



MEDICAL BOARD OF THE NORTHERN TERRITORY

TITLE: Guidelines for the Practice of Alternative and Experimental Treatments

EFFECTIVE DATE: May 2004

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From an ethical and disciplinary standpoint three broad areas of practice might be identified. The first area, which might seem most clear-cut is the use of drugs not licensed for human use. The second area involves research, which is carried out in private practice or outside the direct supervision of an institution with an institutional ethics committee. The third area, which is potentially more problematic and much less clear-cut, is the use of alternative therapies by a registered medical practitioner, often as part of a holistic or complementary approach to patient care.

Drugs Not Licensed for Human Use

The Therapeutic Goods Authority and Territory legislation specifically address the use of unregistered products and off label product use by prescribers. After consideration of advice from the Royal Australian College of General Practitioners the Medical Board of the Northern Territory advises that, in conjunction with these regulations, to maintain patient care in such situations the following guidelines shall be followed:

- Notification of the Medical Board of the Northern Territory of intent to use the unlicensed product by the practitioner.
- Consideration by the Medical Board of the safety issues of the unlicensed product for the patient in question.
- Notification by the practitioner of the medical defence provider of intent to use the unlicensed product.
- Fully informed written consent to be obtained from the patient and where appropriate, family members.
- Written documentation to include the risks and benefits of the proposed treatment with the unlicensed product to be supplied to both the Medical Board of the Northern Territory and to the patient as part of fully informed written consent.
- Medicare billing should not be initiated in such situations.

Research

Research in private practice is legitimate and ethical provided that the doctor follows NHMRC Guidelines, including the requirement that the research be conducted under the aegis of an institutional ethics committee. Without such protection the doctor is at risk of being disciplined by the Medical Board for unprofessional conduct.

Alternative Therapies

The use of alternative therapies which are unorthodox or unconventional and which lack significant proof of efficacy is an area, which creates ethical and disciplinary dilemmas. Registered medical practitioners who choose to prescribe such therapy need to be aware that this carries additional ethical responsibilities. The Medical Board of the Northern Territory endorses the Guidelines of the Medical Practitioners Board of Victoria which advise that:

- Special care must be taken to inform patients when the therapy is unproven and to fully inform patients of any risks associated with such therapy.
- Patients who are offered alternative remedies must not be denied access to standard proven therapies of a type, which would be provided by most medical peers.
- For alternate therapies with risks of serious side effects, the patient should be advised to seek a second independent medical opinion.
- Doctors must not gain financial advantage by selling alternative therapeutic substances directly to patients.

PROCEDURE EXPECTED BY THE ROYAL AUSTRALIAN COLLEGE OF GENERAL PRACTITIONERS (RACGP) WHEN GENERAL PRACTITIONERS (GP) CONTEMPLATE USING DRUGS NOT LICENSED FOR HUMAN USE

1. Notification of the State Medical Board of intent to use the unlicensed product by the GP.
2. Consideration by the Medical Board of the safety issues of the unlicensed product for the patient in question.
3. Notification by the GP of their medical defence provider of intent to use the unlicensed product.
4. Fully informed written consent to be obtained from the patient (and family members if relevant) Written documentation to include risks and benefits of the proposed treatment with the unlicensed product.
5. Medicare billing should not be initiated in such situations.