



Australian Government  
Department of Health and Ageing  
Therapeutic Goods Administration

### CATEGORY A FORM SPECIAL ACCESS SCHEME

#### READ CAREFULLY BEFORE COMPLETING

This completed document constitutes the legal authority for an Australian sponsor to supply the specified product and should be forwarded to the Australian Sponsor of the product, accompanied by a prescription where necessary.

A copy of the form must be forwarded to the TGA within 28 days of its completion.

Send to: Medical Officer - SAS, TGA, PO BOX 100, WODEN ACT 2606 [Fax No: (02) 6232 8112 for medicines; and (02) 6232 8785 for medical devices]

The basis for these SAS arrangements is that responsibility for prescribing an unapproved therapeutic good appropriately rests with the patient's medical practitioner and the patient. Category A patients are defined in the legislation as "persons who are seriously ill with a condition from which death is reasonably likely to occur within a matter of months, or from which premature death is reasonably likely to occur in the absence of early treatment". Under s31A(2) and 41JD of the *Therapeutic Goods Act 1989* (the Act) the TGA may seek clarification of the Category A classification of patients. In addition, under s61(3A) of the Act the TGA may release details of inappropriate supply and/or use of unapproved medicines and medical devices to State and Territory authorities. **If you intend to import this product, be aware that an import permit may be required for Customs purposes. Details of goods for which a permit is required may be found at [www.tga.gov.au](http://www.tga.gov.au).**

#### PATIENT AND PRODUCT DETAILS - COMPLETE ALL RELEVANT SECTIONS AND PRINT CLEARLY

PATIENT DETAILS:  
(initials/age or DOB,  
sex)

Mr Sick Citizen  
Sex: Male  
DOB: 03/03/1963

DIAGNOSIS:

Metastatic Liver Cancer

MEDICINE/DEVICE:

Laetrile/Amygdalin

DOSAGE/PRODUCT FORM:

IV Vials & Tablets

STRENGTH:

3gIV & 500mg Tablets

ROUTE/METHOD OF ADMINISTRATION:

IV & Oral

DOSAGE:

3g - 6g /day

DURATION OF TREATMENT:

3 Months

QUANTITY TO BE SUPPLIED:

120 IV 3g Vials & 540 Tablets 500mg

AUSTRALIAN SPONSOR OF PRODUCT:

N/A Imported

NAME AND ADDRESS FOR SUPPLY OF PRODUCT (HOSPITAL, PHARMACIST OR DOCTOR):

N/A - Sourced from overseas

#### MEDICAL PRACTITIONER CERTIFICATION - COMPLETE ALL SECTIONS AND PRINT CLEARLY

I, the undersigned, a registered medical practitioner in a State/Territory of Australia, certify that:

- In my opinion the patient above is a Category A patient as defined in regulation 12A of the *Therapeutic Goods Regulations 1990* /regulation 7.2 of the *Therapeutic Goods (Medical Devices) Regulations 2002* (delete as appropriate)
- I am prepared to prescribe the medicine/medical device requested; and
- I have obtained the informed consent of the patient, or the patient's legal representative, to the proposed treatment.

NAME:

Dr Helpful

SIGNATURE:

PHONE:

02 5555 5555

DATE / /

ADDRESS:

Helpful Medical Centre, 200 Good ST, Sydney