

Victorian Pharmaceutical Reserve

Frequently asked questions

Purpose

What is the pharmaceutical reserve?

The pharmaceutical reserve is part of the department's strategy to safeguard supply of essential medicines during the coronavirus (COVID-19) pandemic. The department established the reserve by bulk purchasing specific items that are likely to be in higher demand due to the pandemic. In the event of a shortage these products will be made available to health services, ensuring patient care is not compromised.

Why does Victoria need a pharmaceutical reserve?

The reserve protects Victoria and mitigates against the risk of medicine shortages due to heightened demand both local and international, or ongoing supply chain disruption. Other Australian jurisdictions are similarly securing supply of essential medicines through creation of a reserve.

Which medicines are in the pharmaceutical reserve?

The reserve comprises approximately 80 pharmaceutical products including; antibiotics, sedatives, analgesics, neuromuscular blockers, anti-nausea medicines, antipsychotics, bronchodilators, antispasmodics, IV fluids and dialysis fluids. The list of essential critical care medicines was identified based on advice from intensive care physicians, pharmacists, Safer Care Victoria, Health Purchasing Victoria (HPV), the Victorian COVID-19 Health Services Pharmaceutical Reference Group as well as other jurisdictions including NSW, Queensland and the Commonwealth.

The reserve focuses on medicines used in the critical care of patients suffering Acute Respiratory Distress Syndrome, Acute Kidney Injury, sepsis or pneumonia. These are the most common presentations of critically ill patients infected with coronavirus (COVID-19). The list of medicines does not include items for non-COVID-19 related presentations at this stage.

How large is the reserve, and will this be enough?

The department is working to secure up to 12 weeks of stock for each item based on historical demand. Reserve stock will be held by Symbion, CH2, Central Healthcare Services and Baxter.

The department will actively monitor stock levels in the reserve and will continue to work with the TGA, sponsors and wholesalers to identify lead indicators of medicine shortages.

Who can access medicines from the reserve?

All Victorian public hospitals can access medicines from the reserve. If private hospitals believe they need to access the reserve, they should send an enquiry to the department via COVID-19Pharmacy@dhhs.vic.gov.au. Community pharmacies cannot access pharmaceuticals from the reserve; most items held in the reserve are used in hospital only and would not generally be dispensed in community pharmacies.

Will building the pharmaceutical reserve impact current pricing or stock availability?

No. Essential medicines are only included in the reserve if there is sufficient stock available. The department has worked with distributors to ensure that any stock committed to the reserve does not impact their ability to provide business as usual supplies to health services. In many instances, reserved stock will be pre-purchased and delivered over a period of months to reduce the risk of immediate supply chain impacts.



How will you manage the risk of medicines expiring while in reserve?

The department is working with wholesalers to manage expiry date risk. Expiry dates will be regularly monitored. Stock nearing expiry will be returned to the commercial supply chain or provided to health services to ensure minimal wastage. The department will develop a framework and work with Directors of Pharmacy in Victoria to guide decisions regarding handling of expiring stock.

Do I need to change how I order pharmaceuticals now?

No. You should continue to order through your usual suppliers and distributors. It is important to order normal quantities so that all health services can access the essential medicines they need.

When can health services access the reserve?

Health services can access reserve stock when they experience a shortage that may adversely impact patient care. For example, if you place an order with your usual supplier, receive a backorder notification and there is risk of stock running out, you should first attempt to mitigate this risk through purchasing from an alternative supplier or reallocating stock from another ward in your hospital. In some situations, it may also be reasonable to consider alternative therapies. If these strategies fail to mitigate the risk of shortage, you should access the reserve to obtain the required medicine.

The threshold for accessing the reserve may vary between hospitals and between medicines due to differences in hospital activity level and storage capacity. Access to the reserve stock is therefore guided by a hospital self-assessment process rather than a minimum stock threshold.

How do I access the reserve stock?

- 1. Use the <u>online dashboard</u> to view the contents of the reserve and identify which wholesaler holds the required item. Please note that the dashboard is not real time but represents stock holdings by each wholesaler at close of business the previous day.
- 2. Place an order directly with the wholesaler, requesting no more than your normal order quantity. Ordering processes for each wholesaler, including reserve item codes, are listed on the dashboard.
- 3. Submit a **self-assessment form** to the department detailing your reasons for accessing the reserve by close of the next business day.

What mechanisms are in place to fairly allocate pharmaceuticals from the reserve?

Health services are required to self-assess their need for reserve stock to ensure fair allocation of resources:

- Health services must confirm they are experiencing a shortage that could impact patient care (i.e. no available stock from their preferred or non-preferred wholesaler and insufficient stock available across all areas of the hospital to cover predicted demand until normal supply resumes).
- To prevent stockpiling, health services are required to **follow their normal ordering pattern** or explain why they are ordering a greater quantity than usual.

The department will monitor ordering from the reserve (including current hospital activity and stock on hand), with the Victorian COVID-19 Health Services Pharmaceutical Reference Group peer-reviewing ordering patterns and volumes. If quantities ordered are found to be excessive, the Reference Group will enquire with the health service, provide advice about accessing the reserve and potentially reallocate stock between health services.

Do health services need to use alternative medicines before accessing the reserve?

Not routinely. Securing access to first line treatments maintains best practice and reduces potential safety risks. Hospitals may not have capacity to spend extra time and effort substituting items during surge periods. However, in some situations it may be reasonable for health services to use clinically appropriate alternatives, particularly when shortages are not associated with demand surges. In addition, some first-line pharmaceuticals, such as antibiotics, may need to be reserved for specific conditions or situations when stock is low. The department has prepared

guidelines about recommended second and third-line medicines (link to medicines substitution table); these are not intended to be prescriptive but rather a support to health services in case shortages arise.

How will you ensure timely access to reserve stock?

We have developed mechanisms to ensure the reserve pharmaceutical stock can be rapidly accessed by health services in the event of a shortage. Health services can order directly from the reserve prior to submitting a self-assessment form, streamlining access. Pharmaceutical wholesalers will store, manage and distribute the essential medicines so that orders can be delivered within normal delivery timeframes (usually the same day or by next business day for metropolitan health services).

Is the department taking over the purchasing of pharmaceutical stock?

No, the department is not taking over purchasing of all pharmaceuticals. Rather, the department has purchased a reserve of specific essential products that is held with existing wholesalers to support their supply during the coronavirus (COVID-19) pandemic. In the event of a shortage these will be released into the existing supply chain. Health services can continue to purchase through their usual sponsors and wholesalers.

What if there is a shortage of a medicine not on this list?

Victoria's pharmaceutical reserve is a contingency measure to maintain supply of specific critical medicines during the coronavirus (COVID-19) pandemic. Medicines that are expected to be subject to business as usual demand are the responsibility of the Commonwealth and TGA, who monitor and manage medicine supply across Australia.

The TGA publishes a list of medicine shortages on its <u>website</u>, including details about supply impact dates, status, reason for shortage, patient impact and alternative medicines, where possible. The TGA also runs a Medicine Shortages Working Party to identify shortage issues and develop approaches to supply chain problems, including in the context of the coronavirus (COVID-19) pandemic. If a health service cannot obtain a product from their wholesaler, and the product is not part of the pharmaceutical reserve, the TGA advises they should call the sponsors directly.

The department will continue to work with the COVID-19 Health Services Pharmaceutical Reference Group to determine whether there are other medicines not currently in the reserve that need to be more closely monitored while the risk of shortages continues during the pandemic.

How long will this arrangement last?

The pharmaceutical reserve is intended to safeguard supply during the coronavirus (COVID-19) pandemic. The department will work with the Victorian COVID-19 Health Services Pharmaceutical Reference Group and the department's pandemic modelling team to review ongoing need for the reserve.

What other approaches is Victoria taking to manage the risk of shortages?

The pharmaceutical reserve is one component of Victoria's coordinated response to maintaining medicine access during the coronavirus (COVID-19) pandemic. Other strategies include encouraging wastage minimisation, sourcing from non-preferred suppliers, potentially sourcing Special Access Scheme or section 19A products, substitution with non-first line therapies, elective surgery prioritisation and stock reallocation between health services.

Victoria is also working with other states and territories and the Therapeutic Goods Administration (TGA) to discuss availability of medicines and opportunities for stock redistribution. The pharmaceutical reserve is a contingency measure in case other measures fail.

How can I contact the department to discuss my issues/concerns?

Please contact COVID-19Pharmacy@dhhs.vic.gov.au with any questions, feedback or relevant information.