Clinical Trial Compensation Guidelines

Preamble

The Irish Pharmaceutical Healthcare Association (IPHA) represents the international research-based pharmaceutical companies who are responsible for developing, manufacturing and bringing innovative medicines to the Irish market and has adopted the following guidelines on clinical trial compensation.

Introduction

IPHA favours a simple and expeditious procedure in relation to the provision of compensation for injury caused by participation in clinical trials. Use of the HSE CTIF, which refers to these guidelines, provides the assurance that the company sponsoring a clinical trial will, without legal commitment, adhere to the following Guidelines in the event of injury caused to a patient attributable to participation in the trial in question.

1. Basic principles

1.1 Notwithstanding the absence of legal commitment, the company should pay compensation to patient-volunteers suffering bodily 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 administration of a medicinal product under trial or any clinical intervention or procedure provided for by the protocol that would not have occurred but for the inclusion of the patient in the trial.

1.3 Compensation should be paid to a child injured in utero through the participation of the subject's mother in a clinical trial as if the child were patient-volunteer with the full benefits 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 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 the patient from consideration for compensation under these Guidelines unless the adverse reaction was a known side effect and the patient was fully informed prior to submitting to the trial, 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 the producer, the company 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 patients involved in Phase II and Phase III trials, that is to say, patients under treatment and surveillance (usually in hospital) and suffering from the ailment for which the medicinal product under trial is intended but for which a product licence does not exist or where the product licence does not authorise supply for administration under the conditions of the trial.

2.2 These Guidelines also apply to injuries arising from studies in non-patient volunteers (Phase I), whether or not they are in hospital.

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 clinical trials, which have not been initiated by the company providing the product for research (whether sponsored by the company or not). When trials of products are initiated independently by doctors under the appropriate legislative exemptions, responsibility for the health and welfare of patients rests with the doctor alone (see also paragraph 5.2 below).

3. Limitations

3.1 No compensation should be paid for the failure of the 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 to patients to the extent that the injury suffered is a direct result of a patient's failure to disclose that they are taking a particular medication (prescription or otherwise).

3.5 No compensation should be paid (or should be abated as the case may be) to the extent that the injury has arisen:

3.5.1 through a significant and/or material departure from the agreed protocol;

3.5.2 through the wrongful act or default of a third party, including a healthcare professional's failure to deal adequately with an adverse reaction and/or failure by a healthcare professional to provide the necessary standard of care; or

3.5.3 through contributory negligence by the patient and/or (as relevant) any other party (apart from the company).

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 in general terms be consistent with the quantum of damages commonly awarded for similar injuries by the Irish Courts in cases where legal liability is admitted.

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; or

4.2.2 the risks and benefits of established treatments relative to those known or suspected of the trial medicine.

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 of an 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 the 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.

4.3 In any case where the company concedes that a payment should be made to a patient but there exists the difference of opinion between company and patient as to the appropriate level of compensation, it is recommended that the company agrees to seek at its own costs (and make available to the patient) the opinion of a mutually acceptable independent expert, and that his opinion should be given substantial weight by the company 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 patient to the company, preferably via the investigator, setting out details of the nature and background of the claim and, subject to the patient providing on request an authority for the company to review any medical records relevant to the claim, the company should consider the claim expeditiously (taking into account the nature of the injury and the effect of time on the severity/abatement of said injury and its effects).

5.2 The undertaking given by a 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 beyond the end of the trial at the instigation of the investigator. The use of unlicensed products beyond the trial period is wholly the responsibility of the treating doctor and in this regard attention is drawn to the desirability of doctors notifying their protection society / insurers of the use of unlicensed products. In the event that injury arises under such circumstances the doctor/investigator shall be held fully liable irrespective of whether there was a cumulative effect on the injury that commenced at the beginning of treatment.

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. Nonetheless, patients will normally be asked to accept that any payment made under the Guidelines will be in full and final 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 the IPHA Guidelines relating to compensation for injury arising in the course of clinical trials and have available copies of the Guidelines should they be requested.

5.5 Where studies are carried out in a hospital, the hospital continues to have a duty of care to the patient being treated within that hospital, whether or not the patient is participating in a study. Therefore the company does not accept liability for negligence on the part of employees of, or staff engaged by, hospitals. This applies whether the hospital is private or public sector. The pharmaceutical companies cannot be held liable for any breach in the hospital's duty of care.