Republic of Latvia

Cabinet

Regulation No. 299

Adopted 2 July 2019

**Epidemiological Safety Measures for the Limitation of the Spread of Tuberculosis**

*Issued pursuant to*

*Section 3, Paragraph two and Section 19, Paragraph one of the Epidemiological Safety Law*

**I. General Provisions**

1. This Regulation prescribes the epidemiological safety measures to be taken to limit the spread of tuberculosis, including the procedures for the determination, initial medical examination, laboratory examination, and medical observation of persons exposed to tuberculosis.

2. This Regulation determines the following epidemiological safety measures:

2.1. the diagnostics of tuberculosis and tuberculosis infection;

2.2. the identification and examination of exposed persons;

2.3. the medical treatment of tuberculosis;

2.4. the prophylactic treatment of tuberculosis infection;

2.5. planning, distribution of tuberculin and accounting of tuberculin diagnostics;

2.6. the methodological management of diagnostics and medical treatment of tuberculosis and planning of medicinal products.

**II. Diagnostics of Tuberculosis and Tuberculosis Infection**

3. A medical treatment institution shall ensure diagnostics of tuberculosis and tuberculosis infection by informing a patient or exposed person (or their legal representative), in a timely manner, of the necessity to carry out the relevant examinations in conformity with medical indications.

4. A medical treatment institution shall ensure examinations for the diagnostics of lung and upper respiratory tract tuberculosis and tuberculosis infection for the persons who belong to any of the tuberculosis risk groups according to the conditions for the examination of tuberculosis infection and disease diagnostics published on the website of the Centre for Disease Prevention and Control (hereinafter – the Centre).

**III. Determination, Initial Medical Examination, Laboratory Examination, and Medical Observation of Exposed Persons**

5. The determination, initial medical examination, laboratory examination, and medical observation of exposed persons shall be ensured:

5.1. if for a patient with lung and upper respiratory tract tuberculosis:

5.1.1. acid resistant bacteria (ARB positive bacterioscopically) have been detected in the sputum;

5.1.2. acid resistant bacteria (ARB negative bacterioscopically) have not been detected in the sputum, however, there are justified suspicions that in conformity with the clinical form of tuberculosis (for example, destruction cavities in lungs) the patient discharges agents of tuberculosis from respiratory tract. The relevant activities shall be carried out also in case if tuberculosis has been diagnosed after the death of the person by detecting destruction cavities in lungs;

5.1.3. the agent of tuberculosis has been detected bacteriologically or by molecular diagnostic method (TM positive);

5.2. if tuberculosis or tuberculosis infection has been diagnosed for a child up to the age of four years (including).

6. In the cases specified in Paragraph 5 of this Regulation the attending physician of the patient or the nurse who is working under management of the attending physician shall:

6.1. ensure a survey of the patient (legal representative) in order to identify the contact person at the place of residence of the patient (persons living together) or other exposed persons (relatives, friends) who have been in a close contact with the patient, including the persons who frequently visited the place of residence of the patient;

6.2. upon filling out a notification of a medical treatment institution on the diagnosed tuberculosis in accordance with the laws and regulations regarding the procedures for the registration of infectious diseases and record-keeping of medical documents, indicate the identified exposed persons of the tuberculosis patient in the notification.

7. The Centre shall:

7.1. inform in writing the pneumonologist who is practising close to the place of residence of the tuberculosis patient of the registered case of tuberculosis and append a copy of the notification of the medical treatment institution to the letter of the Centre on the diagnosed tuberculosis (form No. 89/u-t) for further identification of exposed persons at the place of residence of the patient, performance of medical examination and medical observation (hereinafter – the examinations), as well as for entering the information regarding the patients who have been diagnosed with tuberculosis in the register of the patients who are ill with certain diseases;

7.2. in the cases referred to in Paragraph 5 of this Regulation organise the determination of exposed persons by assessing the risk of infection:

7.2.1. at a medical treatment institution, the institution which is providing surveillance services for children, an interest educational institution, a camp, a social care institution, work place, and other places of stay of persons (including at a place of imprisonment, temporary place of detention, accommodation premises for detained asylum seekers and accommodation centre for foreigners, accommodation centre for asylum seekers, shelter, barracks, official accommodation facility) outside the place of residence of the patient (hereinafter – the place of stay);

7.2.2. in an inpatient medical treatment institution in the health care service programme of which the treatment of tuberculosis is not included;

7.2.3. in international vehicles;

7.3. ascertain the medical practitioner (if any) of the place of stay referred to in Sub-paragraph 7.2.1 of this Regulation and inform him or her in writing of the necessity to organise the examinations of the identified exposed person and ensuring the continuity thereof. The examinations shall be carried out by a competent medical practitioner of the place of stay, family doctor, or pneumonologist;

7.4. if there are no medical practitioners at the places of stay referred to in Sub-paragraph 7.2.1 of this Regulation, provide recommendations according to which the employer of the place of stay or the head of the place of stay referred to in Sub-paragraph 7.2.1 of this Regulation shall inform the exposed person present in his or her institution of the necessity to perform the examinations. The employer or the head of the place of stay is entitled to organise the abovementioned examinations which are carried out by a family doctor or pneumonologist;

7.5. provide recommendations according to which the medical treatment institution referred to in Sub-paragraph 7.2.2 of this Regulation shall organise identification of exposed persons of the tuberculosis patient and inform the Centre thereof in writing for organising the examinations;

7.6. inform a foreign competent public health authority of the exposed person who is living abroad for the performance of the examinations;

7.7. ascertain the family doctor of the exposed person identified in Paragraph 6 and Sub-paragraph 7.2 of this Regulation (or the family doctor who practices in the territory where the place of residence of the exposed person is located if the exposed person is not registered with the family doctor) and send the information to the family doctor in writing:

7.7.1. in the case referred to in Paragraph 6 and Sub-paragraph 7.2.1 of this Regulations – for information;

7.7.2. in the case referred to in Sub-paragraphs 7.2.2 and 7.2.3 of this Regulation, as well as if the information regarding the exposed person has been received from a foreign competent public health authority – regarding the necessity to organise the examinations of the exposed person by the family doctor.

8. Upon instruction by the epidemiologist of the Centre, an employer or the head of the place of stay shall inform the exposed person (a legal representative thereof) of the necessity to perform the examinations, as well as ensure the possibility to perform the necessary examinations and ascertain the performance of the instruction.

9. The outpatient pneumonologist shall:

9.1. on the basis of the received information referred to in Sub-paragraph 7.1 of this Regulation, identify the exposed persons at the place of residence of the tuberculosis patient (persons living together) or other exposed persons (relatives, friends) who have been in a close contact with the patient, including who have often visited the place of residence of the patient;

9.2. perform the initial medical examination of the exposed persons identified in accordance with Sub-paragraph 7.1 or 7.2 of this Regulation;

9.3. perform medical observation (repeated medical examinations) for two years after the last contact with the infectious tuberculosis patient:

9.3.1. for adults not less than once a year;

9.3.2 for children not less than twice a year;

9.4. document information in the outpatient medical card of the patient.

**IV. Treatment of Tuberculosis and Tuberculosis Infection**

10. A pneumonologist shall confirm the diagnosis of tuberculosis infection and tuberculosis, except for the case referred to in Paragraph 15 of this Regulation, and start treatment by determining medicinal products and medical treatment regime.

11. The pneumonologist shall determine prophylactic treatment in the case of tuberculosis infection for children and persons infected with HIV. The pneumonologist may determine prophylactic treatment in the case of tuberculosis infection for other tuberculosis risk groups.

12. The outpatient care of a tuberculosis patient may be performed by a family doctor or physician-specialist by agreeing with the attending pneumonologist on ensuring tuberculosis treatment for the patient.

13. During the medical treatment of tuberculosis the medicinal products shall be administered under direct observation of a medical practitioner.

14. A medical practitioner shall perform the following in the medical documentation of the patient in accordance with the laws and regulations regarding the procedures for record-keeping of medical documents:

14.1. register the issuance of medicinal products to a tuberculosis patient during outpatient treatment;

14.2. indicate the data on the administration of medicinal products;

14.3. document the examinations performed for the determination of the presence of tuberculosis microbacteria;

14.4. enter information regarding the summary of medical treatment of multi-drug resistant tuberculosis and summary of sensitivity test of medicinal products for a multi-drug resistant tuberculosis patient;

14.5. enter the decision of the doctors’ council referred to in Paragraph 15 of this Regulation.

15. Confirmation of diagnosis of drug resistant tuberculosis patients and determination of medical treatment, as well as review thereof not less than once in three months shall be ensured by the doctors’ council established by sabiedrība ar ierobežotu atbildību “Rīgas Austrumu klīniskā universitātes slimnīca” [limited liability company Riga East University Hospital] (hereinafter – the limited liability company Riga East University Hospital].

16. An attending doctor who has professionally substantiated doubts regarding drug resistant tuberculosis shall ensure examination of the case of the patient by the doctors’ council established by the limited liability company Riga East University Hospital.

17. The limited liability company Riga East University Hospital shall ensure the methodological management of medical treatment of tuberculosis patients and prophylactic treatment of tuberculosis infection and consultative medical assistance.

**V. Planning of Purchase, Distribution and Accounting of Tuberculin and Medicinal Products Intended for the Medical Treatment of Tuberculosis**

18. A medical treatment institution shall:

18.1. designate a person responsible for the receipt of tuberculin, safe storage thereof according to the requirements stipulated by the manufacturer of tuberculin, the utilisation, accounting, write-off, and destruction of tuberculin (hereinafter – the responsible person);

18.2. plan and order the necessary amount of tuberculin which does not exceed the average utilisation of tuberculin in two months by the medical treatment institution, taking into account the planned number of tests and tuberculin left in stock, using the following formula:

Pmax = I x 2 – A, where

Pmax – maximum order of tuberculin;

I – average utilisation of tuberculin per month;

2 – two months;

A – tuberculin left in stock on the day of placing an order;

18.3. each month by the fifth date, submit the tuberculin order to the relevant regional division of the Centre for the following month and report on the utilisation of tuberculin in the previous month (Annex 1). If in addition to the amount of the current order an extraordinary order of tuberculin is necessary, the medical treatment institution shall prepare a written request for the receipt of tuberculin (Annex 1, Paragraph 2), indicating the justification, and submit it to the relevant regional division of the Centre;

18.4. accept tuberculin from the medicinal product wholesaler with which the National Health Service (hereinafter – the Service) has entered into the contract for the purchase of tuberculin;

18.5. if tuberculin has become unsuitable for administration, submit a report on the write-off and return of tuberculin, indicating the reason why the tuberculin has been written off and returned, to the relevant regional division of the Centre within five working days.

19. Regional divisions of the Centre shall, by the twelfth date of each month, evaluate and compile the order and utilisation of tuberculin by the medical treatment institutions existing in the territory to be serviced, making adjustments if inaccuracies have been detected or the order exceeds the average use of tuberculin by the medical treatment institution without justification, as well as if the amount of tuberculin left in stock in the medical treatment institution is not taken into account. The compiled data shall be submitted to the Centre.

20. The Centre shall:

20.1. plan the total amount of tuberculin and syringes necessary per calendar year for diagnostics of tuberculosis, as well as shall provide for the reserve of tuberculin up to 10 %, taking into account the average consumption of tuberculin and information regarding the write-off of tuberculin, and co-ordinate the abovementioned plan with the Ministry of Health;

20.2. each month by the eighteenth date, compile data on the order of tuberculin by medical treatment institutions, make adjustments, and submit the total order of tuberculin to the Service and medicinal product wholesaler with which the Service has entered into the contract for the purchase of tuberculin;

20.3. ensure compilation of the data on the utilisation of tuberculin;

20.4. once a month, compile the information provided by medical treatment institutions regarding tuberculin left in stock and the reasons for its write-off, and submit the information regarding the total tuberculin left in stock to the Centre.

21. The limited liability company Riga East University Hospital shall plan the purchase of medicinal products necessary for the medical treatment of tuberculosis, make a centralised procurement in accordance with the procedures laid down in the Public Procurement Law, distribution among medical treatment institutions, and accounting.

22. Medical treatment institutions which are providing State paid health care services shall request the medicinal products necessary for the medical treatment of patients, as well as submit a report to the limited liability company Riga East University Hospital on the utilisation of tuberculosis medicinal products according to the contract entered into between the medical treatment institution which provides health care services to persons suffering from tuberculosis and the Service.

**VI. Closing Provision**

23. Paragraphs 5, 6, 7, 8, and 9 of this Regulation shall come into force on 1 January 2020.

Acting for the Prime Minister –

Deputy Prime Minister, Minister for Justice J. Bordāns

Minister for Health I. Viņķele

**Annex 1**

Cabinet Regulation No. 299

2 July 2019

**Report on the Utilisation of Tuberculin and Order of Tuberculin**

Name and address of the medical treatment institution

|  |
| --- |
|   |
|   |

Code 

|  |
| --- |
|   |
| (given name, surname, telephone number of the medical practitioner) |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 20 |   | (year) |   |   |
|   |   |   | (month) |   |

**1. Tuberculin diagnostics**1

|  |  |  |
| --- | --- | --- |
| A | Total | including children |
| The number of tuberculin tests |   |   |

**2. Tuberculin left in stock and order**

|  |  |
| --- | --- |
| Tuberculin left in stock1 | Tuberculin order |
| doses | vials | doses | vials |
| 01 | 02 | 03 | 04 |
|   |  |  |  |

|  |  |
| --- | --- |
| Justification2 |   |

Please, deliver tuberculin by \_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 20\_\_\_\_\_\_\_\_\_\_\_2

|  |  |
| --- | --- |
| Working hours of the medical treatment institution2 |   |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Date3 |   | Head of the institution |   | Signature3 |   |
|   |   |   | (given name, surname) |   |   |

Place for a seal3

Notes.

1 Shall not be filled out in case of an extraordinary order of tuberculin.

2 Shall be filled out only in case of an extraordinary order of tuberculin.

3 The details of the document “date”, “signature”, and “place for a seal” need not be completed if the electronic document has been prepared in accordance with the laws and regulations regarding drawing up of electronic documents.

Minister for Health I. Viņķele

**Annex 2**

Cabinet Regulation No. 299

2 July 2019

**Report on the Write-off and Return of Tuberculin**

Name and address of the medical treatment institution

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| --- |
|   |
|   |

Code 

|  |
| --- |
|   |
| (given name, surname, telephone number of the medical practitioner) |

**Information regarding tuberculin**

|  |  |  |
| --- | --- | --- |
| 1. | Name |   |
| 2. | Batch number |   |
| 3. | Period of validity |   |
| 4. | Date of receipt |   |
| 5. | Reason for the write-off/return (indicate the code from the classification) |   |
| 6. | Quantity |   |
| 7. | Date of discovering the fact |   |
| 8. | Date of the write-off or change |   |
| 9. | Date of destruction |   |
| 10. | Type of destruction |   |

Classification of the reasons for the write-off/return of tuberculin

|  |  |
| --- | --- |
| Code | Reason for the write-off/return of tuberculin |
| 01 | The term of validity of tuberculin has expired |
| 02 | The vial of tuberculin does not have a labelling |
| 03 | Information on the labelling is not legible |
| 04 | Non-conformity of information provided in the labelling with the content is detected |
| 05 | Damaged tuberculin has been received (impact of unfavourable manufacturing or transport factors) |
| 06 | Tuberculin has been obviously damaged at the medical treatment institution |
| 07 | There are suspicions of or signs of non-conformity with the storage regime of tuberculin |
| 08 | Visible non-conformity of tuberculin or solvent with the physical properties indicated in the instructions for use is detected |
| 09 | Solvent has not been intended for the particular tuberculin |
| 10 | Use of the tuberculin has been suspended or withdrawn |
| 11 | A medical treatment institution discontinues its operations |
| 12 | Other reasons (specify)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Date1 |   | Head of the institution |   | Signature1 |   |
|   |   |   | (given name, surname) |   |   |

Place for a seal1

Note. 1 The details of the document “date”, “signature” and “place for a seal” need not be completed if the electronic document has been prepared in accordance with the laws and regulations regarding drawing up of electronic documents.

Minister for Health I. Viņķele