Unofficial translation

PHARMACEUTICAL INJURIES INSURANCE

General Terms and Conditions (effective as of 1 January 2012) issued by the Finnish Mutual Insurance Company for Pharmaceutical Injury Indemnities ("Insurance Company")

1. Purpose of the insurance

1.1 Compensation is payable under the Pharmaceutical Injuries Insurance in respect of any bodily injury (pharmaceutical injury) resulting from

1.1.1. the therapeutic use of a pharmaceutical, provided the product manufacturer, importer or marketer that is a Signatory to this Contract has, in the normal course of business, supplied the pharmaceutical for consumption in Finland.

1.1.2. an investigational medicine while tested in a clinical trial by or under the sponsorship of a Signatory to the Contract in accordance with the legislation governing clinical pharmaceutical research conducted in Finland (Act 488/1999). Bodily injuries resulting from pharmaceuticals used as comparators in the trial are covered if the criteria of subsection 1.1.1 are met.

In the context of these Terms and Conditions, the term 'Signatory to this Contract' refers to any pharmaceutical manufacturer, importer or marketer or research company that has signed the Contract. Likewise, 'Signatory to the Contract' is deemed to refer to any pharmaceutical manufacturer on whose behalf another company of the same group or any other entity has signed the pharmaceutical insurance contract.

1.2 A pharmaceutical injury is deemed to have taken place when the Injured seeks treatment for the injury or dies from the injury.

1.3 Compensation is payable in respect of a pharmaceutical injury when a claim for compensation has been submitted to the Insurance Company or to the product manufacturer, importer, marketer or research company referred to in Section 1.1, during the insurance period on or after 1 January 2012.

The period of insurance is one calendar year.

1.4 Serial Claim

The bodily injuries resulting or allegedly resulting from one event, cause or handicap or from the failure to warn, are deemed to constitute one occurrence of the insured event, irrespective of the time or the number of injured persons or organisations. Likewise, the injuries are deemed to have taken place during the insurance period in which the claim was submitted to the Insurer for the first time, irrespective of the number of claimants or the period of time during which the bodily injury would probable lead to a claim or whether claims against the Insurer will be made later in the future.

2. Pharmaceutical

The term ‘pharmaceutical’ shall refer to a preparation or substance, as specified in Section 3 of the Medicines Act (395/1987), intended for human consumption but excluding preparations as referred to in Section 5a to 5b of the Medicines Act. The term shall also refer to intrauterine devices.

3. Insured

The Users of pharmaceuticals shall be the Insured.

4. Pharmaceutical injury

The term 'pharmaceutical injury' shall refer to any bodily illness or injury or a psychic disease likely to result from a pharmaceutical taken by the Injured Party.

Pharmaceutical injuries shall not include illnesses or injuries:

- resulting from a pharmaceutical failing to produce the desired effect; or
- occurring in connection with action or measures that should not have been taken in view of the intended or recognised effect of the pharmaceutical concerned; or
- resulting from an error in the prescription or administration of the pharmaceutical or from the fact that the prescription of the pharmaceutical or its administration for experimental purposes has not been medically justifiable.

5. Injuries covered

Compensation is payable in respect of a pharmaceutical injury when, as a consequence of the injury, the Injured Party:

- has been incapable of work for an uninterrupted period of at least 14 days or his/her bodily functions have been otherwise impaired for a period of at least 14 days;
- has sustained a permanent bodily injury or illness; or
- has deceased.

Notwithstanding the provisions of the first paragraph of this Section, the Injured Party shall be compensated for costs and loss of earnings provided these exceed an aggregate sum of 85 euro, calculated as specified in Section 7 below.

6. Limitations

6.1 No compensation is payable in respect of a pharmaceutical injury if the illness or injury results from a medically inevitable risk inherent in the treatment of an illness or injury that, left untreated, would be mortal or might cause severe bodily injury.

Neither is any compensation payable for such injury as should reasonably have been tolerated as an adverse effect of the pharmaceutical involved, taking into account:

- the nature and severity of the illness in question;
- the general health of the Injured Party;
- the extent of the injury;
- the opportunities available to an expert to foresee the effects of the pharmaceutical; and
- other such factors.

6.2 Neither is compensation payable for a pharmaceutical injury if the pharmaceutical has been supplied, with the User's or Injured Party's knowledge, in a manner contrary to the provisions concerning the sale or possession of pharmaceuticals.

6.3 No compensation is payable for a pharmaceutical injury that has been deliberately caused by the User of the pharmaceutical or the Injured Party him/herself.

6.4 Compensation for a pharmaceutical injury may be reduced or refused if:

- the User of the pharmaceutical or Injured Party has, through an obvious misuse of the medicine or otherwise, contributed to the injury by gross negligence; or
- some factor other than a fault by the manufacturer or importer of the pharmaceutical or another person acting on their behalf has been the principal cause of the injury.

6.5 No compensation is payable for injuries that directly or indirectly arise from acts of terror. An act of terror refers to any act committed by one person or a group of persons which involves the use of force or violence or threat thereof, where the objective of the act, either by its nature or connection, is to promote any political, religious or ideological goal and/or to intimidate or influence any government, nation or part thereof.

7. Extent of injury

Compensation for pharmaceutical injuries shall be determined in application of the provisions of Sections 2, 2a to 2d, 3, 4, 7 and 8 of Chapter 5, Section 1 of Chapter 6 and section 3 of Chapter 7 of the Damages Act (412/1974). Where applicable, compensation shall be determined in accordance with the Rules and Instructions of the Traffic Accident Board.

When the amount of compensation is calculated, any benefits likely to be due to the Injured out of public funds or under statutory insurance schemes shall be deducted.

8. Sum insured

Liability for any each Injured person is limited to 2 million euro, including the value of annuities capitalised, at the date they are fixed, in accordance with sound insurance principles and 30 million euro for all injuries that are reported during one and same year.

Should the amount of compensation in this Section not be sufficient to satisfy those entitled to compensation, all compensation paid shall be reduced in an equal proportion. If there is reason to believe that such a reduction may become necessary after the occurrence of an injury, the Complaints Board may order that only a certain proportion of the compensation be paid out until further notice.

9. Payment of compensation

9.1 Compensation for a pharmaceutical injury shall be paid by the Insurer.

9.2 Any party entitled to compensation in accordance with these Terms and Conditions may collect such compensation only if he relinquishes to the Insurer any right he/she may have to damages in Finland or in any other country from the party that has caused the injury or from any other party liable to pay compensation in respect of the injury.

The obligation of the Injured Party to relinquish his right to compensation to the Insurer in accordance with the first paragraph of this Subsection does not apply to any compensation to which he may be entitled out of public funds or under any statutory insurance scheme.

10. Period of limitation

Any claim for compensation in accordance with these Terms and Conditions shall be submitted to the Insurer within three years of the date on which the person claiming compensation became aware of the injury caused by the pharmaceutical involved.

All claims for compensation shall be submitted no later than 10 years of the date on which the Injured Party discontinued taking the pharmaceutical in question.

11. Complaints Board

An independent Complaints Board issues statements to Injured parties, Insurers and Policyholders concerning compensation of pharmaceutical injuries. If a request for a statement is considered unjustified, no statement need be issued.

12. Appeal against Insurer's decision on claim

12.1 Complaints Board

If an Injured is dissatisfied with the Insurer's decision on a claim for compensation, the Injured may ask the Complaints Board for a statement on the case.

The request for a statement shall be submitted to the Complaints Board no later than six months from the date on which the Injured was informed of the Insurer's decision on the claim.

The Board's statement is given free of charge.

12.2 Appeal through courts

12.2.1 Court of arbitration

Any dispute between an Insurer and an Injured may be settled in the order provided in the Arbitration Proceedings Act (967/1992), if the parties so agree between themselves.

Even if the Injured lost the case, the Insurer shall pay the arbitration fees, providing the Injured was reasonably justified in submitting the dispute to the court of arbitration.

12.2.2 District Court

If an Injured is dissatisfied with the Insurer's decision on a claim, the Injured may also bring action against the Insurer. This action may be brought in the District Court of the Injured Party's domicile.

12.2.3 Time limit for legal action

The time limit for bringing action in either of the above-mentioned courts is three years from the date on which the Injured was informed in writing of the Insurer's decision and of the time limit. After the expiry of the time limit, the Injured shall no longer be entitled to take legal action against the Insurer's decision.

13. Application of policy terms

These Terms and Conditions will be applied to pharmaceutical injuries occurring on or after 1 January 2012 as well as to such injuries as have taken place before 1 January 2012 and reported after 30 June 2012 as cannot be compensated on the basis of the former insurance system.

These Terms and Conditions apply for the compensation payable for serial injuries, with the first claim submitted to the Insurer on or after 1 January 2012.