

**MEDICINES NEW ZEALAND
GUIDELINES ON CLINICAL TRIALS COMPENSATION FOR INJURY RESULTING FROM
PARTICIPATION IN AN INDUSTRY-SPONSORED CLINICAL TRIAL**

Preamble

Medicines New Zealand Incorporated favours a simple and expeditious procedure in relation to the provision of compensation for injury caused by participation in clinical trials. Medicines New Zealand recommends, therefore, that a member company sponsoring a clinical trial should, without legal commitment, provide to the investigator - and through him/her to the relevant research ethics committee - a written assurance that the following guidelines will be adhered to in the event of injury caused to a patient that is attributable to participation in the trial in question. These guidelines are an adaptation of those used by the Association of British Pharmaceutical Industry.

1. Basic Principles

- 1.1 Notwithstanding the absence of legal commitment, and having cognisance of the “no fault” nature of the New Zealand Accident Compensation Act 2001, the sponsor company should pay compensation to patient-volunteers suffering bodily injury (including death) in accordance with these guidelines.
- 1.2 Where there is a difference of opinion as to if, on the balance of probabilities, the injury was attributable to the inclusion of the patient in the trial then the opinion of an independent mediator will be available at the cost of the sponsor company. The decision of the mediator will not be binding.
- 1.3 Compensation should be paid to a child injured in utero through the participation in a clinical trial of the subject’s mother as if the child were a patient-volunteer with the full benefit of these guidelines.
- 1.4 Compensation should only be paid for 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 curable complaints.

- 1.5 Where there is an adverse reaction to a medicinal product under trial 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 medicinal product under trial.
- 1.6 Neither the fact that the adverse reaction causing the injury was foreseeable or predictable, nor the fact that the patient has freely consented (whether in writing or otherwise) to participate in the trial should exclude a patient from consideration for compensation under these guidelines, although compensation may be abated 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 patient is able to prove that the company has been negligent in relation to research or development of the medicinal product under trial or that the product is defective and therefore, as producer, the company is subject to strict liability in respect of injuries caused by the product.

2. Type of Clinical Research Covered

- 2.1 These guidelines apply to injury caused to patients involved in clinical trials, that is to say, patients under treatment and surveillance and suffering from the ailment which the product under trial is intended to treat but for which a product licence does not exist or does not authorise supply for administration under the conditions of the trial (including Phase I, II and III clinical trials).
- 2.2 These guidelines also apply to injuries arising from Phase I 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 trials on marketed products (Phase IV) where a product licence exists authorising supply for administration under the conditions of the trial, except to the extent that the injury is caused to a patient as a direct result of procedures undertaken in accordance with the protocol (but not any product administered) to which the patient would not have been exposed had treatment been other than in the course of the trial.
- 2.4 These guidelines do not apply to injury to clinical trials that have not been initiated or sponsored directly by the company providing the product for research.
- 2.5 Where trials of products are initiated independently by medical practitioners under the appropriate Medicines Act 1981 exemptions, responsibility for the health and welfare of patients rests with the medical practitioner alone.

3. Limitations

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

- 3.2 No compensation should be paid for injury caused by other licensed medicinal products administered to the patient for the purpose of comparison with the product under trial.
- 3.3 No compensation should be paid to patients 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 injury has arisen through:
 - 3.4.1 a significant departure from the agreed protocol;
 - 3.4.2 the wrongful act or default of a third party, including a medical practitioner's failure adequately to deal with adverse reaction;
 - 3.4.3 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 and should be no less than would be awarded for similar injuries by New Zealand's accident compensation scheme.
- 4.2 Compensation may be abated, or in certain circumstances excluded, in the light of the following factors (on which will depend the level of risk the patient can reasonably be expected to accept):
 - 4.2.1 the seriousness of the disease being treated, the degree of probability that adverse reactions will occur and any warnings given;
 - 4.2.2 the risks and benefits of established treatments relative to those of the trial medicine known or suspected.

This reflects the fact that flexibility is required given the particular patient's circumstances. As an extreme example, there may be a patient suffering from a serious or life-threatening disease who is warned of a certain defined risk or adverse reaction. Participation in the trial 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 reasonable, therefore, that the patient accepts the high risk and should not expect compensation for the occurrence of the adverse reaction about which he or she was told.

- 4.3 In any case, where the company concedes that a payment should be made to a patient but there exists between company and patient a difference of opinion as to the appropriate level of compensation, it is recommended that the company agree to seek, at its own cost (and make available to the patient), the opinion of a mutually acceptable independent arbiter, and that this arbiter's decision on the appropriate payment to be made is binding.

5. Miscellaneous

- 5.1 Claims pursuant to the guidelines should be made by the patient to the company, preferably via the investigator, setting out details of the nature and background of the claim. Subject to the patient providing, on request, an authority for the company to review any medical records relevant to the claim, the company shall consider the claim expeditiously.
- 5.2 The undertaking given by the company extends to injury arising (at whatever time) from all administrations, clinical interventions or procedures occurring during the course of the trial but not to treatment extended, at the instigation of the investigator, beyond the end of the trial. The use of unlicensed products beyond the trial period is wholly the responsibility of the treating medical practitioner.
- 5.3 The fact that a company has agreed to abide by these guidelines in respect of a trial does not affect the right of a patient to pursue a legal remedy in respect of injury alleged to have been suffered as a result of participation. Nevertheless, patients will normally be asked to accept that any payment made under the guidelines will be in full settlement of their claims.
- 5.4 A company sponsoring a trial should encourage the investigator to make clear to participating patients that the trial is being conducted subject to Medicines New Zealand Incorporated Guidelines on Clinical Trials Compensation for Injury Resulting from Participation in an Industry-Sponsored Clinical Trial, and have available copies of the guidelines should they be requested.

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