Terms and Conditions of pharmaceutical injuries insurance in force as of 1 January 2021

General Terms and Conditions (effective as of 1 January 2021) 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 pharmaceutical injuries insurance in respect of any bodily injury (pharmaceutical injury) resulting from

1.1.1. therapeutic use of a pharmaceutical, provided the product manufacturer, importer, distributer 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 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. 'Pharmaceutical research' refers to medical research performed on the assignment of a pharmaceutical company under circumstances approved by the Authorities in compliance with the Medicines Act (395/1987) and the Medical Research Act (488/1999). 'Pharmaceutical research' also refers to medical research performed on an assignment of another party that is Signatory to the Contract under circumstances approved by the authorities and complying with the Medicines Act (395/1987) and the Act on Medical Research (488/1999) (so-called researcher-driven studies), provided that this research focuses on a medicinal product provided by a pharmaceutical company that is a Signatory to the Contract for research purposes or on a medicinal product registered in Finland as a medicine.

1.1.3 In the context of these Terms and Conditions, the term 'Signatory to the Contract' refers to any pharmaceutical manufacturer, marketer or distributor as well as party performing research referred to in Subclause 1.1.2 (hereinafter 'researcher') that is a Signatory to the Contract. Likewise, 'Signatory to the Contract' is deemed to refer to a pharmaceutical manufacturer on whose behalf another company of the same group or any other entity has signed the Insurance Contract. In the context of these Terms and Conditions, the term 'Signatory to the Contract' also refers to a Blood Service Provider operating as a manufacturer,

[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

importer, marketer, distributor or researcher under the Finnish Blood Service Act (197/2005), with an authorisation to engage in blood service operations in Finland and a Signatory to the 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, distributer, marketer or researcher referred to in Subclause 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, distributer, marketer or researcher referred to in Subclause 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 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 effects or the clinical trials have been discontinued due to the above injurious effects; or
- the injurious effect is caused by a manufacturing defect.

If such injuries are recognised during different insurance periods, they will be matched to the insurance period in which the first claim was presented in line with Subclause 1.3.

The criteria of ‘serial claim’ are not met in case of such injurious effects under this Subclause where the claim under Subclause 1.3 was made two years 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 vaccines as well as to intracorporeal contraceptive devices dispensed with prescriptions or requiring an internal procedure performed by a healthcare professional. Moreover, the term ‘pharmaceutical’ (‘medicinal product’) shall also comprise blood or blood components supplied for human transfusion use as per the Finnish Blood Service Act (197/2005) and Appendix 1 of the Commission Directive (2004/33/EC).

Only vaccines administered to prevent COVID-19 that are obtained through the European Union joint procurement mechanism and administered in Finland shall nevertheless be deemed medicinal products within the meaning of these terms and conditions of insurance. *European Union joint procurement mechanism* shall denote a joint procurement agreement concluded in accordance with Article 5 of Decision No 1082/2013/EU of the European Parliament and of the Council.

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 referred to under Clause 2 of these Terms and Conditions, taken by the Injured Party. The Insurance Company does not maintain lists of the Insured persons.

Pharmaceutical injuries shall not include illnesses or injuries:

- resulting from a pharmaceutical failing to produce the intended effect;
- 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 essential and necessary healthcare 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.

6.6. No compensation shall be paid for pharmaceutical product damage resulting from a vaccine administered to prevent COVID-19 that has not been obtained through the European Union joint procurement mechanism referred to in clause 2.

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 and Patien Injury 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 4 million euros, including the value of annuities capitalised, at the date they are fixed, in accordance with sound insurance principles and 30 million euros 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 he/she 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 Subclause does not apply to any compensation to which he/she 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 a year of the date on which the person claiming compensation became aware of the validity of the Insurance, the injury caused by the pharmaceutical or blood product involved and the injured event.

The claim form for compensation must be submitted no later than within 10 years from the occurrence of the injured event.

11. Appeal against Insurer's decision on claim

11.1. FINE's The Finnish Financial Ombudsman Bureau and Insurance Complaints Board

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

The request for a statement shall be submitted to FINE no later than three years from the date on which the Injured was informed of the Insurer's decision on the claim and the applicable time limit.

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 also bring action against the Insurer. The action can be bought at the District Court of the Insurer's domicile, 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 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.

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

12. Amendment of terms and conditions of insurance

The Insurance Company shall be entitled to amend these terms and conditions of insurance on the following grounds during the insurance period or when the said period changes:

1) new or amended legislation

2) an unforeseen change in circumstances, such as an international or national crisis, an international pandemic, a national epidemic, or other emergency affecting public health, an exceptional development, introduction or authorisation procedure for a medicinal product, vaccine or other preparation referred to in these terms and conditions of insurance, an exceptional natural event, major accident, or some other change in circumstances comparable to the foregoing.

The Insurance Company shall also be entitled to make minor modifications to the terms and conditions of insurance that do not affect the principal content of the insurance contract.

13. Application of policy terms

These terms and Conditions will be applied to pharmaceutical injuries occurring on or after 1 January 2021.

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 2017.

14. Applicable law

These Insurance Terms and Conditions are construed under Finnish legislation.