



## File Note

<b>Matter name:</b>	National Pharmaceutical Services Association (NPSA) application for revocation and substitution		
<b>ACCC parties</b>	Gavin Jones, David Hatfield, Sophie Mitchell, Tom Lyle, Gemma Smith		
<b>TRACKIT No</b>	AA1000571		
<b>Other parties</b>	Therapeutic Goods Administration ( <b>TGA</b> ): <ul style="list-style-type: none"><li>• Elspeth Kay (Assistant Secretary – Pharmacovigilance &amp; Special Access)</li><li>• Cath Brown (Director – Medicine Shortages)</li></ul>		
<b>Time:</b>	10:30 AEDT	<b>Date:</b>	8 October 2021
<b>Phone to</b> <input type="checkbox"/>	<b>Phone from</b> <input type="checkbox"/>	<b>Meeting</b> <input checked="" type="checkbox"/>	<b>Other</b> <input type="checkbox"/>

The ACCC met with the TGA on 8 October 2021 and the TGA made the following points:

1. The TGA has less visibility over the NPSA authorisation conduct compared to the conduct under the Medicines Australia authorisation. The TGA is not involved in, nor the trigger point for, the meetings that take place but the TGA does see a coordinated approach to constraining supply in response to demand spikes.
2. The demands spikes continue to happen as people feel anxious about case numbers and wholesalers have had a consistent approach to limiting supply to their customers which has really helped with consistent messaging, avoiding extreme stockpiling and stock-outs.
3. NPSA was giving the TGA regular updates about how they were constraining supply which was really useful. They haven't had to do as much of that recently but as states open up, the TGA will again be suggesting that wholesalers coordinate the restriction of certain products when supply rushes happen.
4. Under the previous authorisation last year, wholesalers were applying more regular constraints and it was more of a discussion between them, then reporting back to the TGA.
5. The TGA is not aware of the NPSA members applying coordinated restrictions beyond written directions during 2021.
6. The TGA gets wholesaler reports that can sometimes show concerning demand spikes that may result in a shortage if not constrained. The TGA then takes action to manage the potential shortage, which may include asking wholesalers to apply sales limits. o

7. The wholesaler reports are consolidated (rather than being from individual wholesalers) and are consolidated by the NPSA, so the wholesalers don't have visibility over each other's' reports.
8. The TGA will let the ACCC know if they can identify how the reports may work better or how the TGA could have increased visibility over the conduct under any future authorisation if granted.
9. The TGA is not concerned about the wide definitions for products covered by the conduct. While the definition of the conduct is quite broad, there has been no evidence that the parties are restricting supply beyond the products they ought to and it may be an issue if it was too narrow. Medicines are what the TGA are interested in, but clinical products like devices (syringes, nebulisers) or PPE etc. could be affected if the definitions were too narrow.
10. The parties seem to have been applying the authorised conduct in an ethical way with no signs of abuse. The TGA has no concerns at this stage and is reasonably confident the parties have behaved responsibly so far. Therefore, the TGA has no concerns about the requested 12-month length of the new authorisation even if it turned out to be longer than necessary. The pandemic has global effects that can impact on supply in Australia through increases in demand, impacts on freight and effects on manufacturing workforces. Having this mechanism in place is reassuring as it is a useful tool for TGA to work with stakeholders to respond to supply issues. This call also discussed another matter, the Medicines Australia application for revocation and substitution. A record of that portion of the call can be found at <https://www.accc.gov.au/public-registers/authorisations-and-notifications-registers/authorisations-register/medicines-australia-1>.

Call ended at approximately 11:00 AM AEDT