The Pharmacy Guild of Australia

SUBMISSION

Consultation: Management and communication of medicines shortages

Invitation to comment

The TGA is seeking comments from interested parties on a proposal that would require medicine sponsors to report all medicines shortages in confidence to the TGA and those medicines shortages classified under a revised medicines shortages protocol as 'extreme' or 'high' patient impact to mandatorily published via the Medicines Shortages Information Initiative on the TGA website.

The consultation paper seeks input on a number of matter that will shape how the changes to the management and communication of medicines shortages are implemented.

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National Secretariat
Level 2, 15 National Circuit, Barton ACT 2600
PO Box 310, Fyshwick ACT 2609
P: +61 2 6270 1888 • F: +61 2 6270 1800 • E: guild.nat@guild.org.au
www.guild.org.au

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MANAGEMENT AND COMMUNICATION OF MEDICINE SHORTAGES: COMMENTS

Consultation issue 1: Proposed Definition of a Medicine Shortage

Is the definition of a medicine shortage clear?

The Guild supports the definition in principle but believes further clarity is needed as to what a partial shortage may mean:

- insufficient stock within the supply chain to meet demand for an extended period or
- localised shortage e.g. in a state

Management of the shortage by the supply chain, communications and the clinical management of patients will vary depending on the type of shortage.

Is the definition of a medicine shortage appropriate, noting that it will be required to be stated in the Therapeutic Goods Act through the proposed amendments?

The definition is appropriate as it focusses on patient care in regards to medicine shortages, and it covers different states of availability.

There are a couple of points that would need clarification, e.g. partial availability is not defined, and there are no examples or a clear definition regarding “other constraints on a medicine’s availability’.

Is the proposed scope for covered medicines clear?

Yes.

Is the proposed scope for covered medicines appropriate?

Yes, this scope would cover critical medicines taken by a large part of the population. There would be a small number of medicines that patients are accessing via one of the TGA’s unapproved goods schemes that would not be covered by this scope, however as these medicines only affect a small part of the population, then arrangements could be made on a case-by-case basis for these items, also noting that the revised Protocol does not apply to these items.

Consultation issue 2: Reporting Obligations

Do you support the suggested timeframes? Do you have an alternative proposal?

The suggested timeframes will help ensure early notification, which is essential for patient care. The flow on effect from timely reporting down the supply chain will mean that communication and identification of alternatives can happen much more quickly and this will provide the most benefit to patients.

The Guild believes that there needs to be greater clarity with “as soon as practicable after becoming aware of it” in regards to reporting shortages, as this does not set a time limit to reporting shortages early so that the TGA is able to take steps to ensure alternative medicines are available. Our recommendation is that this be amended to “as soon as practicable within two business days after becoming aware of it”

The timeframes for reporting a discontinuation also seem practical.

Sponsors reporting resolved shortages should provide evidence to the TGA that the shortage has been completely resolved before they are able to confirm this via the MSII website. An example is EpiPen®, which is reported as a resolved shortage on the MSII website1 yet the communication to pharmacists on 6 April 2018 from the company2 indicated ‘that distribution of Epipen® via wholesalers to pharmacies is ongoing, as shipments continue to arrive in Australia’ and that it ‘will take some months for stocks to be replenished’. This communication is at odds to the report that the shortage has been resolved.

Do you support the required notification content?

The required notification content is comprehensive, however this information needs to be available to health care professionals and other stakeholders (e.g. pharmaceutical wholesalers or consumer support groups) when they are looking for information on a medicine in shortage. Some of the information is available on the MSII website, but a detailed reason for the shortage, alternative access to stock and information about substitutes is not currently displayed on the website, which would be useful information for health care professionals.

There may need to be more scope for providing a detailed reason for a shortage, rather than generic reasons selected from a drop down menu. Options that might be available from a drop down menu may be ‘Manufacturing issues’ or ‘transport problems’ or ‘other’. These are very broad and may cover a range of reasons for a shortage, some being more long term than others. More detail regarding the reason for the shortage may be more useful to stakeholders in the supply chain in estimating the duration of the shortage.

The shortage type is not defined and could cause some confusion. It could be taken to mean that the sponsor needs to differentiate between a complete or partial shortage (with clarity on what is meant by partial), or between resolved/current/anticipated/discontinuation – as is set out on the MSII website.

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

Is the list comprehensive/adequate?

Yes, however the list should be dynamic, with regular reviews to ensure the list remains current and topical.

[1] https://apps.tga.gov.au/Prod/msi/Search/Details/adrenaline-epinephrine [updated 4 April 2016]
[2] Letter from Mylan to pharmacists 6 April 2018 re Process for ordering Epipen® 300mcg Adrenaline (epinephrine) Auto-Injector (copy available on request)

Are there other products that would have an extreme or high patient impact if they were in short supply?

There are other medicines that could have extreme or high patient impact if they were in short supply, for example, short acting insulin. However referencing Figure 1 of the new protocol, the Guild notes that exclusion from the Watch List does not preclude a medicine shortage from being categorised as high or extreme risk. We note the intent that for medicines not on the Watch List there will be an assessment of the risk by a group including a doctor and a pharmacist with relevant expertise relating to the shortage. With regards to shortages that affect community based care, it is critical to include representation from a general practitioner and a community pharmacist and perhaps the relevant consumer support group.

What would be the best mechanism to add or remove medicines from the list?

To get items added to the list, a submission to a TGA/expert stakeholder committee for review and a decision may be the best mechanism. Similarly, removal could also be via a submission to this committee. Submissions could be received from either stakeholders or sponsors. The list should also be reviewed on a regular basis by the expert stakeholder committee. Recommend that this be done at least annually, but it may need to be reviewed more frequently initially (e.g. 6 monthly).

Consultation issue 4: Compliance Obligations and Options

Do you support particular options? Why?

With regards medicines shortages, the primary concerns for pharmacists in order of priority are:

1. Reducing the number of shortages which have been escalating over the past few years
2. Preventing medicines shortages
3. Managing shortages effectively

While incentives and penalties may be a means to address some of the above concerns and noting the limitations to this consultation, in addition to managing the impact of any medicine shortage that occurs it is important that the Department of Health continues to review medicines shortages within the context of its medicines programs and policies, including the Pharmaceutical Benefits Scheme (PBS). Identifying specific policies that may be contributing to the occurrence of medicines shortages may assist in developing strategies that will facilitate the overall management of shortages.

With regards to the proposed penalties:

Option 2 would be the preferred option, as the sponsor is publicly identified as well as being liable to pay financial penalties, without the more extreme penalties of criminal matters. This would be more of a disincentive for non-compliance and would be more likely to change practice.

Another option or complementary action may be to offer incentives for compliance rather than disincentives for non-compliance.

Which option, or combination of options, do you believe would be the most effective?

The most effective would appear to be option 2. It has the potential to change practices without excessive penalties, and without the offence being criminal. Excessive penalties may lead to further medicine shortages in the future if the sponsor makes a decision that supplying to Australia is no longer financially viable, or if criminal penalties result in the sponsor having restrictions on their business in Australia.

However, Option 2 may be more effective if the civil penalties were higher, i.e. the same as they are in Option 3. Noting that this would be the maximum penalty, and the application of the maximum penalty would be discretional, it may be more of a disincentive than the civil penalties in Option 2.

Other Issues

Who is responsible for reporting?

While the Guild believes the responsibility lies with the medicine sponsor to report any shortage, there must be the ability for other stakeholders to report apparent shortages for investigation, in particular reports from pharmacists, prescribers, consumers or consumer support groups.

The effect of shortages on patient care

Lack of communication and information regarding medicine shortages can result in delays for patients getting to a prescriber for consultation about an alternative treatment. Pharmacists and prescribers may face uncertainty in recommending an alternative treatment if there is no clear information as to how long the shortage will last. Communication regarding a resolution of a shortage will affect patient care if not handled correctly – if a prescriber does not know a medicine that was in short supply is again available, they will not prescribe it. Similarly, if a shortage is reported as resolved but supply is still erratic, there will remain ongoing problems for patient care for prescribers and pharmacists. Timely and accurate information with regular updates is critical for health care professionals responsible for a particular patient's care.

Timely reporting and communication about the shortage will enable patients and health care professionals to determine the best alternative for a patient in a timeframe that will support best patient outcomes.

Communication of shortages and available alternatives to pharmacy, doctors and patients

Communication about shortages and any available alternatives is very important in regards to health care professionals being able to provide the best level of care for a patient. The timing of this communication is also critical, as communication regarding shortages needs to reach the relevant health care professional in as little time as possible to facilitate best patient care. Where clinical information is also required to complement information about a shortage (e.g. substituting to other available products), there needs to be consistent information being provided to prescribers, pharmacists, hospitals and patients. The protocol

acknowledges communication with professional colleges but the Guild believes it is important to include agencies such as NPS Medicinewise[3] and the Council of Australian Therapeutic Advisory Groups (CATAG)[4] so that if clinical information is warranted, these groups can collaborate and work with the relevant professional bodies and other stakeholders to disseminate the information.

Exclusive direct supply

Exclusive supply of medicines directly from manufacturers to pharmacies is another problem that should be addressed, particularly for PBS medicines. Under these arrangements, the distribution of the medicine bypasses the pharmaceutical wholesalers that distribute PBS medicines and adhere to stringent standards and requirements under the Community Services Obligation (CSO)[5] with oversight by an independent administrator. As part of the CSO, the wholesalers must meet strict delivery timelines and report on shortages and their performance with regards delivery timeframes. Companies that distribute medicines outside the CSO wholesaler system do not have the same reporting requirements, limiting the effectiveness of CSO shortage reports for early identification and management of a shortage.

CSO wholesalers also have a redundancy of supply that can be moved between warehouses to help manage spikes in demand and reduce the incidence of regional shortages. There is a high degree of co-operation between all CSO wholesalers to manage any short-term stock shortages.

Ensuring all PBS listed medicines are available through CSO wholesalers and subject to the CSO standards and requirements will help minimise the risk of medicine shortages and assist in earlier identification and management of a shortage, for better patient care.

Any other improvements to the revised protocol and proposed approach to management and communication

Noting that the TGA will be responsible for notifying consumer support groups of shortages 'as appropriate', it may be beneficial for consumer support groups to be part of the notification process in every situation regardless of the severity rating. The consumer groups will then have the discretion of whether to initiate further communication with the consumers that they represent if they decide that it is necessary.

Communication to the consumer from relevant consumer support groups has the potential to be more effective than that initiated by other stakeholders, as the consumer is the primary focus. Consumer groups will often have more experience in what is significant for the consumer and will be able to target communication accordingly. Also, consumers themselves are more likely to have knowledge of consumer groups and their communication channels rather than those commonly used by health care professionals and other supply chain stakeholders.

[3] www.nps.org.au
[4] www.catag.org.au
[5] http://www.health.gov.au/internet/main/publishing.nsf/Content/community-service-obligation-funding-pool

Consumer support groups may need to be invited to register for notifications from the TGA regarding shortages, as there may be some instances where a shortage may not be reported to all relevant consumer groups.

Sponsors should also be encouraged to make contact with the relevant consumer support groups regarding shortages. This will facilitate better communication overall in shortage situations.