Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

PMF File No: 2012/008467
Submission No: PMF 24-0027

The Managing Director
CSL Behring (Australia) Pty Ltd
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cc: Iris.Mcgregor@cslbehring.com.au

Our Reference: D24-5024194

Dear Sir/Madam

Subject: Compliance with condition on Manufacturing Licence No. 49211 - PMF Taiwan (Type II)

Compliance with the Therapeutic Goods (Manufacturing Principles) Determination No. 1 of 2020 is a condition of the CSL Behring (Australia) manufacturing licence No 49211. The manufacturing principles for plasma include a requirement for licensees of blood processing plants that are to be used to process any plasma collected from a source outside Australia to submit a Plasma Master File (PMF) to the Secretary in relation to that particular source. The manufacturer must also obtain from the Secretary, prior to processing, advice that such plasma will not contaminate the Australian product with any blood borne pathogens.

The current Secretary's advice to CSL Behring in relation to the foreign plasma source covered by the CSL Behring Type II PMF expired on 30 November 2024 and extension beyond this date was subject to evaluation of the annual update of this PMF. In relation to the PMF annual update submitted by CSL Behring on 30 August 2024, TGA considers that the evaluation process is now complete.

The PMF annual update was assessed to be in accordance with the EMA Guideline on the scientific data requirements for a Plasma Master File (EMEA/CPMP/BWP/3794/03 Rev.1), and the Guideline on epidemiological data on blood transmissible infections (EMA/CHMP/BWP/548524/2008 Rev.1), both adopted by the TGA. The epidemiological data and changes contained within the submission have been evaluated and found to be acceptable.

Considering the PMF submitted and the plant's processes, I advise that this plasma is unlikely to present a risk of contamination to the Australian product with any known foreign blood borne pathogens. This advice is current until 30 November 2025. Please note that this letter does not constitute permission to fractionate Taiwan plasma for products supplied in the Australian market.

If CSL Behring (Australia) seeks to renew the Secretary's advice, please ensure that the updated PMF is prepared in accordance with the Manufacturing Principles and includes epidemiological data for the period 1 January 2024 and 31 December 2024. To allow

sufficient time to assess, please submit the updated PMF to the Secretary by 31 August 2025.

Sincerely

[signed electronically]

Drew Wagner

Delegate of the Secretary
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3 December 2024