Republic of Latvia

Cabinet

Regulation No. 272

Adopted 3 May 2022

**Regulations Regarding Compensation for Serious or Moderately Serious Harm to the Health or Life of a Patient Inflicted due to Adverse Effects Caused by Vaccination against COVID-19 Infection**

*Issued pursuant to*

*Section 49.7 of the Law on the Management of the Spread of COVID-19 Infection*

**I. General Provisions**

1. The Regulation prescribes:

1.1. the requirements and procedures for the requesting and granting, or refusing to grant compensation for serious or moderately serious harm to the health or life of a patient inflicted due to the confirmed adverse effects caused by vaccination against COVID-19 infection (hereinafter – the compensation);

1.2. the procedures for the disbursement of the compensation from the funds from the State budget;

1.3. the amount of the compensation to be disbursed according to the severity of harm inflicted to the health or life of a patient.

2. The following terms are used in this Regulation:

2.1. serious harm – ongoing health disorders which inflict significant irreversible restriction on or loss of self-care, functioning, capacity for work, and quality of life and are directly related to an adverse effect caused by vaccination against COVID-19 infection, and conform to the signs indicated in Paragraph 3, 4, or 5 of Annex 1 to this Regulation, or death;

2.2. moderately serious harm – long-lasting health disorders which inflict partial (also irreversible) restriction on self-care, functioning, capacity for work, and quality of life and are directly related to an adverse effect caused by vaccination against COVID-19 infection, and conform to the signs indicated in Paragraph 1 or 2 of Annex 1 to this Regulation.

3. The compensation shall be granted if the serious or moderately serious harm inflicted on the health or life of a patient is directly related to an adverse effect caused by vaccination against COVID-19 infection (hereinafter – the vaccine against COVID-19) and the following conditions are met:

3.1. the patient has been vaccinated in Latvia with the vaccine against COVID-19 which has been registered in a centralised registration procedure in conformity with Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, and serious or moderately serious harm to the health or life has occurred to him or her;

3.2. the adverse effect is referred to in the product characteristics of the vaccine against COVID-19;

3.3. the patient displays ongoing or long-lasting health disorders which have lasted for at least 26 weeks, counting from the day of occurrence of the harm, or death has occurred.

4. The State Agency of Medicines (hereinafter – the Agency) shall be the responsible authority for the establishment of serious or moderately serious harm caused to the health or life of a patient, for the determination, granting, and disbursement of the amount of the compensation.

**II. Procedures for Requesting the Compensation**

5. In order to request the compensation, the patient referred to in Paragraph 3 of this Regulation (hereinafter – the submitter) shall, in conformity with the time periods for requesting the compensation provided for in Section 49.7, Paragraph three of the Law on the Management of the Spread of COVID-19 Infection, fill in and submit a submission for requesting the compensation (hereinafter – the submission) to the Agency in accordance with Annex 2 to this Regulation, an opinion of a physician on the potential causal link between the adverse effect caused by the vaccine against COVID-19 and the harm inflicted on the health or life of the patient (hereinafter – the opinion), and also medical documents certifying it.

6. In case of death of a patient, a heir of the patient is entitled to submit the submission by appending a certificate for the share of the spouse’s property or an inheritance certificate and the protocol of the pathologic-anatomical investigation or an opinion of a forensic medical expert.

**III. Requirements and Procedures for the Assessment of the Request for the Compensation and the Harm Inflicted, and also the Procedures for Taking the Decision and the Disbursement of the Compensation**

7. Upon receipt of the submission, the Agency shall assess the information included therein and the documents appended. If the Agency establishes that the submission or the documents appended are incomplete, it shall, within 15 working days after receipt of the submission, request the submitter in writing to submit additional information within a month. In such case, the time period referred to in Paragraph 8 of this Regulation is suspended until the day when the requested additional information is submitted to the Agency.

8. In assessing the submission and the documents appended thereto, the Agency shall, within a month (excluding the time period necessary for receipt of the additional information referred to in Paragraph 7 of this Regulation), take the decision to refuse to examine the submission in the following cases:

8.1. the potential adverse effect of the medicinal products is not included in the product characteristics of the vaccine used against COVID-19;

8.2. the opinion of a physician and the medical documents attesting to the causal link between the adverse effect caused by the vaccine against COVID-19 and the harm inflicted on the health or life of the patient have not been appended, and the submitter has not submitted the relevant information also upon request of the Agency;

8.3. the necessary information has not been included in the submission, and the submitter has not submitted the relevant information also upon request of the Agency;

8.4. the patient has not been vaccinated in Latvia with the vaccine against COVID-19 which has been registered in a centralised registration procedure in conformity with Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency;

8.5. in case of death of the patient, a protocol of the pathologic-anatomical investigation or an opinion of a forensic medical expert has not been submitted, and the submitter has not submitted the relevant information also upon request of the Agency;

8.6. in case of death of the patient, a certificate for the share of the spouse’s property or an inheritance certificate has not been submitted, and the submitter has not submitted the relevant information also upon request of the Agency;

8.7. the harm to the health or life of the patient is not directly related to an adverse effect caused by the vaccine against COVID-19;

8.8. the information included in the submission and the documents appended do not attest that the harm inflicted on the patient is to be classified as serious or moderately serious in accordance with Annex 1 to this Regulation;

8.9. the time periods for requesting the compensation indicated in Section 49.7, Paragraph three of the Law on the Management of the Spread of COVID-19 Infection have not been conformed to.

9. When assessing the submission, it shall be necessary to establish:

9.1. existence or non-existence of serious or moderately serious harm to the health or life after an adverse effect caused by the vaccine against COVID-19;

9.2. the potential causal link of the adverse effect caused to a patient with the vaccine against COVID-19;

9.3. the potential causal link between the adverse effect caused by the vaccine against COVID-19 and the serious or moderately serious harm inflicted on the health or life of a patient.

10. If the Agency establishes the potential causal link referred to in Sub-paragraph 9.2 of this Regulation, it shall, within five working days, prepare all the necessary information and medical documentation and submit it to the physician-specialist of the relevant field of a clinical university hospital or a commission of physicians-specialists (hereinafter – the expert) for assessment in order to establish the causal link referred to in Sub-paragraph 9.3 of this Regulation or its non-existence.

11. The opinion of an expert on the potential causal link established and referred to in Sub-paragraph 9.3 of this Regulation or its non-existence shall be submitted to the Agency within 30 days. If more time is necessary for the assessment of the situation, the expert shall inform the Agency; however, the total time for the provision of the opinion shall not exceed 60 days.

12. In order to assess the submission, the Agency is entitled:

12.1. to request and receive the medical documents of the patient from the family doctor of the patient, medical practitioners, and medical treatment institutions;

12.2. to invite the expert for the assessment of the causal link of adverse effects caused by the vaccine against COVID-19 or for the establishment of serious or moderately serious harm by ensuring access to the medical documentation of the patient;

12.3. to enter into a contract with the expert for the assessment of the potential causal link referred to in Sub-paragraph 9.3 of this Regulation or its non-existence and to cover expenditures for the provision of the opinion referred to in Paragraph 11 of this Regulation.

13. After receipt of the opinion referred to in Paragraph 11 of this Regulation, the Agency shall assess all the information at its disposal and determine existence or non-existence of the serious or moderately serious harm inflicted on the health or life referred to in Sub-paragraph 9.1 of this Regulation after an adverse effect caused by the vaccine against COVID-19.

14. If the Agency establishes the causal links referred to in Paragraph 9 of this Regulation, it shall, in conformity with Annex 1 to this Regulation, determine the amount of the compensation to be disbursed and take the decision to grant the compensation, indicating existence of the harm and the amount of the compensation to be disbursed.

15. The Agency shall take the decision to refuse to disburse the compensation if one of the following circumstances exists:

15.1. the established harm to the health or life is not to be classified as serious or moderately serious;

15.2. a causal link between the serious or moderately serious harm inflicted on the health or life of the patient and the adverse effect caused by the vaccine against COVID-19 has not been established;

15.3. the potential causal link of the reported adverse effect caused by the vaccine against COVID-19 has not been established;

15.4. the compensation for the medical treatment referred to in the submission has been received within the scope of civil proceedings.

16. The Agency shall take the decision within the time periods specified in Section 49.7, Paragraph two of the Law on the Management of the Spread of COVID-19 Infection.

17. The Agency shall store the documents related to the assessment of the submission for 10 years after taking the decision.

18. The Agency shall, within three working days after taking the decision to grant the compensation, send it to the submitter and the Ministry of Health. The Ministry of Health shall, within five working days after receipt of the decision, prepare a draft Cabinet order regarding a request of the funds from the State budget from the State budget programme 02.00.00 “Funds for Unforeseen Events” and advance it for approval at the Cabinet.

19. The Agency shall, within five working days after receipt of the funds from the State budget programme 02.00.00 “Funds for Unforeseen Events” into the account of the Agency, disburse the compensation:

19.1. to the patient;

19.2. in case of death of the patient – to the heir of the patient in proportion to the share of an inheritance if a certificate on the share of the spouse’s property or an inheritance certificate has been submitted;

19.3. to the lawful representative of the minor patient.

20. The decision of the Agency may be contested to the Ministry of Health. The decision of the Ministry of Health may be appealed to a court in accordance with the procedures laid down in the Administrative Procedure Law.

**IV. Closing Provision**

21. The compensation may be received for the harm inflicted on the patient after 28 December 2020 when vaccination of the public against COVID-19 infection was commenced in Latvia.

Acting for the Prime Minister – Minister for Finance J. Reirs

Minister for Health D. Pavļuts

**Annex 1**

Cabinet Regulation No. 272

3 May 2022

**Characterisation of the Signs of Serious or Moderately Serious Harm and Amount of the Compensation**

|  |  |  |
| --- | --- | --- |
| No. | Characteristic signs | Amount of the compensation, euro |
| **I. Moderately serious harm to the health which is directly related to an adverse effect caused by the vaccine against COVID-19 infection** | | |
| 1. | There shall be the following signs altogether:  1.1. the person is undergoing medical treatment of at least 26 weeks and/or has temporary incapacity for work for at least 26 weeks (if the person is employed);  1.2. the person requires medical procedures, surgical interventions, and/or rehabilitation | 5 000 |
| 2. | There shall be the following signs altogether:  2.1. the person is undergoing medical treatment of at least 26 weeks and/or has temporary incapacity for work for at least 26 weeks (if the person is employed);  2.2. due to an adverse effect caused by the vaccine against COVID-19 infection (without direct threats to the life), the person required provision of emergency medical assistance or inpatient medical treatment;  2.3. the person needs pain relief prescribed by a physician or additional medicinal products the discontinuation of the use of which would endanger the life of the person or deteriorate the quality of life, or medical procedures and/or surgery are required | 10 000 |
| **II. Serious harm to the health or life which is directly related to an adverse effect caused by the vaccine against COVID-19 infection** | | |
| 3. | There shall be the following signs altogether:  3.1. the person displays significant adverse effects caused by the vaccine against COVID-19 infection due to which inpatient medical treatment and temporary intense care, serious/high-risk surgery or procedures were required;  3.2. serious restrictions on the functioning have been established for the person and Group II disability has been determined | 50 000 |
| 4. | In addition to the signs indicated in Paragraph 3 of this Annex, there is at least one of the following signs:  4.1. the person has lost a physiological or mental function or has a serious pathology as a result of which the person is able to carry out everyday life activities by himself or herself however at a significantly lower pace, with more effort, at a worse quality, the person episodically requires assistance or supervision;  4.2. the person is partially dependent on assistance in everyday life, the person is only able to carry out the simplest activities for ensuring self-care;  4.3. the person requires repeated or long-term inpatient medical treatment and/or high-risk surgeries/procedures and repeated long-term rehabilitation | 75 000 |
| 5. | 5.1. Group I disability has been determined for the person, due to health disorders and functional disorders the independent functioning of the person is limited or is practically impossible, the person requires assistance and supervision in everyday life activities.  5.2. Death of the person | 142 290 |

**Annex 2**

Cabinet Regulation No. 272

3 May 2022

**Submission for Requesting the Compensation**

|  |  |
| --- | --- |
|  |  |
|  | (given name, surname) |
|  |  |
|  | (personal identity number) |
|  |  |
|  | (address of the place of residence) |
|  |  |
|  | (contact telephone, e-mail) |

I request disbursement of the compensation to me for serious or moderately serious harm inflicted on the health or life which has been caused to the patient due to the approved adverse effects of the vaccine against COVID-19 infection

|  |  |
| --- | --- |
|  | . |
| (given name, surname, personal identity number of the patient) | |

I provide the following information:

Date and place of vaccination – \_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 20\_\_\_\_

|  |  |  |
| --- | --- | --- |
| Family doctor of the patient |  |  |
| Attending physician of the patient |  |  |

Health care practitioner who provided the report on the established potential adverse effect:

|  |  |  |
| --- | --- | --- |
| speciality |  |  |
| given name, surname |  |  |
| medical treatment institution |  |  |

Period of medical treatment in relation to an adverse effect caused by the vaccine against COVID-19 infection:

from \_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 20\_\_\_\_ to \_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 20\_\_\_\_

Description of the situation and additional information certifying the harm inflicted on the health or life of the patient:

|  |
| --- |
|  |
|  |

I request to transfer the calculated compensation to:

|  |  |  |  |
| --- | --- | --- | --- |
| name of the settlement institution |  | |  |
| bank code |  | |  |
| account number |  | |  |
|  | | |  |
| (given name, surname, and personal identity number on whose behalf the settlement account has been opened) | |  | |

The following documents have been appended to the submission for requesting the compensation:

|  |  |  |
| --- | --- | --- |
| 1) |  |  |
| 2) |  |  |
| 3) |  |  |
| 4) |  |  |
| 5) |  |  |
| 6) |  |  |

1. I certify that the information provided is true and complete and I undertake to notify the State Agency of Medicines of changes in the information referred to in the submission for requesting the compensation within seven days after I have become aware of the changes.

2. I am informed that the State will recover the compensation disbursed if false information has been provided knowingly in order to receive the compensation.

3. I am informed that the State Agency of Medicines, in examining the submission for requesting the compensation, will request and receive medical documents of the patient from my medical practitioners or medical practitioners of the person represented by me and/or from medical treatment institutions, and also will send my medical documents or medical documents of the person represented by me to third parties (physicians-specialists) in accordance with Article 6(1)(e) and Article 9(2)(h) of the General Data Regulation.

4. I have not received a compensation for the medical treatment referred to in the submission for requesting the compensation within the scope of civil proceedings. If the information referred to in this Paragraph is to change, I undertake to inform the State Agency of Medicines thereof within seven days.

I agree to receive the decision\*:

▢ to the e-mail address indicated in this submission for requesting the compensation

▢ sent by post to the postal address indicated in this submission for requesting the compensation

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Date\*\* |  |  |  |  |
|  |  |  | (given name, surname, signature) |  |

Notes.

1. \* If the account of official electronic address has been activated, the decision will be sent to the official electronic address.

2. \*\* The details “date” and “signature” of the document need not be filled in if the electronic document has been prepared in accordance with the laws and regulations regarding drawing up of electronic documents.