Management and communication of medicine shortages – proposed implementation approach consultation paper (Implementation Approach)

Consultation issue 1: The definition of a medicine shortage. For consideration proposed definition of a medicine shortage

Proposed scope for medicines in this context: The kinds of medicines intended to be covered for the purposes of the proposed medicine shortage reporting requirements are prescription medicines that are entered on the Australian Register of Therapeutic Goods. However it is also proposed to include a small number of non-prescription medicines.

The criteria for inclusion of a non-prescription medicine would be:

- The medicine is critical to the ongoing health of the patient (an example would be salbutamol asthma inhalers); and/or
- Inclusion of the medicines is critical for public health (an example would be naloxone injections for opioid overdose).

Some questions to consider:	
• Is the definition of a medicine shortage clear?	Yes
• 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?	Yes
• Is the proposed scope for covered medicines clear?	Yes
• Is the proposed scope for covered medicines appropriate?	Yes

Consultation issue 2: Reporting obligations

For consideration - SUGGESTED TIMING FOR SPONSORS TO REPORT AN ANTICIPATED OR CURRENT SHORTAGE

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.
A medicine is taken to be in shortage once patient care may need to be revised due to unavailability.

SUGGESTED TIMING FOR SPONSORS TO REPORT A DISCONTINUATION:

Sponsor 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.

Note: These timeframes are those currently set out in the medicines shortages Interim Business Specifications and Guidance Supplement available in TGA's eBusiness Services (eBS) portal. Refer to p8 of the Implementation Approach for more information. Details of the content requirements for notifications when reporting a medicine shortage are outlined on p8-9 of the Implementation Approach.

Some questions to consider:	
• Do you support the suggested timeframes? Do you have an alternative proposal?	Yes
• Do you support the required notification content?	Yes

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

A specific watch list of known critical products would help simplify and speed decision-making when deciding if a medicine shortage has 'extreme' or 'high' patient impact. Only medicines that are included in the ARTG would be considered for the list. A shortage of a medicine on the watch list would automatically prompt TGA to publish a notification provided to us by the medicine sponsor. However, as described in the Protocol there may be some other medicine shortages that on a case-by-case basis could justify publication of a notification on public health grounds.
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. The proposed list can be found on p10-11 of the Implementation Approach.

Some questions to consider:	
• Is the proposed medicines watch list (see p10-11) comprehensive/adequate?	More work needs to be done on this list – it currently doesn't appear extensive enough and there are possibly more important agents in the therapeutic groups that are not listed. e.g. Whilst supporting the listing of antibacterial agents some of the agents listed are not as critical as others as there are alternatives with similar activity e.g. flucloxacillin could be used instead of dicloxacillin should dicloxacillin not be available. I note ergometrine is listed under obstetrics but oxytocin is given post every delivery and if it wasn't available would create significant impact; similarly so would vitamin K. Under anticonvulsants IV phenytoin is listed – so whilst it is still used for acute seizures its use is waning and IV levetirecetam is being used more frequently and it's shortage might possibly cause more issues. Similarly IV midazolam is probably more widely used than diazepam for seizures and might be more of an issue.
• Are there other products that would have an extreme or high patient impact if they were to be in short supply?	Chemotherapy agents are not listed and these are critical; often with no alternative agents

	Bee venom / Epipens are not listed and these agents are currently causing problems due to shortages.
• What would be the best mechanism to add or remove medicines from the list?	Consultation / advice from the professional colleges / pharmacy groups (e.g. SHPA; PSA)
Consultation issue 4: Compliance obligations and potential penalties	
The introduction of mandatory reporting of medicines shortages raises 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. Details of the proposed compliance obligations and penalties can be found on p12-15 of the Implementation Approach.	
The TGA is seeking feedback on which of the options is most appropriate, see p12-14 of the Implementation Approach for details of the options. **Note:** Options 2 and 3 are more aligned to Canada's enforcement approach which takes a graduated, risk-based approach, in which available regulatory measures range from public warnings or advisories to investigation and referral for prosecution of an offence, with applicable fines and penalties. The UK is also proposing significant financial penalties for non-reporting of medicine shortages.	
• Option 1: Publicly identifying non-compliant sponsors, without additional sanction	
• Option 2: Focus on civil penalties and infringement notices as outlined on p13	
• Option 3: Substantial civil penalties and criminal offence as outlined on p14	
Some questions to consider:	
Do you support particular options? Why?	
Which option, or combination of options, do you believe would be the most effective?	