



18 February 2021

Dear Chief Medical Officer

Update: Tenecteplase supply shortage

We wish to update you on our earlier communication dated 28 January 2021 on the issue of supply shortages for tenecteplase and the decisions from a meeting of representatives from the sectors affected on 15 February 2021.

We wish to acknowledge the prompt and detailed response from all DHBs, ambulance services, and cardiac and stroke registries to the request for information regarding the current state of tenecteplase stock and use patterns. We also wish to acknowledge the rapid and full commitment from clinical services to plan and execute changes to their treatment delivery protocols. The global pharmaceutical company considers the New Zealand response to be an international exemplar.

Supply State Update (as of 15 February 2021):

- Nationally we have fairly secure access to 1100 doses of tenecteplase to see us through the date when supply from the pharmaceutical company is re-established. This is expected to be some time in October but is not confirmed. We are therefore working to a December timeline for secure re-supply.
- To put this in context, the supply to (and demand from) all of New Zealand last year was 1500 doses.
- Of the 1100 doses that are available in 2021:
 - 325 are not yet in the country (but are expected)
 - 185 doses are currently located in ambulance services throughout the country
 - 425 doses are located in DHB facilities (main hospitals and rural facilities)
 - 175 doses are in stock with the main supplier (Boehringer Ingelheim).
- 140 doses are due to expire by October, half of which are in ambulances and cannot be re-allocated due to uncertain temperature storage conditions. The pharmaceutical company (Boehringer Ingelheim) is awaiting confirmation in the next 24-48 hours from their global team confirming the possibility of extending the expiry date with a particular focus on stock expiring up to October. Any extension will require Medsafe approval.
- Extra supply has been secured via CDC who have approval to bring an extra 150 doses into New Zealand over the next 10 months (@ 15 units a month). This is included in the 1100 doses. There is a possibility this supply could be increased if required. This stock is provided under section 29 of the Medicines Act 1981 (ie, it will be an unapproved medicine) and cannot be used under standing orders by paramedics.

Use of tenecteplase in New Zealand:

DHB Services:

- All main DHB services are proactively switching to using alteplase to preserve supply of tenecteplase for use in ambulances and rural and remote facilities / hospitals.
- NB: For the purposes of tenecteplase supply, rural and remote facilities/hospitals are considered to be in the same category as ambulance services. This is because of the difficulty in temporary transition to alteplase in extremely low volume situations.

Stroke Services:

- As of the 15th February all 14 DHBs who were previously using tenecteplase for stroke are expected to have implemented the switch to alteplase. This will reduce demand by more than 400 doses this year.

Ambulance Services and rural/remote facilities:

- St John is looking to streamline tenecteplase stock to the minimum possible number of locations. This may free up to 29 doses.
- Rural and remote facilities / hospitals should work with their local cardiology services to determine the best treatment strategies for their populations. Tenecteplase can be supplied if that is the option chosen by local services.

Risks:

On the face of it we appear to have an adequate tenecteplase supply to see us through to the end of the supply shortage provided the changes being made to treatment protocols are fully implemented. However, we have identified a number of risks:

- While the indication from the supplier is that we should have stock coming into the country again in October, we have no certainty of this date. Tenecteplase is difficult to manufacture and hence scaling production is challenging.
- Some of our expected stock for the year is not yet in the country.
- We need to continue to hold stock in over 200 locations (mainly road ambulances). This creates significant challenges in supply chain efficiency.
- Ambulance temperature storage conditions are challenging leading to loss of flexibility in reallocating stock.
- New Zealand has a comparatively short approved shelf life for tenecteplase, increasing the risk of waste from expiry.

We remind you of our earlier requests below to preserve supply:

- 1) Please prioritise existing stock supplies to support use of tenecteplase for out-of-hospital STEMI thrombolysis. For the purpose of this recommendation, rural and remote facilities are considered "out-of-hospital".
- 2) Please use alteplase as the thrombolytic of choice for massive pulmonary embolus.
- 3) Please use alteplase as the thrombolytic of choice for ischaemic stroke.
- 4) Please use alteplase as the thrombolytic of choice for STEMI in hospitals.
- 5) Maintain tight stock management in DHBs and ambulances to inform ongoing national supply decisions.
- 6) Please consider removing tenecteplase stocks from DHB areas other than hospital pharmacies.
- 7) Please put aside out-of-date tenecteplase and do not dispose of it in pending decisions on expiry date extension.

Review:

This group will continue to monitor developments and will review supply states and recommendations in three months. We ask that you ensure these recommendations are disseminated to the relevant people in your organisation.

This information is being sent to all Chief Medical Officers, DHB chief pharmacists, Ambulance services, DHB stroke teams via the National Stroke Network, DHB Cardiology services via the National Cardiac Network and Cardiac Society, Emergency Medicine Specialists via the Australasian College of Emergency Medicine, and to Rural Hospital Medical Officers via the Division of Rural Hospital Medicine of the RNZCGP.



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