Management and communication of medicines shortages – proposed implementation approach

TGA Consultation Paper March 2018

Sunshine Coast Hospital and Health Service Feedback Submission 23rd April 2018

Report name / title:	Management and communication of medicines shortages – SCHHS feedback submission
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The Government is considering making reporting of all medicines shortages to the TGA by sponsors mandatory from 1 January 2019. Proposed mandatory reporting would be subject to the passage of legislation. The purpose of this report is to provide stakeholder feedback to the TGA on each pf the specific issues raised within the consultation paper.
The consultation paper and accompanying documents can be reviewed at:-
https://www.tga.gov.au/consultation/consultation-management-and-communication-medicines-shortages

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Consultation issue 1: The definition of a medicine shortage

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

-*'A **medicine shortage** covers all instances where a patient's care may need to be revised as a result of……..'* We do not agreed with this statement as it implies a need for patient care to be affected before a shortage is defined. A shortage occurs where there is an inability for supply to meet demand, without the need for a patient's treatment to be affected.

-the specification of when to report anticipated / current shortage is too vague and does not specify *when* there is an expectation for manufacturers to alert. The current statement of 'as soon as practicable' puts the onus on the manufacturer to decide when to report. A short timescale (eg number of days) should be defined.

- 'partial availability' is equally vague. Does this relate to a particular percentage in reduced supply/ production? At what point does a manufacturer report a production issue if there are what they deem to be sufficient residual stocks of a medication in storage – is this an anticipated shortage? When should a manufacturer be required to alert the TGA? This may be very difficult to clarify more robustly- however the more concise the expectation of what is mandatory to report is, the more likely the system is to function as intended.

- Does an urgent drug recall automatically trigger the shortage cascade if the medicine is included on the watch list? If significant stocks of the medication in question are to be quarantined then this should automatically prompt review of the medication as per the watch-list protocol.

Consultation issue 2: Reporting obligations

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

-*'A medicine is taken to be in shortage once patient care may need to be revised due to unavailability.'* We do not agree with this statement. A medicine is in shortage where the supply cannot meet the demand, without directly impacting upon patient care.

-'As soon as practicable' as a timeframe for manufacturers to notify the TGA is too vague and not clearly defined, which may result in delayed reporting. There needs to be a defined numerical timescale given that some shortages require considerable co-ordinated action.

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

  - The 'drop down' menu for defining the reason for the shortage has not been provided for the consultation review.

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

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

  -the terminology for categorisation of medications as 'extreme' 'high' 'medium' and 'low' for the category of critical medications included on the 'Watched Medicines List' are not clearly defined. Clear definitions are required at the beginning of the section.

  - if one particular manufacturer / brand of a medication alerts the TGA to a shortage as per the protocol, will TGA have the ability to review the market share of the manufacturer in question, in order to assess whether this would equate to an overall shortage of the medication?

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

  - See *Appendix 1* (end of document) for medications we consider would have high/extreme patient impact in the event of short-supply

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

  - The TGA should review as part of the registration process – all new applications for medications and the need for inclusion in the list to be considered with appropriate specialists / craft groups at that time

  - The TGA should review all discontinuation notices and the impact such product discontinuation will have on current medications on the list, or whether the discontinuation may affect other medications for consideration for the list.

Consultation issue 4: Compliance obligations and potential penalties

- ***Do you support particular options? Why?***
  - We do not believe option 1 would be a viable incentive to ensure mandatory reporting of medication shortages. As described in the consultation, the Australian market share of pharmaceuticals is not sufficient such that manufacturers would be incentivised. Nor would a 'name and shame' approach affect supply and demand of products in order for there to be repercussions.
  - We would support financial penalties however in order to act as a deterrent to non-compliance they would need to be significant. $12600-$210000 as per the civil infringement notice proposed is, in our opinion not substantial enough to encourage mandatory reporting.
  - Significant financial penalties in addition to potential criminal charges for serious or repeat offenders would be more likely to ensure mandatory reporting.
- ***Which option, or combination of options, do you believe would be the most effective?***
  - Option 3, but possible in combination as option 2 and 3

Appendix 1.

The SCHHS pharmacy department wishes the following medications to be considered for inclusion in the Medicines Watch List

Antibiotics, antifungals and antivirals

Cephazolin
Amoxiclav IV
Aciclovir IV
Fluconazole IV
Amikacin
Ceftolozane/Tazobactam
Erythromycin IV –not required on list
Dicloxacillin – not required on list

Emergency and Critical Care

Levetiracetam IV
Sodium Valproate IV
Dobutamine IV
Dopamine IV
Eptifbatide
Glyceryl trinitrate IV
Isoprenaline IV
Levosimendan
Milrinone
Salbutamol IV and nebs
Ipratropium nebs
Hydrocortisone IV
Sodium Chloride 3%
Bivalirudin
Cisatracurium
Rocuronium
Midazolam
Danaparoid
Esmolol
Frusemide IV
Clonidine
Dexmedetomidine
Morphine
Fentanyl
Nimodipine IV and PO
Magnesium sulphate IV
Phosphate IV
Thiamine IV
Tenectaplase
Short acting insulin