

Simon Bell
Assistant Director, Adjudication Branch
Australian Competition and Consumer Commission
Level 2, 23 Marcus Clarke Street
CANBERRA ACT 2601

Dear Mr Bell,

National Pharmaceutical Services Association (NPSA) – AA1000480 – Draft Determination

Thank you for the opportunity to comment on the draft Determination by the Australian Competition and Consumer Commission (ACCC) in respect of the application for authorisation lodged by the NPSA (Authorisation AA1000480).

The Department of Health (Health) supports the range of activities that form the Proposed Conduct defined in the draft Determination, and concurs that the Proposed Conduct will support the desired outcomes of facilitating supply of, and access to, Medicines and Pharmacy Products. Health also supports the inclusion of the proposed reporting condition and permitting the Proposed Conduct only as necessary for the purposes of addressing shortages in supply that may arise from the COVID-19 pandemic.

Health provides the following feedback for consideration by the ACCC as part of finalising the Determination.

Authorised duration of the Proposed Conduct

Health notes that the original application by the NPSA for authorisation to engage in the Proposed Conduct was for a period of 12 months to March 2021, and that the ACCC is proposing to grant conditional authorisation until September 2021.

Health recognises that the evolving nature of the COVID-19 pandemic, particularly recent developments in Victoria, has created challenging circumstances for all medicines supply chain stakeholders, and that flexibility in respect of the duration of authorisation in response to future uncertainties is appropriate. Health notes that in response to the ongoing uncertainty and evolving circumstances in Australia, the submission by Medicines Australia to the draft Determination for its own application now requests a longer duration of authorisation (i.e. through to August 2021) than that initially proposed by the ACCC.

On this basis, Health is supportive of the ACCC's proposal for conditional authorisation through to September 2021, on the understanding that flexible extensions to a shorter initial authorisation

period may not be possible under the *Competition and Consumer Act 2010*, or add unnecessary burden to the ACCC's operations.

Scope of the Proposed Conduct

Health notes that the current definition of Pharmacy Products in the proposed draft
Determination at Section 1.12 is: "all other goods available for sale at community pharmacies
(such as personal protective equipment, face masks, gloves, hand sanitisers and toilet paper)".

In its current form, this definition would appear to cover household goods generally available in other retail environments (such as toilet paper and discretionary food items) and other discretionary consumer goods (such as perfumes and cosmetics) sold at community pharmacies. It is unclear how activities relating to the coordinated acquisition, inventory management and logistical arrangements for such household and discretionary goods are directly relevant to supporting a health-related response to the COVID-19 pandemic.

Health also notes that the oversight of such items are beyond the scope of Health-related oversight mechanisms outlined at Section 4.29 of the draft Determination (such as the referenced Therapeutic Goods Administration Medicine Shortages Working Group).

On this basis, Health recommends the ACCC give further consideration to whether the definition of Pharmacy Products should be narrowed in scope given the broad nature of the current definition, and encourages further consultation with the NPSA and interested parties on the scope of this definition prior to issuance of the final Determination. Definitions used in the *Therapeutic Goods Act 1989*, the *Industrial Chemicals Act 2019* and related legislative instruments may be relevant for informing consultation and refinement of definitions.

Alternatively, should amendments to the definition of Pharmacy Products not be possible due to practical difficulties in narrowing the scope of the definition, Health encourages the ACCC to give additional consideration to how the reporting condition (and any associated monitoring arrangements) may best be utilised during the authorisation period to ensure that the Proposed Conduct is being applied to only address relevant shortages due to the COVID-19 pandemic.

Other matters

Health notes that while a significant volume of Medicines and Pharmacy Products are supplied through appointed Community Service Obligation (CSO) Distributors (some of whom are NPSA members), there are a number of other non-CSO pharmaceutical wholesalers and distributors which supply essential Medicines and Pharmacy Products, but would be excluded from engaging in the Proposed Conduct without being NPSA members and/or participating in the CSO Funding Pool arrangements.

Prior to finalisation of the Determination, Health encourages the ACCC to consider and discuss with interested parties whether conditional authorisation of the Proposed Conduct may be extended to relevant organisations that engage in similar activities supporting the desired outcome of facilitating access to Medicines and Pharmacy Products during this health emergency, without unnecessary barriers to participation.

Should the ACCC wish to discuss the feedback	provided in this letter,	please contact E	Ben Sladic in
the first instance at			

Yours sincerely

Penny Shakespeare
Deputy Secretary
Health Resourcing Group

August 2020