abbvie

30 April 2018

Reg ref: RegAffairs\consultation-commentary\60-medicines-shortage-28mar18

Therapeutic Goods Administration
Medicines Authorisation Branch
PO Box 100
WODEN ACT 2606

Re: Management and communication of medicines shortages – proposed implementation approach

Dear Sir / Madam,

Please find enclosed AbbVie Pty Ltd comments to the document on 'Management and communication of medicines shortages – proposed implementation approach'.

Should you have any queries regarding this submission please contact me by email at [redacted]

Yours faithfully,

[redacted]

[redacted]

[redacted]

AbbVie Pty Ltd

[redacted]

AbbVie Pty Ltd
ABN 48 156 384 262

Level 7, 241 O'Riordan St
Mascot NSW 2020
Australia

+61 477 022 806 (OFFICE)
+61 2 9035 8741 (FAX)
AbbVie.com

Management and communication of medicines shortages – proposed implementation approach

Consultation Issue 1: The definition of a medicine shortage

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

AbbVie response

AbbVie agrees that the definition of a medicine shortage is clear, however recommend to provide examples to clarify the following terms:

- "patient's care"
- "other constraints on the medicine's availability".

- **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?**
- **Is the proposed scope for covered medicines clear?**
- **Is the proposed scope for covered medicines appropriate?**

AbbVie response

AbbVie agrees that the definition of a medicine shortage and scope for covered medicines is appropriate and clear.

Consultation Issue 2: Reporting Obligations

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

AbbVie response

Medicines Shortage

To date, AbbVie Pty Ltd has voluntarily reported medicines shortages to the TGA via the MSI portal. The experience with using the current MSI process identified that providing the required information and supporting documentation to the TGA was a resource intensive activity. It required numerous discussions at both a local and global level to make a determination of whether there was an anticipated or current medicine shortage. The development of supporting documents e.g. Dear Healthcare Professional letter required internal review and approval by a cross-functional team at both the local and global level.

With the knowledge of the number of stakeholders involved in the process, AbbVie is of the view that the timeframes suggested by the TGA are restricted and inflexible.

With regards to the suggested timing for sponsors to report an anticipated or current shortage, AbbVie agrees that sponsors must report to the TGA "as soon as practicable" once a sponsor has concluded there is an anticipated or current medicine shortage. In terms of the suggested timeframe, AbbVie proposes the following alternative options:

- from 2 business days to 'up to 7 business days' for sponsors to respond as a result of being contacted by the TGA regarding a report of a shortage of their medicine.

  If the TGA mandates notification within 2 business days, AbbVie requests that MSI form and the information TGA considers to be crucial to make an assessment be re-evaluated.

- from 5 to 7 business days with regards to reporting resolved shortages.

In addition, AbbVie proposes an amended process for TGA to consider:

- Could the TGA explore a two-step process whereby Sponsors can notify the TGA of a potential out of stock situation that requires further investigation by the sponsor ('initial notification') and once confirmed, complete and lodge an "official notice" via the MSI portal?

Discontinuation

AbbVie suggests that the mandatory reporting of a Sponsor's intention to discontinue products occur only for Extreme/High impact products only. In addition, AbbVie suggests that the TGA provide a recommended timeframe for reporting i.e. "at least 6 to 12 months prior to discontinuation from market".

If Sponsors must report planned discontinuations 12 months prior, this could be challenging, as plans could change due to a number of factors e.g. changes in commercial strategies or local reimbursement environment. The suggestion to mandate reporting of discontinuation of products for medium and low impact would place additional administrative burden on company resources.

If the TGA insists on mandatory reporting of discontinuations:

- Is there an avenue to easily withdraw a planned discontinuation within the TGA system?
- Can the sponsor have the option to amend the proposed discontinuation date?

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

AbbVie response

AbbVie generally supports the required notification content. However, recommends the following changes for consideration:

- Under the ARTG Entry tab, the suggestion to remove the ATC Description field or not make it a mandatory field to complete. AbbVie questions whether this field adds any value to the TGA?
- Remove 'Estimated normal demand volumes for Australia' and 'Estimated % Market Share'.
    - This information can take time to obtain and provide as part of the initial form as it requires discussions with relevant functions across the business. With the proposal for Sponsors to submit notifications within a short timeframe, undertaking such an activity may prove difficult. AbbVie proposes to remove this detail from the form, and to relocate this section to the investigation phase when the TGA is assessing suitable pathways to address the shortage.

- Remove Sponsor's rating of impact of the shortage – TGA is responsible for making the risk assessment. AbbVie proposes that TGA work with Sponsors to determine an appropriate impact rating during the investigation phase.

In addition, AbbVie kindly requests the TGA to consider providing screen captures of the MSI e-form to assist Sponsors with preparation of MSI in line with TGA expectations. For instance, the Guidance for overseas GMP clearance provides clear and detailed information below the screen captures to aid Sponsors to complete the form.

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

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

AbbVie response

AbbVie agrees that the proposed medicines watch list is comprehensive.

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

AbbVie response

AbbVie does not have any comment.

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

AbbVie response

AbbVie suggest TGA perform a periodic review of the medicines watch list e.g. every 6 or 12 months in consultation with experts in the field.

AbbVie also suggests reviewing new chemical entities, fixed-dose combination or indication extensions when registered on the ARTG and deciding whether or not to include the medicine on the medicines watch list.

Consultation Issue 4: Compliance Obligations and Potential Penalties

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

AbbVie response

AbbVie supports Option 1 with "naming and shaming" the company and also to include the number of times the company has not consistently reported a medicine shortage in the stipulated timeframes.