Submission to the TGA consultation
Building a more robust medicine supply: Proposals to help prevent, mitigate and manage medicine shortages.

About RDAA

The Rural Doctors Association of Australia (RDAA) is the peak national body representing the interests of doctors working in rural and remote areas and the patients and communities they serve.

RDAA's vision for rural and remote communities is simple – excellent medical care. This means high quality health services that are: patient-centred; continuous; comprehensive; collaborative; coordinated; cohesive; and accessible, and are provided by doctors and other health professionals who have the necessary training and skills to meet the needs of their communities.

Introduction

RDAA thanks the Therapeutic Goods Administration (TGA) for the opportunity to provide feedback on *Building a more robust medicine supply: Proposals to help prevent, mitigate and manage medicine shortages*.

While the proposals presented in the consultation paper may have some short-term merit, the degree to which they can contribute to the outcome of building a more robust medicine supply is uncertain. Given the focus on administrative processes rather than addressing critical underlying issues, the impact is likely to be minimal. As presented, these proposals ignore the need to address the lack of Australian sovereignty in the manufacture of medicines, particularly generic medicines.

Shortages of medicines have life-threatening impacts on Australians, even more so in rural and remote communities where isolation, complex supply chains and limited workforce capacity combine to greatly increase the risk that unmanaged shortages will occur. The fact that Australia is so heavily reliant[1] on international manufacturers to supply its medicines exacerbates issues. Australia is at the far distant end of global supply chains.

The advent of the COVID-19 pandemic has focused attention not only on the demand and supply problems that can occur with this model – including the tenuousness of global supply chains, the risk that manufacturing countries will reserve stocks for their own populations when demand is high, and potential astronomical cost increase when shortages occur (as happened with Personal Protective Equipment) – but has also highlighted Australia's lack of resilience when under threat. Doctors and public health advocates, among others, continue to warn about Australia's vulnerabilities and its lack of resilience as a problem that needs to be immediately addressed.

[1] The Global Access Partners & Institute for Integrated Economic Research Australia Ltd, 2020 report highlights that imported medicines comprise over 90 per cent of medicines in Australia.
https://www.globalaccesspartners.org/GAP_IIERA_Healthcare_System_Report_Dec2020.pdf

Planning for short-term interim solutions is needed – including for when and in what circumstances they will be used to prevent any undermining of rigorous approval processes – but it must be underpinned by foundational work to ensure that such short-term solutions are required to be implemented remains very low. Improving reliability of supply is a key issue, not just for current shortages, but as a matter of preparedness for a future of global unpredictability.

While some work has been done in relation to medical products, including pharmaceutical and biologics, under the *Medical Products: National Manufacturing Priority road map* developed by the Department of Industry, *S*cience Energy and Resources as part of the Australian Government's Modern Manufacturing Strategy[2], the focus is on the broader economic vision rather than the development of a strategy to support the health and wellbeing of Australians.

It is essential that the TGA takes a lead role in:

- ensuring that the health perspective informs the work of other government departments and agencies at the federal and state/territory levels
- developing a longer-term strategy to mitigate the risks of clinically critical medicine shortages that is cross-government, cross-industry, and most importantly includes clinicians – including rural and remote clinicians – to determine what medicines are essential
- ensuring that the vested interests of the bigger pharmaceutical companies are acknowledged and nullified during the development of such a strategy
- exploring incentives to support existing local generics manufacturers to expand their capacity.

RDAA identifies a number of key issues followed by responses to the specific consultation questions for consideration by the TGA below.

Recommendation

The TGA should lead the development and implementation of a broad strategic framework that is geared toward enhancing and growing Australia's capacity to provide the essential medicines it needs nationally, with particular emphasis on rural and remote Australia, by:

- Defining what medicines are essential to inform strategy development in consultation with clinicians, particularly rural and remote clinicians
- Assessing current local manufacturing capacity and chain of supply for each of products on the essential medicines list and identifying possible incentives to support the Australian manufacture of these medicines
- Developing a longer-term cross-government and cross-industry strategy for the supply of essential medicines that has the health of Australians as the driving principle.

[2] https://www.industry.gov.au/sites/default/files/February%202021/document/medical-products-national-manufacturing-priority-road-map.pdf Viewed 30 May 2021

Key issues

Australian sovereignty in manufacturing

There is a lack of generic manufacturing capacity in Australia has been eroded by previous Pharmaceutical Benefits Scheme (PBS) reforms[3,4]. As a consequence, Australia is now much more vulnerable to the vagaries of manufacturing in other countries and any event that increases global demand or interrupts complex supply chains.

Added to this are the risks associated with being at the end of a very long global supply chain. In some instances, Australia provides the most critical raw material to an overseas production company only to ship the manufactured product back. The Tasmanian poppy industry is an example of this being the world's largest producer of licit alkaloid material extracted from poppies (almost half of the world's demand)[5]. Most of the processed raw material is shipped overseas to be manufactured into morphine products, some of which is then transported back to Australia.

Australia's reliance on the manufacturing capacity of other have been underscored by the COVID-19 pandemic, but they are not new[6].

Although the TGA is primarily a regulatory body, it must act urgently to advocate for the development and implement a long-term, cross-government and cross-industry strategy to ensure sustainable pharmaceutical supply chains, particularly of essential medicines.

Impact of medicine shortages in rural and remote Australia

National shortages as a result of global short supply, and/or supply chain issues, are more impactful in rural and remote places. Issues include not having the required medicine on hand, having limited or no stockpiles at community or state/territory level, no access to other stockpiles, and competition with much better resourced hospital networks around Australia for medications that run into national and global short supply.

> *"In rural, as you know, loss of essential medicines is life threatening for patients. We can't simply call the neighbouring pharmacy/ hospital to get supply." (Rural Generalist)*

Shortages of medicines in rural and remote Australia can be exacerbated by panic buying as was demonstrated by public responses to the COVID-19 pandemic[7] as transport links may not be as frequent, may be more at risk from adverse weather events making restocking more difficult or for other reasons, even if the medicine is more readily available in metropolitan areas.

It is critical that confidence in medicine supply be improved to avoid any repetition of these events.

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[3] Harper, I. (2011). Opinion: PBS Reform - an Impact Update. AJP: The Australian Journal of Pharmacy, 92(1088), 18. https://search.informit.org/doi/10.3316/ielapa.804330451451079

[4] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1894805/pdf/1743-8462-4-9.pdf Viewed 30 May 2021.

[5] https://dpipwe.tas.gov.au/agriculture/plant-industries/tasmanian-poppy-industry Viewed 30 May 2021.

[6] https://www.crikey.com.au/2019/10/07/pharmaceutical-supply-chain-australia/ Viewed 30 May 2021.

[7] https://medicalrepublic.com.au/panic-buying-creates-rural-drug-shortages/25803 Viewed 30 May 2021.

Essential medicines

A key aspect of building a robust medicine supply is the identification of essential medicines to inform planning priorities. This list must be reflective of needs in rural and remote Australia as well as metropolitan centres.

The TGA should develop an Essential Medicines list in consultation with clinicians, including rural clinicians, to determine what medicines should be classed as essential. The TGA's Medication Watchlist could be used as a starting point for discussions.

Possible ways to support existing local generics manufacturers to expand their capacity to produce these medicines must be identified. These may include financial or other incentives to underpin commercial viability.

Response to Select Proposal Questions

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?

This may assist in some instances where the product is in readily available globally. However, if there is a global shortage or increased global demand, enhancing Australia's sovereign manufacturing capacity is the only way to ensure supply.

As seen in the COVID-19 pandemic peak of medication shortages, Australia was unable to address shortages as manufacturing countries prioritised and reserved supply for their own communities. The TGA needs to engage with Department of Industry, relevant Government departments and other stakeholders, including the remnant generic manufacturing industry in Australia, to work towards preventing any future incapacity.

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

This will only be of assistance if there are no global demand or supply issues. It does not address the issue of diminishing Australian industry capacity to manufacture our own generic medications. Priority review does not address sovereign risk.

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?

Registration of new products should not be seen as a major mechanism for ensuring the long-term sustainable supply chain of generic medications. The TGA needs to engage at high levels with relevant government departments and with the generic manufacturing industry. This should be reflected in its consultations, processes and operations, and in documents such as this consultation paper, to ensure balanced approaches to redressing problematic issues and proposals for solutions.

It is essential that the TGA recognise the lobbying influence of organisations that represent sections of the pharmaceutical industry that have substantial patent advantages and are often in direct competition with generic medication manufacturing and distribution.

The business model must consider resilience as an important foundational value for building and maintaining medicines supply, particularly for essential medicines.

Support for the generic manufacturing and supplier industries could be provided by the use of a range of financial or other incentives, including longer-term supply contracts (10-plus years) to local suppliers.

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.

Waiving fees may have limited, short-term value but is of no value in the longer term to ensure safe and timely supply of medicines to all Australians.

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

A list of clinically essential medicines, whether off-patent or not, determined by practicing clinicians should inform planning and processes for ensuring a robust medicine supply, particularly in rural and remote communities. RDAA is the key organisation representing rural and remote clinicians and the communities they serve and, as such, can provide valuable insights into essential medicine needs in these areas.

This list of essential medicines needs to be incorporated within a broader government policy that recognises resilience to be of real value. Incentives should be offered to local suppliers of such essential medicines to support commercial viability.

Lobby groups who are primarily concerned with pharmaceutical brand interests should have no role in the definition of such a list of essential medicines.

Proposal 3 – Improving reliability of supply for known shortages

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?

Providing this is done with appropriate funding and capacity, and providing that there are no loopholes that may result in importation of substandard of counterfeit medicines, this process may improve supply of medicines imported under section 19A. Once again however, we would like to emphasise that this is a temporising measure only and has no long-term pharmaceutical supply chain sustainability impact. It should be viewed as a very short-term mechanism only.

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

ARTG registration proposals and Section 19A should be used only when no other alternatives are available. Such proposals as in the ARTG process are very short-term and should only be considered in terms of a broader strategy that addresses sovereign manufacturing capacity, particularly for the most clinically important medicines used in rural hospitals and communities. Access to sustainable supply of these medicines is currently extremely challenging in many of these areas.

The TGA **must** lead the development of a more strategic, cross-governmental, cross-industry strategy that:

- is geared toward enhancing and growing the Australian medicines manufacturing and supply industries
- is informed by clinicians, including rural clinicians, to determine what is classed as an essential medicine
- addresses conflicts of interest to ensure that policy and initiatives are designed around the clinical needs of Australians.

Proposal 4 – Managing alternative supply if medicines are discontinued

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?

It is perplexing to note that the Federal Government's current approach to medication shortages is directed only at encouraging imports, when the supply crisis associated with the COVID pandemic proved that in the case of a global emergency, international supply chains fail to provide what Australia needs.

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?

This is a minor administrative tweak to encourage applications. Waiving TGA fees may be a useful mechanism for this, but the bigger issue is ways to support the commercial viability of locally produced medicines to minimise the risk that that the supply of essential medicines in Australia is interrupted by global events.

If this is TGA's only response, the risk is that the opportunities that arise from a national recognition of the impact of medication shortages in a global pandemic will be missed. The TGA must have a broader cross-government cross-industry approach to sovereign capacity.

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

The first step needs to be to recognise what medicines are clinically essential. This step needs to be taken by clinicians, and rural doctors will have a very important role to play in such definitions. "Big Pharma" and the pharmaceutical manufacturing and supply industry should have no role in defining what is considered essential.

The second step would then be to assess the supply chain and local manufacturing capacity of each of the limited products on the list of essential medicines.

The third step would be for the TGA to develop, and work within, a cross-government, cross-industry strategic framework to develop sovereign capacity to manufacture essential medicines.

The TGA must begin to engage in a broader conversation around sustainable pharmaceutical supply, beyond mechanisms to simply open doors more easily to overseas suppliers.