

Attention:

[REDACTED]
Health Products Regulation Group
Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606 Australia

Consultation on *Management and communication of medicines shortages – proposed implementation approach*

Please find a submission attached from the National Pharmaceutical Services Association. You are welcome to contact me in the first instance should you have any queries.

[REDACTED] or on [REDACTED].

Yours sincerely

[REDACTED]
[REDACTED]
[REDACTED]

20 April 2018

NPSA submission to TGA Consultation: Management and Communication of Medicines shortages

Consultation issue 1: Proposed Definition of a Medicine Shortage

- *Is the definition of a medicine shortage clear?*

The NPSA supports the definition in-principle, but considers further clarity is required as to what a 'partial shortage' may mean: insufficient stock within the supply chain to meet demand for an extended period or localised shortage e.g. in a geographical area?

- *Is the definition of a medicine shortage appropriate, noting that it will be required to be stated in the Therapeutic Goods Act through the proposed amendments?*

Yes.

There are a couple of points however, that require clarification. Partial availability is not defined, and there are no examples or a clear definition regarding "other constraints on a [redacted] bility".

[redacted] *posed scope for covered medicines clear?*

[redacted] *posed scope for covered medicines appropriate?*

Consultation issue 2: Reporting Obligations

- *Do you support the suggested timeframes? Do you have an alternative proposal?*

Prompt reporting is to be encouraged.

The timeframes for reporting a discontinuation seem practical.

- *Do you support the required notification content?*

The content is comprehensive, but this information needs to be available to health care professionals (and potentially the whole supply chain) in order for it to be useful. Some

information is available on the MSII website already, but currently it is insufficiently comprehensive.

The shortage type is not defined and could cause some confusion. It could be taken to mean that the sponsor needs to differentiate between a 'complete' or 'partial' shortage, or between resolved/current/anticipated/discontinuation – as is set out on the MSII website.

Consultation issue 3: Which products should be on the 'Medicines Watch List' defining an 'extreme' risk shortage?

- *Is the list comprehensive/adequate?*
- *Are there other products that would have an extreme or high patient impact if they were in short supply?*

Clinicians are better placed to comment on the Medicines Watch List but it appears comprehensive.

[REDACTED] *ould be the best mechanism to add or remove medicines from the list?*

[REDACTED] er committee could be the best mechanism, with review of the list by a [REDACTED] rty on a regular basis.

Consultation issue 4: Compliance Obligations and Options

- *Do you support particular options? Why?*

Option 2 appears more feasible i.e. for a sponsor to be publicly identified and liable to pay financial penalties if they do not report a shortage that they are aware of.

The TGA could also consider offering incentives for compliance rather than disincentives for non-compliance.

More extreme penalties of criminal sanctions could be problematic to enforce.

- *Which option, or combination of options, do you believe would be the most effective?*

Of the Options offered, the more effective would appear to be option 2.

Other Issues

- *The CSO funding mechanism and its associated standards for wholesale distribution of medicines is an important and effective mechanism for minimising and managing medicines shortages – these supply guarantee and out-of-stock reporting standards should apply equally to ALL distributors of PBS medicines in Australia. Exclusive distribution monopoly is a risk to Australian consumers as should it fail, for whatever reason, there is no contingency. All PBS-listed medicines should be made available to all CSO Distributors (at equivalent pricing), in addition to any direct distribution channels pharmaceutical manufacturers may choose to explore. This will help minimise the risk of medicines shortages to Australian patients.*

The effectiveness of the National Medicines Policy and all who rely on it for timely and continuous access to medicines, depends on the application of clear and consistent regulation throughout the PBS supply chain.

██████████ Pool is open to all companies that meet the very high community service compliance requirements set by Government.

██████████ CSO pool, a distributor must, among other things:

- Meet the 24-hour delivery requirement
- Sell to every pharmacy (5,500 of them)
- Meet a rural/remote percentage
- Meet a low volume percentage
- Self-report any non-supply circumstances (e.g. out-of-stocks or medicines shortages)
- Complete a monthly CSO Agency report, and
- Be subject to any external audit requirements on their service obligations.

This has created a highly secure system of pharmacy supply chain for Australia in which consumers have the same access to medicines, no matter where they live.

When it comes to minimising and managing medicines shortages, the CSO works well for both the Commonwealth Government and the Australian public in that:

- There is strict and extensive reporting on non-supply
- All CSO distributors provide standardised and timely reporting of out-of-stocks to an independent party (AHA); and
- There is a high degree of cooperation between CSO Distributors for timely and continuing access to medicines in the event of spikes in demand (such as the recent asthma event in Victoria) or natural disaster (such as the floods in Brisbane) which could otherwise lead to medicines shortages.

This system and the patients who depend on it however, is at risk from the recent advent of exclusive-direct supply arrangements by logistics companies entering the market who are not bound by the same regulations as Government-approved suppliers with guarantees around their medicines supply. Exclusive distribution monopoly is a risk to Australian consumers as should it fail, for whatever reason, there is no contingency.

NPSA calls on government to ensure all PBS-listed medicines be made available to all CSO Distributors (at equivalent pricing), in addition to any direct distribution channels pharmaceutical manufacturers may choose to explore. This will help minimise the risk of medicines shortages to Australian patients.

END