9 August 2021

Ministry of Health
PO Box 5013
Wellington 6140
pharmacy@health.govt.nz

Re: amendments to the schedule of the Medicines (Designated Pharmacist Prescribers) Regulations 2013 and Schedule 1B of the Misuse of Drugs Regulations 1977

Executive summary

Thank you for the opportunity to respond to the proposed schedule amendment for pharmacist prescribing. The NZSA has serious concerns about the appropriateness and safety of the proposed changes to pharmacist prescribing. The level of training and experience required of a registered pharmacist prescriber falls far below that required for autonomous independent medical anaesthetic practice. Additionally, we cannot envisage when, or why, it would ever be appropriate or necessary for pharmacists to prescribe these medicines, even within a multidisciplinary health team setting. In our submission we outline in detail why these drugs must not be added to the amended schedule for Pharmacist Prescribers.

About the NZSA

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 specialty and the safety of patients. As an advocacy organisation, we develop submissions on government policy and legislation, work collaboratively with key stakeholders, and foster networks of anaesthetists nationwide. The NZSA, established in 1948, also has strong global connections, and is a Member Society of the World Federation of Societies of Anaesthesiologists (WFSA).

Comments

In the document of amendments to the schedule it states:

'*The current schedule of 1,517 prescription medicines has been in effect since the Medicines (Designated Pharmacist Prescribers) Regulations passed into legislation in June 2013. Since then, additional medicines have become available in New Zealand, to which wider access would benefit patients. The schedule needs to be amended to reflect these additional medicines.'*

The medications relevant to anaesthesia that have been added are not new and have been in circulation since before the Act was published in 2013 (with the exception of Dexmedetomine, which became available in 2018, and Sugammadex, which became available in 2014):

Non-depolarising neuromuscular blocking agents (NMBAs):

- Atracurium
- Mivacurium
- Pancuronium
- Rocuronium
- Vecuronium

Depolarising neuromuscular blocking agents:
- Suxamethonium

Specific reversal agent for the aminosteroids NMBAs (Panc, vec, roc):
- Sugammadex

Controlled drugs:
- Short acting opiate – Alfentanil

Centrally acting Alpha agonist
- Dexmedetomidine (available in New Zealand since Dec 2018)

Furthermore, the submission states:

'Designated pharmacist prescribers must prescribe within a collaborative and multidisciplinary health team setting.'

'The designated pharmacist prescriber must only prescribe within the limits of their professional expertise, competence and ethical codes of practice. They are responsible and accountable for the prescribing decisions they make and the care they provide. A designated pharmacist prescriber may only prescribe a medicine if they: possess the appropriate knowledge and competence (both clinical and cultural); the condition and medicine lie within their specified clinical area of practice, and; the clinical lead of the collaborative team is satisfied that pharmacist prescribing of the medicine is safe, aligns with legal and workplace protocols, and is in the best interests of the patient.'

There are few drugs which when administered properly in appropriate dosage will cause immediate death once administered unless there is prompt intervention. NMBAs are one such group. NMBAs pose particular risks if administered by anyone other than a medically trained practitioner with the skills detailed below, in particular the skills to manage the airway and required ventilation that will be necessary post-administration.

Alfentanil is a potent short acting opiate, and again administration can result in hypoventilation, chest wall rigidity and respiratory arrest and should only be administered by a medically trained practitioner.

The prescribing of NMBAs, Dexmedetomidine, Alfentanil and Sugammadex presupposes their administration. These two aspects of anaesthetic practice cannot be separated.

The NZSA is unconvinced that prescribing rights for these agents are necessary or safe. The level of training and experience required of a registered pharmacist prescriber falls far below that required for autonomous independent medical anaesthetic practice.

The NZSA believes the following caveats are necessary for the safe prescription (and subsequent administration) of NMBAs, Alfenantanil and Dexmedetomidine, and that the Pharmacist Prescriber Scopes of Practice cannot meet these requirements.

The requirements for the safe prescribing (and attendant administration) of NMBAs, Alfentanil and Dexmedetomidine includes the following:

1. Detailed knowledge of the pharmacokinetics and pharmacodynamics (i.e. the pharmacology) of the agents.

2. The theoretical knowledge and practical skills to secure and safeguard the airway, maintain oxygenation and optimise gas exchange in patients paralysed by NMBAs or who experience hypoventilation or apnoea with the other agents;

3. Detailed knowledge of the pharmacology of other anaesthetic drugs given in conjunction with NMBAs, in particular the following:
   Opiates;
   Induction agents;
   Hypnotic and sedative drugs;
   Volatile anaesthetic agents;
   Vasoactive agents.

4. Practical skills necessary for the induction, maintenance of and recovery from general anaesthesia;

5. Understanding and practical skills for monitoring the depth of general anaesthesia in paralysed patients;

6. Practical skills and theoretical knowledge of monitoring neuromuscular blockade and the use of nerve stimulators;

7. Detailed knowledge of the pharmacology of drugs used to reverse the actions of NMBAs;

8. Knowledge of the physiology and pharmacology of the autonomic nervous system, and of the drugs used to modify the autonomic effects of NMBA reversing agents, in particular atropine and Glycopyrolate and Sugammadex;

9. Skills and experience in the correct timing of NMBA reversal;

10. Skills, experience and knowledge to manage failure of NMBA reversal;

11. Knowledge of the pharmacology of drugs that may interact with NMBAs, in particular antibiotics, and the clinical implications and management of such interactions;

12. Detailed knowledge of the physiology and pathophysiology of intermittent positive pressure ventilation (IPPV), and in particular effects of IPPV on the respiratory, cardiovascular and central nervous systems;

13. Skills and experience to manage IPPV and the ability to correct any adverse effects of IPPV;

14. Understanding of the theory and practice of capnography;

15. Understanding of the theory and practice of pulse oximetry;

16. Ability to detect, diagnose and manage situations where pathological conditions or anatomical variations where the use of NMBAs is contra-indicated;

17. Theoretical and practical skills to manage anaphylactoid reactions to NMBAs, noting such reactions are often sudden and severe, and are potentially fatal;

18. Knowledge of the pharmacology of vasoactive and inotropic drugs used to modify or support the circulation when NMBAs, IV opiates and Dexmedetodine are administered;

19. Theoretical and practical skills to monitor the circulation under the influence of NMBAs;

20. Detailed knowledge of the physiology and pathophysiology of the respiratory system;

21. Knowledge and practical skills to monitor the respiratory system under the influence of NMBAs, IV opiates and Dexmedetodine.

Further requirements for the safe prescribing of Suxamethonium and Mivacurium are:

- Knowledge of the pathophysiology of pseudocholinesterase deficiency;

- Knowledge and practical skills of the management of pseudocholinesterase deficiency.

Further requirements for the safe prescribing of Suxamethonium are:

-Understanding of the pathophysiology of malignant hyperpyrexia;

-Understanding, experience and skills to manage malignant hyperpyrexia;

-Understanding of the pharmacology of drugs used in the management of malignant hyperpyrexia.

The requirements for the safe prescription and administration of NMBAs, Alfentanil, Dexmededetomidine and Sugammadex presuppose a wide knowledge of physiology, pathophysiology and pharmacology, which can come only from the acquisition of a medical degree. The use of these drugs is safely and properly the role of a medically trained practitioner.

The NZSA therefore submits that these drugs must not be added to the amended schedule for Pharmacist Prescribers.

We are happy to discuss our comments and to answer any questions in relation to this consultation. I can be contacted at president@anaesthesia.nz

Yours sincerely

Sheila Hart
President