K&L GATES

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Application for Reauthorisation AA1000571-1: Submission in response to Interim Authorisation dated 10 September 2021

1. Summary

1.1 The Applicants seek to provide the ACCC with additional information following its Interim Authorisation dated 10 September 2021 (**Interim Authorisation**) to:[1]

(i) respond to the queries raised in its email to the Applicants dated 21 October 2021 (**Information Request**). The Applicants have extracted the ACCC's questions below in its response for clarity; and

(ii) the issues raised by the Australian Government Department of Health (**DoH**) and the Therapeutic Good Administration (**TGA**)'s submissions dated 5 October 2021 and 8 October 2021 respectively.

1.2 The Applicants summarise their responses/submissions as follows:

(i) the ACCC has had oversight of the Proposed Conduct on a fortnightly basis for over 12 months since the ACCC's Final Determination in the previous authorisation application AA1000480-1 dated 17 September 2020. This has included detailed insight into the nature of any supply chain restrictions imposed by the Applicants and the sequence of events that led to such restrictions being imposed. The Applicants consider the ACCC and key Government stakeholders such as the DoH and the TGA will continue to maintain close oversight of the Proposed Conduct under the Reauthorisation Application;

(ii) the Applicants do not consider that the cessation of the DoH's broad direction to the Applicants to impose COVID-19 related supply chain restrictions on Medicines is likely to materially impact the scope of the Proposed Conduct or the DoH's oversight of the Proposed Conduct;

(iii) the Applicants consider that the scope of the Proposed Conduct is appropriate. The inclusion of Pharmacy Products in the Proposed Conduct is necessary having regard to the fact that there is an integrated supply chain for the delivery of both Pharmacy and Medicines (such that COVID-19 related impacts could affect all such products) to community pharmacies. In addition, the Applicants have responsibly applied the broad scope of Pharmacy Products to date (and will continue to do so);

(iv) in respect of the identity of the proposed participants, in the absence of further information or consultation regarding the need or interest to broaden the scope of the participants in the manner suggested by the DoH, the Applicants cannot make a considered decision on whether such expansion is necessary; and

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[1] For the purpose of clarity, references to 'the Applicants' in this submission are interchangeable with references to both 'Applicant', 'Operating Applicants' and 'Other Participants' in the NPSA reauthorisation application dated 6 September 2021 (**Reauthorisation Application**). All other capitalised terms, unless defined or indicated otherwise, bears the same meaning as set out in the Reauthorisation Application.

(v) the Applicants consider that it is highly likely, given various contextual factors (including the possible endemic nature of the COVID-19 virus), that the Proposed Conduct will be required for the entirety of the 12 month authorisation period proposed in the Reauthorisation Application. More generally, the indicators that are expected to be relevant to cessation of the Proposed Conduct include the restoration of supply chain stability, both locally and internationally for a sustained period, the substantial abating of the COVID-19 pandemic and/or the lack of Government impetus/support for the Proposed Conduct.

2. Response to the ACCC's Information Request

1. Please provide detail about each instance where supply was restricted under the previous authorisation, including the circumstances in which the applicants discussed and imposed the supply restrictions. Specifically, please include:

   (a) Information on the regulatory framework (including the roles of the Department of Health (DOH) and Therapeutic Goods Administration (TGA)) and any relevant standing orders or directions that relate to the ability to impose supply restrictions.

   (b) In relation to the standing order which ended in December, how its end affected conduct under the authorisation.

   (c) When and in what detail were the TGA and DOH notified of any supply restrictions imposed.

2.1 The Applicants have consistently and regularly provided updates to the ACCC regarding the progress of the Proposed Conduct on a fortnightly basis, including by over 20 unredacted fortnightly reports, of which redacted versions are accessible on the ACCC's public register for the NPSA's authorisation application AA1000480-1 (**Previous Authorisation**).[2] The Applicants consider that the ACCC's access to the unredacted versions of these reports, in addition to the Applicants' submissions pursuant to the Previous Authorisation and their fortnightly reports and submissions under the Reauthorisation Application, are a sufficient response to Q1(a) and (c).[3] Included within these fortnightly reports are details of any relevant standing orders or directions that relate to the ability of the Applicants to impose supply restrictions on Medicines and Pharmacy Products. The Applicants will continue to provide such updates to the ACCC on a fortnightly basis pursuant to the reporting condition as set out in paragraph 36 of the ACCC's Interim Authorisation.

2.2 It is also relevant to note that the Applicants have kept the key Government stakeholders, namely the TGA and the DoH, apprised prior to the imposition of supply restrictions under the Previous Authorisation, and will continue to do so under the Reauthorisation Application.

2.3 In the Reauthorisation Application, the Applicants have provided the ACCC with specific examples of scenarios where the Applicants identified a potential COVID-19 related supply issue and informed the DoH/TGA of the need for further action, or where a Medicine

[2] https://www.accc.gov.au/public-registers/authorisations-and-notifications-registers/authorisations-register/national-pharmaceutical-services-association-npsa.

[3] For example, see section 4 of the Reauthorisation Application dated 6 September 2021 which provided an overview of the relevant regulatory framework applicable to the Proposed Conduct.

manufacturer/sponsor has alerted the TGA to a potential Medicine shortage, and in turn the TGA/DoH has alerted the Applicants to impose appropriate supply restrictions.[4]

2.4 [redacted]

2.5 In particular, both the Previous Authorisation and the Reauthorisation Application not only anticipated scenarios where the Applicants will collaborate pursuant to Government directives, but also anticipated scenarios broader than that. These broader scenarios include where the Applicants need to be able to impose appropriate COVID-19 related supply chain restrictions on Medicines and Pharmacy Products due to interruption of downstream logistics chain (for example, at an Applicants' distribution centre or logistics partners' facility as a result of a COVID-19 outbreak).[5]

2.6 [redacted]

2. Detail of any instances in which DOH disagreed with NPSA's supply restrictions and the outcome (if none have occurred, what the outcome would be if a disagreement did occur).

2.7 To date, there have been no instances where the DoH has not agreed with a proposal by the Applicants to impose supply restrictions (pursuant to either the Previous Authorisation or the Reauthorisation Application).

2.8 To the extent that a disagreement may occur between the DoH and the Applicants regarding the above issue in the future, it is likely that the Applicants would seek to negotiate an agreed way forward with the DoH but if this were not possible, would respect (and defer) to the DoH's view, [redacted]

3. Whether there will be any changes to the circumstances in which supply restrictions are imposed and the consequent interactions with the DOH going forward.

2.9 Please refer to the Applicants' response to Q1 above. In essence, the Applicants reassert that there will be no material changes to the circumstances in which supply restrictions are

[4] Both types of scenarios have been described in section 8 of the Reauthorisation Application as part of the Applicants' effort to evidence the public benefits arising from the Previous Authorisation.

[5] See section 5 of the Previous Authorisation and the Reauthorisation Application respectively which sets out the scope of the Proposed Conduct.

imposed or the DoH's oversight of the Proposed Conduct. While the Applicants clarified in the Reauthorisation Application that:

- the scope of Medicines includes COVID-19 Vaccines, booster shots and directly related consumables, and that;

- potential participants in the Proposed Conduct include Other Participants affected by COVID-19 related supply chain issues on an 'as needed basis', including MA/GBMA (and their respective members) for all aspects of the Proposed Conduct other than the NPSA's potential collective negotiations with the DoH,

the Applicants do not consider either of the above aspects will affect their interactions with the DoH going forward or the circumstances under which they will impose supply restrictions. We understand that the Applicants' record of engaging in the Proposed Conduct in a responsible manner and keeping key stakeholders such as the TGA updated on any material implementation of the Proposed Conduct have been recognised by the TGA recently in its meeting with the ACCC on 8 October 2021.[6]

4. Noting these measures under consideration are intended to be temporary - the factors or circumstances that need to occur or change for the conduct to no longer be necessary.

2.10 While the global cessation of the COVID-19 pandemic would be an obvious indicator that the Proposed Conduct is no longer necessary, the Applicants believe that this is unlikely to occur during the next year or two. In particular, Mike Ryan, the Executive Director of the World Health Organisation, has already indicated that the COVID-19 pandemic is likely to become an endemic, similar to the influenza pandemic.[7] With more specific focus on Australia, the Federal National Plan capturing the transition of Australia's national COVID-19 response also indicates that the new phase of COVID-19 management may continue to require highly targeted lockdowns and reflects the continuing unforeseeable risks of new COVID-19 virus strains mutating.[8]

2.11 Overlaying these contextual considerations are the possibilities of local and international supply chain disruptions due to unexpected COVID-19 outbreak clusters, and the need for a national recurring booster shot programs (including potential associated supply issues) for the foreseeable future. In particular, a contributing factor to the foreseeable supply chain strain for both Medicines and Pharmacy Products is COVID-19 related impacts on shipping and port congestions, resulting in cargo log jams which in turn can have flow on consequences for shipping container availability, the precise scope of such impacts difficult to foresee and will take some time to manage effectively.

2.12 Another key contributing factor to COVID-19 related supply chain strain for Medicines is the significant increase in demand for Medicines that have emergent applications in a COVID-19 treatment context, in addition to its traditional use for various non COVID-19 related medical conditions. [redacted]

[6] Refer to paragraphs 3 and 10, https://www.accc.gov.au/system/files/public-registers/documents/Submission%20by%20Therapeutic%20Goods%20Administration%20-%2008.10.21%20-%20PR%20-%20AA1000571%20NPSA.pdf.

[7] https://www.cnbc.com/2021/09/07/who-says-covid-is-here-to-stay-as-hopes-for-eradicating-the-virus-diminish.html.

[8] https://www.pm.gov.au/sites/default/files/media/national-plan-060821_0.pdf.

[redacted] The Applicants anticipate that it is likely that there will be other Medicines that will fall into this category as more sophisticated exploration of the potential use of existing Medicines as part of COVID-19 treatments continue globally. For each such instance, there will likely be a spike in market demand for a period of months which need to be appropriately managed, to ensure that all Australians can access such Medicines in an equitable and timely manner.

2.13 Notwithstanding that the COVID-19 situation may continue to be volatile for the foreseeable future with no clear 'crystal ball' solution in sight, the Applicants consider the following list of non-exhaustive factors may be used as a guidance for when the Proposed Conduct may no longer be needed:

(i) where there have been no material international COVID-19 related supply chain interruptions of Medicines and Pharmacy Products for a reasonable and sustained period;

(ii) where there have been no material domestic supply chain interruptions for Medicines and Pharmacy Products for a reasonable and sustained period;

(iii) where the domestic/Australian COVID-19 circumstances have been sufficiently stabilised such that sudden COVID-19 outbreaks in the Applicants' distribution centres/logistics partners' centres are no longer likely (or can be readily managed);

(iv) where there are no longer Medicine (such as vaccination) responses required to the COVID-19 pandemic; and

(v) where there are no longer any significant Government (e.g. DoH, TGA) impetus for the Applicants to collaborate in respect of Medicines and Pharmacy Products (i.e. lack of key stakeholder support).

5. Why the authorisation needs to extend to 'all other goods available for sale at community pharmacies'. As noted by the DOH, the range of products available at pharmacies is broad and includes consumer goods such as perfumes, cosmetics and even food items. Please also detail any potential issues with using any of the definitions suggested by the DOH and/or suggest an alternative refined definition.

2.14 The Applicants note that the DoH has raised this issue previously in a submission to the Previous Authorisation dated 6 August 2020.[9] The Applicants consider that their previous responses to this issue pursuant to the Previous Authorisation remain relevant.[10] In particular, there are a number of potential scenarios in the COVID-19 pandemic that could significantly disrupt the Applicants' supply chains, including for Pharmacy Products, including:

(i) potential COVID-19 outbreaks at an Applicants' distribution centre; and

(ii) potential COVID-19 outbreaks in the Applicants' logistics partners' facilities.

2.15 The Applicants consider these two scenarios have already materialised during the course of the Previous Authorisation and the Reauthorisation Application, which demonstrate the need for the Proposed Conduct to capture Pharmacy Products in a broad manner:

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[9] https://www.accc.gov.au/system/files/public-registers/documents/Submission%20by%20Department%20of%20Health%20-%2006.08.20%20-%20PR%20-%20AA1000480%20NPSA.pdf.

[10] https://www.accc.gov.au/system/files/public-registers/documents/Submission%20by%20Applicant%20-%20response%20to%20Draft%20determination%20-%2025.08.20%20-%20PR%20-%20AA1000480%20-%20NPSA.pdf.

(i) [redacted]

(ii) [redacted]

[redacted]

2.16 As a practical matter, the Applicants have not imposed any supply chain restrictions on Pharmacy Products (for the entire duration of the Previous Authorisation) or to date under the Reauthorisation Application. However, the Applicants have discussed and considered the need to impose supply chain restrictions for particular Pharmacy Products such as [redacted] The Applicants continue to require the ability to impose such restrictions if required, so as to appropriately address the community's needs during the COVID-19 pandemic. The Applicants have not considered or imposed supply restrictions for Pharmacy Products that are household goods generally available in other retail environments (such as toilet paper and discretionary good items) and other discretionary consumer goods. The Applicants are applying the Proposed Conduct in respect of Pharmacy Products in a narrow and sensible manner. However, the potential for the scenarios in 2.14 to be realised (and the fact that they have been realised as evidenced in 2.15) means it is important for the Proposed Conduct to cover Pharmacy Products as defined in the Reauthorisation Application.

2.17 We understand that the TGA explicitly expressed support for the Reauthorisation Application, when it engaged with the ACCC on 8 October 2021 noting that it considers the scope of the Pharmacy Products (as currently defined) is appropriate. In particular, the TGA noted that "*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.*"[11] The Applicants support this observation and consider that there are no satisfactory alternatives for a narrower definition of Pharmacy Products having regard to the above considerations. The Applicants also consider any narrowing of the definition of Pharmacy Products is unduly warranted having regard to the close oversight the ACCC (and other key Government stakeholders) will have over the Proposed Conduct.

6. Whether any Government representatives are entitled or invited to attend the monthly meetings.

2.18 While no Government representatives have been invited to attend the MSSR Working Group monthly meetings, both the DoH and the TGA are updated on any key decisions arising from

[11] https://www.accc.gov.au/system/files/public-registers/documents/Submission%20by%20Therapeutic%20Goods%20Administration%20-%2008.10.21%20-%20PR%20-%20AA1000571%20NPSA.pdf.

these meetings. Conversely, where possible, the MSSR Working Group (including the Applicants) also seeks to have regard to any concerns that the DoH or TGA may have in its decision making.

2.19 As the ACCC may be aware, at the commencement of the Previous Authorisation, the MSSR Working Group participated in broader working group meetings convened by the TGA and essentially 'reported' their decisions for discussion at these broader working groups.

2.20 While the broader TGA-convened working group has not met since August 2021, as a practical matter, the NPSA's Executive Director communicates with the TGA and DoH representatives regularly and prior to the monthly MSSR Working Group meetings. In doing so, the NPSA is ensuring that both Government stakeholders are apprised of any relevant issues and any outstanding queries/comments these stakeholders may have can be promptly communicated and considered at the monthly meeting.

2.21 Outside of the formal discussion forums outlined above and as outlined in Q1 response, the Applicants have consistently, and collaboratively, involved Government representatives in key supply chain restriction discussions. By way of illustrative examples:

[redacted]

- [redacted]
- [redacted]

[redacted]

3. Other comments regarding interested parties' submissions

3.1 The Applicants consider that they have responded to the key issues raised by the interested parties' submissions to the ACCC's Interim Authorisation decision pursuant to the Reauthorisation Application above. For completeness, the Applicants will address two additional points raised in the DoH and the TGA's submission below.

3.2 The DoH submission observed that there are a number of other non-CSO pharmaceutical wholesalers and distributors that supply essential Medicines and Pharmacy Products and that it "*welcomes the opportunity for current, future, and non-NPSA member to participate under the Authorisation if they choose.*" The Applicants note that the DoH has made a similar comment in its submission to the Previous Authorisation dated 6 August 2020, and the Applicants' previous response remains relevant. Having regard to this, the Applicants make the following points:[12]

(i) the identity of the Participants as defined in the Reauthorisation Application dated 6 September 2021 is sufficiently broad as it encompasses future NPSA members, other

[12] Please refer to paragraphs 3.7 - 3.9 of the Applicants' submission to the Previous Authorisation.

CSO wholesalers as well as Other Participants on an 'as needed basis' as set out in section 2.2 of the Reauthorisation Application, including:

- MA (and its members); and/or
- GBMA (and its members); and/or
- other manufacturers/sponsors of Medicines and manufacturers of Pharmacy Products;

(ii) the Applicants have invited the two other current CSO wholesalers in Australia, being Clifford Hallam Healthcare Pty Ltd and Barrett Wholesalers Distributors Pty Ltd, to participate in the Previous Authorisation. However, neither of the wholesalers have expressed an interest in participating in the Previous Authorisation or the Reauthorisation Application; and

(iii) in the absence of further information or consultation regarding the need or interest for non-CSO wholesalers and distributors to join the Reauthorisation Application, the Applicants cannot make a considered decision on whether expanding the scope of the participants in the manner suggested by the DoH submission is necessary or appropriate.