Technical and Safety Improvement Section
Pharmacovigilance and Special Access Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606
PSAB.communications@tga.gov.au

Dear Sir/Madam

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

The Australian Private Hospitals Association welcomes the opportunity to contribute to the Therapeutic Goods Administration's (TGA) consultation on Management and Communication of Medicines Shortages in Australia – a new protocol.

As the TGA is aware, medicines shortages have been an enduring issue which has affected hospital pharmacies for many years. In 2017, pharmacists working in APHA member hospitals participated in a survey undertaken by the Society of Hospital Pharmacists of Australia (SHPA) to measure the prevalence of medicine shortages. The survey confirmed what our members were already telling us about the severe clinical and financial repercussions of medicines shortages.

We are strongly supportive of revisions to the previous protocol and an increased focus on notification and management of shortages. We are pleased to see these elements are well supported by the proposed protocol including:

- the requirement for sponsors to mandatorily notify the TGA of shortages as soon as they are known or anticipated, and
- the coordinated and systematic publication and distribution of shortage information.

Adoption of a patient-oriented definition with regard to medication shortage is essential. This recognises that optimal patient-centred care is the priority for all medicines management, and that frequent disruption of therapeutically preferred treatment due to medicine supply is unacceptable.

In addition, APHA supports the revision of legislation to ensure that medicine sponsors are incentivised to report shortages likely to have a clinical impact, and that widespread compliance is mandated.

We note that SHPA has recommended additions to the Medicines Watch List. APHA is supportive of these recommendations and establishment of a process to support the ongoing review and maintenance of the list to ensure that it reflects current clinical practice and any changes to the utilisation of PBS and non-PBS drugs within the Australian context.

APHA is also supportive of SHPA's proposal for an ongoing independent and clinically expert body charged with evaluating the impact of shortages, the identification of alternative treatments and clinical recommendations to support the safe management of patients affected by medicine shortages. It is also imperative that this independent advisory body draw on expert pharmacists with relevant specialist expertise and an understanding of the contingencies that apply in public hospital, private hospital and community settings.

Consultation issue 1: The definition of a medicine shortage

APHA supports the proposed definition of a medicine shortage which identifies a shortage by the requirement for revision of patient care. This reflects the appropriate priority of patient care over supply management in a healthcare setting. APHA supports the suggestion that revision should be interpreted as including: *substitution with alternative medicine, alternative strength, alternative brand or alternative route of administration.*

APHA also agrees that notification should be required 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.

The definition of 'critical to the ongoing health of the patient' and 'critical for public health' require further clarification. APHA is of the view, however, that where there is any doubt, the weight of interpretation should favour conventional Australian clinical practice.

Given that the TGA anticipates that a 'small number' of non-prescription medicines will be included in the scope for medicines shortages reporting, APHA supports SHPA's request for the opportunity to provide feedback to ensure there are no omissions related to the hospital pharmacy setting.

Consultation issue 2: Reporting obligations

APHA supports the proposed two-day timeframe for sponsors to report on anticipated or current shortages, as well as the timing for sponsors to report discontinuations (3-12 months). The timelines proposed are appropriate to enable meaningful changes to procurement management.

Further work is required to define the thresholds or conditions that would trigger a notification of shortage to the TGA. Consensus across all stakeholders is needed regarding the definition of key terms, in the interests of transparency and compliance.

Standards for how medicines sponsors report information on shortages to customers, health groups and the public are essential. Currently, medicines sponsors have very variable approaches to how they notify stakeholders along the supply chain. APHA notes that research by SHPA has identified that some will notify only wholesalers or only pharmacies through a varied mix of media such as facsimiles, letters or emails. In many instances, the information is not available on the sponsors' website. Further, the information can be contradictory, causing significant confusion to health services and impinging on their ability to plan health services accordingly and minimise disruption to patient care.

APHA believes that when sponsors are reporting a medicine shortage they should also be

requested to identify alternatives that would require importation via S19A, if there are no available substitutes on the Australian market. When the shortage is listed on TGA's website, it should also report on whether a S19A alternative has been arranged or if the sponsor has attempted to do so, and if the S19A product is eligible for PBS subsidy with a link back to TGA's S19A database. Providing this information to stakeholders will reduce some of the administrative burden encountered by hospital pharmacists when dealing with medicines shortages.

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

APHA recognises the valuable role played by the Medicines Watch List and supports its use as part of the risk assessment framework. The adoption of the list will speed up the development of clinical alternatives and provide support for clinicians. It will also provide an informal guide for manufacturers aiming to support the medicine supply chain.

In the interests of clarity and transparency, APHA strongly supports the publication of the rationale or criteria for inclusion on the Medicines Watch List and the designation of 'extreme' risk shortage. This would support a transparent process for annual or bi-annual review or consultation, and a pathway for the addition of new medicines listed on the Australian Register of Therapeutic Goods. APHA is supportive of the following criteria forming a starting point for inclusion on the Medicines Watch List:

- This medicine is used in life-saving, emergency or mass casualty situations or public health events.
- This medicine is routinely used in high-risk patients i.e. immunocompromised patients, transplant patients.
- Unavailability of treatment with this medicine will lead to significant deterioration of patient's health or death and there is not an appropriate alternative substitute medicine.
- Sudden unavailability of treatment with this medicine will lead to significant deterioration of patient's health or death if there is insufficient supply for dose reduction and/or transition to alternative medications to be managed safely.
- Unavailability of this medicine will lead to significantly lengthier hospitalisations and there is not an appropriate alternative substitute medicine.

APHA notes that SHPA's initial assessment of the medicines included in the draft Medicines Watch List indicates that roughly 25 percent of these medicines were in shortage at this time last year. This would equate to more than 42 percent of the individual reported shortages by SHPA members presenting 'extreme' risk to patients. This assessment underlines the essential nature of the proposed reforms. SHPA's analysis also underlines that it is imperative that pharmacists and hospitals have an on-going opportunity to report experienced shortages and to identify medications and classes of medications where the clinical consequences of shortage are deemed unacceptably high.

Consultation issue 4: Compliance obligations and potential penalties

APHA supports Option 3, the introduction of substantial civil penalties and possible criminal charges to deter sponsors from not meeting their reporting requirements. We believe this is the most appropriate option to ensure widespread compliance to the new medicines shortages protocol.

APHA is also pleased to see that Option 3 includes the publication of names of sponsors that do not comply with the mandatory requirements for notification of medicines shortages. Not only will this as act as a deterrent to sponsors, it will also inform government procurement agencies and private hospital procurement operations about the reliability of certain sponsors to provide upfront information about actual and anticipated medicines shortages. A sponsor's compliance history with the new medicines shortages protocol could potentially inform procurement decisions during the tendering process.

Given that the new medicines shortages protocol aims to encourage sponsors to be more proactive with their notifications, APHA believes that in the instances where the TGA receives a notification of a potential shortage from a stakeholder that is not a medicines sponsor and is subsequently verified by the sponsor, this should be deemed as an infringement as the medicines sponsor was not proactive in this case.

APHA believes the severity of penalties should be tiered according to factors such as previous compliance history and the patient impact of non-reporting of the medicines shortage, particularly if the medicine is on the Medicines Watch List.

Issue of particular concern in the private hospital sector

Unlike community pharmacies the wholesale supply of PBS medicines to hospitals is not supported by the Community Service Obligation which potentially makes hospitals more vulnerable to supply disruptions. It is therefore essential that any assessment of shortage and/or supply-chain failure be well-informed by information gathered from across the sector. It is important to note that, particularly in the early stages, shortages may be experienced differently by different parts of the health system because of regional and/or supply chain factors.

APHA is supportive of the new protocol and its focus, and we thank the TGA for the opportunity to contribute to its development.

If you have any queries or would like to discuss our submission further, please do not hesitate to contact Lucy Cheetham, Director Policy and Research on lucy.cheetham@apha.org.au or (02) 6273 9000.

Yours sincerely

Michael Roff
CHIEF EXECUTIVE OFFICER
23 April 2018