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Technical and Safety Improvement Section
Pharmacovigilance and Special Access Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

To whom it may concern,

RE: MANAGEMENT AND COMMUNICATION OF MEDICINES SHORTAGES – PROPOSED IMPLEMENTATION APPROACH

Thank you for providing Pfizer Australia with the opportunity to make a submission to the above consultation.

Pfizer Australia is one of Australia's leading providers of prescription medicines and consumer health products. We manufacture medicines and vaccines that millions of Australians use every day to live longer, healthier and more productive lives. We are proud of the active role we play in Australia's health system and the wider contribution we make as an innovator, employer and manufacturer.

Pfizer Australia acknowledges that medicine shortages have become an increasing problem over the past few years in the Australian market. We strongly support the Australian Government's efforts in addressing this challenge in collaboration with industry and the broader health sector.

Pfizer Australia's submission (Attachment 1) is provided in two parts. Part 1 addresses each of the consultation questions in turn. Part 2 provides additional comments on a number of specific provisions within the draft protocol.

Pfizer Australia is a member of Medicines Australia, the peak body representing innovative pharmaceutical companies in Australia. We encourage TGA to carefully consider the insights and recommendations presented within Medicines Australia's submission to this consultation.

Thank you again for the opportunity to contribute to this consultation. Pfizer Australia is available at any time to provide further information to the TGA, as required.

Yours sincerely,

[redacted]

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ATTACHMENT 1

Submission to the TGA's consultation on the Management and communication of medicines shortages – proposed implementation approach

PART 1 Response to Consultation Issues

1. The definition of a medicine shortage

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

The proposed definition of a medicine shortage is not clear enough in the document. In particular, Pfizer Australia seeks further clarity on the definition of an *anticipated* medicine shortage. The definition references a shortage anticipated to commence "at a future date". How far in advance is this - 4 weeks, 8 weeks, 12 weeks? And to what degree of certainty should the anticipation be based? For example, a company may speculate on the emergence of a supply constraint in the broader market in nine months' time based on market intelligence. However, the risk of a shortage remains low given market conditions projected for the following quarter and the short lead time of the product. What would the reporting obligations be in this scenario?

In this context, Pfizer Australia proposes the definition of a medicine shortage be amended [as per blue text] to read:

> *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 medicines from a sponsor, wholesaler or manufacturer, as confirmed by the medicine sponsor; or*
> *(b) The partial availability of a medicines from a sponsor, wholesaler or manufacturer, as confirmed by the medicine sponsor; or*
> *(c) Other constraints on the medicine's availability, as confirmed by the medicine sponsor.*
>
> *Different types of medicines shortage are defined:*
>
> - ***Anticipated medicine shortage** means medicine shortage that is anticipated to commence at a future date - specifically, stock levels have been compromised with the next delivery unconfirmed or significantly delayed. It is considered an anticipated medicine shortage when the stock on hand is 8 weeks or less with no certainty on replenishment within the next 4 weeks to restore the stock level to above 8 weeks;*
> - ***Current medicine shortage** means a medicine shortage that has commenced, i.e. there is no inventory held by a manufacturer/wholesaler(s) to support market demand;*
> - *…*

Pfizer Australia also seeks clarity from TGA on whether the protocol applies to supply constraints as a result of a recall. Will a sponsor be required to complete the MSI in this scenario given TGA will be aware of the issue in advance?

Is the proposed scope for covered medicines clear and appropriate?

Pfizer Australia agrees that the protocol should cover all prescription medicines. We also agree that a small number of non-prescription medicines warrant inclusion in the Medicines Watch List, per the criteria outlined in the protocol.

2. Reporting obligations

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

Suggested timing for sponsors to report an anticipated or current shortages

Pfizer Australia agrees that sponsors should report a medicine shortage as soon as practical after becoming aware of it. This is particularly pertinent for products with significant lead time, such as sterile injectable products, and where there may be a limited number of sponsors in the market and the constrained sponsor has a high market share of the medicine.

However, we do not believe that reporting within two business days after being contacted by the TGA regarding a report of a shortage is practical. Experience shows this is not enough time to verify an out-of-stock, particularly if the report has originated at patient level and/or a sponsor is required to ascertain stock levels held by both the manufacturer and various wholesaler(s). Reports also often lack the necessary detail to investigate quickly. Pfizer Australia proposes that, depending on the complexity, reporting within five business days after being contacted by the TGA regarding a report of a shortage is more practical.

Suggested timing for sponsors to report a discontinuation

Pfizer Australia does not agree with the suggested timing for sponsors to report a discontinuation for products deemed to be of medium or low impact level. According to the criteria outlined in the protocol, these products have a number of alternatives in the market. We would therefore propose the following revised reporting times [as per blue text] for such products:

> *Sponsor must report*
>
> - …
> - *3 months prior to the discontinuation, for a discontinuation with a medium impact level;*
> - *1 month prior to the discontinuation, for a discontinuation with a low impact level.*

Pfizer Australia notes that it is not always possible to report a discontinuation 12 months prior to the actual discontinuation – e.g. if an API supplier stops producing suddenly and the sponsor cannot arrange an alternative. We, therefore, recommend the guidelines are adjusted to read as follows [per blue text]:

> *Sponsor must report*
>
> - *12 months prior to a foreseeable discontinuation or as soon as practical after becoming aware of constraints which necessitate a discontinuation, for a discontinuation with an extreme or high impact level;*
> - …

Do you support the required notification content?

Pfizer Australia supports the required notification content, given it broadly aligns with the current voluntary system. We do, however, have a few additional comments:

- What options will be available in the 'Reasons for the shortage' drop down menu?
- Would TGA consider expanding the 'Estimated duration of shortage' to include a 'Confidence level'?

- Which fields will be included in a subsequent shortages publication? For example, will stakeholders be able to view the reason and duration/duration confidence level for the shortage, and other critical information such as proposed alternative supply arrangements and the jurisdiction(s) affected?

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

Is the list complete/adequate? Are there other products that would have an extreme or high patient impact if they were to be in short supply?

Pfizer Australia agrees with the development of a Medicines Watch List.

We would propose that, utilizing the rating methodology outlined in the protocol, a shortage of the following products could be considered to have an extreme patient impact and should be considered for inclusion in the Medicines Watch list:

- Saline/ sodium chloride
- Sterile water for injections
- Promethazine
- Desferrioxamine.

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

Pfizer Australia agrees that the list should be reviewed regularly to ensure it remains up-to-date and aligns with contemporary evidence and international best practice. In this context, we would propose:

- A formal review of the list is undertaken every two years
- The review is led by the TGA in consultation with the Chief Medical Officer (CMO)
- In making their recommendation, the TGA and the CMO should consider state/territory hospital emergency and life saving drug lists, as well as WHO's Model List of Essential Medicines
- Stakeholders are given an opportunity to make a submission for consideration by the TGA and the CMO prior to the commencement of the review (e.g. clinical groups/societies such as SHPA and CATAG); and
- Sponsors are afforded a right to appeal prior to publication of the revised list.

To ensure the list is kept up-to-date between formal reviews, Pfizer Australia recommends that TGA consider a medicine's inclusion on the Medicine Watch List when considering a sponsor's initial ARTG listing application. It will also be important for the TGA to review the list when a sponsor formally exits the market (i.e. delists). If a medicine has previously been assessed as medium impact, but then a competitor leaves the market, this could easily move a medicine into the 'high patient impact' category.

4. Compliance obligations and potential penalties

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

Pfizer Australia supports the TGA's proposal that industry should be afforded time to adjust to the new framework. Pfizer Australia notes and supports the TGA's proposal that, in most cases, sponsors will be given an opportunity to comply with the requirement in the first instance; and only where there is non-compliance will enforcement proceedings commence.

However, we believe it is premature to discuss penalties and sanctions in such detail at this time—given the definition of a medicine shortage and the required reporting timelines (the factors against

which compliance is to be assessed) have yet to be finalized—other than to comment that it seems that a criminal offense regime would not be appropriate in the circumstances.

Regardless of the option(s) the TGA chooses to advance, Pfizer Australia strongly recommends that the effectiveness of the compliance and penalty system is formally assessed after 12 months of operation.

5. Miscellaneous / overarching comments

The new protocol dictates that shortages deemed to be of 'extreme' or 'high' patient impact would be mandatorily published on TGA's website. Pfizer Australia seeks clarity on whether TGA intends to publish an *anticipated* shortage for a medicine in this category, or whether mandatory publication will be limited to *actual* shortages. If TGA intends to publish an *anticipated* shortage, it is critical that appropriate due diligence is undertaken prior to publication (e.g. if a sponsor reports an anticipated shortage to TGA, but other sponsors confirm with TGA, upon consultation, that they can supply the anticipated shortfall, publication may not be required and may even be counterproductive).

PART 2 Comments on specific areas of the Draft Protocol

#	Chapter / Section	Text Reference	Pfizer Australia Response
Steps in the Reporting, Management & Communication of Medicines Shortages			
1.	Reporting of a shortage to TGA (page 9)	"16. …the TGA is able to publish information about medicine shortages under a legislative instrument under section 61 if the Act that provides the TGA with the authority to release information to the website regardless of consent."	Pfizer Australia is concerned that there is no proposed mechanism for a sponsor to appeal the assessment outcome. Moreover, sponsors must be given notification of intent to publish and a chance to redact, if needed.
2.	Reporting of a shortage to TGA (page 9)	"13. Information from other parties may be used to inform the TGA…"	It is critical that TGA verifies the accuracy of the information reported by these stakeholders with the sponsor of the medicine. This should be reflected in the protocol.
3.	Reporting of a shortage to TGA (page 9)	"15. In examples 2 and 3 above, the TGA will verify…"	It is unclear what examples the paper is referring to.
4.	Reporting of a shortage to TGA (page 9)	"12. Product sponsor confidentially and mandatorily reports to TGA of: a. A potential shortage..."	Pfizer Australia seeks clarity from TGA on how a 'potential' shortage differs from an 'anticipated' shortage. A 'potential' shortage is not specifically defined in either document.

#	Chapter / Section	Text Reference	Pfizer Australia Response
5.	Reporting of a shortage to TGA (page 9)	"Whilst reporting would normally be made by the sponsor of the medicine, the TGA may be informed by a different sponsor or health care provider that the supply of a medicine is not likely to meet normal or projected demand. This is then investigated, verified and communicated by TGA."	Pfizer Australia notes that stakeholders other than a sponsor can report a suspected shortage. Pfizer Australia seeks further information on TGA's specific process for investigating and validating such a report. We also propose that consideration should be given to ways in which frivolous complaints can be prevented.
6.	Reporting of a shortage to TGA (page 9)	"13. Information from other parties may be used to inform the TGA or other parts of the Department of Health and the sponsor…"	Pfizer Australia contends that step 13 should include TGA collecting information from other sponsors to establish current unit market share and ability to supply. TGA should not make assumptions in these areas without verifying with relevant sponsors. Furthermore, we would argue that there should be a formal process to assess whether a section 19A is needed. That is, prior to granting a section 19A application, the TGA should contact other registered suppliers to assess their capacity to help resolve the shortage (subject to legal considerations). If there is a risk that market demand cannot be met by existing sponsors, only then should TGA consider section 19A applications or other alternative supply arrangements. This information should then be used to inform the risk assessment framework.

#	Chapter / Section	Text Reference	Pfizer Australia Response
7.	Assessment and verification (page 10)	"There are currently challenges in obtaining accurate and timely information."	Pfizer Australia suggests the assessment should also address the following questions: • Which customers and/or territories are affected? • What is the percentage split each supplier currently provides in dual tender listing scenarios? • What are current demand projections* across the entire market? ** For medicines on the Medicine Watch List, state tender boards and large private hospitals could, for example, take responsibility for maintaining a grid illustrating current demand.*
8.	Communication with industry sponsors in managing supplies when products are available from multiple sponsors but are in short supply (page 14)	"Some aspects of communication and collaboration described above might be seen as anticompetitive…"	Pfizer Australia strongly recommends the TGA consult the ACCC to seek their view on the proposal.
Appendices			
9.	Appendix 1 (page 18)	"3. If the medicine is not on the Medicines Watch list, then the TGA – following further input from the sponsor (if required) – undertakes a desktop assessment using the assessment framework."	Pfizer Australia seeks confirmation that the sponsor will be provided with the detailed rationale/assumptions used in making the assessment when the TGA shares the outcome of the assessment with the sponsor.
10.	Appendix 3 (page 22)	"They also have a role in coordinating responses to medicines shortages where there is a significant public health impact with in their jurisdictions."	Pfizer Australia would argue that a key part of this role is the allocation of stock across hospitals, as well as the prevention of hoarding.

#	Chapter / Section	Text Reference	Pfizer Australia Response
11.	Appendix 5 (page 27)	*<entire section>*	Pfizer Australia recognises that the *National Health Act 1953* provides a number of mechanisms that can be utilized by government and stakeholders to prevent, mitigate or resolve a medicines shortage. In order to fully maximize the effectiveness of these options, however, Pfizer Australia recommends TGA consider the following recommendations: <u>Section 19A</u> TGA should introduce a practical but effective statutory processing time for section 19A applications in the event of a medicine shortage. In our experience, these applications can take weeks to process. <u>Section 14 Exemption</u> TGA should introduce a practical but effective statutory processing time for section 14 exemption applications in the event of a medicine shortage. Similar to our experience under section 19A, these applications can take weeks to process. <u>Import Permits for Controlled Substances</u> Under the current system, an Australian sponsor must apply for and be granted an import permit by the Office of Drug Control (ODC) (which has a 4 week standard lead-time) before the manufacturer offshore can apply for and be granted an export permit from their respective health authority (which can take an additional 4-8 weeks). These activities are sequential and cannot take place in parallel. This whole process is a major delaying factor in responding to controlled drug shortages. Pfizer Australia suggests that a mechanism to enable tighter coordination between the ODC, TGA and sponsor in the event of a drug shortage would be worth exploring. For example, DOC generally processes import permit requests in the order of submission by the various sponsors. Further prioritization based on supply emergency requirement could help mitigate/minimize potential medicines shortages.