Terms and conditions of pharmaceutical injuries insurance in force as of 1 January 2015

General Terms and Conditions (effective as of 1 January 2015) issued by the Finnish Mutual Insurance Company for Pharmaceutical Injury Indemnities ("Insurance Company")[1]

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 Subclause 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 a claim for compensation has been submitted to the Insurance Company or to the product manufacturer, importer, marketer or research company referred to in Clause 1.1, or the Injured dies due to 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 Clause 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 injuries caused by a pharmaceutical or pharmaceuticals containing the same active ingredients or resulting from the same injurious event and affecting several persons, or the injuries caused to several persons and resulting from the same event, cause, defect or failure to warn related to a pharmaceutical or pharmaceutical substance, will be deemed to constitute one insurance event, or a

[1] This is a translation of the original Finnish terms and conditions, which take precedence should there be any differences between the original and the translation

serial claim, irrespective of whether the injuries have taken place during one or several insurance periods if

- the pharmaceutical, pharmaceuticals or pharmaceutical substances have been deregistered in part or in full due to its or their injurious effect
- the clinical trial approval of a trial pharmaceutical, pharmaceuticals or pharmaceutical substances has been cancelled in part or in full due to the above injurious effect or
- the injurious effect is caused by a manufacturing defect.

If such serial claims are recognised during different insurance periods, they will be matched to the insurance period in which the first claim was presented in line with the item 1.3.
The criteria of 'serial claim' are not met in case of such injurious effects under this clause where the claim under clause 1.3 was made two year before it became obvious that a serial claim was at hand or if the pharmaceutical or pharmaceuticals were used after the point in time in which the distributors of the pharmaceutical were informed of the serial claim.

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 'pharmaceutical' shall also refer to an intracorporeal medicinal product dispensed with prescriptions or requiring a procedure performed by a healthcare professional.

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 intended 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 Clause, 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 Clause 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, or the part of it caused by the pharmaceutical, as should reasonably have been tolerated as an adverse effect of the pharmaceutical involved, taking into account:

- the nature and severity of the illness treated
- the health of the Injured Party otherwise
- 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 used or 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 pharmaceutical 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 Clause not be sufficient to satisfy those entitled to compensation, all compensation paid shall be reduced in an equal proportion.

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 they relinquish to the Insurer any right they 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 their right to compensation to the Insurer in accordance with the first paragraph of this Subclause does not apply to any compensation to which they 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. Appeal against Insurer's decision on claim

11.1 Insurance Complaints Board

If an Injured is dissatisfied with the Insurance Company’s decision on a claim for compensation, the Injured may ask the Insurance Complaints Board for a recommended decision in the case.

The request for a recommended decision shall be submitted by the Injured party to the Insurance Complaints Board no later than three years from the date on which the Injured was provided with written information on the Insurance Company’s decision and the deadline applied.

11.2 Appeal through courts

11.2.1 District Court

If an Injured is dissatisfied with the Insurer's decision on a claim, the Injured may bring action against the Insurer. The action can be bought at the District Court of the Insurer, at the District Court located at the Finland-based domicile of the Injured or at the District Court of the place of Injury in Finland.

11.2.2 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 Insurance Company's decision and of the this time limit.

Once the time limit has elapsed, the right to bring action expires.

12. Application of policy terms

These Terms and Conditions will be applied to pharmaceutical injuries occurring on or after 1 January 2015.

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 2015.

13. Applicable law

These Insurance Terms and Conditions are construed under Finnish legislation.