



CATAG submission

TGA Consultation: Management and communication of medicines shortages – proposed implementation approach

April 2018

The Council of Australian Therapeutic Advisory Groups (CATAG) is an authoritative, expert, consensus-based collaboration of representatives from all Australian State and Territory Therapeutic Advisory Groups or their jurisdictional committee equivalents.

CATAG aims to standardise and improve medicines use primarily (but not exclusively) in the hospital sector across Australia through information sharing, advice and advocacy activities.

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CONTEXT

The Council of Australian Therapeutic Advisory Groups (CATAG) believes there is a need for a multi-faceted strategy to address medication shortages in Australia.

MANAGEMENT & COMMUNICATION OF MEDICINE SHORTAGES

Opening remarks.

CATAG is strongly in favour of the substantial progress made by the TGA to address issues related to the management of medicine shortages within Australia. The proposed protocol will greatly assist patients, clinicians and health services to manage medicine shortages and access alternatives in a timely manner, whilst holding manufacturers, sponsors and wholesalers accountable for their role in the market. CATAG acknowledges the TGA's significant work to develop the protocol available for consultation. CATAG and a number of other stakeholders have previously advocated for mandatory reporting through various channels, as there is robust evidence that mandatory reporting reduces the number of shortages and mitigates the effects of shortages (reference). Hence CATAG is strongly in favour of a similar intervention in Australia. CATAG commends the TGA on the development and implementation of the database of section 19A approvals to import and supply medicines to address medicine shortages.

1. The definition of a medicine shortage

Clarity of the definition

The proposed definition of a medicine shortage is clear.

The definition of a medicine shortage is appropriate, however it could be strengthened to have a greater patient focus 'a change in drug supply which has the potential to compromise patient care'. It is recognised the definition is to be stated in the Therapeutic Goods Act and therefore may need to explicitly state the suppliers of medicines (sponsors, wholesalers or manufacturers) to effectively utilise regulatory levers to manage medicine shortages.

Scope of medicines

The scope of medicines covered by the proposed protocol is clear and appropriate.

2. Reporting obligations

The determination of the impact severity that a drug shortage may represent to patient care and the healthcare system should be undertaken by the TGA using an expert panel that includes frontline clinicians in a number of different practice settings. The membership of the panel(s) may need to be flexible to accommodate the wide-ranging and varying impact shortages may have and depend on the specific medicine, clinical area and care setting. The sponsor, manufacturer or wholesaler

should seek advice from a range of stakeholders including clinicians and patients as to the potential impact on the healthcare system and patient care when a product is being discontinued. The timeframes proposed for sponsor to report a discontinuation are appropriate.

CATAG supports the intention to introduce the mandatory publication of shortages that are assessed to be of Extreme or High patient impact. CATAG requests that consideration is given to reviewing the proposed timescale for publication of information regarding Extreme and High impact shortages and suggests publication occurs within 24-48 hours for Extreme or High impact shortages.

The threshold for reporting a medicine shortage should be clearly defined to avoid situations where a sponsor may elect to ration the supply of a medicine to delay the reporting of a shortage. The TGA will need to enforce the definition of medicine shortage, particularly where reports are made of the partial availability of a medicine by those other than sponsors, wholesalers or manufacturers.

There are a significant number of medicines which are not registered on the ARTG which are currently in use in Australia and are medically necessary. These medicines are not addressed within the proposed protocol, such as medicines accessed through the SAS. It is recognised, there is no regulatory lever to influence the reporting or management of these medicines when in shortage. However, CATAG suggests the TGA take an active role in monitoring and supporting patients needs when these medicines, particularly Category C, are in shortage, whenever practicable.

3. Products on the 'Medicines Watch List' and defining an 'extreme' risk of shortage

CATAG recognises the difficulty in determining which medicines should be placed on a watch list and that there will be fine tuning to the watch list as the process matures. Protocol B enables a shortage of a medicine not specified on the watch list to be adequately assessed and managed by the pathway proposed. This will require the TGA to be a) adequately resourced to achieve the intended outcomes of the protocol implementation and b) able to enlist appropriate and timely advice as to the impact of the shortage when Protocol B is triggered.

Medicines, which should be included on the watch list are those which cannot be substituted or easily substituted as these will have an extreme or high patient impact if they are in short supply. Some shortages only become problematic when other shortages arise. For example, an alternate medicine utilised to manage the original shortage, may not be able to meet ongoing demand and result in another shortage. Having oversight of the use of alternative agents when a shortage occurs should also be included in TGA drug shortage assessment processes.

There needs to be a process of 'watch list' review in order to add or remove medicines. As newer medicines come to market, therapies change and therefore the 'watch list' needs to reflect current practice. A framework should be developed for the medicines 'watch list' review process.

4. Compliance obligations and potential penalties

CATAG supports mandatory reporting with an appropriate compliance mechanism

Any penalty applied for non-compliance needs to be an active deterrent, as is the case for failure to report an adverse event.

- Option 1 does not provide a significant incentive to encourage compliance and therefore would be ineffective.
- Options 2 and 3 are suitable and apply a financial penalty for non-compliance with non-reporting and under-reporting.

There also needs to be significant penalties for recidivism.

Other recommendations

The TGA needs to be adequately resourced to achieve the intended outcomes of the protocol and to realise the benefits of mandatory reporting.

SUMMARY

CATAG recognises the value in a multifaceted approach to this complex problem and therefore has provided comment on the protocol proposed. CATAG considers mandatory reporting and penalisation for under or non-reporting will be effective methods to mitigate the impacts of medicines shortages. It will enable more efficient management of shortages and more effectively mitigate the impacts of medicine shortages.