30 April 2018

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

Consultation: Medicines Shortages

Dear Sir/Madam

Roche thanks the TGA for the opportunity to provide comments on the TGA's consultation on Medicines Shortages.

Roche supports the TGA's role in managing medicine shortages and has supported the current voluntary system for the reporting of medicine shortages with notifications and updates related to any shortages of Roche medicines. Roche also support, in principle, enhancements to the reporting and management of medicines shortages.

Responses for consultation issues

Consultation issue 1: The definition of a medicine shortage

Roche support defining a medicine shortage has instances where a patient's care *is* owever the addition of criteria for *(b)* describing 'partial availability' of a medicine from a sponsor, wholesaler or manufacturer, and criteria *(c)* citing 'other constraints' on a medicine's availability, are unnecessarily broad and would recommend these are either removed or further defined to ensure the definition and the intended meaning is clear and precise to avoid over reporting.

Consultation issue 2: Reporting obligations

Roche agrees that all medicine shortages should be reported by the sponsor to the TGA as soon as practicable after becoming aware of it and therefore supports that the timeframes proposed for reporting a shortage anticipated and current shortages.

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Compliance with the reporting periods and avoiding over-reporting requires a clear definition of a medicine shortage and as per the comments on Consultation issue 1, Roche propose that the definition of medicines shortage is more precisely defined and language describing *potential* shortage is replaced to more clearly describe that a shortage is expected rather than might be expected.

The requirement to report to TGA within 2 business days of being contacted by TGA is noted and while response in this timeframe is possible, the response may not include complete details related to a shortage given the time that may be needed to collect information from international supply sources and to collate information on local distribution details.

With respect to the timeframes proposed for reporting of discontinuation, Roche support the need for longer lead times in reporting of discontinuations, particularly for medicines with extreme or high impact, however Roche do have some concerns with the mandatory 12-month lead time proposed. There may be unforeseen situations where a discontinuation is not known 12 months in advance and a provision for exceptions or exemptions to this requirement should be considered.

Consultation issue 3 – Medicines Watch List defining an extreme risk shortage

Roche support the Medicines Watch List as way of simplifying and increasing the speed of decision making for medicines shortages that have an extreme or high impact of patient treatment. The proposed list seems adequate although further details on the criteria for the specific medicines chosen would be helpful to provide and an adequate timeframe provided for sponsor and other stakeholders review of proposed adequate is recommended to ensure consistency and transparency in the medicines included.

Consultation issue 4 - Compliance Obligations and potential penalties

Roche understand that the introduction of mandatory reporting of medicines shortages raises the need for a compliance mechanism and that with consequences for non-compliance, should drive the required reporting. Roche support the proposal for compliance obligations and penalties to align with the principles of the TGA's existing compliance framework.

Roche believe that the clarity of definition and reporting requirements is critical to given the severity of some the proposed penalties.

Thank you again for the opportunity to provide comment.

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Yours sincerely,
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[redacted]

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