GSK and ViiV Healthcare Comments on TGA Consultation: Management and communication of medicines shortages

Overall Comment

GlaxoSmithKline Australia Pty Ltd (GSK) and ViiV Healthcare (ViiV) welcome the opportunity to comment on this consultation and is highly supportive of the introduction of mandatory reporting of medicine shortages. GSK are appreciative of the transparent, open and diligent consultation by the TGA on the Medicines Shortage Initiative over the last year.

In this document, GSK and ViiV have provided view points for consideration on the proposed TGA questions in relation to the guidance material on the management and communication of medicine shortages. There is overall support for the guidance material, however there is still scope for further clarity and refinement.

TGA questions

Consultation issue 1: The definition of a medicine shortage

Is the definition of a medicine shortage clear?

The definition of a medicine shortage is clear and will aid sponsors in determining when mandatory reporting of a supply issue to the TGA is required.

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?

The definition is appropriate for inclusion in the Therapeutic Goods Act.

Is the proposed scope for covered medicines clear?

The proposed scope for covered medicines is clear.

Is the proposed scope for covered medicines appropriate?

The proposed scope for covered medicines is appropriate.

Consultation issue 2: Reporting obligations

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

Feedback on suggested timing for sponsors to report an anticipated or current shortage:

The need to report anticipated shortages as soon as practicable after sponsors become aware of them may lead to a high number of possible shortages being reported which do not ultimately result in a shortage.

Supply or manufacturing issues may lead to delays in production or delivery of a medicine to Australia. Sponsors are often made aware of these issues and monitor the stock levels carefully. In some cases, these delays may lead to a gap in supply and a medicines shortage, as defined by

the TGA. However, quite often the stock levels can be managed by the sponsor to ensure a shortage does not occur. Therefore, further clarity is needed on when an anticipated shortage should be reported to the TGA.

The other suggested timeframes appear acceptable.

Feedback on suggested timing for sponsors to report a discontinuation:

GSK support the timeframes for notifying discontinuations and understand the reasons for the long lead times. However, in some cases sponsors may not be aware 12 months prior to discontinuation of a product and therefore will be unable to adhere to these timeframes. An example of such an instance would be if manufacturing unexpectedly ceases for a product following a manufacturing issue or an audit. Therefore, the following amendment to the requirement is suggested:

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.*

*Sponsors must adhere to the specified timeframes except for instances where information of the discontinuation is unavailable to the Sponsor at the specified time. In these cases, sponsors must report discontinuation as soon as is practicable after becoming aware of it.

Do you support the required notification content?

The required notification content is supported, however, it would be beneficial for sponsors to be able to notify and publish additional information on a shortage to the TGA and the public when necessary.

For instance, if there is a shortage of a vaccine that will only affect private market supply but will not affect supply of the National Immunisation Program, this should be included on the notice published on the MSII website. This is valuable information for the TGA and the public. Currently GSK provides such information via a link from the MSII website to the GSK website. However, as this is vital information for readers to assess the impact of the shortage, GSK believes this should be published at the first level, i.e. directly on the MSII website.

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

Is the list comprehensive/adequate?

GSK agree that the list is comprehensive and adequate. GSK supports the inclusion of all vaccines on the National Immunisation Program due to the high impact such shortages have on the Australian population. However, it should be clearly specified in the guidance that when a shortage of any of these vaccines only affects private market supply and will not affect supply of the National Immunisation Program, these shortages will not be automatically defined as "extreme"risk. These shortages should instead be assessed by the TGA on a case by case basis. Quite often these shortages can have limited impact and would not warrant publication as an "extreme" risk on the TGA landing page.

GSK suggest the following amendment within the text of the Medicines Watch List:

National immunisation program vaccines

Any vaccine on the NIP that includes the following, where the shortage affects the supply of the NIP:

Hepatitis A

Hepatitis B

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

GSK would like to highlight consideration of medicines for a life-threatening condition that require continuous administration. For example, GSK would consider there would be significant patient impact from a shortage of a medicine like epoprostenol sodium (Flolan). We would like to suggest the TGA reflect on medicines which fall into these categories.

ViiV Healthcare has noted that there are no HIV medicines on this list and would welcome the TGA's consideration of this.

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

At a minimal, an annual review of the list by the TGA and appropriate experts to identify any medicines that should be added or removed is warranted. In addition, as new medicines are registered, an assessment as to their appropriateness to be included on the list should be made.

Consultation issue 4: Compliance obligations and potential penalties

Do you support particular options? Why?

As a general position, the preference is for the industry to adopt a culture of transparency and compliance through mechanisms that raise awareness and educate rather than through penalties and sanctions.

However, we do appreciate that in some circumstances a punitive system may be required, particularly in an environment where a voluntary model has proven unsuccessful, if that is in fact the case.

In terms of the options proposed, further consultation around the enforcement process, criteria and thresholds that would apply to each of the options would be required, please refer to the response below.

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

In our view, Option 1 would be preferable.

If penalties are however going to be mandated, we do not support Option 3 and submit that Option 2 would require some amendment and further clarity.

We further submit that option 3 would be inappropriately harsh, except in very limited circumstances where the breach is of an extremely serious nature and there is an element of deliberate non-compliance.

In relation to Option 2, an infringement notice imposing a blanket fine of 60 penalty units and issued 'in most circumstances' may be appropriate in some circumstances but excessive in others. For example, the same fine should not be attached to acts of non-compliance which are repeated, deliberate or relate to products that are critical for patients compared to those which are unavoidable and minor in terms of nature and patient impact.

If a punitive approach of the kind contemplated by Option 2 were to be considered, it is requested that further consideration be given to the criteria and thresholds that would apply for a contravention notice to be issued and would propose a 'scale' of fines for varying degrees of non-compliance, having regard to the nature of the breach, the product and patient impact.

Further, from a procedural fairness perspective, if fines are to be introduced we would request a process allowing alleged offending companies to state their case and provide reasons for the alleged failure to comply before punitive action is taken, particularly where there has not been a history of repeated non-compliance.

Closing Comment

We thank the TGA for providing GSK and ViiV with the opportunity to participate in this very important consultation process.