

# Medicine shortages in Australia: Consultation on challenges and opportunities

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Medicines Australia welcomes the opportunity to respond to the Therapeutics Goods Administration's (TGA) consultation on Medicines shortages in Australia.

Medicines Australia's member companies are committed to ensuring access to a reliable supply of high-quality medicines to meet the aims of the National Medicines Policy.

Whilst companies continuously monitor their supply chains and production processes, shortages can occur for a multitude of reasons that are usually out of the control of the local Sponsor in Australia. Members follow an effective approach by promptly notifying the TGA and collaborating closely with the Medicines Shortages team when anticipating potential shortages or discontinuations. This helps minimise any direct impact on patients and overall public health.

An overview of industry approach to managing shortages and discontinuations, including challenges and opportunities is provided below.

## Medicine shortages and discontinuations

### Planning & Monitoring for Potential Medicine Shortages

- For global organisations supply planning is based on ongoing country demand forecasting to ensure global supply and demand needs can be met.
  - Quantitative and analytical models are used to predict demand. These models analyse historical data, market trends, and other relevant factors to estimate future demand for medicines.
- End to end supply chains can be very complex requiring multi-country operations and dependent on many suppliers. This requires ongoing assessment and intelligence gathering at a local and global level to identify potential risks to supply via a constant exchange of information.
  - Collaboration with healthcare providers, distributors, and retailers helps gather real-time information on patient needs and prescription patterns.
- Real-time tracking of shipments and inventory provides visibility into the supply chain. Companies use technologies like RFID tags and GPS tracking.
  - Collaboration with logistics partners is used to ensure timely delivery and minimise disruptions.
- Factors considered that may impact supply are based on both internal and external risks such as manufacturing constraints, distribution/ logistics challenges,



cybersecurity or a public health crisis in an individual country that requires immediate prioritisation of supply.

- At the individual country level there may not be full awareness of all potential supply impacts until the global assessment has been completed.

## Business Continuity Measures

- At both a global and local level Business Continuity Planning and risk assessments are standard practice to minimise disruption and ensure contingency planning. Various scenarios such as physical and natural disruptions including natural disasters, pandemic preparedness and transportation/logistic issues are considered.
- Business Continuity Plans are kept up to date and regularly reviewed for all type of disruptions, including all vital functions across the company, with clear roles and responsibilities to ensure business continuity.
- Insurance policies enhance preparedness, including documented and tested disaster recovery plans that include pre-wholesaler/logistics providers.
- Pharmaceutical companies also conduct Route Risk Assessments for each transport lane of operation to maintain supply chain resilience, ensuring product quality and patient safety. This is done on a case-by-case scenario based on the type of disaster and operational impact.
- Despite extensive contingency planning, poor weather conditions at manufacturing sites, other natural disasters, pandemics and conflicts can strike unexpectedly and pose significant challenges in procuring supply and utilising standard transport routes.

## Inventory and Storage Management

- Stock is often stored in multiple warehouses in different locations in Australia for geographical diversity in case there are disruptions on certain supply chain routes.
- Shipping documents include clear instructions for storage conditions in case of delays.
- Some companies will keep over 90 days of inventory on hand (DOH) which buffer against unexpected demand spikes or supply disruptions.
- Conducting regular audits of inventory levels and expiration dates to prevent overstocking and wastage is also used to ensure sustainable supply.

## Cybersecurity

- Pharmaceutical companies proactively plan for supply chain disruptions that can be caused by cybersecurity threats such as unauthorised access to supply chain ICT systems and general cybersecurity attack. Companies employ a range of processes to protect the supply of medicines including:
  - **Network and Perimeter Security:** Global cybersecurity ecosystem covering infrastructure, solutions, applications, access, and systems across all functions, including supply chain Firewalls, URL filtering, and antivirus for endpoints.



- **Incident Response and Monitoring:** Global/enterprise-level management of security incidents through an Incident Response process, including alerts generated and triaged by the 24/7 cybersecurity teams.
- **Consistent Protection Across Sites:** Every site benefits from the same level of protection and detection capabilities.
- **IT Business Continuity and Resilience:** IT Resilience and Business Continuity plans that are regularly evaluated.
- **Access Control and User Management:** System registers track personnel with ICT access; and software updates restricted to IT Security rollouts.
- **Secure Sockets Layer (SSL) Certificates and External Language Server Protocol (LSPs):** SSL certificates maintained by external LSPs, with regular updates and integration; and IT security clauses within LSP contracts.

## Barriers and Challenges

- For medicines that are off-patent there are generally multiple manufacturers, so no single company has sole responsibility for the supply chain.
- Discontinuing older products due to regulatory issues, such as changes that cannot be validated according to current standards or difficulties in securing Good Manufacturing Practice (GMP) from a new third-party site.
- Supply Chain Policies that intersect with other Government Departments: The different government entities whose policies affect the medicines supply chains should not function in silos. Embedding collaboration and coordination of policies and legislations that affect medicines supply chains will foster more effective planning and management of shortages and discontinuation. Some examples of policies that can impact medicines supply chains include:
  - The Department of Health and Aged Care's (DOHAC) implementation of Minimum Stockholding Requirements has increased the administrative burden on companies.
  - DOHAC's 60-day Dispensing/Maximum Dispensing Quantity Policy, made it challenging for pharmaceutical companies to plan for potential spikes in demand.
  - Policies from the Department of Climate Change, Energy, the Environment and Water regarding decarbonisation, and international trade negotiations with the Department of Foreign Affairs and Trade, may also affect the planning of a medicine shortage or discontinuation.
- Many new pharmaceutical medicines and treatments are temperature-sensitive and require cold chain storage and transportation. Australia needs targeted investments in robust cold storage and transportation infrastructure, along with a skilled and adaptable workforce, to safeguard the quality and effectiveness of medicines, especially in the face of potential delays due to external factors.



- Australia's domestic supply chain is part of a complex and integrated global supply chain. The challenges lie in the complex global dependencies. Reliance on both domestic and international sources, makes it difficult to anticipate and respond to factors such as natural disasters, trade disputes, or sudden global spikes in demand. This complexity requires a thorough understanding of global dependencies, potential risks, and the need for strategic measures to ensure a stable and consistent supply of essential medicines.
- Implementing robust data analytics systems for demand forecasting requires investment, data privacy considerations, and skilled personnel.
- Medicines Serialisation is the generation of a unique serial number in the form of a barcode at the medicine package unit level (i.e. vial, pack). It can improve supply chain visibility by increasing traceability (track and trace) through accurate recording and managing of data as the medicine moves through the supply chain. However, unresolved practical issues with the implementation of serialisation such as international standardisation, and the resources required to create an infrastructure to accommodate serialisation remain.

## Impact on Time and Resources to Manage Shortages

- At a patient and Healthcare Provider (HCP) level any medicine shortage is a priority. Managing expectations for a high impact shortage in the absence of clarity of progress of an S19 application to procure alternative supply is difficult. This can lead to personnel spending hours of time managing stakeholders and has a serious impact on Sponsor resources, particularly medical information teams.
- DOHAC's Minimum Stockholding Requirements added additional time complete administrative forms to remain compliant, including monitoring, reporting, internal meetings on potential breaches, and managing the breach requirements. It can take several days to gather information from supply chains and several hours a week to process.
  - The arrangements for Minimum Stockholding Requirements are due to be reviewed mid-2024 after one year of implementation. The review should seek to understand whether the additional administrative burden on Sponsors has resulted in improved supply, and if there have been any unintended consequences that are counter to the policy's stated aims of maintaining medicines supply.
  - To remain compliant to the Minimum Stockholding Requirements, some companies shifted to air freight, which increases company costs, impacting cash flow and stockholding allowances for other brands. Utilising air freight also increases the company's environmental footprint.

## Improvement Opportunities for Medicines Shortages

### Simplification of S19 Process to Accelerate Review

- Inflexibilities and regulatory burden in the current process are driven by the legislative framework and a review should be conducted to assess how to create a patient-centred



shortage management framework, to enable faster access to the global supply chain, especially for products where the only difference from the registered product is the packaging.

- For medicines in short supply with a critical public health impact, the S19 process usually operates with close collaboration between TGA and Sponsors to find a rapid solution which is highly appreciated by Sponsors. However, where an application appears to be ‘deprioritised’ the process is untransparent and can create major challenges in procuring overseas supplies due to the lack of standard review timelines and lengthy delays in getting feedback.
- Many companies will not release supplies unless a TGA approval is in place, and allocation of supplies is prioritised to countries which have the required approval in a global marketplace. Delays with review can occur where internal TGA clinical advice is not reflective of real-world patient impact due to lack of familiarity with the true disease burden, creating unnecessary work for Sponsors and delays in addressing a shortage.
- In cases where the risk of ongoing shortages is known, the need to reapply adds extra burden for Sponsors and TGA and a more contemporary approach could be implemented based on review of the current framework.

### Early notification of Market Constraint

- Sponsors appreciate TGA alerts regarding potential shortages, even when they may not always be visible on the Medicines Shortages website. Enhancements to these alerts, particularly sending them as early as possible in the process, will further improve assisting sponsors in assessing options to increase stock levels to meet demand.

### Incentives

- Australia is one market in a complex, global medicines ecosystem. If manufacturers have capacity issues, as occurred during COVID, demand spikes may see supply being prioritised to other markets, despite the best efforts of local affiliates.

### Product Discontinuations

- No medicines are discontinued if they are on the WHO list of essential drugs. If warranted, an agreement to transfer Sponsorship would be executed to ensure continuity of supply.
- Decisions to discontinue products can be based on a variety of factors including:
  - Realignment of therapeutic areas of interest to focus on pipeline products.
  - Changes in standards.
  - Generic/biosimilar competition making supply commercially unviable.
- When making discontinuation decisions, Sponsors always consider the availability of alternatives for products addressing a critical medicine need or alternative Sponsors if sole supply status applies.

For effective management of medicine shortages, seamless communication among government departments is essential. Collaboration between entities such as the TGA and the Department of



Health is crucial, supplemented by the inclusion of industry submissions and consultations with other Government Departments. This approach fosters cooperation, enhances our medicine supply chain resilience, and ensures timely access for all Australians.

Acknowledging the need for a case-by-case approach and understanding the unique operational methods of individual companies is important for effective management. If further information in a specific area is of interest, a discussion forum with a small group of Medicines Australia members may be a useful approach.

Please contact Constantine Tablan, Manager, Policy to discuss any information in relation to this submission.

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### About Medicines Australia

Medicines Australia leads the research-based medicines industry of Australia. Our members discover, develop and manufacture prescription pharmaceutical products, biotherapeutic products and vaccines that bring health, social and economic benefits to Australia. Our members invest in Australian medical research and take local discoveries and developments to the world.