



Therapeutic Goods (Technical Master File and Type II Plasma Master File—Application Form) Approval 2026

I, Nick Henderson, as delegate of the Secretary of the Department of Health, Disability and Ageing, make the following approval.

Dated 12 October 2026

Nick Henderson
First Assistant Secretary
Medicines Regulation Division
Health Products Regulation Group
Department of Health, Disability and Ageing

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1 Name

This instrument is the *Therapeutic Goods (Technical Master File and Type II Plasma Master File—Application Form) Approval 2026*.

2 Commencement

- (1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information		
Column 1	Column 2	Column 3
Provisions	Commencement	Date/Details
1. The whole of this instrument	The day after this instrument is made.	13 October 2026

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

- (2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

This instrument is made under subclause 2(3)(a) of Schedule 5A to the *Therapeutic Goods Regulations 1990*.

4 Definitions

Note: A number of expressions used in this instrument are defined in subsection 3(1) of the Act, including the following:
(a) Secretary.

In this instrument:

Act means the *Therapeutic Goods Act 1989*.

plasma master file means a plasma master file mentioned in or covered by clauses 2 to 5 of Schedule 5A of the TG Regulations.

technical master file means a technical master file mentioned in or covered by clauses 2 to 5 of Schedule 5A of the TG Regulations.

TG Regulations means the *Therapeutic Goods Regulations 1990*.

5 Approved form—technical master file

The approved form for applying to the Secretary for:

- (a) approval of a new technical master file under subclause 2(1)(a) of Schedule 5A to the TG Regulations; or
- (b) an annual update to a technical master file that has been approved under subclause 2(1)(a) of Schedule 5A to the TG Regulations, under subclause 2(2)(a) of Schedule 5A to the TG Regulations; or
- (c) a significant update to an approved technical master file that has been approved under subclause 2(1)(a) of Schedule 5A to the TG Regulations, under subclause 2(2)(b) of Schedule 5A to the TG Regulations

is the online form titled *Application form for a Technical Master File (TMF)* available on the Therapeutic Goods Administration website, as in force or existing at commencement.

Note: The Therapeutic Goods Administration website can be accessed at www.tga.gov.au.

6 Approved form—plasma master file

The approved form for applying to the Secretary for:

- (a) approval of a new plasma master file under subclause 2(1)(b) of Schedule 5A to the TG Regulations; or
- (b) an annual update to a plasma master file that has been approved under subclause 2(1)(b) of Schedule 5A to the TG Regulations, under subclause 2(2)(a) of Schedule 5A to the TG Regulations
- (c) a significant update to an approved plasma master file that has been approved under subclause 2(1)(b) of Schedule 5A to the TG Regulations, under subclause 2(2)(b) of Schedule 5A to the TG Regulations

is the online form titled *Application form for a Type II Plasma Master File (PMF)* available on the Therapeutic Goods Administration website, as in force or existing at commencement.

Note: The Therapeutic Goods Administration website can be accessed at www.tga.gov.au.