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Dear [redacted]

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

The Society of Hospital Pharmacists of Australia (SHPA) welcomes the opportunity to contribute to the Therapeutic Goods Administration (TGA)'s consultation on Management and Communication of Medicines Shortages in Australia – a new protocol.

As the national professional organisation for more than 4,900 pharmacists, pharmacists in training, pharmacy technicians and associates working across Australia's health system, SHPA is committed to facilitating the safe and effective use of medicines in hospitals. SHPA members work alongside medical and nursing staff in public and private hospital nationally, providing clinical services, dispensing medicines and managing medicine supply.

As the TGA is aware, medicines shortages have been an enduring issue which has affected hospital pharmacies for many years. In 2017, SHPA undertook a survey to measure the prevalence of shortages as experienced by our members to support policy development in this important area. Alongside other advocates, we advocated for revisions to the previous protocol and an increased focus on notification and management of shortages. We are pleased to see these elements well supported by the proposed protocol, and that the protocol reflects the negative 'trickle-down' effect shortages had on patient care.

SHPA is pleased to support the new protocol outlined by the TGA to manage and communicate medicines shortages in Australia. In particular SHPA is pleased to see the requirement for sponsors to mandatorily notify the TGA of shortages as soon as they are known or anticipated. The publication or distribution of this information will significantly reduce the burden of addressing systemic shortages on a case-by-case basis.

SHPA also supports the adoption of a patient-oriented definition as appropriate to health service planning. 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 shortages supply is unacceptable.

In addition, SHPA 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.

Finally, SHPA members, as medicines experts working in hospitals every day, have made a range of suggested additions to the Medicines Watch List, and would welcome the opportunity to collaborate with the TGA on the evolution of this list, and assessment of shortages, as they occur. SHPA supports 24 specialty practice groups which correlate with medical specialties and cover all therapeutic groups. These experienced members will be highly relevant as a source of clinical expertise identifying the impact of shortages, suggesting alternative treatments and collaborating with specialists.

## Consultation issue 1: The definition of a medicine shortage

SHPA supports the proposed definition of a medicine shortage which identifies a shortage by the requirement for revision of patient care as below. This reflects the appropriate priority of patient care over supply management in a healthcare setting.

*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 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.*

### Clarifying definitions of resolved vs current medicine shortages

However, the proposed definition of a 'resolved' medicine shortage' is not supported by SHPA as it is potentially contradictory. A shortage according to the definition above can exist when a partial supply is available. Consequently, a shortage could be simultaneously be both 'current' and 'resolved'. For example, a sponsor that has just resumed production of a medicine may believe this constitutes a resolution, however logistically the impact of the shortage would still be felt by health services and patients.

Medicines that become partially available or are subject to rationing after being unavailable, should still be reported as a 'current medicines shortage' that is not resolved. SHPA believes that a medicine shortage should only be defined as 'resolved' when **all** patients being treated with that medicine are able to access it in a timely manner. This would align with the patient-centred definition of shortages and prevent the introduction of perverse incentives for rationing or poorly managed self-reporting.

### Ensuring essential non-prescription medicine shortages are reported

Given that the TGA anticipates that a 'small number' of non-prescription medicines will be included in the scope for medicines shortages reporting, SHPA would appreciate the opportunity to provide feedback on the principles and parameters for medicine to be included in this list. In addition to the two examples included in the discussion paper (salbutamol and naloxone), a starting point for this list would be the inclusion of Schedule 2 and Schedule 3 medicines that are listed on the Pharmaceutical Benefits Scheme (PBS) and the Repatriation Pharmaceutical Benefits Scheme (RPBS). Shortages of these medicines are currently significantly disruptive to patient care in a hospital setting.

SHPA fears that without this list clearly defined there is a significant risk that manufacturers will apply their own interpretation, and this may result in notification of important shortages, such as glyceryl trinitrate as an example, not occurring. The definitions of 'critical to the ongoing health of the patient' and 'critical for public health' as relates to non-prescription medicines is not required if Schedule 2 and Schedule 3 medicines on the PBS are included and the proposed watch list covers "critical products" as detailed under Consultation issue 3.

## Consultation issue 2: Reporting obligations

SHPA 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. Longer timelines would reduce the efficacy of the process.

SHPA believes that the thresholds or conditions that would trigger a notification of shortage to the TGA may need to be defined in order to aid transparency and compliance. For example, how would rationing of medicines so they are available to some, but not all, customers be reported? Would it qualify as a 'current shortage', an 'anticipated shortage' or not a shortage at all? SHPA is interested to hear the thoughts of medicines industry stakeholders on these implementation issues.

Standards for how medicines sponsors report information on shortages (both their notification and resolution) to customers, health groups and the public would be useful to avoid excessive variability.

Currently medicines sponsors have very variable approaches to how they notify stakeholders along the supply chain. Some will notify only wholesalers, or only pharmacies, through a varied mix of media such as facsimiles, letters or emails. It should not be assumed that the information is available on the sponsor's website as in many instances this is not the case. Further, the available 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. A recent example of this is the enduring shortage of adrenaline (Epipen) autoinjectors in which different sources have conflicting messages on its availability and the duration of the shortage.

SHPA believes that when sponsors are reporting a medicine shortage they should also be asked 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 and increase the use and efficacy of the TGA's online information.

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

SHPA 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 reduce the frequent assessment of shortages of medicines commonly used in Australian hospitals, 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.

To ensure clarity and reduce confusion SHPA supports the publication of the rationale or criteria for inclusion on the Medicines Watch List and defined as an '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 ARTG. As a start, SHPA proposes the following criteria for TGA's consideration for medicines to be included 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
- Unavailability of this medicine will lead to significantly lengthier hospitalisations and there is not an appropriate alternative/substitute medicine

SHPA members have provided a list of ARTG medicines for addition to the Medicines Watch List to enhance its efficiency by reducing individual assessment of medicines that present an 'extreme' risk to patients when in shortage. After review, SHPA believes the following medicines should be considered for inclusion as they provide essential treatment for life-threatening conditions and often cannot be substituted.

Please see following page for complete list.

**Additions to Medicines Watch List**

SHPA members would be pleased to provide information about the clinical rationale for the inclusion of each of these medicines.

**Anaesthesia/Analgesia**
Fentanyl
Methoxyflurane
Morphine
Remifentanil

**Anticoagulants**
Ticagrelor
Warfarin

**Anticonvulsants**
Diazepam
Levetiracetam
Midazolam
Sodium valproate

**Antimicrobials**
Aciclovir (IV)
Amikacin (IV)
Amoxycillin/Clavulanic Acid (IV)
Anidulafungin
Artemether with lumefantrine
Artesunate (IV)
Caspofungin
Cefoxitin (IV)
Clindamycin
Ethambutol
Famciclovir
Fosfomycin
Isoniazid
Lamivudine
Lincomycin
Micafungin
Norfloxacin
Tigecycline

**Critical Care/Emergency**
Alteplase
Antithymocyte globulin (rabbit)
Dobutamine
Glyceryl trinitrate
Hydroxocobalamin
Insulin
Isoprenaline
Mesna
Protamine
Sugammadex
Tenecteplase
Terlipressin
Vasopressin

**Corticosteroids**
Betamethasone (IV)
Methylprednisolone (IV)
Prednisolone oral

**Neuromuscular blockers**
Pancuronium
Rocuronium
Suxamethonium

**Obstetrics**
Misoprostol
Magnesium sulphate (IV)

**Transplant medicines**
Basiliximab
Cyclosporin
Mycophenolate mofetil
Mycophenolate sodium
Tacrolimus
Sirolimus

**Other**
Danaparoid
Eculizumab
Neostigmine
Pyridostigmine
Zoledronic acid

## Consultation issue 4: Compliance obligations and potential penalties

SHPA 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.

SHPA is also pleased to see that Option 3 includes the publication of names of sponsors who do not comply with the mandatory requirements for notification of medicines shortages. Not only will this 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, SHPA 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.

SHPA believes the severity of penalties should be tiered accordingly 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.

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. The hospital setting is also where the most unwell patients are treated and where community expectations of treatment are highest. Hospital pharmacists are therefore very supportive of the new protocol and its focus, and we thank the TGA for the opportunity to contribute to its development.

An initial assessment of the medicines included in the draft Medicines Watch List and comparison with SHPA's prevalence data from 2017 indicated that roughly 25% of these medicines were in shortage at this time last year. This would equate to more than 42% of the individual reported shortages by SHPA members, presenting 'extreme' risk to patients. Whilst some shortages have been resolved SHPA remains concerned that this situation places Australian patients at an unacceptable level of risk and would be extremely interested in working with the TGA to provide support for the implementation of this important protocol.

If you have any queries or would like to discuss our submission further, please do not hesitate to contact [redacted]

Yours sincerely,

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