K&L GATES

Non-Confidential Version

Restriction of Publication Part Claimed

Application for Authorisation AA1000480-1: Submission in response to Draft Determination dated 24 July 2020

1. Summary

1.1 The Applicants seek to provide the ACCC with additional information following the Draft Determination dated 24 July 2020 (**Draft Determination**) to facilitate its consideration of:

a) the scope and operation of the reporting requirements outlined in clause 5.9 of the Draft Determination; and

b) the issues raised by the Australian Government Department of Health's submission dated 6 August 2020 (**DoH Submission**).

The Applicants summarise their observations below:[1]

a) The Applicants broadly have no issues with the Draft Determination save for the reporting requirements in clause 5.9.

There are a number of operational difficulties that the proposed reporting requirements would give rise to, including the breadth of the requirements covering all working groups and the possibility for confidential and/or sensitive information in the public domain which may induce unnecessary consumer concerns regarding the availability of certain Medicines and Pharmacy Products.

In light of these issues, the Applicants have proposed amended reporting requirements in section 2 below for the ACCC's consideration.

b) In respect of the DoH Submission, the Applicants consider that:

i. For the reasons previously explained to the ACCC, including the Applicants' integrated supply arrangements with pharmacies to supply both Medicines and significant volumes of Pharmacy Products, retaining the broad scope of 'Pharmacy Products' in the Proposed Conduct is necessary to enable the timely and equitable distribution of such products in the event of a COVID-19 related supply chain interruption. The proposed reporting requirements will also provide the ACCC with sufficient oversight of any collaborations the Applicants may undertake in respect of Pharmacy Products.

ii. The Applicants consider that the scope of the NPSA application for Authorisation is appropriately broad. In the absence of further information or consultation regarding the need or interest for non-CSO wholesalers and distributors to join the NPSA application for Authorisation, the Applicants cannot make a considered decision on whether expanding the scope of the Applicants in the manner suggested by the DoH Submission is necessary.

---

[1] For the purpose of clarity, references to 'the Applicants' are as defined in the NPSA application for Authorisation dated 27 March 2020. The use of terminology of 'the Participants' in the ACCC's Draft Determination should be understood as being interchangeable with references to 'the Applicants' in this submission. All other capitalised terms, unless defined or indicated otherwise, bears the same meaning as in the NPSA application for Authorisation dated 27 March 2020.

iii. Contrary to the DoH Submission, the ACCC has not proposed to extend the authorisation period beyond the period for which the Applicants have applied for, namely 12 months from the date of the ACCC's final determination (expected to be from September 2020).

2. Responding to Reporting Requirements in the Draft Determination

a) Proposed Amended Reporting Requirements

2.1 As a starting point, the Applicants broadly agree with the intention behind the raft reporting requirements in the Draft Determination and are happy to provide the ACCC (or direct the ACCC to liaise with the relevant third party) with any key material that the ACCC considers appropriate to ensure that it has sufficient oversight of the Proposed Conduct.

2.2 However, the Applicants do consider some amendments to the detail of the ACCC's proposed reporting requirements are necessary to accommodate operational realities. The Applicants submit that the ACCC should amend its proposed reporting requirements in clause 5.9 of the Draft Determination as follows (the Applicants will provide the ACCC with details of the reasons for the proposed amendments below):

The ACCC proposes to grant authorisation subject to the following conditions:

*a) The NPSA will provide a report to the ACCC, to be published on the ACCC's public register, within 5 working days following each MSSR Working Group meeting or otherwise on a monthly basis (subject to any confidentiality claims made by the Applicants and/or the ACCC deciding to exclude material from the register) (the **Meeting Report**).*

The Meeting Report shall report on any discussions, developments and decisions collectively by the Applicants in relation to the Proposed Conduct as the COVID-19 pandemic evolves. The Meeting Report must include, insofar as the following information has not already been provided in a previous Meeting Report:

i. any material recommendations made by the MSSR Working Group;

ii. information regarding the MSSR Working Group meeting(s), including:

- *the attendees at the meeting or discussion;*
- *the agenda items of the meeting or discussion that are related to the Proposed Conduct;*
- *any minutes of the meeting or discussion relating to the Proposed Conduct; and/or*
- *an overview of topics discussed that related to the Proposed Conduct;*

iii. any changes to the Participant group

b) To the extent that the MSSR Working Group meetings may occur more frequently than on a monthly basis, the NPSA will provide to the ACCC, within 5 working days of the relevant meeting, information regarding any material changes to the Proposed Conduct that are not covered by a).

c) The NPSA will provide to the ACCC, within a reasonable timeframe, all information reasonably requested by the ACCC in relation to conduct they have engaged in which constitutes the Proposed Conduct.

b) The proposed fortnightly reporting timeframes does not reflect supply chain cycles for existing restrictions and other operational realities

2.3 It is the Applicants' experience to date that observations about impacts of the restrictions and/or changes to supply restrictions of existing Medicines and Pharmacy Products are unlikely to be observed within a fortnightly cycle. [redacted]

2.4 [redacted]

2.5 [redacted]

2.6 In light of the above considerations, the Applicants consider that the proposed reporting timeframes set out in the amended reporting requirements in section 2 above will allow the ACCC to have sufficient oversight of the Proposed Conduct whilst also accommodating the operational realities faced by the Applicants.

c) The reporting requirements covering all 'working groups' are overly broad

2.7 The proposed reporting requirements may potentially require the Applicants to provide meeting records to the ACCC for MSSR Working Group meetings *and* other Working Groups the Applicants are involved in. The Applicants consider this is overly broad:

i. [redacted]

[2] [redacted]

ii. The meetings of other Working Groups are convened by, and attended by, third parties, in addition to the Applicants. The reports created at these meetings are likely to contain information that is confidential to those third parties. These other Working Groups are subject to confidentiality obligations. The Applicants will therefore not be in a position to provide reports of those meetings to the ACCC without the consent of these third parties. Such a process will impose an undue administrative burden on the Applicants.

2.8 To the extent that the ACCC may require meeting records of other Working Groups, it can directly liaise with the relevant Government agencies to obtain this information. In any event, the Applicants' proposed amended reporting conditions in section 2 above will provide the ACCC with appropriate oversight of all of the Applicants' collaborations as a part of the Proposed Conduct.

d) The ACCC should have regard to the confidentiality/sensitivity of information made available on its register to avoid creating unnecessary consumer concerns regarding the availability of certain essential products

2.9 The ACCC should have regard to the need for public transparency of the Proposed Conduct with the need to avoid publishing information that could induce unnecessary consumer concern regarding the availability of certain Medicines and Pharmacy Products. This is an important part of ensuring that additional supply chain strains are not created or aggravated (particularly if such reports have a flow on impact on consumer behaviour if they become concerned about the availability of Medicines and Pharmacy Products more generally). This would be opposite to the supply chain stabilisation objectives of the NPSA application for Authorisation.

2.10 The Applicants consider there is already a significant level of public transparency regarding the supply chain restrictions as:

i. The TGA publishes regular COVID-19 alerts on its website to inform consumers of prescription restrictions for various Medicines.[3] The introduction of an additional channel for consumers to obtain similar information from the MSSR Working Group meeting minutes may result in unnecessary consumer confusion (particularly where there may be timing differences between the relevant TGA alert and the publication of the MSSR Working Group reports).

ii. [redacted]

[3] See, for example, TGA alert on hydroxychloroquine restrictions in late March 2020: https://www.tga.gov.au/alert/new-restrictions-prescribing-hydroxychloroquine-covid-19#:~:text=Given%20the%20limited%20evidence%20for,the%20treatment%20of%20severely%20ill.

2.11 In light of the above risks, the Applicants consider it would be important for them to be able to make appropriate confidentiality claims and can suggest a high level overview of the topics discussed in place of publishing MSSR Working Group meeting minutes.

[redacted]

3. Responding to concerns raised by the DoH Submission

a) Broad scope of 'Pharmacy Products' and sufficiency of relevant oversight mechanisms

3.1 The Applicants submit that they require the full scope of the Proposed Conduct to ensure the timely and equitable distribution of such products in the event of COVID-19 related supply chain interruptions.

3.2 In addition to the potential difficulties in sourcing particular Medicines, as discussed with the ACCC, there are a number of potential scenarios in the COVID-19 pandemic that could significantly disrupt the Applicants' supply chains, including for Pharmacy Products.

3.3 These scenarios include: [4]

i. potential COVID-19 outbreaks in the Applicants' distribution centre;

ii. potential COVID-19 outbreaks in the Applicants' logistics partners' facilities; and

iii. government decisions that may result in significant increases in demand for/potential supply shortages of, Pharmacy Products.

3.4 [redacted]

[4] For example, see the Applicants' operational update to the ACCC for fortnight ending 31 July 2020 and K&L Gates' email to the ACCC dated 14 July 2020 responding to the ACCC's email of 9 July 2020; and section 2 of K&L Gates' letter to the ACCC dated 27 May 2020.

[redacted]

ii. [redacted]

3.5 It is clear that given the COVID-19 related supply chain interruption scenarios that have materialised and the Applicants' integrated supply chain arrangements that covers both Pharmacy Products and Medicines, any limitation on the scope of 'Pharmacy Products' is impractical. It will also inhibit the ability for the Applicants to coordinate a holistic and timely response to COVID-19 related supply chain challenges.

3.6 It is important to note that the reporting conditions set out in the ACCC's Interim Authorisation and in the Draft Determination involve the Applicants providing ongoing updates to the ACCC on all material developments relating to the Proposed Conduct (including collaborations in respect of Pharmacy Products).[7] The Applicants' proposed amended reporting requirements in section 2 above also continue to reflect their intention to regularly and proactively update the ACCC of all collaborations the Applicants will engage in as a part of the Proposed Conduct.

b) Inclusion of non-CSO pharmaceutical wholesalers and distributors

3.7 The Applicants consider that the scope of the 'Applicants' as defined in the NPSA application for Authorisation dated 27 March 2020 is sufficiently broad as it encompasses future NPSA members as well as other CSO wholesalers.

3.8 [redacted]

3.9 In the absence of further information or consultation regarding the need or interest for non-CSO wholesalers and distributors to join the NPSA application for Authorisation, the Applicants cannot make a considered decision on whether expanding the scope of the Applicants in the manner suggested by the DoH Submission is necessary.

c) Authorisation period

3.10 The DoH Submission considers that the ACCC is proposing to grant authorisation for the Applicants until September 2021 which DoH mistakenly perceives to exceed the 12 month authorisation period applied for by the Applicants.

[redacted]

[7] Refer to clause 21 of the ACCC's Interim Authorisation dated 31 March 2020; clause 5.9 of the ACCC's Draft Determination.

[redacted]

3.11 This misinterpretation may have stemmed from the DoH's assessment of the period from which the authorisation period is calculated being the date that the NPSA application for Authorisation was made rather than the date of the ACCC's final determination (currently slated for September 2021).[9]

3.12 The Applicants confirm that ACCC's proposal to grant the Applicants conditional authorisation until September 2021 is consistent with the authorisation period set out in the Applicants' initial application for Authorisation.[10]

[9] Refer to s91(1A) of the *Competition and Consumer Act 2010* (Cth).
[10] See also section 5.5 of the NPSA application for Authorisation dated 27 March 2020.

[redacted]

Confidential Annexure A

[redacted]