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AMA submission to the Therapeutic Goods Administration – building a more robust medicine supply

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Executive Summary

The AMA supports the proposals by the TGA that aim to build a more robust medicine supply. The TGA should be adequately funded and resourced by the government to ensure any losses in revenue from these proposals do not result in a reduction in other TGA work.

The proposals listed are a good start. However, the AMA perceives these proposals to be small in scope where there needs to be innovative, wider-ranging solutions to ensure patients receive the medicines they need, when they need them.

Introduction

Medicine shortages has been a long term issue for AMA members and their patients. The AMA has been working with the TGA and other stakeholders through the Medicine Shortages Working Party and has already provided feedback on the proposals below through this avenue. However, the AMA makes this submission in the interest of visibility for AMA members and the public.

Proposal 1 – Prioritising evaluation of important generic medicines

The AMA supports the proposal to prioritise the evaluation of generic medicines and encourage more generic versions of a medicine to be registered on the Australian Register of Therapeutic Goods (ARTG). Diversifying supply is a well-known strategy to mitigate the risk of a shortage[1], because if 'sole source' products are disrupted this can mean that the particular drug is not available at all. The TGA should evaluate where a potential medicine shortage may occur and prioritise generics that would diversify supply and mitigate the shortage.

[1] Productivity Commission (2021) *Vulnerable supply chains – productivity commission interim report*.

Proposal 2 – Mitigating the effects of a medicines shortage

The AMA supports the TGA waiving or reducing approval and registration fees for new generic versions of medicines to mitigate the effects of medicine shortages. However, in doing so the TGA should receive additional resources from the Government that do not detract from other health system services and projects. The TGA should prioritise medicines for the most vulnerable patient groups, and those medicines which are most at risk of experiencing a shortage. However, access to medicines is a fundamental element of the right to health so any medicines that are going to alleviate shortages and increase accessibility in Australia should be considered eligible.

Proposal 3 – Improving reliability of supply for known shortages

The AMA supports the process of evaluating a medicine to be registered on the ARTG to ensure that medicines supplied in Australia have been thoroughly assessed for quality, safety, and efficacy, and are monitored. The AMA agrees that having a significant number of medicines available under Section 19A of the Act undermines the integrity of the ARTG process. Therefore, the AMA would encourage as many medicines supplied in Australia to be listed on the ARTG as appropriate.

Proposal 4 – Managing alternative supply if medicines are discontinued

The AMA supports a timely ARTG application process without compromise on medicine safety, quality, and efficacy assessments. The AMA supports the proposal to waive the annual fee for medicines that are no longer available on the market but should still be on the ARTG to enable supply of a substitute medicine under section 19A of the Act. The AMA would not support a reduction in TGA revenue required for post market monitoring activities. The TGA must be adequately funded and resourced to ensure they can carry out these activities plus be able to waive fees to ensure medicine supply when there is a shortage. Medicine shortages can have extreme impacts on patients if they cannot get the medicine they require when they need it, and this may result in more expensive downstream costs if these patients require hospital care for their condition in the absence of the medicine. Equally as important is post-market monitoring carried out by the TGA, as it is essential to ensure that medicines remain safe, of high quality, and effective.

Other methods to build a robust medicine supply

The AMA believes that while the above proposals are important in progressing towards a more robust medicine supply, there are other strategies that need to be considered. Some of these require a multifaceted approach from several government jurisdictions. The government needs to explore 'big picture' strategies to ensure a more robust medicine supply. The AMA understands there is ongoing work at varying stages and levels of impact. The AMA supports consideration of strategies such as increasing domestic manufacturing of therapeutic goods, the use of the National Medical Stockpile, obligations on suppliers with respect to buffer stock, ensuring affordable medicines when there is a shortage, and gathering information on medicine shortages from the end of the supply chain (i.e. doctors and pharmacists). The AMA is currently exploring

methods to improve medicine supply in Australia and would welcome further discussions once it has formalised its policy positions.

Conclusion

The AMA supports the proposals outlined in this consultation to build a more robust medicine supply. The effectiveness of these proposals should be monitored and analysed to ensure that they are working as intended. The TGA must be adequately resourced and funded to ensure it can implement these proposals without compromising its other important work. The AMA believes there are bigger picture issues with medicine shortages in Australia that need to be thoroughly explored and acted on beyond these proposals to ensure no patient goes without their medicines.

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