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Medicines Australia Submission

Building a more robust medicines supply: Proposals to help prevent, mitigate and manage medicine shortages

Medicines Australia

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Overview

Medicines Australia believes that better managing and mitigating medicines shortages by strengthening the supply chain requires greater regulatory agility and a more commercially sustainable reimbursement system that can meet vulnerable patients' needs.

Medicines Australia thanks the Therapeutic Goods Administration (TGA) for the opportunity to respond to its consultation on "Building a more robust medicine supply: Proposals to help prevent, mitigate and manage medicine shortages". This paper was developed alongside Medicines Australia's members, particularly those from the Regulatory Affairs Working Group (RAWG). Members of the RAWG are selected for their deep and trusted domestic and international regulatory and industry policy experience.

Medicines Australia welcomes the Department of Health's, through the TGA, initial approach to addressing some of these more longstanding issues, including where they relate to protracted shortages of specific medicines or categories of medicines. The options proposed in the TGA paper show some potential for addressing medicines shortages, for example, in relation to fee waivers, accelerated pathways and sole source suppliers. More work will need to be undertaken to ensure that such options do not create unintended consequences, such as lowering safety and efficacy assessment standards and triggering price reductions in an already commercially strained market. As such, this paper should be read alongside Medicines Australia's submission to the Productivity Commission's work into vulnerable supply chains which we have shared with the department separately.

Medicines Australia hopes that future consideration of these issues will take into specific consideration the broader market environment, such as its relationship to the Pharmaceutical Benefits Scheme (PBS), as this is where the crux of industry's challenges lie. While we appreciate that this is not in the scope of this consultation, we cannot discuss medicines shortages issues without referring to pricing and market forces that impact medicines supply and shortages.

Future discussions could relate to government pricing, tendering and procurement mechanisms (such as in hospitals) and streamlined variations as per ICH Q12 (Pharmaceutical Product Lifecycle Management).

Please find our detailed response below and please do not hesitate to contact myself (anne-maree.englund@medicinesaustralia.com.au) or Peter Komocki (Manger, Industry and Regulatory Policy, peter.komocki@medicinesaustralia.com.au).

Yours sincerely,

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Introduction

Over several decades, Medicines Australia members have carefully built robust global supply chains to ensure patients around the world have ongoing access to medicines.

Medicines Australia companies and the broader industry have invested significantly in the design and maintenance of manufacturing facilities and high-quality systems to ensure that medicines are produced safely and efficiently, at scale, so that patients have access to them as soon as possible. These carefully implemented measures continue to ensure the stability of international supply chains.

On a global level, companies are implementing robust risk management plans and carefully tracking and managing all the inputs required to maintain safe and reliable manufacturing, either domestically or offshore, as well as the delivery of their medicines to Australia. Manufacturing facilities around the world have, for the most part, remained open and continue to make millions of doses of medicines and vaccines every day having increased capacity and manufacturing output throughout the pandemic. Strict measures are in place to ensure staff and facilities are protected and able to maintain production. It must be noted that increasing production capacity in rapid response to global increases in demand is in itself a considerable feat.

Even under 'normal' circumstances, the ordering of medicines from manufacturing facilities requires adequate lead time. Filling and prioritising such orders requires additional consideration of patient population sizes and pricing. In a multi-brand market where medicines are largely off-patent and thus genericised, reaching larger markets becomes particularly important to meet more patient needs and make manufacture and supply a commercially sustainable exercise. This allows for manufacture of smaller quantities for niche markets like Australia possible, but no less difficult. It must be noted that this situation holds for both originator and generic sponsor companies.

In this context, it is no coincidence that the bulk of items cited in the consultation paper as being in frequent shortage are generic and at the lowest end of PBS funding. A genericised multi-brand competitive market, coupled with F1/F2 PBS price reductions, has driven down prices which creates challenges for sponsors' buying power. Low prices create an unsustainable commercial environment that can lead to market failure and medicine shortage in an internationally competitive market. In addition, the PBS is not relevant for all of the initially identified products as hospital tender processes have also driven down medicine prices. The challenge is balancing fostering a commercially competitive market while not racing to the bottom where prices are so low that the market is no longer commercially sustainable with multiple competitors in it.

While the commercial realities of supplying such medicines can sometimes be extremely difficult, Medicines Australia members continue to do all they can to ensure patients continue to have access to medicines they need, when they need them. This includes utilising existing TGA processes and even supplying products at a loss, including when generic brands have pulled out of the market due to the difficult commercial environment. This was also recently demonstrated throughout 2020 when fewer flights were available due to COVID-19, including cargo flights, which increased freight costs exponentially. Even when this made the import of medicines commercially unviable, our

members continued to bring in products at a loss to meet Australian patient needs. Medicines Australia members did not pass on these additional costs to the government or patients.

TGA Proposals

Proposal 1 – Prioritising evaluation of important generic medicines

Medicines Australia assesses that this proposal would have a limited impact on addressing medicine shortages. Evaluation processes for generic medicines are not particularly long so it is unclear how prioritising their assessment would substantially alleviate shortages.

For originator medicines, in addition to a commitment to ongoing patient care, there are often sufficient economic incentives for companies to avoid an out-of-stock. That is, foregone revenue, and lost market share during an out-of-stock period. Generic medicines, on the other hand, are available at the point of loss of exclusivity, hence prioritising these would not necessarily have a net positive impact. If there was a shortage prior to patent expiry, any generic would still be infringing a patent if it was supplying a product in the market.

Medicines Australia would be keen to know if the TGA has conducted an analysis that would demonstrate what shortages may have been avoided if this proposal had been available. Is there any evidence to suggest a current slow entry of generic medicines post patent expiry? We suggest that the TGA conduct an analysis of originator medicines that have had shortages where there was a subsequent generic and whether accelerating the generic's evaluation would have mitigated the shortage.

From a more practical perspective, Medicines Australia has the following observations and questions for the TGA's further consideration:

- any out-of-stock should be considered in the context of the duration of the shortage, relative to the lead time to have an alternative product in market
- how would an 'important' medicine be identified?
- could the proposal risk creating an inequitable system where generics are prioritised over innovative medicines that would bring new treatments to patients?
- potential risks of implementing prioritisation and acceleration processes leading to lowering of current standards of quality, safety and efficacy, particularly where sponsors may be unwilling or unable to generate new data and would require concessions from the TGA
- the potential impact of the proposal on PBS price disclosure policy would need to be clarified and possibly reconciled to avoid any unintended or perverse consequences for sponsors
- approval of a product earlier will not necessarily impact the manufacturing and supply lead time
- prioritising these applications should not impact timelines for other applications.

In relation to the proposal to prioritise evaluations of new generic versions of 'sole source' medicines, Medicines Australia is cautiously optimistic. The proposal may assist in cases where there is a shortage of a sole sourced medicine and an application is made for a generic to be registered (assuming there is another manufacturing source of course). It must be noted that the supply timelines for the new generic would need to be considered.

The proposal is not without its challenges. Sole source products are often sole sourced for specific reasons, including (but not limited too):

- insufficient global manufacturing capacity or capability
- lack of commercial opportunity for multiple suppliers in the Australian market.

Therefore, the introduction of a second generic may not solve the problem but result in a reversion to a sole source situation if the market is no longer viable for the original supplier or a multi-brand market overall.

Also, the proposals would presumably trigger price reductions under the PBS's price disclosure policy thus creating a disincentive for other sponsors to pursue ARTG and PBS listing or, as noted above, lead the existing sponsors to exit the market as the new lower price would not be commercially viable. Likewise, applying some form of exclusivity to try to remove any disincentive would be contrary to the whole intent of these proposals to build a more robust supply chain through diverse sources. The potential impact on PBS price disclosure policy would need to be clarified and possibly reconciled to avoid any unintended or perverse consequences for sponsors and patients alike.

Our optimism for this proposal is also tempered by Medicines Australia members who voiced concerns that sole source suppliers represent only a small percentage of generic medicines. The reasons for shortages in this space are complex and usually stem from problems at overseas production sites and supply chains. Hence, offering any kind of prioritisation becomes moot since supply from the source remains constrained.

Proposal 2 – Mitigating the effects of a medicine shortage

Waiving or reducing fees has the potential to positively impact a return-on-investment calculation for sponsors considering regulatory applications. This proposal, however, does not consider the out-of-scope consideration of expensive and lengthy PBS listing fees and processes. Further clarification would be required to ensure the criteria relating to fees were specific enough to directly address the issue. Medicines Australia would want to ensure that such mechanisms were used sparingly to avoid cross-subsidisation from increased fees elsewhere.

The TGA could consider other cost-related options that impact sponsors' return on investment, including for bioequivalence studies, application preparations and lifecycle maintenance costs. Also, the TGA could investigate alternative mechanisms, such as a "Special Access Scheme S" to fast-track the import of substitute goods for products in short supply in Australia.

In developing this proposal further, Medicines Australia recommends the TGA take the following concerns and comments into consideration. Firstly, broader commercial factors may outweigh the impact of waiving or reducing fees, such as the ability to enter the market through tender arrangements, or the impact of Statutory Price Reductions resulting from listing on the PBS, or ongoing Price Disclosure related impacts. Similar to the issues noted under the first proposal, the proposal could unfairly distort the market as a new competitor will benefit from a less expensive market entry process (thereby making a potentially easier return on investment) while the original sponsor/s suffer price reductions thereby potentially making that medicine commercially unsustainable.

Secondly, the proposal would only be effective if a reliable alternative medicine source can be identified. If the reason for supply stems from constraints at overseas production sites or global supply chain routes to Australia (as was typically the case during the pandemic), then it is difficult to see how such an incentive could assist.

Thirdly, the TGA could consider (if it has not already) approaching suppliers of s19A medicines that are providing alternatives during shortages to the impact that fees may have on moving from s19A supply to a formal application. This could also include asking if there are clinical data issues with longstanding s19A medications that need to be addressed or, in fact, cannot be easily addressed.

Proposal 3 – Improving reliability of supply for known shortages

As noted above, faster evaluations and lower fees have the potential to address some of the issues related to medicines shortages. But we must also acknowledge that ARTG listing does not ensure supply, while faster evaluation should not undermine the rigour of assessment processes.

The broader commercial opportunity outside of the medicine shortage period itself is an additional key determinant here. The commercial opportunity for an alternative product may be related to the shortage period only, thus mitigating any incentive to invest resources in a formal approval. Ongoing supply of the alternative outside of the shortage period will be informed by the broader commercial arrangements. That is, if the ability to access established tenders is limited, or PBS price reductions would apply and make the ongoing supply of the alternative product in the market unviable, then having an alternative also registered may have limited ongoing impact. Further, manufacturing and supply lead times will also then be a factor if the product is registered, but not routinely supplied in market in the event of a subsequent shortage.

This notwithstanding, the proposal to implement a designation step to confirm the eligibility of an application before it is formally submitted to the TGA could increase transparency and clarity to generics sponsors. The additional time and resources this would require may be a constraint.

Proposal 4 – Managing alternative supply if medicines are discontinued

As for proposal 2, Medicines Australia sees some value in this proposal. The proposal may enable the use of the s19A approach for products that have otherwise been removed from the ARTG due to the cost of ongoing fees.

In pursuing this option, we would expect the TGA ensures it is used judiciously and that fees and charges elsewhere in the cost-recovery framework are not unnecessarily increased to cross-subsidise such proposed waivers. Also, the reason for discontinuation of an ARTG entry would need to be considered and the criteria for the waiver applied clearly and consistently.

Medicines Australia encourages the TGA to further consider that maintaining the ARTG registration may not necessarily mean the product can be supplied. If it can be supplied, manufacturing and supply lead times may mean that a shortage still occurs.

About Medicines Australia

Medicines Australia is the peak body representing the innovative, research-based, medicines industry in Australia. Our members discover, develop and manufacture medicines and vaccines that help people live longer, healthier lives and bring social and economic benefits to Australia.

Medicines Australia's members play a vital role in the health of the Australian economy and its citizens. Our members contributed approximately $9 billion to the Australian economy in 2016-17; employ, directly and indirectly, over 23,000 Australians; invest over $1 billion into research and development annually to help 33,000 Australians get early access to emerging innovative therapies. In 2017-18, our industry exported $1.6 billion worth of medicinal products (rising to nearly $4 billion if medicaments are included). None of this, of course, accounts for the additional and largely unquantified benefits to Australian patients' health, wellbeing and the significant economic spill-over effects.

Pharmaceutical companies represented by Medicines Australia have a broad and deep pipeline of innovative medicines, diagnostics, treatments and vaccines. Our members develop, manufacture, and supply critical medicines and vaccines available on the pharmaceutical benefits scheme (PBS), the Life Saving Drugs Program (LSDP), the national immunisation program (NIP) and companion diagnostics or other treatments available through the Medical Benefits Scheme (MBS) and National Blood Authority (NBA). Our membership comprises small, medium, and large Australian and multi-national companies. Many of the world's multi-national medicines manufacturers are members of Medicines Australia through their local affiliates. These local affiliates provide a critical worldwide connection that enables Australians to access globally developed breakthrough medicines and therapies.