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

Product:	**Paxlovid**
Component 1:	
Active Ingredient:	Nirmatrelvir 150mg
Dosage Form:	Film coated tablet
Component 2*:*	
Active Ingredient:	Ritonavir 100mg
Dosage Form:	Film coated tablet
New Zealand Sponsor:	Pfizer New Zealand Limited
Manufacturers:	AbbVie Deutschland GmbH & Co KG, Ludwigshafen, Germany Pfizer Manufacturing Deutschland GmbH, Freiburg, Germany

Provisional consent is granted for a period of two years.

This consent is given subject to the following conditions.

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

1. Confirm the synthetic route used to manufacture starting materials used in commercial manufacture and provide relevant discussion of possible impurities, carry-over reagents and solvents from the process. Due date: 30 September 2022.
2. Provide revised starting material specifications with appropriate limits for each impurity, and any other tests such as for residual solvents. Due date: 30 September 2022.
3. Provide an updated set of intermediate specifications, which include an identification parameter and any further tests (impurities, reagents or solvents) as required. Due date: 30 September 2022.
4. Provide details of further in-process controls to be used in the drug substance manufacturing process. Due date: 30 September 2022.
5. Provide a risk assessment and batch testing data for carry-over benzene in the drug substance. Due date: 30 September 2022.
6. Provide full method validation in line with ICH Q2 for the assay/identification/achiral impurity test, which should include specific discussion of validation for each impurity. Due date: 30 September 2022.
7. Provide 12-month stability data for primary drug substance batches manufactured by Route F and G. Due date: 31 March 2023 and 30 June 2023.
8. Provide the results of further studies for the nirmatrelvir substance particles size. Due date: 30 September 2022.
9. Provide an update from the continued assessment of the necessity to include microbiological tests in the drug product specifications. Due date: 30 September 2022.
10. Provide process validation data along with the manufacturing process validation protocol for the maximum scale commercial batches of the nirmatrelvir 150mg film-coated tablets. Due date: 30 September 2022.
11. Provide the results of additional studies for the formulation and manufacturing process development, critical steps and intermediates. Due date: 30 September 2022.
12. Provide the results of studies for the hold times to be implemented to the manufacturing process. Due date: 30 September 2022.
13. Implement a suitability justified control limit for assay at release and expiry. Due date: 30 September 2022.
14. Continually review the dissolution acceptance criteria as additional batch experience is gained and provide in vitro and in vivo data to justify the final control limit. Due date: 30 September 2022.
15. Provide 6-month and 12-month stability data from the three primary drug product batches. Due dates: 31 March 2022 and 30 September 2022.
16. Provide confirmatory clinical trial data as identified in the sponsor’s plan to submit comprehensive safety and efficacy data within six years from consent being granted within five working days of any reports being produced.

17. Provide updates regarding the clinical activity, efficacy, and effectiveness against the current and future Variants of Concern and Variants of Interest identified by the World Health Organization (WHO) within five working days of any reports being produced.
18. Provide further data relating to efficacy in immunocompromised subjects, pregnant women, lactating mothers, paediatric subjects, patients with hepatic impairment as well as additional pharmacology and long-term safety data and information relating to post-market safety and efficacy studies with five working days of any reports being produced.
19. Provide long-term data from study C4671005 (i.e. at Week 34) to ensure that no further events onset potentially impacting the main outcomes. Due date: 30 September 2022.
20. Provide interim reports for study 1002 and 1006. Due date: 30 June 2022.
21. Provide the final study reports for ongoing studies proposed in the clinical development plan: study 1010, 1012, and 1013 within five working days of the reports being produced

Dated this 1st day of March 2022.

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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