Queensland Government
Queensland Health

Enquiries to: **Drugs & Poisons Policy & Regulation Unit**
Environmental Health Branch
Telephone: (07) 3328 9310
Facsimile: (07) 3328 9354
Our Ref: GV050545

OFFICE OF THE DIRECTOR-GENERAL

CIRCULAR NO. 01/2006

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

This Circular rescinds and replaces Circular 02/2003 of the same title.

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 medical practitioners 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 medical practitioner 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 medical practitioner.

Whilst the TGA issues these import permits, this does not allow the treating medical practitioners 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.

Queensland Health approval

Queensland Health has issued a limited number of approvals to medical practitioners 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 issuing an approval to a medical practitioner 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.

Criteria for obtaining Queensland Health approval

1. Due to relative toxicity concerns, Queensland Health **will not** issue approval for treatment with **oral Amygdalin**, and will only consider applications for intravenous or intramuscular treatment under a strict treatment protocol.
2. Any relevant specialist's/oncologist's reports relating to the patient's medical condition must be included with the application.
3. Approvals will **only** be considered for patients with an advanced malignancy where all possible conventional treatment has been exhausted.
4. The patient who is to be treated with Amygdalin must be informed of the following relating to the facts about Amygdalin and provide written consent to treatment:
    - the process by which the Amygdalin is manufactured may not be subject to quality control;
    - the potential cyanide toxicity associated with Amygdalin; and
    - the lack of scientific evidence relating to the efficacy of Amygdalin.

The form entitled "Drugs and Poisons: Application for Approval to Obtain, Possess and Use Amygdalin - Informed Consent" has been developed to facilitate the provision of such written informed consent. This form is available at the web address www.health.qld.gov.au. A completed and signed (by the patient) informed consent form must be included with the application.

In order for the patient to provide informed consent, the treating medical practitioner must provide and discuss with the patient the two fact sheets compiled by Queensland Health entitled:

- "Drugs and Poisons Fact Sheet: Amygdalin/Laetrile - Patient Information"; and
- "Drugs and Poisons Fact Sheet: Amygdalin/Laetrile - Questions and Answers".

These fact sheets are available at the above web address.

Making application for Queensland Health approval

- All applications must be made in writing by the treating medical practitioner. An application form entitled "Drugs and Poisons: Application by a Medical Practitioner for Approval to Obtain, Possess and Use Amygdalin" has been developed to simplify the process for making application for an approval. This form is also available at the above web address.
- The application form must be completed in full and signed by the treating medical practitioner making the application. (If approvals are issued, they are issued to the treating medical practitioner for a specific patient. Queensland Health approvals are not issued to the patient.)
- Applications must include the following attachments:
    - the informed consent form "Drugs and Poisons: Application for Approval to Obtain, Possess and Use Amygdalin - Informed Consent", completed and signed by the patient; and
    - any relevant specialist's/oncologist's reports relating to the patient's medical condition.

Applications can be made by facsimile, provided the original is submitted by mail as soon as practicable after the facsimile.

Applications should be addressed to:
The Chief Executive, Queensland Health
C/- The Principal Environmental Health Officer
Drugs and Poisons Policy and Regulation
Environmental Health Unit
Queensland Health
PO Box 2368
FORTITUDE VALLEY Q 4006.

Conditions of Queensland Health approval

If an approval is issued, it will contain conditions including, but not necessarily limited to the following:

1. That treatment is limited to the specified patient and in accordance with a specified treatment protocol.

2. That the Amygdalin must be kept in the personal possession of the treating medical practitioner, who will, subject to 4(d) below, be responsible for destruction of any remaining stock following treatment.

3. That the treating medical practitioner explains to the patient the risks and benefits in the use of Amygdalin and obtains the patient's written consent prior to treatment.

4. Monitoring of patient and reporting of any adverse reactions to treatment

(a) Prior to each episode of administration of Amygdalin after the first dose, the medical practitioner assesses the patient clinically for evidence of any adverse effects potentially arising from any previous episodes of administration of Amygdalin. Such assessment is to include monitoring the patient's temperature.

(b) If the patient develops a fever that the medical practitioner reasonably considers may be related to the prior administration of Amygdalin, that further treatment with Amygdalin is ceased immediately and the patient's condition is investigated with microbiological cultures of appropriate clinical specimens, eg. blood.

(c) If the patient develops any other medical condition the medical practitioner reasonably considers may be related to the prior administration of Amygdalin, that further treatment with Amygdalin is ceased immediately and the patient's condition is investigated with appropriate clinical specimens.

(d) If the patient develops any adverse effects the medical practitioner reasonably believes are due to the administration of Amygdalin, the medical practitioner is to retain in his/her possession all remaining stocks of Amygdalin and, if requested, provide those remaining stocks to an authorised officer of Queensland Health to allow for laboratory assessment.

(e) That the medical practitioner report in writing as soon as practicable to the Chief Executive (or delegate) of Queensland Health, any adverse effects the medical practitioner reasonably considers to have arisen from the treatment with Amygdalin. The report is to include the medical practitioner's assessment of the cause of those adverse effects and the results of any pathology or other tests undertaken to assess the patient's condition.

5. That the approval will be time limited in accordance with the specified treatment protocol.

6. That prior to consideration of any application for a re-approval after any initial approval, the approved medical practitioner will need to provide a progress treatment report, in regards to the patient's medical condition, to the Chief Executive (or delegate) of Queensland Health.

Uschi Schreiber
Director-General
Queensland Health
05 / 12 / 2006