelf-lives. It is not uncommon for some anaesthetic drugs to be in short supply e.g. vecuronium. Some of these medications are critical to patient safety, for example in recent years there was a shortage of approved adrenaline. In circumstances where emergency medications are unavailable, it may not be safe to proceed with anaesthesia. These shortages occur for both approved and unapproved drugs under Section 29.

As anaesthetists we need to be able to guarantee supply but also substitute when a drug is in short supply without the substitute being classified as Section 29. In the UK, the Association of Anaesthetists of Great Britain and Ireland (AAGBI) published a National Anaesthesia Essential Drugs List, developed by experts and members of the AAGBI. It has three categories for drugs: essential, necessary and critical. The list offers alternative drugs when there is a drug shortage. The aims, process and benefits of creating such a list are outlined in an editorial in the UK publication Anaesthesia.[4] The United States has also developed a list of essential drugs for anaesthesia.

We understand that a list of essential drugs is not part of the Therapeutic Products Bill but that it is possible that this could be developed by the Regulator in future and we believe this should be a mandated as part of the ongoing process.

Drug labelling

Medication error is one of the leading causes of morbidity and mortality in hospitalised patients, reported to be the seventh most common cause of death.[5] The incidence of adverse drug events in a New Zealand study was found to be 15%.[6] Safe anaesthetic practice depends on the identification of the contents of any ampoule, with appropriate administration, and as such anaesthetists have a strong interest in ampoule labelling.

Although specific electronic record keeping systems may assist with barcode readers, anaesthetists rely on drug ampoule labelling to ensure the correct medication is given. Many drugs can be administered in one day and these drugs are often in close proximity to each

[4] The National Anaesthesia Essential Drugs List, editorial, Dr Harrop-Griffith, Anaesthesia 2015, 70, 637-650
[5] Stelfox HT, Palmisani S, Scurlock C et al. The "To Err is Human" report and the patient safety literature. Qual Saf Health Care, 2006; 15: 174-8.
[6] Davis P, Lay-Yee R, Briant R, et al. Adverse events in New Zealand public hospitals II: preventability and clinical context, NZ Med J, 2003, vol.116, p. U624

other in the drug trolley, increasing the risk of error when the ampoules look similar. Sound alike, look alike drugs are dangerous unless systems are created that make the administration of the wrong medication difficult. Therefore, there needs to be strict labelling criteria and the ability for New Zealand to insist on appropriately easy to read labels and packaging to decrease the likelihood of a drug swap.

The NZSA would support bar coding on the drug vial or ampoule, which should include the drug's generic name, concentration and volume of drug and should not interfere with the label's legibility. It has been normal practice within anaesthesia for Anaesthetists not to have a second person checking ampoules prior to administration. Safety measures such as consistency of ampoule labelling, colour coded syringes, and bar codes with readers are essential for the safe provision of anaesthesia. Provision of anaesthesia often requires rapid responses to changes in physiological parameters and as such rapid drawing up and administration is essential. Anaesthetists are reliant on ampoules being easy to read with labelling specific to the medicine contained.

The ability to have bar code readers, as part of an electronic anaesthetic record keeping system, provides a visual confirmation. With some systems, an auditory feedback provides feedback about the content of the syringe about to be administered and could identify the contents of an ampoule, were it barcoded. In addition, a pull off barcode on either the ampoule or the packaging which is attached to the syringe used to draw up the contents of the ampoule would provide another safety feature. The NZSA also supports the use of pre filled, labelled syringes as they are an invaluable safety mechanism and a potential means of reducing patient infection risk.

Registration of all clinical trials

Clinical trials help to improve health outcomes and provide opportunities for senior clinicians to be involved in research. Clinical trials for all therapeutic products will be a controlled activity requiring authorisation via a licence. This has the potential to increase the administrative burden for those taking on clinical trials. There needs to be assurance that the process will be robust, but not overly complicated, expensive or time consuming. The process for clinical trials must be cost-effective and efficient to prevent barriers to research in New Zealand.

Closing comments

We recognise that the Therapeutic Products Bill is a proposed overarching, principles based legislative framework and that this will be a long-term consultation process before the Bill is passed into law including the drafting of regulations, rules and notices to sit under the Bill. We look forward to further consultation opportunities during this process.

We are broadly supportive of the submissions developed by the Australian and New Zealand College of Anaesthetists and the New Zealand Medical Association.

Thank you for the opportunity to comment. We are happy to answer any questions on our submission if required.

We are happy to appear before the Health Select Committee.

Yours sincerely

Dr Kathryn Hagen
President