NSW Health

Supplementary Pages to an Application for a Licence to Manufacture or Supply by Wholesale Cannabis Products

Poisons and Therapeutic Goods Act 1966 and Poisons and Therapeutic Goods Regulation 2008

This document is to be submitted with any application for a licence to manufacture and/or supply by wholesale cannabis products.

Key requirements

- You must assess if the product is a therapeutic good. Please refer to information published by the Therapeutic Goods Administration regarding assessment of a good for therapeutic use, or consult with a Regulatory Affairs Consultant to assist you in assessing the product.

- You must confirm that the product is not a food or a cosmetic. Products classified as a food or a cosmetic cannot be manufactured or supplied by wholesale under this licence.

- You must assess if the product is in Schedule 4 or in Schedule 8 of the Poisons Standard (SUSMP) and complete the appropriate licence application.
  Please refer to information published by the Therapeutic Goods Administration or consult with a Regulatory Affairs Consultant to assist you in assessing the product.

- You must submit a Certificate of Analysis (CoA) for each product you are applying for (or Finished product Specifications). This must state the cannabinoid content of the product that determines the schedule of the product.
  Note: A cannabis product is in Schedule 4 if the cannabidiol content is ≥98% of total cannabinoid content. If the product is not for human therapeutic use, it is in Schedule 9 and cannot be manufactured or supplied by wholesale under this licence.

- The product must comply with TGO 93 – Standard for Medicinal Cannabis.

For information on approval for import and/or export of cannabis products please refer to information published by the Office of Drug Control or consult with a Regulatory Affairs Consultant.

Details of the product(s)

No.	Name of Product	THC (mg)	CBD (mg)	Total Cannabinoid content (mg)	Therapeutic Good for human therapeutic use (Y/N)	ARTG product (Y/N)	Poisons Schedule of product	Compliance to TGO93 (Y/N)	CoA supplied (Y/N)
1									
2									
3									
4									
5									
6									
7									
8									
9									
10									
11									
12									
13									
14									
15									
16									
17									
18									
19									
20									

Declaration by applicant or agent on behalf of applicant

If signing on behalf of the applicant, please state in what capacity.

☐ I declare that all the information I have given in this document is true to the best of my knowledge and belief.

☐ Privacy Statement: I understand that the NSW Ministry of Health will secure and protect information provided in this document. I acknowledge that the Ministry may disclose any or all of the contents of this document and information provided with it, including personal information as defined in the *Privacy and Personal Information Protection Act 1988*, to law enforcement and regulatory agencies in the Commonwealth, States and Territories as necessary, in order to ensure compliance with all laws and regulations.

Print Name:	Position:
Signature:	Date: