Australian Government
Department of Health
Therapeutic Goods Administration

Office use only

Submission dossier checklist for prescription medicines

The submission dossier checklist is not mandatory for the submission of applications, however it can be used to assist you to standardise the format, packaging and dispatch of both hard copy and electronic copy submission dossiers.

If you are including a completed version of this checklist with your submission, include it in Module 1, box 1 of your submission.

Contact details

Company name	
Submission number	
Person preparing submission dossier	
Position / Title	
Phone number	
Mobile number	
Facsimile	
E-mail address	

1. Physical format

Note: Only tick boxes in the 'Sponsor' column. The 'TGA' column will be used to cross check items when they are received by the TGA.

Step	Detail	Sponsor	TGA
1.1	The submission contains the required number of complete hard and electronic copies of the submission dossier.	☐	☐
1.2	Letter of Application contains a declaration that the hard copy and electronic copy of the submission dossier submitted to the TGA are identical (or if not identical, a specification of the differences between them).	☐	☐
1.3	Letter of Application or cover letter contains the submission number, and a module and volume count.	☐	☐
1.4	All data (including responses to TGA requests for information) that exceed twenty (20) pages is lodged in a binder (volume).	☐	☐
1.5	For Category 1 and 2 applications (other than applications for additional trade names), documents from different CTD modules are in separate volumes.	☐	☐
1.6	The following information is included on the front and side labelling for each volume:		
	Name of sponsor	☐	☐
	Name of medicine	☐	☐
	AAN of the active substance(s)	☐	☐
	Submission ID	☐	☐
	Module and volume number	☐	☐
	Copy number (if applicable)	☐	☐
	Contents of the volume	☐	☐
1.7	The volumes of each module are numbered separately and sequentially using the format: *x of y volumes*.	☐	☐
1.8	The external dimensions of the binders do not exceed: 270 mm wide x 320 mm high x 80 mm thick.	☐	☐

2. Electronic format & security

Step	Detail	Sponsor	TGA
2.1	The electronic copy of the submission dossier is on either CD-R or DVD-R, and discs are:		
	Single-sided	☐	☐
	Single or dual layered	☐	☐
	Archival quality	☐	☐
2.2	The electronic copy of the submission is on the smallest number of discs possible.	☐	☐
2.3	Individual CTD modules have not been split over multiple CDs or DVDs.	☐	☐
2.4	Zipped files have not been used.	☐	☐
2.5	Each disc and case is labelled with the following information:		
	Name of sponsor	☐	☐
	Name of medicine	☐	☐
	AAN of the active substance(s)	☐	☐
	Submission ID	☐	☐
	Format: NeeS	☐	☐
	The four digit number(s) used for the NeeS contained on the CD/DVD (0000 or a sequential number).	☐	☐
2.6	All security requirements have been met.	☐	☐

3. Packaging and dispatch

Step	Detail	Sponsor	TGA
3.1	Boxes are of a quality sufficient to protect the contents from damage in transit.	☐	☐
3.2	Applications consisting of more than two (2) binders are boxed.	☐	☐
3.3	Boxes are packed with the spines to the sides or bottom of the box.	☐	☐
3.4	Binders containing the submission dossier are not overfilled.	☐	☐
3.5	Polystyrene beads, packaging foam peanuts or other loose materials have not been used for packaging.	☐	☐
3.6	The weight of any box does not exceed 16 kilograms.	☐	☐
3.7	All boxes are clearly labelled identifying their contents (including type of submission).	☐	☐
3.8	Each box is numbered sequentially with box 1 containing volume 1 of Module 1.	☐	☐
3.9	Submission dossiers of ten (10) boxes or more are shipped using a pallet(s).	☐	☐
3.10	Boxes are stacked on a pallet in reverse numerical order with the first box (box 1) clearly identified and at the top of the pallet.	☐	☐