



AMA submission – TGA proposals to implement protocols to manage and communicate medicine shortages

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The AMA, in general, supports the TGA's proposed approach to implement a mandatory medicine shortages notification system. The AMA's comments, in response to the questions raised in the TGA's consultation paper, are detail below.

However, the AMA still has ongoing and unaddressed concerns regarding the process to ensure there is appropriate and timely action under the Pharmaceutical Benefits Scheme (PBS) following an announcement by the TGA of a medicine shortage, to ensure that alternative medicines are affordable and accessible to patients.

The AMA is not satisfied that there are transparent and clear protocols in place between the TGA's regulatory functions and the PBS system to ensure that important consequential changes are made to the PBS when shortages of certain medicines occur.

Examples of implications for patients include:

- when a shortage of cheaper brand medicines results in only the brand with a PBS 'brand premium' being available at a patient's local pharmacy
- when access to comparable / alternative medicines are limited because of PBS restriction or PBS Authority requirements.

The AMA has been advised by the Department of Health that these kinds of changes to the PBS during a supply shortage rely on the sponsor of those medicines making an application to PBAC.

This makes no sense. There is no point in announcing a shortage if patients cannot access appropriate alternative medicines on the PBS because of price or restricted indications.

There needs to be a mechanism to rapidly and temporarily substitute either a medicine that is on the PBS but at a higher price, for one not available due to shortage, or temporarily alter PBS indications/restrictions for medicines so they may be used for additional indications where the preferred medicine is not available.

The Department of Health should take this initiative, not medicine sponsors.

Comments on TGA proposals

Issue 1 – Definition of a medicine shortage

The AMA supports the TGA's proposed definition of a medicine shortage.

Issue 2 – Reporting obligations

The proposed timeframes and details to be reported seem appropriate.

Issue 3 – Medicines Watch List

The AMA agrees the medicines listed on the draft watch list are appropriate. However, the additional following medicines are also suggested.

Anaesthesia-related medicines

- Fentanyl
- Suxamethonium

Rationale: Certain shortages of 'essential' anaesthetic medicines have occurred recently including propofol and ephedrine, which are both already included on the list, but also fentanyl, metaraminol and thiopentone. The non-availability of these medicines could severely impact on the ability to provide anaesthesia services. Other 'essential' anaesthesia medicines that have not yet been subject to shortage include suxamethonium, desflurane and sevoflurane. On balance, fentanyl and suxamethonium should, at least, be added to the Medicines Watch List.

Diabetes-related medicines

- Metformin (in all its forms)
- Insulin (in all its forms)

Rationale: It is very difficult to treat diabetes without these medicines. Diabetes is prevalent in the Australian population. While perhaps less 'critical', these medicines are very widely used and a shortage would have a significant impact.

Issue 4 – Penalties for failing to report shortages

The AMA considers that merely publicly 'naming and shaming' non-compliant sponsors will be insufficient without additional sanctions, given many sponsors are currently ignoring the voluntary reporting system despite media and other reports about unexpected shortages.

The AMA supports applying a range of infringement notices, civil penalties and criminal penalties commensurate to the severity of breaches and past history. Penalties should be set at a level which is sufficient to deter well-resourced pharmaceutical companies.

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