Submission

Consultation Paper: Management and Communication of Medicines Shortages - Proposed Implementation Approach

April 2018

[redacted]

[redacted]

GENERAL COMMENTS ON THE CONSULTATION

While xxxxx [redacted] xxxxx supports the principles behind the Medicine Shortage Notification system, we believe there are multiple points that need clarification before the consultation moves ahead. Primarily, these relate to the information required at the time of sponsor reporting, registration/availability of multiple generic brands, penalties for non-compliance and consumer/stakeholder reporting of potential shortages.

A distinction also needs to be made between being out of stock and a medicine shortage. For example, a sponsor may be out of stock, and will not be releasing stock for two weeks. However, the wholesaler still has three weeks' worth of stock. As such, consumers are not affected by the sponsor being out of stock. In such out of stock situations, a notification to TGA should not be required as there is no patient impact.

As mentioned in the guidance document, the sponsor is not the only party that can notify the TGA of an available product. This can have its problems. There are multiple cases where the TGA is contacted by a pharmacy reporting a shortage, when it is a simple case of there being no stock at the pharmacy's preferred wholesaler but there being stock available at the other two wholesalers. The pharmacy has chosen to obtain stock exclusively from one wholesaler. This same situation also applies to consumers, who are unable to get their script at their local pharmacy. It may be that the pharmacy hasn't ordered the stock, or is waiting on a delivery etc. In the case of third parties (i.e. anyone else besides the sponsor) reporting a shortage, [redacted] xxxxx believes it would be beneficial if the TGA received a minimum of three reports before contacting sponsors to confirm a shortage. This would reduce the burden on both the TGA and sponsor in chasing up unfounded reports.

With respect to medicine shortages, whether it is reporting an anticipated shortage or resolving one, it needs to be managed carefully, as it is highly likely that many pharmacies will stock pile as soon as they are made aware of an issue. Panic buying will have a bigger effect on a shortage and even the replenishment of stock, as it means that efforts to maintain supply will be further impeded. It is for this reason, that it is often the best course of action to have a controlled release once a shortage has been resolved to ensure that stock is distributed in a fair manner to all wholesalers.

CONSULTATION ISSUE 1: THE DEFINITION OF A MEDICINE SHORTAGE

The proposed definition of a medicine shortage is as follows:

A medicine shortage covers all instances where a patient's care may need to be revised as a result of:

a) *The unavailability of a medicine from a sponsor, wholesaler or manufacturer; or*
b) *The partial availability of a medicine from the sponsor, wholesaler or manufacturer; or*
c) *Other constraints*

Different types of medicine shortage are defined as:

- ***Anticipated medicine shortage** means a medicine shortage that is anticipated to commence at a future date;*
- ***Current medicine shortage** means a medicine shortage that has commenced;*
- ***Resolved medicine shortage** means a medicine is now available because the supply of the medicine is no longer unavailable, partially available, or affected by other constraints;*
- ***Discontinuation** means a decision by a sponsor to permanently cease the supply of a medicine.*

Some Questions to Consider

- ***Is the definition of a medicine shortage clear?***

  The definition provided in parts a) and b) are clear, however greater clarity needs to be provided around part c). It is unclear what the term, "other constraints", refers to. For example, if we were supplying a "non-PBS" product to only our tender customers and no one else, would the TGA class this as an "other constraint" so that by the definition we are experiencing a medicine shortage even though we have stock?

  The TGA should clarify and give examples of what is meant by the term "other constraints".

- ***Is the definition of a medicine shortage appropriate, noting that it will be required to be stated in the Therapeutic Goods Act trough the proposed amendments?***
  The proposed definition is very broad and it may be unclear as to what constitutes a true constraint. [redacted]xxxxx considers that the definition needs to be tightened to ensure that there is no confusion or ambiguity moving forward.

  The definition of a medicine shortage may not be appropriate in relation to the statement regarding a patient's care and instead should be revised to read, "…. a patient's care needs to be revised as a result of…", rather than "may need to be".

  Further to this, [redacted]xxxxx is of the view that it may not be appropriate to include the term, "or" and that the word "and" should be used instead. There also needs to be a distinction between being out of stock and a medicine shortage. For example, a sponsor may be temporarily out of stock for two weeks, however, there is three weeks' worth of stock at the wholesalers, in addition to existing inventory at pharmacies, to satisfy patient needs. Based on the proposed definition, and use of the word "or", we would need to notify the TGA of a potential medicine shortage. However, pharmacies and consumers have not had any impact to supply and after two weeks, the batch is released and the sponsor is returned to having stock.

  As a result, the manufacturer's temporary out-of-stock status will have no impact on patients because there is sufficient stock within the supply chain to satisfy patient demand until the manufacturer is able to provide additional supply.

- ***Is the proposed scope for covered medicines clear?***
  [redacted]xxxxx agrees it is clear.

- ***Is the proposed scope for covered medicines appropriate?***
  [redacted]xxxxx agrees it is appropriate.

CONSULTATION ISSUE 2: REPORTING OBLIGATIONS

The suggested timings proposed by the TGA for sponsors to report an anticipated or current shortage is as follows:

- *Sponsors must report an **anticipated** or **current medicine shortage**: as soon as practicable after becoming aware of it, or within 2 business days after being contacted by the TGA regarding a report of a shortage of their medicine.*
- *Sponsors must report all **resolved shortages** as soon as practicable after it has resolved and within 5 working days of the day the shortage was resolved.*

The suggested timings proposed by the TGA for sponsors to report a discontinuation is as follows:

Sponsors must report:

- *12 months prior to the discontinuation, for a discontinuation with an extreme or high impact level;*
- *6 months prior to the discontinuation, for a discontinuation with medium impact level;*
- *3 months prior to the discontinuation, for a discontinuation with low impact level*

The content that the TGA requires when reporting a medicine shortage includes:

- Sponsor name and contact details
- Product active ingredient and trade name, strength, dose form and ARTG number
- Reason for shortage (selected from a drop-down menu)
- Estimated duration of the shortage
- Shortage type
- Additional supply details about the medicine as appropriate
- Information about substitute medicines or therapeutic alternatives as appropriate

Some Questions to Consider

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

  Reporting an Anticipated or Current Shortage

  [redacted]xxxxx supports these suggested timeframes. However, having said that, [redacted]xxxxx would like to see some set structure around the reporting to the TGA by consumers/pharmacies. There are multiple cases where the TGA is contacted by a pharmacy reporting a shortage, when it is a simple case of there being no stock at the pharmacy's preferred wholesaler, but there being stock available at the other two wholesalers. The pharmacy has chosen to obtain stock exclusively from one wholesaler. This same situation applies also to consumers, who are unable to get their script at their local pharmacy. It may be that the pharmacy hasn't ordered the stock, or is waiting on a delivery etc. In the case of third parties (i.e. anyone else besides the sponsor) reporting a shortage, [redacted]xxxxx believes it would be beneficial if the TGA received a minimum of three reports before contacting sponsors to confirm a shortage. This would reduce the burden on both the TGA and sponsor in chasing up unfounded reports.

  Product Discontinuation

  The suggested timing for sponsors to report a discontinuation is somewhat ambiguous. While it is clear which products fall into the extreme or high impact classification, it is unclear at what point the TGA determines a product to be of medium or low impact level. Is the level being based on therapeutic class, the number of brands being sold or does it

equate to the market share of the individual brand? Without clear criteria, sponsors will not know what reporting timeline is applicable.

In the proposed Medicine Shortage protocol document, an example is given of an ACE inhibitor being classed as a medium level. Ramipril is a very common ACE inhibitor that currently has 10 brands available in the Australian market. However, if the brand being discontinued only has 2% market share, then its exit from the market will have little or no impact, and yet the TGA has classified it to be of medium impact and requiring 6 months' notice of discontinuation.

It may be more appropriate for the TGA to classify products as medium or low impact based on the number of brands available and/or market share, rather than therapeutic class.

Further to this, sponsors don't often know up to 12 months in advance that they may discontinue a product. Often, if it appears that they may not be able to source from their current supplier, they will look for an alternative. Many times, this is possible with stock levels and supply being maintained. However, there are occasions, where possibilities are exhausted and sponsors may get a few months' notice only of discontinuation.

Coupled with this are the low volume products, of which sponsors may receive one or two batches only a year. There are times when just before a batch is received, sponsors are informed that this is the last one and additional batches will not be provided. Sponsors may have no control over this and it may be for a high impact product. As a result, sponsors may not be able to provide notice 12 months in advance for a high impact product, and the best a sponsor can do is provide notice as soon as they become aware.

It would be more realistic if the timeframes set out by the TGA for discontinuation were that it is informed within 10 business days of the final decision being made that the product is being discontinued.

- ***Do you support the required notification content?***

  [redacted]xxxxx has no issue with the content required, as long as it remains confidential and only the product name, active ingredient, strength, dose form and ARTG number are made public.

CONSULTATION ISSUE 3: WHICH PRODUCTS SHOULD BE ON THE 'MEDICINES WATCH LIST' DEFINING AN 'EXTREME' RISK SHORTAGE

The proposed Medicines Watch list has been derived from a consensus review of existing state hospital Emergency and Life Saving Drug Lists and the WHO's Model List of Essential Medicines that are contained in the ARTG.

Some Questions to Consider

- ***Is the list comprehensive/adequate?***

  [redacted]xxxxx considers that the proposed list is adequate.

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

  [redacted]xxxxx considers that the proposed list is adequate.

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

  [redacted]xxxxx proposes that the best mechanism to add or remove medicines from the list is to consult direct with the sponsors of products in question; more specifically the Medicine Shortage Action Group should be consulted to ensure that key stakeholders agree with any changes made to the list.

CONSULTATION ISSUE 4: COMPLIANCE OBLIGATIONS AND POTENTIAL PENALTIES

The introduction of mandatory reporting of medicines shortages raised the need for a compliance mechanism - without penalties of some sort for non-compliance, there are no consequences for failure to provide mandatory reports within the required timeframes and the system would revert to the unsuccessful voluntary model that is currently in place.

The TGA has proposed that where the sponsor's first instance of non-compliance is assessed to be particularly serious, then the TGA would consider pursuing one of the more substantial penalties from the outset. The potential options are as follows:

- Option 1 - Publicly identifying non-compliant sponsors, without additional sanction
- Option 2 - Focus on civil penalties and infringement notices
- Option 3 - Substantial civil penalties and criminal offence.

Some Questions to Consider

- ***Do you support particular options? Why?***

  [redacted]xxxxx does not support any of the options presented. [redacted]xxxx does not agree sanctions are required, as the process has not been mandatory previously and there is no indication that there will not be compliance if the scheme is mandatory. If the TGA has

evidence in the future that compliance is lacking, then sanctions may be appropriate. In the latter case, Option 1 is supported, but only after a sponsor fails to report a certain number of times (i.e. reporting timeframes not met on three occasions).

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

  Any options should only be put forth after it has been determined that they are required***.***