APPROVAL, UNDER SUBSECTION 7D(1) OF THE *THERAPEUTIC GOODS ACT 1989*, OF FORM FOR PROVIDING PRODUCT INFORMATION FOR A RESTRICTED MEDICINE OR OTHER MEDICINE IN RELATION TO WHICH THE SECRETARY REQUIRES PRODUCT INFORMATION TO BE PROVIDED

I, Rohan Hammett, National Manager of the Therapeutic Goods Administration and delegate of the Secretary for the purposes of section 7D of the *Therapeutic Goods Act 1989* (the Act), hereby approve the attached form described below to be the form for use by applicants for registration of restricted medicine to accompany the application in accordance with paragraph 23(2)(ba) of the Act, and for registration of other medicine for which the Secretary has given notice that product information is to be provided to the Secretary as referred to in subparagraph 25(1)(da)(ii) of the Act, for the purposes of subsection 7D(1) of the Act:

- The form titled "FORM FOR PROVIDING PRODUCT INFORMATION FOR A RESTRICTED MEDICINE OR OTHER MEDICINE IN RELATION TO WHICH THE SECRETARY REQUIRES PRODUCT INFORMATION TO BE PROVIDED".

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Dr Rohan Hammett

Delegate of the Secretary for Health and Ageing

12 May 2011

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

FORM FOR PROVIDING PRODUCT INFORMATION FOR A RESTRICTED MEDICINE OR OTHER MEDICINE IN RELATION TO WHICH THE SECRETARY REQUIRES PRODUCT INFORMATION TO BE PROVIDED

Therapeutic Goods Act 1989

This form has been approved under subsection 7D(1) of the *Therapeutic Goods Act 1989* (the Act) for use by applicants for registration of restricted medicine to accompany the application in accordance with paragraph 23(2)(ba) of the Act, and for registration of other medicine for which the Secretary has given notice that product information (PI)[1] is to be provided to the Secretary as referred to in subparagraph 25(1)(da) of the Act.

REQUIREMENTS

PI provided of the kind described in the dot points below in relation to the medicine must be set out under the following specified headings in the order set out below:

i) Name of the medicine

- The Australian Approved Name (AAN) of the therapeutically active ingredient or, in the case of a mixture of active ingredients, of each therapeutically active ingredient.
- The chemical structure of each therapeutically active ingredient, except in the case of therapeutically active ingredients that are:
  - inorganic salts or simple organic compounds where a molecular formula may be included;
  - complex biological molecules such as large peptides and proteins, where a simpler schematic presentation of the structure may be included; and
  - substances where the structure is not defined.
- The CAS[2] Registry Number of the medicine.

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1 Product information is defined in subsection 3(1) of the Act in relation to therapeutic goods as "information relating to the safe and effective use of the goods, including information regarding the usefulness and limitations of the goods".

2 Chemical Abstracts Service.

ii) Description

- A description of relevant physical and chemical characteristics of the medicine and its formulations.
- List of excipients.

Note: Australian Approved Names should be used for the excipients.

iii) Pharmacology

- The pharmacology and pharmacological actions of the medicine, followed by the pharmacokinetics (with subheadings in the following order: absorption; distribution; metabolism; excretion), especially in humans.

iv) Clinical trials

- Clinical trials related to the indications, both positive and negative.

Note: If the medicine was registered prior to 1991 and there have been no applications to the Therapeutic Goods Administration requiring the advice of either the Australian Drug Evaluation Committee (ADEC) or the Advisory Committee on Prescription Medicines (ACPM) since then, it is unlikely that a suitable clinical trial data will be available. In that case, the Clinical Trials section need not be completed.

v) Indications

- The therapeutic applications of the medicine.

Note: The therapeutic applications should be stated clearly and concisely, and should define the target disease or condition, distinguishing between treatment (symptomatic, curative or modifying the evolution or progression of the disease), prevention (primary or secondary) and diagnostic indications. Mandatory conditions of product usage, where relevant, should also be included if not covered more appropriately in other parts of the PI.

vi) Contraindications

- A description of situations in which patients:
    - should never be treated with the medicine, and
    - should generally not be treated with the medicine.

Note: Situations where life threatening or fatal adverse reactions may occur can also be referred to.

vii) Precautions

- Effects on fertility.
- Use in pregnancy (see note below).

- Use in lactation.
- Paediatric use.
- Use in the elderly.
- Genotoxicity.
- Carcinogenicity.
- Effect on laboratory tests.

Note 1: The circumstances where caution is required in relation to the medicine should be described. The actions the health care professional should take should also be described. Information on precautions should include, but not be limited to, information of the kind listed above. Additional information can also be provided if appropriate.

Note 2: Examples of the circumstances where caution is required could be in relation to particular population groups or clinical situations where dosage adjustment is required.

Note 3: An example of the actions the health care professional should take could be to specify particular investigations that may need to be carried out.

Note 4: In relation to use in pregnancy, include a proposed or approved Australian Pregnancy Categorisation, any relevant standard text for the class of medicine and other information consistent with this categorisation, as well as effects on labour and delivery.

viii) Interactions with other medicines

Note: In relation to interactions with other medicines, include known clinically relevant interactions and other potentially serious interactions. Interactions should be grouped according to outcome, for example, potentiation or reduction of effect, and the mechanism of action should also be explained where this is known.

ix) Adverse effects

- Severity, clinical importance and frequency of adverse effects.

Note: For clarity and consistency, the following format is preferred:

1. A table of adverse events (not adverse reactions) at a cut-off of, for example, 1% comparing the frequency of adverse events (n(%) or (%)) on drug with placebo/active comparator (if studies support this comparison) (usually very common and common);

2. A line listing of adverse reactions that fall below the cut-off by System Organ Classes (SOC) using CIOMS[3] frequencies (usually uncommon, rare); and
3. A post-marketing section of adverse reactions by system organ class using CIOMS frequencies (usually rare or very rare).

x) Dosage and administration

- Dosage (dose and interval).
- Dosage adjustment in:
  - renal insufficiency;
  - hepatic insufficiency;
  - dialysis; and
  - concomitant disease.
- Maximum tolerated daily dose and the maximum dose for an entire course of therapy.
- Monitoring advice.
- Other relevant information such as relationship to meals and compatibility with other medicines and fluids.

xi) Overdosage

- Symptoms, signs and recommended treatment of overdosage or accidental poisoning.

Note 1: It is usual to include the following statement under this heading:

For information on the management of overdose, contact the Poison Information Centre on 131126 (Australia).

Note 2: If activated charcoal is considered to be potentially useful in the management of overdose of the medicine, then a suitable statement for inclusion would be:

Activated charcoal may reduce absorption of the medicine if given within one or two hours after ingestion. In patients who are not fully conscious or have impaired gag reflex, consideration should be given to administering activated charcoal via a nasogastric tube, once the airway is protected.

Note 3: Whole bowel irrigation may be useful in the management of overdose of slow release preparations with significant toxicity (eg. slow release calcium channel blockers) or medicine not absorbed by charcoal (eg. iron, lithium). If whole bowel irrigation is considered to be potentially

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[3] Council for International Organizations of Medical Sciences.

useful in the management of overdose of the medicine, then a suitable statement for inclusion would be:

> *Whole bowel irrigation (eg. 1 or 2 litres of polyethylene glycol solution orally per hour until rectal effluent is clear) may be useful for gut decontamination.*

Note 4: For all overdoses, the mainstay of treatment is supportive and symptomatic care. This should be emphasised before discussion of specific antidotes. Information on serious toxicity, T_{max}, elimination half-life (in the setting of overdose) and the effectiveness of haemodialysis and repeated doses of activated charcoal in removing the medicine are very useful in the management of overdose. Any available information on these issues, including animal data, should be considered for inclusion.

Note 5: Syrup of Ipecac and gastric lavage are no longer considered to be standard therapy for gut decontamination. Reference to these interventions therefore need not routinely be included.

Note 6: It is generally inappropriate to include LD_{50} values from any animal studies.

xii) Presentation and storage conditions

- The presentation of the medicine, including information about:
  - dosage form;
  - quantity, proportion or strength of each therapeutically active ingredient;
  - container type;
  - pack sizes; and
  - any other information relevant to the presentation or appearance of the medicine.
- Storage conditions.

Note 1: The pharmaceutical form should be described by the AAN term, together with a visual description of the appearance of the product (colour, markings, etc). In the case of products to be reconstituted before use, a reference to the appearance before reconstitution should be included.

Note 2: Reference should be made to the immediate container for the medicine using the AAN term and the material of construction of the immediate container (for example, "glass vials", "PVC/Aluminium blisters"). Any other component of the product should be listed (for example, needles, swabs, measuring spoons, syringes or inhaler devices). The container of any solvent provided with the medicine should also be described.

Note 3: All pack sizes should be listed. Pack sizes mentioned should include the number of units, total weight or volume of the immediate container (as appropriate) and the number of containers present in any outer carton.

xiii) Name and address of the sponsor

- Name and street address of the sponsor of the medicine.

xiv) Poison Schedule of the medicine

- The schedule of the current Poisons Standard in which the medicine is included (if applicable).

xv) Date of first inclusion in the Australian Register of Therapeutic Goods (the ARTG)

[To be completed when the medicine is included in the ARTG.]

xvi) Date of most recent amendment

[Item to be completed at the time of any approval of a variation to the approved PI.]