

Medicines Manufacturing & Supply Chain is Robust and Complex

Legislative changes that impact local demand and inventory levels of medicines should consider the complexity of the supply chain. These changes require close collaboration and extensive planning.

Time from order to ready for distribution in AU

- Ranges from **6 to 12 months**
- Depends on freight mode, site capacity, and manufacturing location
- Deliveries happen **every month to every 6 months** depending on demand volume and minimum order quantities
- Australian specific packaging required (by the TGA) usually means produced stock cannot be shared with other countries



Order Planned

Rolling forecast¹ covering **12 - 36 months** provided every month to reserve manufacturing slots for order



Freight

60% by air
1-2 days from Asia
2-3 days from EU and US

40% by sea
3-4 weeks from Asia
2 months from EU and US

Air freight – smaller quantities due to cost and space limitations, cold chain products due to temp control requirements; risks – temp excursions if direct flights not possible & left on tarmac in warmer countries for extended periods

Sea freight – larger quantities; risks – dock allocation in AU



Manufacturing Location

- **Asia:** 39% of companies
- **Europe:** 100% of companies
- **North America:** 56% of companies
- **Australia:** 11% of companies

These locations are based on finished product locations. However, manufacturing can occur at different stages (e.g., for active pharmaceutical ingredient (API), bulk product, and finished product), and at different locations with their own supply chain requirements.



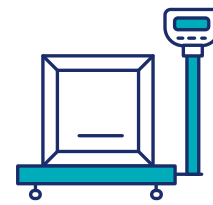
Order Placement

- **3-9 months** order lead time²
- Changes only possible in 60% of the cases once order has been placed
- Changes limited depending on site capacity, component availability, and timing (i.e., not possible if already produced)
- Packaging³ changes require additional time **1-6 months**



AU Customs Clearance⁴

Air: **2-3 days** for custom clearance
 Sea: **3-5 days** for custom clearance



Order in Warehouse

1-2 weeks to be booked in and Quality Assurance (QA) released for supply



Product Delivered to Hospitals, Pharmacies, Wholesalers, Patients



Order Ready for Distribution

- Over 90% of products are manufactured overseas due to economies of scale and specialised manufacturing process
- Minimum stockholding requirements need to be planned in advance
- Stock shortages can arise unexpectedly for various reasons and are hard to plan for
- Collaboration is essential, such as during the COVID-19 pandemic

19 companies responded to the Medicines Australia survey to understand the complexity of Pharmaceutical Supply Chains

1. Rolling forecasts are based on historical demand and do not take into account unexpected demand eg competitor/generic stock out issues

2. Lead time = time from order to availability to ship to AU

3. Includes pack inserts; changes can TGA required, or company driven.

4. SB and biologics (usually cold chain) need licences to import and/or export permits which companies must abide to the conditions of the licences and usually use air freight