

PATIENTS

GUIDELINES

Clinical Trials - Compensation for Medicine-Induced Injury

It is becoming common practice for ethical committees to expect assurance that patients participating in clinical trials will be appropriately compensated, by a simple procedure, should they be adversely affected by reason of their involvement in the trial. While such adverse effects are very uncommon, the Association of the British Pharmaceutical Industry (ABPI) accepts this as a guiding principle and has noted that quite different considerations apply to medicines undergoing clinical trial compared to medicines generally available on prescription. Consequently, in cases where injury is attributable to a medicine in clinical trial, the ABPI recommends to its member companies that the following guidelines should be accepted without legal commitment on the part of the member companies:-

- (a) The company should favourably consider the provision of compensation for personal injury, including death, in accordance with these guidelines but without the requirement for negligence to be proved against the company.
- (b) Compensation should only be paid when there is a balance of probabilities that the injury (including exacerbation of an existing condition) was attributable to the company's medicine under trial.
- (c) Compensation should only be paid for the more serious injury of an enduring and disabling character, and not for temporary pain or discomfort or less serious or curable complaints such as skin rashes.
- (d) These guidelines only apply to injuries to patients involved in clinical trials, conventionally known as Phase II or Phase III trials, that is to say, patients under treatment and surveillance (usually in hospital) and suffering from the ailment which the medicine under trial is intended to treat. These guidelines do not apply to injuries arising from studies on healthy volunteers (Phase I), whether or not they are in hospital, for which separate guidelines for

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compensation already exist. These guidelines also do not apply to injuries arising from clinical trials on marketed products, except when the trial is on a marketed medicinal product being tested for a prospective indication not yet authorised by inclusion in a product licence.

- (e) These guidelines apply to an injury whether or not the adverse reaction causing the injury was foreseeable or predictable although compensation may be abated or excluded in the light of the factors mentioned in paragraph (j) below.
- (f) Compensation should not be payable (or should be abated, as the case may be) (i) when there has been a significant departure from the agreed protocol, (ii) where the injury was attributable to the wrongful act or default of a third party, including a doctor's failure to deal adequately with an adverse reaction, or (iii) when there has been contributory negligence by a patient.
- (g) Compensation should only be payable to patients receiving the medicine under trial and, therefore, not to control patients not receiving the trial medicine nor to patients receiving placebos, nor to patients receiving other non-trial drugs or medicines for the purpose of comparison with the medicine under trial.
- (h) The giving of consents to participate in a clinical trial, whether in writing or otherwise, should not exclude a patient from the benefits of compensation or in any way prejudice his position under the guidelines, although compensation may be abated or excluded in the light of the factors mentioned in paragraph (j) below.
- (i) No compensation should be paid for the failure of a medicine to have its intended effect or to provide any other benefit to the patient. This includes the failure of any vaccine or other preparation to provide the preventive or prophylactic effect for which it is under trial, and the failure of any contraceptive preparation or device to prevent pregnancy.
- (j) The amount of any compensation paid by the company should be appropriate to the nature, severity and persistence of the injury. However such compensation may be abated, or in certain circumstances excluded, in the light of the following factors (on which will depend the kind of risk the patient should be expected to accept):-
 - (i) the seriousness of the disease being treated, the degree of probability that adverse reactions will occur and any warnings given;

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- (ii) the hazards of established treatments relative to those known or suspected of the trial medicine, and
- (iii) the availability and relative efficacy of alternative treatments that the patient could have had if he had not volunteered for the trial.

Note: This guideline assumes that the level of any compensation paid will depend upon the circumstances in the light of the factors mentioned above. As an extreme example, there may be a patient suffering from serious or mortal disease such as cancer who is warned of a certain defined risk of adverse reaction. Participation in the trial is then based on an expectation that the benefit/risk ratio associated with participation is better than that associated with alternative treatment. It is, therefore, reasonable that the patient accepts the high risk and should not expect compensation for the occurrence of the adverse reaction of which he or she was told.

The Association of the British Pharmaceutical Industry

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