17 May 2021

Jennifer Burnett
Director, Medicines Shortages Management Section
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606

Submitted via email: medicine.shortages@health.gov.au

Dear Ms Burnett,

**RE: TGA Consultation on Building a more robust medicine supply**

The Society of Hospital Pharmacists of Australia is the national professional organisation for more than 5,000 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, which is the core business of pharmacists, especially in hospitals.

SHPA welcomes the opportunity to provide feedback to the TGA's consultation on Building a more robust medicine supply. After reforming the Medicines Shortage Information Initiative, SHPA commends the TGA on their ongoing commitment to addressing medicines shortages in Australia, a long-standing concern for SHPA members and its impact on timely, safe and quality patient care in all healthcare settings.

Please see attached SHPA's submission. In principle, SHPA supports all four proposed actions to enable more robust medicines supply in Australia:

- Prioritising evaluation of important generic medicines
- Mitigating the effects of a medicine shortage through increasing commercial viability of alternative products
- Improving reliability of supply for known shortages
- Managing alternative supply if medicines are discontinued

We understand that Budget 2021-22 announced the planned creation of the Office of Supply Chain Resilience with pharmaceuticals in its purview, and look forward to contributing to this work on behalf of our members responsible for medicines procurement in hospitals around Australia.

If you have any queries or would like to discuss our submission further, please do not hesitate to contact Jerry Yik, A/g General Manager, Advocacy and Leadership on jyik@shpa.org.au.

Yours sincerely,

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Kristin Michaels
Chief Executive

## Submission to TGA Consultation on Building a more robust medicine supply

### Proposal 1 – Prioritising evaluation of important generic medicines

**Q1. Do you think that prioritising TGA's evaluation of first and second generic versions of innovator medicines will assist in preventing medicine shortages? Why?**

Yes. SHPA believes that prioritising TGA's evaluation of first and second generic versions of innovator medicines will assist in preventing medicine shortages. This will allow for faster market access for medicines for which there is currently no alternative brand on the Australian Register of Therapeutic Goods (ARTG), which will assist to prevent medicine shortages.

**Q2. If the TGA were to prioritise the evaluation of first and second generic versions of innovator medicines, how would this affect you? Can you quantify the effect for us?**

Prioritisation of the evaluation of first and second generic versions of innovator medicines would reduce the risk of medicine shortages for which there is only one brand. This is a significant concern for hospital pharmacists that often leads to an increase in workload to procure Special Access Scheme (SAS) stock of alternative medications for their patients.

According to SHPA's *2017 Medicines Shortages in Australia: A snapshot of shortages in Australian hospitals* report, 20% of the most common shortages prompted use of the SAS, which impacts on hospital budgets given the higher procurement costs of sourcing medicines internationally, the most common use of the scheme.

Furthermore, over 32% of the actions taken in response to medicines shortages have a direct impact on patient care through either the substitution of a less efficacious medicine, change in the route of administration due to a different formulation or a lack of alternatives for treatment.

Using a less efficacious medicine means taking more time to treat the same condition, thus potentially increasing the length of a hospital admission and subsequent cost to the taxpayer. Using less efficacious medicines may also mean exposing patients to medicines with more adverse effects which will also incur extra costs to monitor and treat – both of these workarounds may negatively impact a patient's quality of life during care episodes.

**Q3. Do you think that prioritising TGA's evaluation of new generic versions of 'sole source' medicines will assist in preventing medicine shortages? Why?**

Yes. Prioritising TGA's evaluation of first and second generic versions of 'sole source' medicines may assist in preventing medicine shortages by ensuring that more than one version of a medication is available to Australians. However, if there is a world-wide shortage in the raw product or raw ingredient, approving new generic versions of this medication may have limited effect on preventing medicine shortages, but rather delay its actualisation.

**Q4. If the TGA were to prioritise the evaluation of new generic versions of 'sole source' medicines, how would this affect you? Can you quantify the effect for us?**

In a recent 2021 Medicines Shortages in Pharmacy survey of hospital pharmacists, 50% of respondents said that switching a patient to an SAS medicine in response to a medicine shortage was an 'often' occurrence.

Ordering through a specific scheme presents a significant burden of administration for hospital staff including returning to the prescribing doctor for authorisation and completing the TGA form. Medicines that are not registered in Australia often have labelling and packaging that do not comply to Australian standards, do not feature English, or do not have Product Information or Consumer Medicines Information documents. This

presents challenges for pharmacists, nursing staff and consumers in pursuit of optimal medication safety and quality use of medicines.

Hence, prioritising the evaluation of first and second generic versions of 'sole source' medicines would improve access to generic versions of key originator molecules, improve safety and quality of patient care, and reduce the financial burden on hospital pharmacies and hospital budgets.

**Q5. If you gave us feedback on this proposal as part of our 2019 consultation on 'Reforms to the generic medicine market authorisation process', has there been any change to your stated position? If so why?**

Not applicable.

**Q6. Do you have any other suggestions on how the TGA could change evaluation, or any other business, processes to support the registration of new generic medicines?**

SHPA suggests that the TGA accept applications for new generic versions for 'sole source' medicines earlier to expedite the process when the originator medicine's patent expires.

## Proposal 2 – Mitigating the effects of a medicine shortage

**Q7. Do you think that waiving or reducing application and/or evaluation fees for new generic versions of medicines known to be often in shortage or limited supply in Australia will assist in preventing future shortages? Please tell us the reasons for your answer.**

**Q8. If we waived or reduced application and evaluation fees for new generic versions of certain medicines, how would this affect you? Can you quantify the effect for us?**

Yes. SHPA believes that waiving applications and/or evaluation fees for new generic versions of medicines known to often be in shortage or limited supply may encourage suppliers of generic medicines to bring their products into the Australian market and/or invest in Australia's medicine industry. This would improve access to medicines that are often in shortage and will assist in preventing future shortages.

Data collected in SHPA's *2017 Medicines Shortages in Australia: A snapshot of shortages in Australian hospitals* report shows hospital pharmacists are required to respond to medicine shortages on a daily basis, resulting in a range of actions including using emergency stock; alternative brands and formulations available in Australia; and stockpiling and using the TGA's SAS to obtain alternatives from overseas. Fundamentally, hospital pharmacists have developed sophisticated and administratively burdensome 'workarounds' to mitigate medicines shortages, which are costly in terms of staff time and hospital expenditure, in order to minimise the impact on patient care as much as possible.

Waiving application and evaluation fees for new generic versions of certain medicines would encourage sponsors to register their medicine in Australia, improving access to medicines that are often in shortage and therefore reducing the administrative and financial burden on hospital staff and budget.

**Q9. Do you have any suggestions on which criteria could be used to identify medicines eligible for a fee waiver or reduction?**

SHPA suggests criteria to consider would be:

- Whether the medicine is on the Medicines Watch List
- The frequency of it being an actual or anticipated shortage in the previous three years
- Whether the assessed impact of the shortage receives a Critical rating
- The volume of patients requiring this medication

- How substitutable the medication is for each of its ARTG-approved indications and the number of alternatives available
- Quality and safety issues involved with switching to other similar medications.

### Proposal 3 – Improving reliability of supply for known shortages

**Q10. Would implementation of a new TGA process that provided faster evaluation times and lower fees encourage you to make an application to register one of the medicines that are subject to longstanding section 19A approvals?**

Not applicable.

**Q11. What value do you see in having a designation step to confirm the eligibility of an application before it is formally submitted to the TGA?**

The recent 2021 Medicines Shortages in Pharmacy survey of hospital pharmacists found that switching a patient to a Section 19A medicine was considered an 'often' occurrence by 59% of respondents. Given the frequency of use in Australian hospitals, reflecting the reluctance of overseas sponsors to register their medicines with the TGA, SHPA believes that a designation step may provide reassurance and reduce the financial risk to sponsors, encouraging them to make an application. A transparent process such as this will ultimately provide more certainty in the supply chain.

**Q12. Do you think introduction of the proposed process will assist in supporting a more reliable supply of overseas-registered medicines currently imported under section 19A?**

SHPA believes that the proposed designation process will improve confidence among sponsors to place an application for their product. Assuming their data dossier does indeed meet the criteria that supports a simplified evaluation approach, the cost savings and shorter evaluation time is likely to be an incentive for overseas-registered medicines currently imported under Section 19A to register their medicines in Australia.

**Q13. Do you have any other suggestions to encourage ARTG registration of medicines currently supplied under section 19A?**

No.

### Proposal 4 – Managing alternative supply if medicines are discontinued

**Q14. Would introduction of a new annual charge waiver encourage you to retain your ARTG entry, if it was eligible?**

Not applicable.

**Q15. Do you think introduction of a new annual charge waiver will assist in supporting a more reliable supply of overseas-registered medicines imported into Australia as substitutes when the Australian medicine is in longstanding or repeated shortage?**

The introduction of a new annual charge waiver to support certain discontinued medicines will potentially ease significant cost burdens on sponsors and maintain an appetite for their products to return to the Australian market.

However, this may not fully address other risk factors, such as limited global demand for certain medicines (i.e. recent discontinuation of phenelzine to treat severe depression) and Australia comprising less than 2% of the global pharmaceutical market.

**Q16. Do you see any risks associated with introduction of a new annual charge waiver for medicines where there is a lack of therapeutic alternatives on the ARTG?**

SHPA queries whether this may cause the unintended consequence of alternative sponsors who can provide reliable supply, potentially not applying to register their medicine in Australia if they can see that the regulator is providing waivers to the current sponsor and that in their view, there is no commercial viability for more than one brand in Australia.

**Q17. Do you have any comments or suggestions on the proposed criteria to establish eligibility for the new annual charge waiver?**

SHPA recommends that a new annual charge waiver is considered when the shortage is anticipated for greater than three months and is afforded to sponsors whose medicines have a lack of therapeutic alternatives.

**Q18. Do you have any other suggestions on ways to prevent, mitigate or manage medicine shortages in Australia?**

SHPA believes that as part of subsequently on the ARTG, and subsequently listing on the Pharmaceutical Benefits Scheme if the sponsor wishes to do so, that these are accompanied by assessment of and commitment on reliable supply guarantees in seeking ARTG registration and PBS listing.

Furthermore, SHPA welcomes recent announcements on the $1.3 billion Modern Manufacturing Initiative which will include pharmaceutical products, and believes this is another opportunity to prevent, mitigate and manage medicine shortages in Australia.