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Ayman Guirguis
Partner
K&L Gates

By email

Dear Ayman

Re: NPSA application for revocation and substitution

As previously advised by telephone on 28 February 2023, the ACCC did not grant interim authorisation in respect of the National Pharmaceutical Services Association's (**NPSA**) application for revocation and substitution (the **Application**), and the prior authorisation AA1000571 expired on 28 February 2023.

Consequently, the ACCC is unable to further consider the Application for revocation and substitution as there is no longer an existing authorisation in effect.

The ACCC was given only a very short time to consider the request for interim authorisation due to the lateness of the application being lodged relative to the expiry of the existing authorisation. In this very limited time, the ACCC did not make a decision to grant interim authorisation.

A number of factors are worth highlighting in relation to the Application.

The conduct is defined very broadly, with uncertainties in relation to the wording used. While this may have been acceptable at the height and urgency of the COVID crisis, in the current circumstances, this needs to be reconsidered.

In the limited time available, the ACCC was not able to consult sufficiently to inform its assessment as to whether the scope of the conduct could be appropriately limited or whether suitable conditions could be imposed such that interim authorisation could be granted.

While the Application has lapsed, the applicant may wish to consider lodging a fresh application for authorisation, including a request for interim authorisation. To assist in the making of any such application, the ACCC makes the following additional comments on the Application below.

Breadth, lack of clarity, and lack of justification regarding conduct

The ACCC's initial view is that the proposed conduct in the Application was unnecessarily broad and could allow anti-competitive conduct beyond that necessary to address medicine shortages, with the potential for continuing impacts on competition.

The ACCC acknowledges that the conduct proposed in the Application was substantially similar to that which the ACCC has previously authorised during the unprecedented circumstances of the COVID-19 pandemic. Such broad framing was accepted on an urgent basis at the height of the pandemic. In circumstances where several years have elapsed since the start of the pandemic, and where the authorisation is now said to be precautionary rather than an urgent reaction to the unfolding pandemic, such broad-framing of the conduct, particularly involving potential cartel conduct, is no longer likely to be satisfactory unless it is accompanied by strong justification that the circumstances and potential responses that may be required remain similarly unknown and rapidly changing as was the case at the beginning of the pandemic.

In general, the ACCC considers that industries need to transition away from – or at the very least significantly narrow the scope of – authorisations for broad conduct which were aimed at responding to issues related to the COVID-19 pandemic. While Australia and the world is not yet 'COVID-stable' and environments could still change, we are no longer at the peak of a rapidly evolving crisis, and broad-reaching emergency exemptions should be replaced with more specific and targeted arrangements, where it can be demonstrated that ongoing exemptions are required and there is a demonstrable net public benefit.

The ACCC also notes that the proposed conduct in the Application was neither sufficiently clear nor limited to what was demonstrated to be necessary to respond to any ongoing or likely future supply chain challenges related to COVID-19. The drafting in the Application would have allowed the parties a wide discretion to engage in what would otherwise (i.e., without authorisation) be likely to be cartel conduct, in relation to both prescription and non-prescription medicines, and potentially encompassing the entire pharmaceutical industry.

In addition, the Application did not address the extent to which the claimed benefits could be achieved through less restrictive means, such as through using existing regulatory frameworks to reduce the extent to which authorisation is needed.

The applicant has had the benefit of almost 3 years of experience and discussions with relevant stakeholders regarding the effects of COVID-19, as well as the benefit of authorisation during that time, and should be in a much better position now, as compared to in March 2020, to identify the specific conduct that it submits is necessary to achieve the aims stated in the Application. We are also aware that there has been a recent review of COVID-19 vaccine and treatment purchasing and procurement, the 'Halton review'¹, and if there is any need for longer-term industry coordination to implement elements of this review, that should be put forward to the ACCC in a new application.

Parties to the conduct

The parties to the application are the 4 biggest wholesalers of medicines and pharmacy products in Australia. Major parties in any industry working together on an ongoing basis is prima facie a serious concern to the ACCC. Additionally, the Application sought to extend authorisation to other CSO Distributors, Medicines Australia and its members, Generic Biosimilar Medicines Association and its members, and other manufacturers/sponsors of

¹ The Halton Review of COVID-19 Vaccine and Treatment Purchasing and Procurement

Medicines on an 'as needed' basis. The need for the Other Participants to be included on an 'as needed basis' is unclear and created additional concern for the ACCC.

Potential future application

If a future application is made, the ACCC suggests it include specific and detailed information in relation to each of the following:

- How the circumstances relating to COVID-19, particularly global supply chain challenges, have changed compared to the previous 2 years and how supply chain pressures have resulted in, or accentuated, shortages of Medicines.
- How the circumstances are different currently compared to pre-COVID, given the ACCC understands there is no appreciable increase in the amount of shortages experienced.
- In respect of monitoring for possible shortages, why this needs to occur collectively, and why it could not occur (even collectively) in a way that involved a lesser degree of potential coordination or agreement.
- How the conduct is said to ensure access to medicines that is 'equitable', and precisely what this means in practice.
- What is meant by the 'potential' for the 'Other Participants' to be involved, and under what circumstances their participation would be 'needed' and would occur.
- The basis on which the applicants assert that the public benefits claimed in the application are likely to result, and how they will outweigh the detriment that is likely to result from the conduct for which authorisation is sought, which includes cartel conduct involving the major pharmacy wholesalers and other parties.
- Why the public benefits claimed cannot be achieved via less restrictive means.

As discussed with you, the ACCC encourages the applicants to provide the ACCC with a draft of any future application for authorisation, to enable the ACCC to provide initial comments on it prior to lodgement.

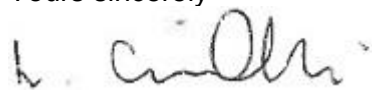
Timeframe for seeking interim authorisation

Finally, and as communicated to you prior to the application being made, a request for interim authorisation on only a few days' notice prior to when it is needed is unlikely to be able to be accommodated by the ACCC.

Consistent with the ACCC's published Guidelines for Authorisation of conduct (non-merger), the ACCC aims to make decisions on requests for interim authorisation within 28 days of the request. While the ACCC will seek to respond to urgent requests on a timely basis, applicants should not expect that the ACCC will be able to assess a request for interim authorisation and make a decision in relation to it in a shorter timeframe than this.

If you have any questions in relation to this letter, please contact David Hatfield or Gemma Smith in the first instance.

Yours sincerely



Lyn Camilleri
General Manager
Competition Exemptions