

## Renewal of Provisional Consent to the Distribution of a Medicine

Pursuant to section 23(4A) of the Medicines Act 1981, the Minister of Health hereby renews the provisional consent to the sale, supply or use in New Zealand of the medicine set out in the Schedule hereto:

### Schedule

|                             |   |
|-----------------------------|---|
| <b>Product:</b>             | <b>JYNNEOS</b>  |
| <i>Active Ingredient:</i>   | Modified vaccinia Ankara - Bavarian Nordic (MVA-BN) virus 0.1GVP/mL |
| <i>Dosage Form:</i>         | Suspension for injection  |
| <i>New Zealand Sponsor:</i> | Pharmacy Retailing (NZ) Limited t/a Healthcare Logistics            |
| <i>Manufacturer:</i>        | Bavarian Nordic A/S, Kvistgard, Denmark                             |

*Note:* This consent is given subject to the following conditions:

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. Batches manufactured after 2022 intended for distribution in New Zealand must be manufactured and tested according to the same process and specifications, at the same sites, as batches manufactured in 2022. Any changes made to the product since 2022 must be submitted as a Changed Medicine Notification pursuant to section 24 of the Medicines Act 1981. This includes changes to manufacturing sites and process, changes to testing or release specifications, introduction of additional pack sizes, changes to master/working viral seed bank manufacture/qualification, and changes to the primary reference standard.
2. Provide PBRERS to Medsafe within one month of these being submitted to the EMA.
3. Ensure that information regarding safety signals is received from the manufacturer and provide this to Medsafe in a timely fashion.
4. Ensure that suspected adverse reaction reports are collected and provide these to the Centre for Adverse Reaction Monitoring.
5. Provide the results of any efficacy studies required by the EMA.

*Note:* This renewed consent is valid for two years from 11 March 2025.

Dated this 10th day of March 2025.

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