NSW Health

Application for Authority to Prescribe or Supply an Unregistered or (Pharmacy) Extemporaneously – Compounded Schedule 8 Product for Human Therapeutic Use

as required under the Poisons and Therapeutic Goods Act 1966 (NSW)

This application is to be used for:

- **unregistered Schedule 8 medicines other than cannabis medicine**
- **any extemporaneously – compounded Schedule 8 products**

If you hold a valid NSW Ministry of Health **authority** to prescribe or supply a Schedule 8 medicine then you do not need to apply for additional authority to prescribe or supply an extemporaneously compounded form of that same medicine. This means you **DO NOT** need a separate authority. Please write your existing authority number on the prescription. Failure to write the authority number on the prescription for an extemporaneously compounded schedule 8 medicine will render it invalid.

Australian Register of Therapeutic Goods (ARTG).

The NSW Ministry of Health recommends that preference be given to the use of medicines listed on the ARTG. Unregistered and compounded medicines have not been evaluated by the Therapeutic Goods Administration (TGA) for safety or efficacy and should only be used when a suitable ARTG medicine is not available.

Before starting the application, please make sure that you have:

- **Approval from the Therapeutic Goods Administration (TGA) Special Access Scheme (SAS)** if the product is a proprietary product being imported from overseas. Approval from the TGA is not required for Pharmacy extemporaneously – compounded products
- **Contacted the authorised Opioid Treatment Program prescriber** if the patient is currently enrolled on the Opioid Treatment Program (OTP) and have obtained written agreement from the OTP prescriber supporting treatment
- **Sought a review and obtained a second opinion from an appropriate medical specialist if** for extemporaneously-compounded products the indication for use does not match the ARTG listed equivalent medicine

Where possible the second opinion should be in writing from an appropriate medical specialist independent of the prescriber.

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Clinical Advice and Support

The NSW Ministry of Health recommends the use of **SafeScript NSW** to assist practitioners to make informed clinical decisions https://www.safescript.health.nsw.gov.au/. Consider checking **SafeScript NSW** for evidence of alerts or other issues related to the prescribing and supply of high-risk monitored medicines.

Applicants can contact experienced clinical advisors and can access relevant medical specialists to obtain general clinical advice and support when managing patients, by calling the free ***SafeScript NSW Clinical Advice Line (SCAL)*** on ***1800 434 155***, available 24/7. **This advice line cannot provide support for an application for an authority.**

Applicants are advised to consider if the patient would benefit from a review by an **addiction medicine specialist** to manage any perceived drug dependence concerns.

Applicants can contact experienced clinical advisors and addiction medicine specialists to obtain general clinical advice and support when managing patients with drug and alcohol issues, by calling the free **Drug & Alcohol Specialist Advisory Service (DASAS)** on **Metropolitan Area: (02) 8382-1006; Regional, Rural & Remote NSW: 1800 023 687**, available 24/7. **This advice line cannot provide support for an application for an authority.**

Applicants can find information on the TGA Special Access Scheme at www.tga.gov.au/form/special-access-scheme

Privacy Statement: The information set out in this form is required by the NSW Ministry of Health for the issuance of an authority to prescribe or supply a Schedule 8 medicine as required under the law. The collection, use and disclosure of the information provided will be in accordance with privacy laws. Information collected as part of the application process may be used and disclosed as part of assessing the application. Medicare numbers may be used for the purpose of patient identification. Practitioner information, and data regarding the number of patients for whom they hold authorities to prescribe or supply a Schedule 8 medicine , may also be used, and disclosed for policy and planning purposes. The information collected may be disclosed to health practitioners when necessary to facilitate coordination of treatment and patient safety or where required or authorised by law. The application may not be processed if all information and all declarations requested on the form are not completed. For further information on privacy, visit http://www.health.nsw.gov.au/patients/privacy

☐ **I confirm that I have read and understood all the information above including 'Clinical Advice and Support' and the 'Privacy Statement'**

(This declaration is mandatory and must be completed)

Enquiries:

Please direct any enquiries to the Pharmaceutical Regulatory Unit: Tel: **(02) 9424 5923** or email: MOH-S8Auth@health.nsw.gov.au

Submitting the application:

Fax completed form to the Pharmaceutical Regulatory Unit: Fax: **(02) 9424 5889** or email to: MOH-S8Auth@health.nsw.gov.au

Processing Time:

Please allow up to **30 business days** for the processing of applications.

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SECTION A – PRESCRIBER DETAILS

Prescriber Name: (as displayed in AHPRA)

First Name: _____ Middle Name(s): _____

Family Name: _____

Name of Practice: _____

Address: _____ Suburb/town: _____

Postcode: _____ Telephone: _____ Fax: _____

Mobile: _____

Email: _____ (please note this email address will be used for all correspondence)

AHPRA Registration No.: _____ PBS Prescriber No.: _____

SECTION B – PATIENT DETAILS

Patient Name: (as shown on Medicare card)

First Name: _____ Middle Name(s): _____

Family Name: _____

Patient also known as: (if applicable)

First Name: _____ Middle Name(s): _____

Family Name: _____

Address: _____ Suburb/town: _____

Postcode: _____ Medicare number (if applicable): _____ Ref no.: ___

DVA number (if applicable): _____

DOB: _____ (dd/mm/yyyy) Sex: ☐ Male ☐ Female ☐ Another term

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SECTION C – PRE-QUESTIONS

1. DO YOU CONSIDER THIS PATIENT TO BE DRUG DEPENDENT?

A 'drug dependent person' means a person who has acquired, as a result of repeated administration of:

(a) a drug of addiction, or

(b) a prohibited drug within the meaning of the Drug Misuse and Trafficking Act 1985,

an overpowering desire for the continued administration of such a drug. **(section 27 of the Poisons and Therapeutic Goods Act 1966).**

☐ **Yes**. Go to **question 2**

☐ **No**. Go to **Section D: Drug Authorisation Details**

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2. IS THE PATIENT CURRENTLY ENROLLED ON THE OPIOID TREATMENT PROGRAM (OTP)

☐ **No**. Go to **Section D: Drug Authorisation Details**

☐ **Yes**. **I am the authorised OTP prescriber**. Go to **Section D: Drug Authorisation Details**

☐ **Yes**. **I am NOT the authorised OTP prescriber.** Has the patient been reviewed by the authorised OTP prescriber and written agreement to the proposed treatment obtained?

- ☐ **Yes**. Go to **Section D: Drug Authorisation Details**
- ☐ **No**. Contact the authorised OTP prescriber and obtain written agreement before submitting this application. **This application cannot proceed** and will not be considered until written agreement is obtained.

SECTION D – DRUG AUTHORISATION DETAILS

Schedule 8 substance(s): _____

Maximum daily dose of the Schedule 8 substance(s): _____ mg

Specify product form for extemporaneously-compounded products (e.g., capsule, troche, lozenge, injection, cream, gel, mixture, spray): _____

If cream, gel, ointment, lotion, or eye/ear drops specify: _____ %

☐ **This product is to be extemporaneously-compounded**

The prescriber is advised to seek evidence from the pharmacist that the quality and stability of the formulation is in accordance with the guidelines on compounding medicines published by the Pharmacy Board of Australia. Go to **Section E: Indications for Prescribing**

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SECTION D – DRUG AUTHORISATION DETAILS (CONT.)

☐ This product is a proprietary product being imported from overseas.Have you complied with the appropriate TGA Special Access Scheme approval (Category A, B or C) or are you an Authorised Prescriber?

☐ **Yes**. Go to **Section E: Indications for Prescribing**

☐ **No**. Obtain approval from TGA Special Access Scheme or as an Authorised Prescriber. You must have approval before this application can proceed.

SECTION E – INDICATIONS FOR PRESCRIBING

Clinical indication(s) for use: _____

FOR EXTEMPORANEOUSLY-COMPOUNDED PRODUCTS, IS THE PATIENT'S CONDITION AN ARTG APPROVED INDICATION FOR USE OF THE SCHEDULE 8 SUBSTANCE(S) CONTAINED IN THE PRODUCT?

Therapeutic goods entered in the Australian Register of Therapeutic Goods (ARTG) can be lawfully supplied in Australia. The ARTG holds information on product name and formulation details, as well as sponsor and manufacturer details

☐ **Yes**. Go to **Section F: Declaration**

☐ **No**. **Has the patient been reviewed by an appropriate medical specialist and written support obtained for the proposed treatment?**

- ☐ **Yes**. Go to **Section F: Declaration**
- ☐ **No**. Refer the patient to an appropriate medical specialist and obtain written support. Go to **Section F: Declaration**

SECTION F – DECLARATION

☐ **I have explained the following to the patient:**

- that the product (as an unregistered or compounded medicine) has not been assessed for safety, or efficacy by the TGA
- the nature of treatment and potential harms associated with the use of unregistered or compounded medicines **and I confirm that the patient has consented to the treatment**.

☐ **I confirm that the information I have provided in this application is true and complete to the best of my knowledge.**

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SECTION F – DECLARATION (CONT.)

Where required, please also tick the option which applies:

☐ I confirm, where required, that I have sought a review and obtained written support from an appropriate medical specialist for the proposed treatment.

☐ I confirm I will seek specialist review and obtain written support from an appropriate medical specialist to support this application.

Signature: Print and Sign _____ Date: _____ (dd/mm/yyyy)