SHPA submission to TGA follow-up consultation on Repurposing of medicines – April 2022

The Society of Hospital Pharmacists of Australia (SHPA) is the national professional organisation representing over 6,100 hospital pharmacists, hospital pharmacist technicians and intern pharmacists who work in Australia's public and private hospitals.

SHPA members have vast experience with off-label use of medications and acknowledge that it is poorly understood by clinicians and patients. The lack of regulatory approval for these indications impacts on clinician confidence and ability to safely provide evidence-based and transparent care. SHPA's Medicines Information Speciality Practice Leadership Committee members noted that approximately two-thirds of all medicines information inquiries they received in hospitals were in relation to the off-label use of medications.

SHPA members believe that expanded regulatory approval of medications used for off-label indications, where supported by evidence or reputable overseas medicines regulators, would be of great benefit too. Improving this process will result in these medications being used more appropriately where indicated, alleviate practitioner concerns and allow patients to be more involved with their healthcare.

SHPA was pleased to have participated in the workshops and roundtables convened by the Therapeutic Goods Administration (TGA) in 2021 regarding repurposing of medicines and has consulted further with our numerous Specialty Practice Groups who use off-label medicines. Please see below our responses to the consultation questions.

Should you have any further queries, please do not hesitate to contact Jerry Yik, Head of Policy and Advocacy on jyik@shpa.org.au.

Challenge A: Commercial and intellectual property (IP) issues

1. **What practical options may encourage an innovator to work with a third party to allow an on-patent medicine to be brought to market?**

SHPA believes that providing expectations around possible commercial benefits and decreased regulatory burdens including costs in making repurposed applications for patient medicines would assist a third party to allow an on-patent medicine to be brought to market.

Providing ongoing protections for medicines on-patent, or ongoing incentives relating to patent may assist sponsors to allow alternative sponsors to market the medicine for a repurposed indication.

2. **How could product stewardship issues be managed in this circumstance?**

Independent clinical groups with relevant expertise could be engaged to assist in the development of frameworks in dealing with stewardship in these circumstances. Hospital pharmacists are responsible for medicines governance and stewardship in hospitals, and SHPA convenes these members via our Medicines Safety Specialty Practice Group and Medicines Information Specialty Practice Group.

3. **What would be the most effective method to engage with potential non-traditional sponsors (such as non-profit groups, clinical colleges etc) where no interest is displayed by current sponsors of registered medicines?**

SHPA suggests allowing stakeholders to be on a register for contact should there be no sponsor engaging in supporting the new indication. This will ensure interested stakeholder parties are confident that they will be appropriately consulted if the need arises and minimises the risk for omitting pertinent groups in the option to be involved in sponsorship or co-sponsoring new indications.

4. **How could product stewardship issues be managed in this circumstance?**

SHPA suggests establishing a reference group with the relevant expertise and interest capable of managing stewardship issues such that repeated requests are able to be dealt with in an efficient manner. SHPA suggests that groups are supported by set frameworks and terms of reference agreed upon at a national consensus level.

Challenge B. Identifying potential candidates

5. **Of these four options, which do you support, and why?**

SHPA supports choosing group 3 given the impact medicines have within the healthcare system but would like to highlight the need for hospital pharmacy representatives to be appropriately consulted being experts in the operational and clinical management of medicines in the Australian healthcare system, particularly in medicines for repurposing.

SHPA suggests that if group 4 is chosen, it should include representatives from the hospital Drugs and Therapeutics Committees (DTC) including hospital pharmacy representation given that they are highly relevant to identifying potential candidates as they use significant amounts of medicines for off-label purposes in hospitals.

6. **Is there a combination of the above four options that would be most effective?**

Groups 3 and 4.

7. **Are there other practical methods possible?**

Using a register to communicate with list of known stakeholders to submit their interest in being involved where a repurposed medication is being reviewed.

SHPA suggests also considering utilising the Council of Australian of Therapeutic Advisory Groups representing statewide therapeutic advisory groups (TAG). However, this group only represents public hospitals.

SHPA as a representative of both public and private hospital sectors should be included in these reference sponsor groups for consultation and review, which will facilitate access to our specialist pharmacist insights and views via our Specialty Practice Group networks. Many of our members sit on their hospitals' DTCs and/or are active on TAGs.

Challenge C: Prioritising candidates

8. **What potential criteria or checks would support the intention to prioritise novel clinical uses over more traditional extension of indications?**

Potential criteria or checks to support the intention to prioritise novel clinical uses over more traditional extension of indications could include:

- Data submitted around submissions for drug and therapeutic hospital approvals of medicines for novel indications
- Lack of clinical alternatives
- Lack of alternative side-effect or efficacy profiles
- Lack of accessible or cost-effective treatment options
- The need to distinguish a distinct indication that is not merely an extension of a known indication for safety and QUM purposes
- The identification of clinical need and demand within the Australian population

9. **Would these criteria identify the most valuable candidates? Are there others that should be considered?**

Ideally these criteria would represent a transparent method of identifying the most valuable candidates.

10. In which phase should the patient perspective be a focus? What is the best process for this?

The patient perspective should be included with regard to meeting unmet clinical needs or where there is a large patient demand amongst the Australian population.

11. At what stage should commercial factors be assessed? What is the best process for this?

Commercial factors should not override the clinical relevance and importance these novel indications provide, however SHPA understands that market demand and viability should be assessed to ensure continuity of medicines supply for repurposed medicines

12. What type of skills/knowledge should an independent committee seek to have (noting not all areas of expertise can be available in a single committee)?

Knowledge about the general medicine landscape particularly in hospital clinical areas and operational management of medicines should be included. Hospital pharmacists should be represented on the independent committee, given this sector utilises the majority of off-label medicines and provides hospital-wide governance activities on medicines use.

13. Should the Department (in conjunction with other groups) set priority therapeutic area foci?

Yes, this would allow the Department to seek out repurposing of medicines which address national health priority areas. However, this must be not come at the expense of other repurposed medicines for rare conditions and diseases which have novel indications as this may unfairly prejudice certain already marginalised patient populations.

Challenge D: Encouraging sponsors to apply by removing obstacles and/or providing incentives

14. Are these actions the most important for sponsors?

SHPA believes these actions are most important for sponsors to support applications for repurposing of medicines and would assume these are already undertaken to some degree.

15. What forms of coordination support from the TGA and PBAC would be most effective for sponsors?

Streamlined processes without additional expense or burdens.

16. Will giving an exclusivity period to a repurposed indication give incentive for sponsors to pursue a repurposing opportunity?

SHPA believes that this would provide additional incentive for sponsors to pursue repurposing applications.

17. How should they be funded?

Funding could be devolved across all applications that are made in Australian for application for registration on the Australian Register of Therapeutic Goods (ARTG).

18. Are there other options that should be considered?

The Department could potentially use a combination of these actions to improve the viability for sponsors to apply to extend the indication. As well as these direct actions, the Department may also choose to enable sponsor(s) to extend indications within a coordinated TGA and PBAC evaluation process.

The Department would provide an offer to all sponsors holding marketing authority on the ARTG for the medicine. If a medicine is protected by patent, the Department would only engage with the sponsor holding the patent.

Feedback has shown it can be difficult to encourage a company to make a regulatory submission for a new indication where the medicine's patent has expired because in such cases, if a particular sponsor receives TGA approval for an extension of an indication, other sponsors may similarly benefit for a significantly reduced application complexity and fee. This is considered a socialised benefit.

One option may be to allow sponsors to either apply individually, or as a collective to share the fees and efforts outlined in the offer (this would require legislative change). Where exclusivity was offered, it would apply to any sponsor who responds within a set period. Again, any changes to exclusivity would require legislative change.

19. **Would there be interest in collaborative submissions by sponsors? Under what circumstances could this be attractive to sponsors?**

This could be attractive for sponsors if it reduces their costs and administrative burdens.

20. **Are there other practical options to overcome the socialised benefits in order to secure at least one application?**

Relieving the regulatory burdens placed upon sponsors and funding an independent body to make applications on behalf of consumers and health professionals, where there is benefit for public health outcomes.