

Policy

DRUGS AND POISONS: Approvals - Queensland Health Policy on the Issue of Approvals for Amygdalin (Vitamin B17 /Laetrile) Under the *Health (Drugs and Poisons Regulation 1996*

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OFFICE OF THE DIRECTOR-GENERAL

CIRCULAR NO. 02/2003

QUEENSLAND HEALTH POLICY ON THE ISSUE OF APPROVALS FOR AMYGDALIN (VITAMIN B17/LAETRILE) UNDER THE *HEALTH (DRUGS AND POISONS) REGULATION 1996*

Background

Amygdalin is listed in Appendix C of the Standard for the Uniform Scheduling of Drugs and Poisons (the Standard). Substances listed in Appendix C of the Standard are those poisons that are considered of such danger to health as to warrant prohibition of sale, supply and use. Accordingly, all Appendix C poisons of the Standard are regulated poisons under Queensland's *Health (Drugs and Poisons) Regulation 1996* and specific approval is required for them to be obtained, possessed and used.

The Commonwealth Therapeutic Goods Administration (TGA) controls the Special Access Scheme. Category A of this scheme is for use by doctors in the treatment of patients with a life-threatening illness. This scheme is a notification scheme only. The scheme provides for access to normally inaccessible drugs where the doctor certifies the drug is necessary for a life threatening illness in the particular patient. The TGA is also responsible for regulating which substances are allowed to be imported into Australia. Amygdalin is contained in Schedule 8 to the *Customs (Prohibited Imports) Regulations 1956*. Therefore, for any Amygdalin that needs to be sourced from overseas, an import permit is issued by the TGA following their receipt of a Category A notification form by a treating doctor.

Whilst the TGA issues these import permits, this does not allow the treating doctor or the patient to be in possession of or to use Amygdalin under Queensland Health legislation. Specific approval is still required from Queensland Health for this purpose.

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Queensland Health Approval

Queensland Health has issued a small number of approvals to doctors to use Amygdalin under strict guidelines in specific patients. This policy document has been developed to provide clear and concise information concerning the circumstances under which Queensland Health will consider the issue of an approval to a doctor for the treatment of a patient with Amygdalin. It should be noted that approval applications are considered on a case-by-case basis and that not all previous applications have been approved.

Circumstances under which Queensland Health will consider the issue of approval

1. All applications must be received from the treating doctor and in writing. If approvals are issued, they are issued to the treating doctor for a specific patient. Approvals are not issued to the patient.
2. The application will need to include:
 - (a) The patient's name, sex, date of birth and current address; and
 - (b) Clinical detail of the patient's medical condition including relevant specialist's reports; and
 - (c) Details of all treatment to date;
(These details are required, as approvals will **only** be considered for patients with an advanced malignancy where all possible conventional treatment has been exhausted.)
 - (d) Current prognosis of the patient;
 - (e) Details of the treatment protocol with Amygdalin intended to be undertaken.
(Due to relative toxicity concerns, Queensland Health **will not** issue approval for treatment with **oral Amygdalin**, and will only consider applications for intravenous treatment under a strict treatment protocol.)
3. If an approval is issued, it will contain conditions including, but not necessarily limited to:
 - (a) That treatment is limited to the specified patient and in accordance with a specified treatment protocol;
 - (b) That the Amygdalin must be kept in the personal possession of the treating doctor, who will be responsible for destruction of any remaining stock following treatment.
 - (c) That the treating doctor explains to the patient the risks and benefits in the use of Amygdalin and obtains the patient's written consent prior to treatment.
 - (d) That the approval will be time limited in accordance with the specified treatment protocol.
 - (e) That prior to consideration of any application for a re-approval after any initial approval, the approved doctor will need to provide a progress treatment report, in regards to the patient's medical condition, to the Chief Executive of Queensland Health.
4. Applications should be addressed to:

The Chief Executive
C/ The Assistant Principal Adviser
Drugs, Poisons and Therapeutic Goods
Environmental Health Unit
Queensland Health
GPO Box 48
Brisbane Q 4001

(Dr) Robert Stable
Director-General
Queensland Health
2003