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

RE: Consultation: Management and communication of medicines shortages

Dear Sir/Madam,

Bristol-Myers Squibb (BMS), a diversified global BioPharma company, is pleased to have the opportunity to offer comments on the Therapeutic Goods Administration (TGA) consultation *Management and communication of medicines shortages*. Bristol-Myers Squibb Australia (BMSA) is a sponsor of innovative biopharmaceutics registered on the Australian Register of Therapeutic Goods.

BMSA currently reports instances of anticipated and actual medicines shortage in accordance with TGA's Medicine Shortages Information Initiative (MSII). In principle, BMS does not object with mandatory reporting, but provides some important caveats for TGA consideration on the Consultation issues, as follows:

Consultation issue 1: Proposed Definition of a Medicine Shortage

BMS agrees that the application of a patient-centric **definition** is appropriate. However, the TGA's proposed definition is unduly broad, and creates ambiguity and unnecessary regulatory burden.

- The use of the term '…where a patient's care *may need to be revised…*' is subjective and creates ambiguity, as it is unclear a) who makes this assessment, and b) at which point an assessment of impact on patient care is made.

- The addition of criteria *(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.

Both elements taken together suggest that all incidences of *potential* shortages will need to be reported, regardless of their likelihood of eventuating in an anticipated or actual shortage impacting patient care. Sponsors will be driven to report every instance of potential shortage to avoid penalties, increasing regulatory burden.

The TGA can expect to be inundated with copious volumes of unnecessary reports, creating a high level of background 'noise'.

It is unclear whether the TGA intends to actively manage every potential shortage report submitted for assessment by sponsors. The impact this may have on resourcing and the TGA's ability to appropriately and effectively triage and manage genuine cases of medicine shortage is questioned.

The ambiguity and breadth of reporting created by the proposed definition does not align with the TGA's own principles of adopting a risk-based approach to regulation.

BMS, like many other sponsors, has robust protocols in place through which supply is proactively managed in order to mitigate any adverse impact of supply to patients. This is standard business practice for the management and supply of medicines, which sponsors utilise to largely ensure continuity of supply to patients. Application of the proposed definition creates a duplicate layer of activities to those currently undertaken by sponsors, and penalises those who are compliant with the TGA MSII reporting.

Consultation issue 2: Reporting Obligations

- BMS agrees with **reporting obligations** proposed by the TGA to report an *anticipated* or *current* shortage as soon as practicable after becoming aware of it, or within 2 business days of being contacted by the TGA regarding a report of a shortage.

  Given the complexity of manufacturing supply chains, it should be recognised that the extent of information that will be available within 2 days of a hitherto unknown situation is likely to be limited, and this should be clearly acknowledged in the protocol.

- BMS believes that TGA intends that the appropriate trigger for reporting an instance of anticipated shortage is the identification of a date in the future at which patient care is expected to need to be revised as a result of medicine unavailability.

  The current version of the proposed medicines shortage definition is open to interpretation, does not articulate this clearly, and arguably describes all cases of *potential* shortages, not just anticipated or actual shortages.

BMS suggests edits to the TGA's proposed definition of a "medicine shortage", as outlined in Annex 1, as an alternative to avoid introducing unnecessary layers of confusion in the definition, potentially resulting in superfluous reporting and increased regulatory burden to both sponsors and the TGA.

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

BMS believes that the proposed 'Medicines Watch List' is a suitable tool to assist the TGA with the management of instances of medicine shortages of significant public health impact, and supports any reasonable periodic review mechanism which involves relevant stakeholders.

Consultation issue 4: Compliance Obligations and Options

BMS believes that the introduction of penalties for failing to meet reporting obligations will help to drive compliant reporting in the case of sponsors who do not currently report anticipated or actual medicine shortages.

BMS supports a penalty system that is graduated, risk-based and commensurate with the impact of the non-compliance. Reasonable defences for non-compliance should be considered, as well as a sponsor's intent and track record, in any contemplation of penalties.

Given the severity of some the proposed penalties, including potential imprisonment, the TGA must ensure that its reporting requirements, including the definition and boundaries of interpretation thereof, are reasonable and clear.

Overall, BMS believes that the proposed 'Medicines Watch List', together with a reasonable regime of penalties, should help TGA to capture relevant notifications that are evaluable and actionable, and support efficient and effective use of TGA resources in safeguarding the public health interest.

BMSA appreciates the opportunity to provide comments. We would be pleased to provide additional pertinent information or clarification as may be requested.

Sincerely,

[redacted]
[redacted]
[redacted]
Global Regulatory Sciences, Australia & New Zealand
Bristol-Myers Squibb Australia

Annex 1: Proposed definitions

DEFINITION OF A MEDICINE SHORTAGE

*A **medicine shortage** covers all instances where a patient's care ~~may need~~ is expected to be revised as a result of~~:~~*

~~*a) the unavailability of a medicine from a sponsor, wholesaler or manufacturer; or*~~
~~*b) the partial availability of a medicine from the sponsor, wholesaler or manufacturer; or*~~
~~*c) other constraints on the medicine's availability.*~~

Different types of medicine shortage are defined:

- ***Anticipated medicine shortage** means a medicine shortage that is anticipated to commence at a future date;*
- ***Current medicine shortage** means a medicine shortage that has commenced;*
- ***Resolved medicine shortage** means a medicine is now available ~~because the supply of the medicine is no longer unavailable, partially available or affected by other constraints~~;*
- ***Discontinuation** means a decision by the sponsor to permanently cease supply of a medicine.*

REPORTING AN ANTICIPATED OR CURRENT SHORTAGE

*Sponsors must report an **anticipated** or **current medicine shortage**: as soon as practicable after becoming aware of it, or within 2 business days after being contacted by the TGA regarding a report of a shortage of their medicine.*

*Sponsors must report all **resolved shortages** as soon as practicable ~~after it has resolved~~ and ~~within~~ no later than 5 working days ~~of~~ from the day the shortage was resolved.*

A medicine is taken to be in shortage once patient care may need to be revised due to unavailability.

REPORTING A DISCONTINUATION

Sponsors 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 a medium impact level;*
- *3 months prior to the discontinuation, for a discontinuation with low impact level.*

Commented [GM1]: Revised to reduce ambiguity

Commented [GM2]: Revised to align with proposed definition of medicine shortage

Commented [GM3]: Revised for clarity