

Thursday April 23, 2018

Technical and Safety Improvement Section
Pharmacovigilance and Special Access Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Consultation: Management and communication of medicines shortages

Thank you for the opportunity to provide comment on the Therapeutic Goods Administration's proposal for the management and communication of medicines shortages.

The Australian and New Zealand College of Anaesthetists (ANZCA), including the Faculty of Pain Medicine (FPM), is committed to high standards of clinical practice in the fields of anaesthesia, perioperative medicine and pain medicine. As the education and training body responsible for the postgraduate training programs of anaesthesia and pain medicine for Australia, New Zealand and parts of Asia, ANZCA is committed to ongoing continuous improvement, promoting best practice, and contributing to a high quality health system.

Overall, ANZCA supports the proposal that addresses long standing issues that have significant impacts on the provision of health care in Australia. As is acknowledged in the proposals, the current mechanisms of notification are haphazard and it is essential that these are streamlined and made effective.

ANZCA would appreciate the opportunity to contribute a list of "essential medicines". Many are already included on the 'Medicines Watch List' but a number of vasoactive medicines, local anaesthetics and opioids also require prompt notification when supply is disrupted.

Additional feedback specific to the consultation issues is outlined below.

Consultation issue 1: The definition of a medicine shortage

The criteria for inclusion of a non-prescription medicine in the proposed medicine shortage reporting requirements should not unintentionally exclude anaesthetic, analgesic and resuscitation medicines that are critical for short term medical management of patients.

Consultation issue 2: Reporting obligations

The required content of notifications should be required to include information about substitute medicines available from competitor sponsors or manufacturers.

"To serve the community by fostering safety and high quality patient care in anaesthesia, perioperative medicine and pain medicine."

Consultation issue 3: Which products should be on the 'Medicines Watch List' defining an 'extreme' risk shortage

The pathways outlined in the protocol for response to a medicines shortage should be retrospectively tested with some working examples of existing shortages, such as fentanyl, remifentanyl, EpiPen, isoprenaline and dantrolene.

The 'Medicine Watch List' should include medicines that may be in the same class as drugs without supply restriction but are significantly superior in patient care. For example, remifentanyl is an opioid essential in the conduct of neuro-anaesthesia. Other substitute opioids are far inferior in patient management and safety and quality of care are significantly compromised by use of other opioids which have a very different pharmacokinetic profile.

Broad classes of drugs should be considered - while one or two from a class can be substituted with alternates, eventually options get limited and significant clinical impact may occur.

Consideration should be given to whether drugs should be graded as 'critical' or 'essential'. Critical (extreme impact) anaesthesia drugs include:

- On the watch list: atropine, naloxone, dantrolene, adrenaline, noradrenaline, propofol, intralipid, ketamine, lignocaine
- Not on the watch list: suxamethonium, neostigmine, remifentanyl, sevoflurane
- Not on the watch list but as a class of drugs: non-depolarising muscle relaxants, intermediate acting opioids, injectable benzodiazepines, injectable beta-blockers, long-acting local anaesthetics, intravenous steroids (e.g. dexamethasone).

Essential (high impact) anaesthesia drugs include:

- On watch list: flumazenil, glycopyrolate
- Not on the watch list: phenylephrine, metaraminol, magnesium sulphate, paracetamol
- Not on the watch list but as a class of drugs: antiemetics (5HT3 antagonists).

Other products that would have high patient impact if they were to be in short supply include:

- morphine (oral and parenteral); oxycodone (oral and parenteral)
- non-drug agents such as antiseptics (e.g. chlorhexidine) and radiological contrast media.

Patient safety is also compromised when concentrations of medicines are changed without due warning and thus it is imperative that notification of practitioners is timely and efficient. The impact of drug shortages should be noted to include:

- Loss of therapeutic opportunity (patient impact)
- Cost of alternate supply
- Risk of alternate supply – drug purity / efficacy / error (different presentation / concentration)
- Risk of alternate therapy – for example, choosing to do some different technique because the first choice therapy wasn't available (such as general anaesthetic because no local anaesthetic available).

An overseas example worth consideration is the National Essential Anaesthetic Drug List (NEADL) produced by the Association of Anaesthetists of Great Britain and Ireland. It provides a rationale and other therapeutic options if any exist. The current National Essential Anaesthetic Drug List 2015 can be viewed at <https://www.aagbi.org/safety/needl>

Ongoing monitoring of existing state hospital Emergency and Lifesaving Drug Lists and the WHO List of Essential Medicines is suggested as the best mechanism to add or remove medicines from the list.

Consultation issue 4: Compliance obligations and potential penalties

Of the options presented, *Option 2 – Focus on civil penalties and infringement notices* is the option that ANZCA fellows have expressed support for striking the right balance, agreeing that it would provide an effective incentive to comply while not deterring supply being maintained.

Should you require any further information in relation to this response, please contact [REDACTED]

[REDACTED]

Yours sincerely

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