GUIDELINES FOR COMPENSATION FOR INJURY RESULTING FROM PARTICIPATION IN A COMPANY SPONSORED CLINICAL INVESTIGATION

Preamble

The Medical Technology Association of Australia (MTAA) favours a simple and expeditious procedure in relation to the provision of compensation for injury caused by participation in clinical investigations.

MTAA therefore recommends that a member company sponsoring a clinical investigation ("the Sponsor") should provide a written assurance to the investigator - and through him or her to the relevant Ethics Committee - that the following Guidelines will be adhered to, without legal commitment, in the event of injury caused to a Subject attributable to participation in the investigation in question. Non-members of the MTAA are encouraged to adhere to the principles outlined in these Guidelines.

These Guidelines, for use in Australia, are an adaptation of those developed by Medicines Australia.

1. *Basic Principles*

1.1. Notwithstanding the absence of legal commitment, the Sponsor should pay compensation to participants in clinical investigations ("Subjects") suffering personal injury (including death) in accordance with these Guidelines.

1.2. Compensation should be paid when, on the balance of probabilities, the injury was attributable to the use of a product under investigation or any clinical intervention or procedure provided for by the protocol that would not have occurred but for the inclusion of the Subject in the investigation.

1.3. Compensation should be paid to a child injured in utero through the participation of the child's mother in a clinical investigation as if the child were a Subject with the full benefit of these Guidelines.

1.4. Compensation should only be paid for the more serious injury of an enduring and disabling character (including exacerbation of an existing condition) and not for temporary pain or discomfort or less serious or readily curable complaints.

1.5. Where there is an adverse reaction to a product under investigation and injury is caused by a procedure adopted to deal with that adverse reaction, compensation should be paid for such injury as if it were caused directly by the product under investigation.

1.6. Neither the fact that the adverse reaction causing the injury was foreseeable or predictable, nor the fact that the Subject has freely consented (whether in writing or otherwise) to participate in the investigation should exclude a Subject from consideration for compensation under these Guidelines, although compensation may be reduced or excluded in the light of the factors described in paragraph 4.2 below.

1.7. For the avoidance of doubt, compensation should be paid regardless of whether the Subject is able to prove that the company has been negligent in relation to research or development of the product under investigation or that the product is defective and therefore the Sponsor is subject to strict liability in respect of injuries caused by it.

2. *Type of Clinical Research Covered*

2.1. These Guidelines apply to injury caused to Subjects involved in clinical investigations, that is to say, Subjects using or having the product used on or in them that is under investigation for whom the product is intended to be used by, on or in but for which an inclusion in the Australian Register of Therapeutic Goods (ARTG) does not exist or does not authorise supply for use under the conditions of the investigation.

2.2. These Guidelines also apply to injuries arising from studies in either patient or non-patient volunteers, whether or not they are hospitalised.

2.3. These Guidelines do not apply to injury arising from clinical investigations on marketed products where an inclusion in the ARTG exists authorising supply for use under the conditions of the investigation, except to the extent that the injury is caused to a Subject as a direct result of procedures undertaken in accordance with the protocol (but not from any product used) to which the Subject would not have been exposed had treatment been other than in the course of the investigation.

2.4. These Guidelines do not apply to clinical investigations that have not been initiated or directly sponsored by or on behalf of the company providing the product for research.

2.5. Where investigations of products are initiated independently by doctors under the appropriate *Therapeutic Goods Act 1989* exemptions, responsibility for the health and welfare of Subjects rests with the doctor alone (see also paragraph 5.2 below).

3. *Limitations*

3.1. No compensation should be paid for the failure of a product to have its intended effect or to provide any other benefit to the Subject.

3.2. No compensation should be paid for injury caused by other included, registered, or listed products in the ARTG administered to or used by, on or in the Subject for the purpose of comparison with the product under investigation.

3.3. No compensation should be paid to Subjects receiving placebo in consideration of its failure to provide a therapeutic benefit.

3.4. No compensation should be paid (or it should be reduced as the case may be) to the extent that the injury has arisen through:

- a significant departure from the agreed protocol;
- the wrongful act or default of a third party, including a doctor's failure to deal adequately with an adverse reaction; or
- contributory negligence by the Subject.

4. *Assessment of Compensation*

4.1. The amount of compensation paid should be appropriate to the nature, severity, and persistence of the injury.

4.2. Compensation may be reduced, or in certain circumstances excluded, in the light of the following factors (on which will depend the level of risk the Subject can reasonably be expected to accept):

- the seriousness of the reason for which the product is being used, the degree of probability that adverse reactions will occur and any warnings given;
- the risks and benefits of established uses relative to those known or suspected of the product under investigation.

This reflects the fact that flexibility is required given the particular Subject's circumstances. As an extreme example, there may be a Subject suffering from a serious or life-threatening disease who is warned of a certain defined risk of adverse reaction. Participation in the investigation is then based on an expectation that the benefit/risk ratio associated with participation may be better than that associated with alternative treatment. It is, therefore, reasonable that the Subject accepts the high risk and should not expect compensation for the occurrence of the adverse reaction of which he or she was told.

4.3. In any case where the Sponsor concedes that a payment should be made to a Subject but there exists a difference of opinion between the Sponsor and Subject as to the appropriate level of compensation, it is recommended that the Sponsor agrees to seek at its own cost (and make available to the Subject) the opinion of a mutually acceptable independent arbiter, and that this arbiter's opinion should be given substantial weight by the Sponsor in reaching its decision on the appropriate payment to be made.

5. *Miscellaneous*

5.1. Claims pursuant to the Guidelines should be made by the Subject to the Sponsor, preferably via the investigator, setting out details of the nature and background of the claim and, subject to the Subject providing on request an authority for the Sponsor to review any medical records relevant to the claim, the Sponsor should consider the claim expeditiously.

5.2. The undertaking given by the Sponsor extends to injury arising (at whatever time) from all uses, clinical interventions or procedures occurring during the course of the investigation but not to injury arising from the use of the product beyond the end of the investigation. The use of unregistered, unlisted products or products not included in the ARTG beyond the investigation period is wholly the responsibility of the treating doctor.

5.3. The fact that the Sponsor has agreed to abide by these Guidelines in respect of an investigation does not affect the right of a Subject to pursue a legal remedy in respect of injury alleged to have been suffered as a result of participation. Any payment made to a Subject by the Sponsor will be made without admission of liability and Subjects may be asked to accept that any payment made to them is in full settlement of their claims.

5.4. The Sponsor should encourage the investigator to make clear to participating Subjects that the investigation is being conducted subject to the *Medical Technology Association of Australia Guidelines for Compensation for Injury Resulting from Participation in a Company-sponsored Clinical Investigation* and to have available copies of the Guidelines should they be requested.