Terms and conditions of insurance

Terms and Conditions of Pharmaceutical Injury Insurance in Force as of 1 January 2023

General terms and conditions of the Finnish Mutual Insurance Company for Pharmaceutical Injury Indemnities (hereinafter referred to as ***the Insurance Company***), in force as of 1 January 2023[1].

1. Purpose of the insurance

1.1. Pharmaceutical Injury insurance shall cover personal injury (hereinafter referred to as ***Pharmaceutical Injury***) arising from:

1.1.1. therapeutic use of a Pharmaceutical Product as such, that a manufacturer, importer, distributor or marketer of the product who is a party to the insurance (hereinafter referred to as a Party) has supplied in the course of its customary business operations for consumption in Finland.

1.1.2. an Investigational Pharmaceutical Product, when a Party conducts its own clinical trials in Finland in accordance with the Medical Research Act (488/1999) or collaborates in the conduct of such trials. Personal injury arising from a Pharmaceutical Product that is used as a comparator in a study shall be covered if the conditions of subclause 1.1.1. are satisfied. ***Pharmaceutical research*** shall denote medical research in accordance with the Medicines Act (395/1987) and the Medical Research Act (488/1999) that is commissioned by a pharmaceutical undertaking and conducted under conditions approved by public authorities. Medical research that is conducted on the assignment of another Party in accordance with the Medicines Act (395/1987) and the Medical Research Act (488/1999) under conditions approved by public authorities (known as ***researcher-oriented studies***) shall also constitute pharmaceutical research, provided that

[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

such research is conducted on a Pharmaceutical Product that has been submitted for study by a pharmaceutical undertaking Party, or the research is conducted on a Pharmaceutical Product that is registered as a medicine in Finland.

1.1.3 A *Party* under these terms and conditions shall denote any manufacturer, importer, marketer or distributor of a Pharmaceutical Product, as well as a party conducting the research referred to in subclause 1.1.2 (hereinafter referred to as a *Researcher*) that is a party to the insurance. A pharmaceutical manufacturer on whose behalf a company or any other entity belonging to the same group has become a party to the insurance shall likewise be deemed a Party. A blood service provider under the Blood Service Act (197/2005) that serves as a manufacturer, importer, marketer, distributor or researcher, is licensed to conduct blood service operations in Finland, and is a party to the insurance shall also be deemed a Party hereunder.

1.2. A *Pharmaceutical Injury* shall be deemed to have occurred when a compensation claim has been submitted to the Insurance Company or to the product manufacturer, importer, distributor, marketer or researcher referred to in subclause 1.1., or when the injury causes the death of the Insured.

1.3. Compensation shall be payable for a Pharmaceutical Injury for which a compensation claim has been submitted to the Insurance Company or to the product manufacturer, importer, distributor, marketer or researcher referred to in subclause 1.1, during the insurance period on or after 1 January 2012. Compensation shall nevertheless not be payable for pharmaceutical injuries caused by the vaccine that was marketed under the Pandemrix® brand name in 2009-2010 to prevent infection with influenza A virus subtype H1N1 known as swine flu.

The insurance period shall be the calendar year.

1.4. Serial injury

Irrespective of whether they occur during a single or several insurance periods, injuries caused to several persons by one or more Pharmaceutical Products containing the same active ingredient, or arising from the same incident, or an injury caused to several persons by an incident, cause, deficiency or lack of warning related to the same Pharmaceutical Product or pharmaceutical substance, shall be deemed a single insurance event or serial injury in the event that:

- the Pharmaceutical Product(s) or substances have been partially or entirely removed from the market due to their adverse reactions,
- the licence to use Investigational Pharmaceutical Product(s) or substances has been partially or entirely withdrawn due to their adverse reactions, or the clinical trial has been terminated due to the said reactions, or
- the Pharmaceutical Injury was caused by a manufacturing defect.

Serial injuries of this kind that are recognised during varying insurance periods shall be deemed to relate to the insurance period in which the first claim was submitted under subclause 1.3.

Pharmaceutical Injuries for which a claim under subclause 1.3 was submitted more than two years before the case of serial injury became evident, or where the Pharmaceutical Product or substance was used after its distributors in Finland had been notified of the serial injury, shall not be deemed to constitute the same serial injury under this provision.

2. Pharmaceutical Product

Pharmaceutical Product shall denote a preparation or substance that is intended for human consumption in accordance with section 3 of the Medicines Act (395/1987), with the exception of the preparations referred to in sections 5a – 5b of the said Act. *Pharmaceutical Product* shall also denote an internal contraceptive product that may be dispensed under prescription, or that requires a procedure performed by a healthcare professional. *Pharmaceutical Product* shall also denote blood or a blood component supplied for blood transfusion by a blood service provider in accordance with the Blood Services Act (197/2005) and Annex 1 to Commission Directive 2004/33/EC.

Only vaccines administered in Finland to prevent COVID-19 disease and procured through the European Union joint procurement mechanism shall nevertheless be deemed Pharmaceutical 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. The Insured

The Insured shall denote the users of Pharmaceutical Products.

4. Pharmaceutical Injury

Pharmaceutical Injury shall denote a physical illness or injury or a mental illness that probably arose from use by the injured party of a Pharmaceutical Product referred to in clause 2 of the terms and conditions. The Insurance Company does not maintain a list of insured persons.

Pharmaceutical Injuries shall not include any illness or injury:

- resulting from the failure of a Pharmaceutical Product to produce the intended effect,
- arising in the context of some action or measure that should not have been taken, having regard to the intended or previously known effect of the Pharmaceutical Product concerned, or
- caused by an error in prescribing or administering the Pharmaceutical Product, or due to a lack of medical justification for prescribing the Pharmaceutical Product or administering it for experimental purposes.

5. Compensable injuries

Compensation shall be payable for a Pharmaceutical Injury when, in consequence of the injury, the injured party has:

- been incapacitated for work, or has otherwise sustained impaired bodily functions, for a continuous period of not less than 14 days;
- sustained a permanent physical injury or illness, or
- died.

Notwithstanding the first paragraph of this clause, an injured party shall be reimbursed for essential and necessary medical expenses and loss of earnings exceeding a total of EUR 85 when calculated in the manner specified in clause 7.

6. Limitations

6.1. No compensation for Pharmaceutical Injury shall be payable when an illness or injury results from taking a medically necessary risk in treating an illness or injury that would be life-threatening or that could cause severe physical injury if left untreated.

Nor shall compensation be payable for an injury, or for the part thereof caused by the Pharmaceutical Product, that should reasonably have been tolerated as an adverse effect of using the Pharmaceutical Product, having regard to the following:

- the nature and severity of the illness treated,
- the general health of the injured party,
- the extent of the injury,
- the ability of a specialist to predict the effects of the Pharmaceutical Product, and
- other similar factors.

6.2. Nor shall compensation be payable for a Pharmaceutical Injury if the Pharmaceutical Product was used or supplied in a manner contrary to provisions governing the sale or possession of Pharmaceutical Products with the knowledge of the user or injured party.

6.3. No compensation for Pharmaceutical Injury shall be payable when the user of the Pharmaceutical Product or the injured party caused the injury wilfully.

6.4. Compensation for Pharmaceutical Injury may be reduced or denied if

- the user of the Pharmaceutical Product or the injured party contributed by gross negligence to the occurrence of the injury through obvious misuse of the Pharmaceutical Product or in some other manner – or

- the principal cause of the injury was a factor other than negligence on the part of the manufacturer or importer of the Pharmaceutical Product, or of some other person acting on their behalf.

6.5. No compensation shall be payable for injuries arising directly or indirectly from an act of terrorism. *Act of terrorism* refers to an act committed by one or more persons that involves the use of force or violence or the threat thereof, when the aim of the act in relation to either its nature or context is to promote some political, religious or ideological goal, or to intimidate or influence any government, nation or part thereof.

6.6. No compensation shall be payable for injuries arising directly or indirectly from an act related to cyber security, a cyber attack, or some other attack or act related to an information system. *Act related to cyber security* shall denote an unauthorised, malicious or criminal act or a series of such mutually related acts, irrespective of time and place, or a threat or swindle related thereto, that concerns access to a computer system, processing that takes place therein, or the use or operation thereof. *Cyber attack* shall denote an error or omission, or a series of mutually related errors or omissions, concerning access to a computer system, processing that takes place therein, or the use or operation thereof, and a partial or complete outage or failure, or a series of partial or complete mutually related outages or failures that prevent access to a computer system, processing that takes place therein, or the use or operation thereof. *Computer system* shall denote any computer, hardware, software, communication system, electronic device, server, cloud, or micro-controller incorporating a similar system, or any assembly of the foregoing kind, that includes an input, output, data storage device, network device or backup medium that is owned or used by the Policyholder, the insured or another party.

7. Extent of injury

The compensation payable for Pharmaceutical Injury shall be determined by applying the provisions of sections 2, 2a-2d, 3, 4, 7 and 8 of chapter 5, section 1 of chapter 6 and section 3 of chapter 7 of the Tort Liability Act (412/1974). The compensation shall be determined using the norms and directions of the Traffic Accident and Patient Injury Board where applicable.

Any benefits from public funds or statutory insurance to which the injured party is evidently entitled shall be deducted when calculating the compensation.

8. Sum insured

Compensation liability to each injured party shall not exceed EUR 4 million, including the value of annuities capitalised on the day when they are determined in accordance with good insurance practice, and EUR 30 million for all injuries for which a claim has been submitted during the same year.

The compensation shall be reduced in the same proportion if the sum specified in this clause is insufficient to satisfy all entitlements to compensation.

9. Payment of compensation

9.1. Compensation for Pharmaceutical Injury shall be paid by the Insurer.

9.2. Persons entitled to compensation under these terms and conditions may only collect compensation if they surrender to the Insurer any right to compensation for injury from the party that caused the injury or that is otherwise liable to pay compensation for the injury that they may have in Finland or in any other country.

The duty of injured parties to surrender their right to compensation to the Insurer in accordance with the first paragraph of this clause shall not apply to compensation that they are entitled to receive from public funds or from statutory insurance.

10. Period of limitation

Compensation claims under these terms and conditions shall be submitted to the Insurer within one year of the date on which the claimant became aware of the validity of the insurance, the injury caused by the Pharmaceutical Product or blood product involved, and the injurious consequence. A compensation claim shall be submitted no later than 10 years after the injurious consequence was sustained.

11. Review of compensation decision

11.1 FINE Finnish Financial Ombudsman Bureau and Insurance Complaints Board

An injured party who is dissatisfied with a compensation decision of the Insurer may ask FINE for a recommended solution in the case. The injured party must request a recommended solution from FINE no later than three years after receiving written notice of the decision of the Insurance Company and of the applicable time limit.

11.2. Judicial review

11.2.1. District Court

An injured party who is dissatisfied with a compensation decision of the Insurance Company may also bring an action against the Insurance Company. The action may be brought either at the District Court where the Insurance Company is domiciled, at the District Court where the injured party is domiciled in Finland, or at the District Court of the place of injury in Finland.

11.2.2. Time limit for legal action

An action at the foregoing court arising from a compensation decision issued by the Insurance Company must be initiated within three years of the date on which the injured party received written notice of the decision of the Insurance Company and of the said time limit.

The right of action shall lapse when this time limit expires.

12. Amendment of the 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 is renewed:

- new or amended legislation
- an unforeseeable change of circumstances, such as a national or international crisis, an international pandemic or national epidemic, or some other exceptional situation that affects the health of the population, the exceptional development, introduction or authorisation procedure of a Pharmaceutical Product, vaccine or other preparation referred to in these terms and conditions of insurance, an exceptional natural event, a catastrophe, or some other change in circumstances that is 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 contract of insurance.

13. Application of the terms and conditions of insurance

These terms and conditions shall apply to Pharmaceutical Injuries occurring on or after 1 January 2023.

These terms and conditions shall apply to compensation paid for serial injuries for which the first compensation claim was submitted to the Insurer on or after 1 January 2023.

14. Applicable law

These terms and conditions of insurance shall be governed by Finnish legislation.