

Module 1.0.1: Cover Letter

FarmaMelb Ltd.
Dixon Street, Malvern VIC

9 January 9, 2026

To: The Delegate of the Secretary Medicines Authorisation Branch Therapeutic Goods Administration PO Box 134, Woden VIC 3144 Australia

SUBJECT: Submission of Initial eCTD Sequence (0000) for Amoxicillin Oral Suspension (eIdentifier: e123456)

Dear Delegate,

1. Description of Submission FarmaMelb Ltd. is pleased to submit a Category 1 Application for the registration of a new generic medicine: **Amoxicillin 250 mg/5 mL powder for oral suspension**. This submission seeks to include the product in the Australian Register of Therapeutic Goods (ARTG).

2. Regulatory Information

- **Submission Number:** PM-2026-00123-1 (Allocated via Pre-submission Planning Form)
- **Regulatory Activity Category:** Category 1
- **Regulatory Activity Type:** New Generic Medicine (Section 23)
- **Trade Name:** AmoxiForte
- **Active Ingredient:** Amoxicillin (as Trihydrate)
- **Dosage Form:** Powder for Oral Suspension
- **Strengths:** 250 mg / 5 mL (when reconstituted)
- **AUST R Numbers:** N/A (New registration)

3. Previous Evaluations No studies included in this dossier have been previously evaluated by the TGA. All data provided represents original validation and stability studies conducted by the applicant.

4. Electronic Dossier Characteristics

- **eIdentifier:** e123456
- **Sequence Number:** 0000 (Initial)
- **Media Type:** Secure Electronic Upload (TGA Business Services Portal)
- **Submission Size:** Approximately 450 MB
- **Number of Media:** 1 (Digital upload)

5. Technical Contacts

- **Regulatory Point of Contact:** Georgios Sopasis | Ph: +61 423407650 | Email: sopasis@gmail.com
- **IT Point of Contact:** Michael Jakson | Ph: +61 423407650 | Email: Michael_J@hotmail.com

6. Virus Statement and Validation We certify that the electronic files provided in this sequence are virus-free. The dossier was scanned using **McAfee Endpoint Security (Version 22.23)**.

The dossier was validated using the **LORENZ docuBridge (Version 23.xx)** validation tool. The validation report is included in this sequence. There are no "High" or "Medium" severity errors reported; all "Low" severity warnings relate to specific legacy document formatting and do not impact the navigability of the eCTD.

Yours Sincerely,

My singature

Georgios Sopasis BSc (Hons) Authorised Regulatory Officer FarmaMelb Ltd.