Medicines Australia and the Generic and Biosimilar Medicines Association:

Minimum Stockholding Requirements 12-month Review Submission

May 2024

Medicines Australia (MA) and the Generic and Biosimilar Medicines Association (GBMA) welcome the opportunity to provide written feedback for the Minimum Stockholding Requirements (MSR) 12-month Review.

MA and GBMA support the Department of Health and Aged Care's (the Department) intent of the MSR policy to ensure a consistent supply of essential medicines to Australian patients. However, it is important that the implementation of this policy does not impose additional administrative burdens or costs that could hinder the pharmaceutical industry's ability to efficiently maintain supply of medicines to the Australian market.

MA and GBMA acknowledge that legislative changes are out of scope in the MSR 12-month review. However, we note there are opportunities for improving efficiencies that remain compliant to the legislation before the 24-month review.

In addition to the MSR roundtable discussions, the results of an MA survey of its members, and the Department's survey findings, this submission will provide additional feedback, as well as elaborate on issues that may not have been fully explored as part of the MSR Roundtable that took place May 3, 2024. We further note the Meeting Outcomes from the roundtable as supporting documentation to this submission.

Policy intent

MA and GBMA recognise the overarching intention of the MSR policy and its intended outcomes.

This policy was designed to collaboratively create buffers to better protect Australians against global disruptions. At its core is an exchange of information between the regulators, industry, patient advocacy groups and healthcare professionals to support the supply chain.

If the increased stockholding policy worked as intended, it would significantly lessen the impact of avoidable medicine shortages on Australians. The additional buffer provided by the stockholding guarantee would help compensate for any shortfalls and support continuity of supply for patients through brand substitution.

It is therefore crucial that any assessment of its effectiveness focus on the intent of the policy rather than the binary of compliance and non-compliance. In the event of a shortage, the supply of the same medicine by an alternative sponsor can fill this void. In this scenario, the alternative sponsor should not be considered in breach/non-compliant, or penalised if they fall below MSRs as a result of fulfilling that shortfall, as this is the policy working as intended.

Online portal

MA and GBMA welcome the Department's proposal to develop an online portal to streamline notification processes. The administrative burden of implementing the MSR policy was a recurring theme in industry feedback, highlighted in the MA member survey, and discussed at the MSR roundtable. With 2861 designated brands as of 1 April 2024, this policy would have placed administrative pressures on the Department as well.

The online portal is expected to be launched before the end of 2024, but as the Department has not confirmed this timeline, MA and GBMA would like to work with the Department to develop interim solutions to streamline the notification processes until then.

Sponsors with a large volume of designated brands have reported that they have been given permission to report notifications through Excel workbooks. Sponsors reporting this way have stated it to be more efficient than completing individual forms, which can take approximately an hour to complete (according to the MA member survey).

To make reporting via Excel even more efficient, the Department could develop a simple Excel template, in consultation with sponsors, that contains the necessary fields. A standardised template would prevent the need to reinvent the wheel with each individual sponsor, and make it easier for sponsors to input data, and easier for the Department to extract data.

Additionally, the development of the portal should consider the existing portals, for example the Health Products Portal (HPP), that sponsors already use. Integrating notification reporting for MSR into existing online portals could also make administrative processes more efficient and reduce the administrative burden on sponsors and the Department.

Reporting

Periodic Reporting

As discussed at the roundtable, while reporting notifications 'as soon as practicable' provides flexibility, it creates constant urgency to report, which can be inefficient when managing multiple designated brands.

Periodic reporting, for example: on a monthly basis, may alleviate administrative burden. Periodic reporting can ensure that notifications are reported at regular intervals. This predictability allows sponsors plan and coordinate more efficiently with relevant staff members. It also provides a more systematic approach to monitoring shortages, making it easier to track trends and identify recurring issues.

In-line with periodic reporting by sponsors, MA and GBMA would see benefit in a similar periodic reporting framework, from the Department, whereby industry can view the effectiveness and improvements brought by the policy. This would further support alignment in our messaging to market and patients.

Medicines Shortage Reports Database

Whilst out of scope for the MSR policy, MA and GBMA further note the challenges in medicines shortage reporting through the Therapeutic Goods Administration's Medicines (TGA) Shortage Reports Database website, as they correlate to sponsor activity under this policy.

MA and GBMA recognise the need to report medicines shortages of reportable medicines in Australia to the TGA, which is then published publicly on their website for transparency and accountability. However, due to the broad definition of 'medicine shortage' that looks to both actual and potential shortages over a 6-month period, consumers may not fully understand these nuances and complexities.

The TGA publication of stock fluctuations to consumers can potentially cause undue concern about medicine availability and influence purchasing habits. A discussion regarding the publication of critical shortages to consumers and limiting other levels of shortages for industry purposes could be considered.

Regular meetings with the Department and broader communication

Regular meetings with the Department can help sponsors with implementation and improve compliance with the MSR policy. Regular meetings provide a platform to clarify the specifics of the MSR policy, ensuring that all stakeholders understand their obligations, not just those who have requested information. The Department will also save administrative time by avoiding the need to repeatedly answer the same questions from multiple sponsors.

Additionally, regular meetings allow the Department to identify where the implementation is working well and where and what is causing compliance issues. Sponsors can raise any challenges or barriers they are facing in meeting stockholding requirements, allowing for collaborative problem-solving.

MA and GBMA acknowledge that it can be burdensome to plan and attend regular meetings for both sponsors and the Department. However, brief but regular meetings to facilitate information exchange could lead to greater efficiencies for both parties in the long term.

Other considerations

Australia's market size and global position

Compared to larger markets like the US and the EU, Australia's pharmaceutical market is relatively small. During global shortages, sponsors may prioritise larger markets to maximise their sales and impact, potentially delaying supplies to smaller markets like Australia.

Further, Australia's Health Technology Assessment (HTA) and reimbursement system can influence market prioritisation for sponsors. The time taken from the initial submission to the final PBS listing can be substantial. Sponsors may prioritise markets with faster access to reimbursement to ensure quicker returns on their investment. This prioritisation can extend to, and be particularly evident during, periods of medicines shortages.

Medicines Australia and the Generic and Biosimilar Medicines Association are committed to ensuring the security of the supply of medicines to Australian patients through the Minimum Stockholding Requirements policy. Effective collaboration between sponsors and the Department will be key to ensuring the implementation of the policy successfully achieves the intended outcomes.

Should you have any questions about this submission or sponsor perspectives relating to MSR policy, please do not hesitate to contact:

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