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*

Complete these supplementary pages if you are applying to manufacture and/or supply by wholesale cannabis products.

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.

You must assess if the product is in Schedule 4 or in Schedule 8 of the NSW Poisons List or Poisons Standard and use the appropriate application form. 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 will need to furnish a Certificate of Analysis that shows the total cannabinoid content of the product to be able to determine the schedule of the product. 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. The Therapeutic Goods Administration will require you to certify compliance to the Standard before the product can be supplied.

Some governments do not allow the export of cannabis products. Approval must be granted by the national governments of both the importing and exporting countries. Please refer to information published by the Office of Drug Control or consult with a Regulatory Affairs Consultant to assist you in the import and export of the cannabis product.
If you hold a licence to manufacture under the *Narcotic Drugs Act 1967* and/or the *Therapeutic Goods Act 1989*, or if you hold a Customs Licence to import, you must provide a copy of the licence.

SECTION I

Purpose of application

☐ Application for a licence to supply by wholesale a cannabis product in Schedule 4 (restricted substance)

☐ Application for a licence to supply by wholesale a cannabis product in Schedule 8 (drug of addiction)

☐ Application for a licence to manufacture or supply by wholesale a cannabis product in Schedule 8 (drug of addiction)

SECTION II

Details of the product(s)

1. Name of the cannabis product(s) [add separate pages if the space provided is insufficient]

Product 1:

Product 2:

Product 3:

2. Classification of the product in Australia [For information see Therapeutic Goods Administration]

Product 1: ○ therapeutic good for human therapeutic use ○ food or cosmetic → do not use this form

Product 2: ○ therapeutic good for human therapeutic use ○ food or cosmetic → do not use this form

Product 3: ○ therapeutic good for human therapeutic use ○ food or cosmetic → do not use this form

3. Registration on the Australian Register of Therapeutic Goods (ARTG)

Product 1: ○ Yes → ARTG ID: _____ ○ No (unregistered)

Product 2: ○ Yes → ARTG ID: _____ ○ No (unregistered)

Product 3: ○ Yes → ARTG ID: _____ ○ No (unregistered)

4. Active cannabinoid content of each product [provide a Certificate of Analysis for each product]

Product 1: THC _____ mg CBD _____ mg Other _____ mg Total cannabinoid content _____ mg

Product 2: THC _____ mg CBD _____ mg Other _____ mg Total cannabinoid content _____ mg

Product 3: THC _____ mg CBD _____ mg Other _____ mg Total cannabinoid content _____ mg

5. Schedule of each product [Note: Schedule 4 when CBD is ≥98% of total cannabinoid content]

Product 1: ◯ Schedule 4 ◯ Schedule 8 ◯ Schedule 9 → do not use this form

Product 2: ◯ Schedule 4 ◯ Schedule 8 ◯ Schedule 9 → do not use this form

Product 3: ◯ Schedule 4 ◯ Schedule 8 ◯ Schedule 9 → do not use this form

6. Source of cannabis products (Importation)

Cannabis products to be imported? ◯ Yes ◯ No [If yes provide copy of Customs Licence]

Are the imported products finished products? ◯ Yes ◯ No ◯ N/A

Are the imported products active pharmaceutical ingredients for manufacture? ◯ Yes ◯ No ◯ N/A

Will the overseas government allow exportation of the cannabis product? ◯ Yes ◯ No ◯ N/A

7. Source of cannabis products (Supply from another Australian State or Territory)

Cannabis products to be supplied from another Australian State or Territory? ◯ Yes ◯ No

Are the products finished products? ◯ Yes ◯ No ◯ N/A

Are the products active pharmaceutical ingredients for manufacture? ◯ Yes ◯ No ◯ N/A

8. Source of cannabis products (Cultivation in Australia)

Cannabis to be cultivated in Australia? ◯ Yes ◯ No

9. Compliance to TGO 93 Standard for Medicinal Cannabis

Products comply with TGO 93 ◯ Yes ◯ No

SECTION III

Documents and information to include with the application

Supporting documents:

- ☐ Certificate of Analysis for each product (or Finished Product Specifications)
- ☐ Licence to manufacture under the *Narcotic Drugs Act 1967*
- ☐ Licence to manufacture under the *Therapeutic Goods Act 1989* (GMP Licence)
- ☐ Customs licence to import under the *Customs (Prohibited Imports) Regulation 1956*

SECTION IV

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 on this application form is true to the best of my knowledge and belief.

I enclose the prescribed licence application fee.

Privacy Statement: I understand that the NSW Ministry of Health will secure and protect information in, and attached to, this application. I acknowledge that the Ministry may disclose any or all of the contents of this application 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: