## Provisional Consent to the Distribution of a New Medicine

Pursuant to section 23(1) of the Medicines Act 1981, the Minister of Health hereby provisionally consents to the sale, supply or use in New Zealand of the new medicine set out in the Schedule hereto:

**Schedule**

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|---|---|
| ***Product:*** | **COVID-19 Vaccine Janssen** |
| *Active Ingredient:* | Ad26.COV2.S 100GVP/mL |
| *Dosage Form:* | Suspension for injection |
| *New Zealand Sponsor:* | Janssen-Cilag (New Zealand) Limited |
| *Manufacturers:* | Grand River Aseptic Manufacturing Inc, Michigan, United States of America<br>Catalent Indiana LLC, Indiana, United States of America |

Provisional consent is to be granted for nine months.

This consent is given subject to the following conditions:

This vaccine may only be sold to the New Zealand Government and distributed in accordance with the New Zealand Government's COVID-19 vaccine rollout or donated to other countries.

The New Zealand Sponsor must fulfil the following obligations within the timelines specified, the dates of which may be altered by mutual agreement with Medsafe:

1. Prepare a "Dear Healthcare Professional" letter or comparable instructive material and provide this to Medsafe for review and approval prior to distribution of this product. Due date: 14 July 2021.

2. The New Zealand site of batch release will only release batches for distribution in New Zealand once the sponsor has verified that the shipping temperature profile meets specifications.

3. Provide Certificates of Analysis to Medsafe for the first three batches of vaccine intended to be distributed in New Zealand prior to distribution.

4. Provide independent batch certification, such as UK National Institute for Biological Standards and Control (NIBSC) certification, EU Official Control Authority Batch Release (OCABR) certification, Australian TGA batch release assessment, or any other certification agreed with Medsafe, on request for all batches distributed in New Zealand.

5. Provide additional data to support the biochemical stability of 50L scale drug substance process intermediates. Due date: 31 December 2021.

6. Provide data to support drug substance manufacture in Street C of the JVL site before implementation via a Changed Medicine Notification. Due date: 30 September 2021.

7. Provide the validation data of the third process validation inoculum batch produced at the JBL site. Due date: 31 December 2021.

8. Provide additional Tier 2 comparability data that confirm 900L scale S-VLF-1/2 drug substance batches manufactured at the JBL site are comparable to 50 L scale material manufactured at the JVL site. Due date 31 July 2021.

9. Provide Tier 2 comparability data to confirm 900L scale drug substance batches manufactured at EBS are comparable to drug substance manufactured at the other commercial sites. Due date 31 July 2021.

10. Provide the results of the re-evaluation of the drug substance and drug product specifications and notify Medsafe of any consequential changes using Changed Medicine Notifications. Due date: 31 December 2021.

11. Provide additional drug substance stability data for the clinical and commercial drug substance batches 20E25-07, 20E25-14, 20G30-08, 964728, 967128, 967591, 969009, 21003042, 21003117 and 21003533 as it becomes available.

12. Provide the results from forced degradation studies performed as part of the comparability analysis between clinical and commercial drug product batches. Due date: 31 July 2021.

13. Provide the Tier 2 comparability data that confirms drug product manufactured at the GRAM site can be considered comparable to the Phase 3 clinical drug product. Due date: 31 July 2021.

14. Provide the results generated in the leachables study of three drug product batches stored inverted at -20°C, 2-8°C and under accelerated (25°C) storage conditions. Due date: 31 December 2021.

15. Provide the results from bulk homogeneity verification during formulation and sterile filtration and filling at the GRAM and Catalent drug product manufacturing sites. Due date: 31 July 2021.

16. Provide a requalification media fill study for the GRAM site and confirm if the GRAM site plans on performing media fill studies with the proposed 2R vial. Due date: 31 July 2021.

17. Provide Tier 2 comparability data that confirms drug product manufactured at the Catalent site can be considered comparable to the Phase 3 clinical drug product. Due date: 30 September 2021.

18. Provide an acceptance criterion for drug product polydispersity. Due date: 31 December 2021.

19. Provide cleaning reports for the process dedicated production bioreactor or a process dedicated alternating flow filter unit used at the JVL site to manufacture 50L scale drug substance batches, and the JBL site to manufacture 900 L scale drug substance batches. Due date: 30 September 2021.

20. Provide further efficacy and safety data from studies COV3001 (and data from COV3009). Due date: 30 September 2021.

21. Provide any reports on the requirement for and timing of booster doses within five working days of these being produced.

22. Provide the final Clinical Study Report for the randomised, placebo-controlled, observer-blind study VAC31518COV3001 within five working days of it being produced.

23. Provide Periodic Safety Update Reports according to the same schedule as required by the EMA.

24. Provide monthly safety reports, as well as all safety reviews they conduct or become aware of.

25. Perform the required pharmacovigilance activities and interventions detailed in the agreed RMP and any agreed updates to the RMP. An RMP should be submitted at the request of Medsafe or whenever the risk management system is modified, especially as the result of new information being received that may lead to a significant change to the benefit/risk profile or as the result of an important milestone being reached.

Dated this 5th day of July 2021.

CHRIS JAMES, Group Manager, Medsafe, Ministry of Health (pursuant to delegation given by the Minister of Health on 11 September 2013).

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