Republic of Latvia

Cabinet
Regulation No. 330
Adopted 26 September 2000

Vaccination Regulations

Issued pursuant to Section 30, Paragraph one, two, three and Section 31, Paragraph five of Epidemiological Safety Law

I. General Provisions

1. These Regulations prescribe infectious diseases against which mandatory vaccination shall be performed, the cohort of persons to be vaccinated (including persons employed in specific occupations or belonging to increased risk groups) and vaccination procedures, as well as mandatory minimum security requirements for performing vaccinations.

2. Vaccinations shall be organised and implemented by vaccination institutions (medical treatment institutions, which conform to the mandatory requirements specified in regulatory enactments, educational institutions, as well as other undertakings (companies) and institutions, which conform to mandatory minimum security requirements for performing vaccinations), and the State supervision and control shall be provided by the Ministry of Welfare and authorities thereof.

3. Within the framework of the State Immunisation Programme vaccination shall be mandatory for:
   3.1. children – against tuberculosis, diphtheria, tetanus, whooping cough, poliomyelitis, measles, rubella, epidemic parotitis, b-type infection caused by Pfeiffer’s bacilli (influenza bacteria), virus hepatitis type B;
   3.2. adults – against diphtheria, tetanus; and
   3.3. children and adults – against rabies after contact with animals or humans who are ill or are suspected of being ill with rabies.

4. The Minister for Welfare shall approve the State Immunisation Programme.

5. Persons who have contraindications to vaccination (the state in which the vaccination is not permissible due to medical considerations) shall be exempted from compulsory vaccination if such is indicated in the medical documentation (documents which confirm the fact of the vaccination of a person and which are stored in an institution in which the vaccination has been performed, or with a medical practitioner) and certified with a signature by a doctor.

6. All expenditures related to the State Immunisation Programme and the vaccinations referred to in Paragraph 3 of these Regulations, their organisation, supervision and control, also to the acquisition of vaccines, drawing up of medical documentation, vaccine injection, as well as to the treatment of complications (side-effects) caused by vaccination which
treatment has been included in the minimum of medical services to be provided for inhabitants specified in regulatory enactments, shall be financed from the State basic budget and the State special health care budget.

7. Vaccination institutions have rights to perform vaccinations for a charge utilising vaccines, which have been acquired outside of the State procurement for implementation of the State Immunisation Programme if the person to be vaccinated or his or her legal representative so agrees. In such cases medical practitioners have a duty to inform the patients regarding the opportunity to be vaccinated free of charge with other vaccines, if such an opportunity exists.

8. In case of an epidemic or threat thereof, the Minister for Welfare is entitled to issue an order regarding the mandatory vaccination of specific groups of the population in cases not provided for in the State Immunisation Programme and to purchase supplementary vaccines within the limits of the budget resources allocated to the Ministry of Welfare. If in case of an epidemic or threat thereof, supplementary mandatory vaccination is necessary which exceeds the resources allocated to the Ministry of Welfare, the decision on supplementary mandatory vaccination shall be taken by the Cabinet on the basis of a proposal of the Minister for Welfare.

9. In order to professionally evaluate the issues related to vaccination and the State Immunisation Programme and to provide proposals for the solution thereof, as well as in order to evaluate orders for vaccines, the Minister for Welfare shall establish the State Immunisation Advisory Council and approve its by-laws. Members of the Council shall not receive remuneration for their work in the Council.

II. Planning and Organising of Vaccination within the Framework of the State Immunisation Programme

10. The vaccination institutions shall, in accordance with the procedures specified by the Minister for Welfare:
   10.1. prepare the necessary vaccine order for the territorial offices of the Public Health Agency, taking into account the number of persons to be vaccinated in the territory under their supervision and/or that of the vaccination institutions; and
   10.2. submit a report on the vaccination results and utilisation of vaccines to the territorial office of the Public Health Agency.

11. The Health Fund together with the territorial office of the Public Health Agency shall at regular intervals evaluate the utilisation of resources and vaccines and agree on improvements of vaccination efficiency in the territory under its supervision.

12. The territorial offices of the Public Health Agency shall:
   12.1. order the vaccines from the central office of the Public Health Agency;
   12.2. ensure the obtaining of vaccines from the central office of the Public Health Agency, their storage, records and handing over to the vaccination institutions in conformity with their order; and
   12.3. analyse the indicators of population immunisation and morbidity rate and organise, together with health funds and vaccination institutions, measures in order to provide for the vaccination of the maximum number of inhabitants.

13. The central office of the Public Health Agency shall:
13.1. plan the total necessary amount of vaccines for implementation of the State Immunisation Programme, taking into account the demographic data and average consumption of preparations and co-ordinate it with the Ministry of Welfare;

13.2. store the acquired vaccines and organise the distribution of vaccines to the territorial offices of the Public Health Agency and vaccination institutions, and assign a person (a doctor or pharmacist) to be responsible for storage, transport and distribution of vaccines; and

13.3. provide the supervision of the implementation of the State Immunisation Programme and, if necessary, organise and propose measures for the improvement of vaccinations.

14. The non-profit-making organisation, State stock company “Valsts obligātās veselības apdrošināšanas aģentūra” [State Mandatory Health Insurance Agency] shall organise a competition (by inviting relevant experts and a representative from the Ministry of Welfare) regarding the acquisition of vaccines for the implementation of the State Immunisation Programme and enter into agreements on the acquisition of vaccines in conformity with the results of the competition.

III. Performance of Vaccinations

15. Only certified medical practitioners may perform vaccinations.

16. Medical practitioners and/or vaccination institutions shall in sufficient time notify the patients under care regarding the necessity of vaccination.

17. A room where the vaccination is performed shall be equipped with:

17.1. a medical cupboard for storage of instruments and medicinal products if the vaccination is performed regularly (every day);

17.2. a medical couch;

17.3. a baby table if vaccination of infants is performed;

17.4. a table for preparation of vaccines and instruments;

17.5. a refrigerator for the storage of vaccines which has a technically tested thermometer for the control of temperature regime or automatic temperature recording device. If vaccination in a vaccination institution is performed irregularly, during the vaccination the storage of vaccines in thermocontainers (a box with thermoisolation for transportation of a vaccine in a means of transport or temporary storage at the specified temperature regime) or cold bags (a bag with thermoisolation for carrying or temporary storage of vaccines at the specified temperature regime) is permissible;

17.6. thermocontainers or cold bags if vaccination is performed regularly;

17.7. cold elements (a tank with a frozen substance which maintains the cold continuously) (stored in a freezer of the refrigerator) if vaccination is performed regularly;

17.8. a sink with a supply of hot and cold water;

17.9. means of disinfection and hand washing;

17.10. towels or disposable napkins; and

17.11. a waste container with a polyethylene bag.

18. In performing vaccinations, the room shall be equipped with the following medical equipment and medicinal products:

18.1. medical devices for disinfection and treatment of the injection site;
18.2. disposable syringes and disposable systems for intravenous administration of solutions;
18.3. thermometer, tonometer and phonendoscope; and
18.4. means of anaphylactic shock therapy the list of which shall be approved by the Minister for Welfare.

19. Compliance with the requirements of asepsis and antisepsis shall be ensured during vaccination.

20. During vaccination telecommunications for calling of the emergency medical assistance team shall be accessible.

21. Materials intended for wet cleaning and disinfection shall be utilised for internal finishing of the vaccination room.

22. Inhabitants have the right to choose a vaccination institution or a medical practitioner who shall perform the vaccination, as well as to refuse the vaccination, also the vaccination of a person under guardianship.

23. Vaccination against yellow fever may be performed in vaccination institutions, which have been authorised therefor by an order of the Minister for Welfare.

24. A medical practitioner shall notify the person to be vaccinated or his or her legal representative before the vaccination regarding:
   24.1. efficiency of the vaccine for the prevention of the infectious disease, duration of protection effect and recommended repeat of the vaccination;
   24.2. reaction of the organism which may occur when vaccinating or after the vaccination; and
   24.3. prophylactic measures in order to reduce the seriousness of possible side effects, and cases where the help of a medical practitioner is necessary.

25. A medical practitioner shall perform or organise, before each vaccination (both initial and repeat), an initial health care doctor’s examination of a person to be vaccinated (if necessary – also questioning of his or her parents or other legal representatives) in order to determine the state of health of the person to be vaccinated and possible contraindications. Information obtained shall be recorded in the medical documentation.

26. A medical practitioner shall be responsible for:
   26.1. determination of vaccine contraindications. If contraindications to vaccination have been determined in the person to be vaccinated, the relevant person or his or her legal representatives shall be informed on the time when it is necessary to attend a repeat examination and/or vaccination;
   26.2. compliance with hygienic and epidemic safety requirements of vaccination, also for correct injection of a vaccine, medical observation of the person to be vaccinated in the post-vaccination period in conformity with the instructions for use of the vaccine and provision of emergency medical assistance within the specified time period; and
   26.3. for performing all necessary and possible vaccinations during the visit in accordance with the vaccination calendar of the State Immunisation Programme and in conformity to the state of health to the patient.
27. In performing vaccinations a medical practitioner has a duty to:

27.1. complete the medical documentation and record the name of the vaccine, date of vaccination, series of vaccine and the injected volume, type of injection in an inoculation card, as well as certify the referred to records with a signature. Upon vaccinating against yellow fever, an international certificate of vaccination or revaccination against yellow fever shall be issued (Annex); and

27.2. inform the person in writing regarding the time when it is necessary to have a repeat vaccination or perform other vaccinations.

28. If a person to be vaccinated refuses the vaccination, it is the duty of a medical practitioner to explain to the referred to person the significance of the relevant prophylactic measures in the protection of individual and public health and, if the person to be vaccinated does not change his or her decision, the medical practitioner shall draw up, in the presence of two medical practitioners or other persons, a refusal in writing which shall be confirmed with a signature by the referred to persons and the person to be vaccinated. A medical practitioner shall notify the relevant territorial office of the Public Health Agency of such cases.

29. It is permitted to utilise the existing inoculation cards until the issuance of new inoculation cards. Inoculation cards, which are issued after the coming into force of these Regulations, must contain the following information:

29.1. given name, surname, personal identity number, age of the person on the day of vaccination and immunity examination;

29.2. date of vaccination, name of vaccine, injected volume of vaccine, type of injection, series, producer of vaccine, note on side effects caused by the vaccine, surname, signature and seal of a medical practitioner; and

29.3. date, result of immunity examination, surname, signature and seal of a medical practitioner.

IV. Mandatory Vaccination of Persons Employed in Specific Occupations and Belonging to Increased Risk Groups

30. For preventing occupational infections (an infectious disease with which a person may be infected if in performing the work duties he or she comes into contact with materials of biological origin which contain or may contain agents of infectious diseases, as well as with hosts of disease agents, infected persons or animals) vaccination of employees shall be mandatory against the following infectious diseases: hepatitis type B, rabies, tick-borne encephalitis and yellow fever.

31. Employers and heads of educational institutions (hereinafter – employer) have a duty to:

31.1. evaluate the risk of infection of each employee, student and trainee (hereinafter – employee) taking into account their particular functional duties and conditions of work or practice;

31.2. inform completely, objectively and clearly employees of the risk of infection, the effects of disease, the safety and efficiency of vaccination, as well as of the rights and duties of employees regarding issues related to vaccination;

31.3. in conformity with the risk of infection to provide employees with vaccine free of charge and vaccination against the infectious diseases referred to in Paragraph 30 of these Regulations and, if necessary, – a repeat vaccination (notifying thereof in accordance with Sub-paragraph 31.2 of these Regulations), as well as to provide with an opportunity for performing thereof;
31.4. control the vaccination of employees in conformity with the scheme indicated in the instructions for use of the vaccine and to check the inoculation cards;

31.5. store the lists of employees exposed to the risk of occupational infection and documents regarding the vaccination and laboratory examinations of the relevant employees for not less than 10 years. In cases of occupational infection with virus hepatitis type B the time period for the storage of documents shall be 40 years; and

31.6. if necessary, agree on the complete or partial fulfilment of measures referred to in Sub-paragraphs 31.1 and 31.2 of these Regulations with a medical practitioner or epidemiologist.

32. Heads of educational institutions and social care institutions have a duty to request that a person to be educated or socially cared for, upon entering an educational or social care institution, submits a statement certified by a medical practitioner which statement shall specify which vaccines the person has received in conformity with the vaccination calendar of the State Immunisation Programme

33. Vaccination against hepatitis type B of employees, who regularly (at least once a month) while performing their work duties or during studies come into direct contact with patients or human biological materials that may contain or transfer virus hepatitis type B, or with objects contaminated with such materials, shall be compulsory for:

33.1. medical practitioners who provide medical assistance or perform the following diagnostic of medical procedures:
   33.1.1. blood taking;
   33.1.2. surgical and similar invasive intervention;
   33.1.3. injections;
   33.1.4. wound treatment and dressing;
   33.1.5. care during delivery;
   33.1.6. dental care procedures;
   33.1.7. provision of emergency medical assistance;
   33.1.8. pathological-anatomical examinations;
   33.1.9. laboratory examinations;
   33.1.10. blood transfusion;
   33.1.11. acupuncture;
   33.1.12. servicing of reanimation and anaesthetic equipment;
   33.1.13. microbiological experiments with an active agent of hepatitis type B; and
   33.1.14. physical examination of a hepatitis type B patient;

33.2. auxiliary staff of medical, rehabilitation and prevention institutions, also persons who wash and sterilise medical instruments, cleaners and employees of laundries;

33.3. medical students and medical school trainees who are in medical practice in a medical institution; and

33.4. persons providing manicure and pedicure services, as well as those associated with tattooing and piercing procedures.

34. Employees the vaccination of whom against type B hepatitis shall be mandatory have the right to a single laboratory examination for the determination of transferred or existing type B hepatitis infection before the commencing of the work and activities referred to in Paragraph 33 of these Regulations and the vaccination. Expenditures related to the relevant examinations of employees shall be covered by employers, but of students and medical school trainees – by the educational institution. Persons to whom transferred or existing hepatitis type B infection has been determined, need not be vaccinated.
35. Vaccination against rabies of specialists of veterinary medicine and persons under training who engage in the treatment and care of animals, employees of virology laboratories who work with an active rabies virus, employees of pathological morphology laboratories who work with animal tissues, and catchers of stray animals shall be mandatory.

36. Vaccination against yellow fever of crews of sea-going vessels and planes who travel to countries affected by the referred to infection, and employees of microbiological laboratories who work with active agents of the disease shall be mandatory. The list of states affected by yellow fever shall be determined by the World Health Organisation.

37. Vaccination against tick-borne encephalitis of forest workers, foresters, district foresters, chief forest officers, State environment inspectors, personnel of the National Armed Forces, employees of the system of the Ministry of the Interior with special service ranks, employees of microbiological laboratories who work with active tick-borne encephalitis virus, and other persons who come into direct contact with hosts of tick-borne encephalitis while performing work duties or during studies shall be mandatory.

38. In order to receive a vaccine referred to in Paragraph 30 of these Regulations, an employer or employee shall notify a vaccination institution of the necessary vaccine. The vaccination institution shall, in accordance with Paragraphs 10, 12 and 13 of these Regulations, plan, order and receive vaccines by indicating the purpose of the vaccination, or in cases specified in regulatory enactments acquire the vaccines directly from licensed medicinal product wholesalers if a wholesaler ensures the storage and transport of vaccines in conformity with the requirements specified in regulatory enactments.

39. If an employee refuses vaccination against the diseases referred to in Paragraph 30 of these Regulations, an employer has a duty to draw up the refusal in writing. The employee, employer or his or her representative and two witnesses shall sign the document.

40. If a medical practitioner who performs surgical procedures, invasive manipulations, gynaecology examinations, provides stomatological assistance and assists at delivery, is not vaccinated against hepatitis type B, he or she shall be annually examined in a laboratory for detection of the presence of hepatitis type B agents.

41. If an employee, who is not subject to mandatory vaccination against hepatitis type B, suffers an accident while performing work duties, during which accident biological material containing a virus has been administered, or if the mucous membrane or damaged skin of the employee comes into contact with the referred to material, the employer has a duty to provide the employee with free vaccination against virus hepatitis type B without delay.

42. If the employee belongs to a group of persons the vaccination of which is mandatory, he or she has a duty to present an inoculation card upon the request of the employer, as well as the officials of the State Sanitary Inspection, State Labour Inspection, and epidemiologists of Public Health Service.

43. Students and medical school trainees who have not been vaccinated against the infectious diseases referred to in Paragraph 30 of these Regulations may not participate in studies if during the studies they may be subjected to the risk of infection with hepatitis type B, rabies, yellow fever or tick-borne encephalitis.
44. A non-vaccinated employee, if the employer has not provided the vaccination, is entitled to refuse to perform such work duties as subject him or her to the risk of infection with the infectious diseases referred to in Paragraph 30 of these Regulations.

V. State Supervision and Control of Vaccinations

45. The State Sanitary Inspection shall control premises in which vaccinations are performed and compliance with hygiene and epidemic safety requirements during the vaccination.

46. The Quality Control Inspection for Expert-examination in Medical Care and Ability to Work shall control the registration of vaccinations and vaccination complications (side effects), possession of certificates by medical practitioners who perform vaccinations, and medical documentation.

47. If the hygiene and epidemic safety requirements of vaccination are not observed the officials of the State Sanitary Inspection have the right to take a decision on the suspension of vaccinations in the relevant vaccination institution. They shall notify the relevant territorial office of the Public Health Agency and the territorial health fund of the decision taken without delay.

48. Production, storage, transport, distribution and usage of vaccines shall be controlled within the scope of its competence by the State Pharmaceutical Inspection.

VI. Closing Provisions

49. Paragraph 37 of these Regulations comes into force on 1 January 2001 (except the employees of the system of the Ministry of the Interior with special service ranks with respect to whom Paragraph 37 comes into force on 1 January 2002), Paragraph 33 – on 1 January 2002, except Sub-paragraphs 33.2, 33.3 and 33.4 which come into force on 1 January 2003, and Paragraph 35 – on 1 January 2003.

50. Until the establishment of the Public Health Agency the functions of its central office shall be performed by the National Environmental Health Centre and the functions of the territorial offices of the Public Health Agency shall be performed by the territorial environmental health centres.

51. Cabinet Regulation No. 24 of 18 January 2000, Vaccination Regulations (Latvijas Vēstnesis, 2000, No. 18/19) is repealed.

Prime Minister

A. Bērziņš

Acting for the Minister for Welfare –

Minister for Special Assignments State Reform Matters

J. Krūmiņš
**Annex**

**Cabinet Regulation No. 330**

26 September 2000

**Starptautiskais sertifikāts par vakcināciju vai revakcināciju pret dzelteno drudzi**

**International certificate of vaccination or revaccination against yellow fever**

**Certificat international de vaccination ou de revaccination contre la fièvre jaune**

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<tr>
<td>Date</td>
<td>Signature and professional status of vaccinator Signature et titre du vaccinateur</td>
<td>Manufacturer and batch No. of vaccine Fabricant du vaccin et numéro du lot</td>
<td>Official stamp Cachet officiel du centre de vaccination</td>
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Sertifikāts derīgs tikai tādā gadījumā, ja konkrēto vakcīnu atzinusi Pasaules veselības organizācija un valsts veselības pārvaldes institūcija apstiprināju attiecīgo vakcinācijas iestādi.

Sertifikāts ir derīgs 10 gadus, sākot ar desmito dienu pēc vakcinācijas; revakcinācijas gadījumā – 10 gadus pēc revakcinācijas, ja tā veikta 10 gadu laikā pēc vakcinācijas.

Sertifikātu apstiprina ar personīgo parakstu ārstniecības persona vai cita persona, kuru pilnvarojusi valsts veselības pārvaldes institūcija; personas oficiālais zīmogs neaizstāj tās parakstu.

Sertifikāts ir nederīgs, ja tajā ir labojumi, dzēšumi vai nav aizpildīta kāda daļa.

This certificate is valid only if the vaccine used has been approved by the World Health Organisation and if the vaccinating centre has been designated by the health administration for the territory in which that centre is situated.
The validity of this certificate shall extend for a period of ten years, beginning ten days after
the day of vaccination or, in the event of a revaccination within such period of ten years, from
the date of that revaccination.

This certificate must be signed in his own hand by a medical practitioner or other person
authorized by the national health administration; his official stamp is not an accepted
substitute for his signature.

Any amendment of this certificate, or erasure, or failure to complete any part of it, may render
it invalid.

Ce certificat n'est valable que si le vaccin employé a été approuvé par l'Organisation mondiale
de la Santé et si le centre de vaccination a été habilité par l'administration sanitaire du
territoire dans lequel ce centre est situé.

La validité de ce certificat couvre une période de dix ans commençant dix jours après la date
de la vaccination ou, dans le cas d'une revaccination au cours de cette période de dix ans, le
jour de cette revaccination.

Ce certificat doit être signé de sa propre main par un médecin ou une autre personne habilitée
par l'administration sanitaire nationale, un cachet officiel ne pouvant être considéré comme
tenant lieu de signature.

Toute correction ou rature sur le certificat ou l'omission d'une quelconque des mentions qu'il
comporte peut affecter sa validité.

Acting for the Minister for Welfare –
Minister for Special Assignments State Reform Matters J. Krūmiņš