

**On approval of the rules for registration and investigation, record keeping and reporting of cases of infectious, parasitic diseases and (or) poisoning, adverse effects after immunization**

Order of the Minister of Health of the Republic of Kazakhstan dated October 29, 2020 No. ҚР ДСМ-169/2020. Registered with the Ministry of Justice of the Republic of Kazakhstan on October 30, 2020 No. 21562.

In accordance with paragraph 3 of Article 105 of the Code of the Republic of Kazakhstan dated July 7, 2020 "On the health of the people and the healthcare system", I ORDER:

1. Approve the rules for registration and investigation, record keeping and reporting of cases of infectious, parasitic diseases and (or) poisoning, adverse events after immunization in accordance with the annex to this order.

2. Recognize as invalid:

1) Order of the Minister of Health of the Republic of Kazakhstan dated May 5, 2018 No. 224 "On approval of the Rules for investigating cases of infectious and parasitic, occupational diseases and poisoning of the population" (registered in the Register of State Registration of Regulatory Legal Acts under No. 17039, published on June 22, 2018 in the Etalon control bank of normative legal acts of the Republic of Kazakhstan);

2) Order of the Acting Minister of Health of the Republic of Kazakhstan dated September 16, 2019 No. KR DSM-127 "On approval of the Rules for registration, keeping records of cases of infectious, parasitic, occupational diseases and poisonings, and the Rules for reporting on them" (registered in the State Registration Register normative legal acts under No. 19383, published on September 19, 2019 in the Reference Control Bank of Regulatory Legal Acts of the Republic of Kazakhstan).

3. The Committee for Sanitary and Epidemiological Control of the Ministry of Health of the Republic of Kazakhstan, in accordance with the procedure established by the legislation of the Republic of Kazakhstan, shall ensure:

1) state registration of this order with the Ministry of Justice of the Republic of Kazakhstan;

2) placement of this order on the Internet resource of the Ministry of Health of the Republic of Kazakhstan;

3) within ten working days after the state registration of this order, submission to the Legal Department of the Ministry of Health of the Republic of Kazakhstan of information on the implementation of the measures provided for in subparagraphs 1) and 2) of this paragraph.

4. To impose control over the execution of this order on the supervising Vice Minister of Health of the Republic of Kazakhstan.

5. This order shall enter into force ten calendar days after the day of its first official publication.

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| *Minister of Health*  *Republic of Kazakhstan* | *A. Tsoi* |

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|  | Appendix to the order  of the Minister of Health  of the Republic of Kazakhstan  dated October 29, 2020  No. ҚР ДСМ-169/2020 |

**Rules for registration and investigation, record keeping and reporting of cases of infectious, parasitic diseases and (or) poisoning, adverse events after immunization**

**Chapter 1. General Provisions**

1. These rules for the registration and investigation, record keeping and reporting of cases of infectious, parasitic diseases and (or) poisoning, adverse events after immunization (hereinafter referred to as the Rules) are developed in accordance with paragraph 3 of Article 105 of the Code of the Republic of Kazakhstan dated July 7, 2020 "On health of the people and the health care system" (hereinafter referred to as the Code) and determine the procedure for registration and investigation, record keeping and reporting of cases of infectious, parasitic diseases and (or) poisoning, adverse events after immunization.

2. The following terms and definitions apply in these rules:

1) vaccine reaction - a reaction caused by some components of the vaccine;

2) software error - a reaction caused by errors in the preparation, handling or administration of a vaccine;

3) coincidence - a reaction observed after immunization, but not caused by a vaccine or a software error;

4) reaction to an injection - a reaction caused by fear about an injection (shot).

**Chapter 2. Procedure for registration, record keeping and reporting of cases of infectious, parasitic diseases and (or) poisoning**

3. Registration and registration of cases of infectious, parasitic diseases and (or) poisoning among the population is carried out at the place of detection of the disease, regardless of the place of residence of the patient.

4. Infectious, parasitic diseases and (or) poisoning are subject to individual registration in medical organizations and in territorial divisions of the department of the state body in the field of sanitary and epidemiological welfare of the population (hereinafter referred to as the territorial division) in accordance with paragraphs 1, 2 of the List of infectious and parasitic diseases among the population, subject to registration and accounting in the Republic of Kazakhstan, in accordance with the annex to these Registration Rules (hereinafter - the List).

5. Registration and individual registration of cases of infectious, parasitic diseases and (or) poisoning in the territorial subdivisions is carried out on the basis of a telephone message about the detection of an infectious or parasitic disease (suspicion) further confirmed by an emergency notification.

6. The district (city) center of phthisiopulmonology (department, office) on a monthly basis on the second day of the month following the reporting period, sends for verification to the territorial subdivision summary information on the number of newly diagnosed patients with active tuberculosis based on the notifications received;

7. Accounting and registration of cases of HIV infection is carried out by healthcare organizations engaged in activities in the field of HIV prevention.

8. Health care organizations that carry out activities in the field of HIV prevention in regions, cities of republican significance and the capital on a monthly basis on the second day of the month following the reporting period report to the territorial subdivision summary information on the number of newly detected cases of HIV infection.

9. Individual records in medical organizations and summary records in territorial subdivisions are subject to infectious diseases in accordance with paragraph 3 of the List.

10. Notification of cases of influenza, acute infections of the upper respiratory tract of multiple or unspecified localization, HIV infection and other functional intestinal disorders is not provided, these diseases are recorded in organizations providing primary health care.

11. Organizations providing primary health care, on a monthly basis on the second day of the month following the reporting period, report summary data on the number of patients to the territorial subdivision.

12. In all medical organizations, medical offices of organizations, regardless of ownership, a register of infectious diseases is kept in the form approved in accordance with subparagraph 31) of Article 7 of the Code, in which information about the patient is entered.

13. Registration, accounting of infectious, parasitic diseases and (or) poisoning in medical organizations is provided by the head.

14. The territorial subdivision, when a case of an infectious, parasitic disease and (or) poisoning is detected in the corresponding administrative-territorial unit, in persons arriving from other regions, informs the territorial subdivision at the place of permanent residence of patients to carry out appropriate sanitary and preventive and sanitary and anti-epidemic measures in the foci of diseases.

**Chapter 3. Procedure for investigating cases of infectious, parasitic diseases and (or) poisoning of the population**

15. According to paragraph 4 of Article 105 of the Code, cases of infectious, parasitic diseases and (or) poisoning of the population are investigated by the territorial subdivision, with the exception of cases of HIV infection among the population, the investigation of which is carried out by healthcare entities engaged in the prevention of HIV infection, in the manner determined by the authorized body.

16. The territorial division, within 7 calendar days from the date of receipt of an emergency notification, conducts an epidemiological investigation of cases of infectious, parasitic diseases and (or) poisoning of the population.

17. When registering quarantine and especially dangerous diseases, an epidemiological investigation is carried out within three hours from the moment the emergency notification is submitted. When registering lethal cases, as well as three or more cases of an infectious, parasitic disease and (or) poisoning, related to each other and registered in one incubation period, an epidemiological investigation is carried out within a day (24 hours) from the date of filing the last emergency notification.

18. During the investigation of cases of infectious, parasitic diseases and (or) poisoning, according to epidemiological indications, in order to establish the source of infection, a laboratory examination of contact persons and persons possibly involved in the spread of infection is carried out.

19. In the course of an epidemiological investigation, an epidemiological doctor (parasitologist) analyzes the data of the patient’s medical records, talks with the doctors who provided him with medical care, interviews patients and contact persons, analyzes the available laboratory data and takes samples from the outbreak for a sanitary and epidemiological examination. Organizes a laboratory examination of contact persons in order to find the source of infection (bacteriological, virological, serological, molecular biological (polymerase chain reaction method).

20. The territorial subdivision, together with the laboratory staff, evaluates the reliability of laboratory diagnostics according to the following criteria:

1) technical equipment of the laboratory, timeliness of verification of measuring instruments;

2) compliance with the methods of conducting laboratory tests approved by the department of the state body in the field of sanitary and epidemiological welfare of the population and (or) entered in the register of the state measurement system;

3) the quality of the media used, agglutinating sera, diagnostic kits, test systems (shelf life, compliance with storage requirements, growth qualities);

4) completeness and quality of carrying out within the laboratory control;

5) the professional level of the working personnel of the laboratories.

For the etiological interpretation of the diagnosis, material from patients is examined. According to indications, studies are carried out in the laboratory of organizations of the department of the state body in the field of sanitary and epidemiological welfare of the population, the isolated pathogenic cultures are sent for identification to the appropriate reference laboratory.

21. On the basis of the epidemiological anamnesis and data from a survey of patients obtained by the territorial subdivision during the investigation of cases of infectious, parasitic diseases and (or) poisoning of the population, as well as clinical and laboratory data obtained during the examination of patients, the medical organization establishes the final diagnosis.

22. When interviewing a patient and contact persons, a specialist epidemiologist (parasitologist) finds out the following:

1) the circle of persons with similar symptoms of the disease with whom there was contact during the incubation period;

2) last name, first name, date of birth, place of residence, contact numbers, place of work and (or) study;

3) date of onset of the disease (for diseases with a short incubation period - the exact time of onset of the disease), date of hospitalization, place of hospitalization, main signs of the disease;

4) information about the alleged sources, factors and ways of transmission of infection;

5) the date of the last visit of the organized team, departure from the settlement, region, country;

6) information about received preventive vaccinations.

23. When registering an imported case of infectious, parasitic diseases and (or) poisoning, specify:

1) the timing of the patient's visit to an endemic country over the past 3 years;

2) movement of the patient across the territory of the Republic of Kazakhstan and the city of republican significance, the capital, region, district in the period from the moment of illness to the establishment of a diagnosis during the epidemiological season;

3) the presence of febrile diseases of unknown origin in the last 3 years and the presence of fever in the last 3 days;

4) the presence of facts of blood transfusion in the last 3 months;

5) the presence of facts of arrival in a settlement where cases of zoonotic and quarantine diseases of large groups of the population (seasonal workers, migrants) have been registered, among which there could be parasite carriers or sources of pathogens.

24. When registering quarantine infections, especially dangerous diseases, as well as group diseases, the territorial subdivision organizes house-to-house rounds.

25. When a patient visits an organized team or an epidemiologically significant facility (where further spread of infection is possible) during the incubation period and (or) the disease within 7 calendar days from the date of filing an emergency notification, the territorial subdivision organizes and conducts an inspection of the facility, sanitary, anti-epidemic and sanitary - preventive measures to prevent further spread of the disease, followed by execution of a sanitary and epidemiological survey report, in the form approved by the state body in the field of sanitary and epidemiological welfare of the population in accordance with subparagraph 2) of Article 9 of the Code.

26. During the investigation of cases of infectious, parasitic diseases and (or) poisoning, if a source (s) of infection is suspected among the decreed contingent, by order of the head of the facility or by the decision of the territorial subdivision, the latter are suspended from work until the results of laboratory tests are obtained and the danger to the population is eliminated.

27. In the course of investigating cases of infectious, parasitic diseases and (or) poisoning of the population caused by sources of infection from other regions (suspected product or raw materials) that caused poisoning, in order to organize sanitary and anti-epidemic and sanitary and preventive measures on the spot, the timeliness of the health organization sending a message about the disease to the territorial subdivision.

28. The results of the epidemiological investigation are entered into the Card of epidemiological examination of the focus of an infectious disease, in the form approved by the state body in the field of sanitary and epidemiological welfare of the population in accordance with subparagraph 2) of Article 9 of the Code.

**Chapter 4**

29. All cases of adverse events after immunization (hereinafter referred to as AEFI) are subject to mandatory registration and accounting.

30. In case of suspicion of AEFI, a medical worker within 12 hours sends an emergency notification to the territorial subdivision of the department (hereinafter referred to as the territorial subdivision).

31. Territorial subdivisions submit a report to a higher authority on the "bottom-up" principle, as well as to the state expert organization in the field of circulation of medicines and medical devices.

32. Cases of AEFI, which, according to the results of the investigation, are classified as related to immunization, are subject to state statistical records.

**Chapter 5**

33. AEFI arise due to:

1) vaccinal reaction;

2) software error;

3) random coincidence;

4) reactions to injection.

34. There are the following types of NPPI:

1) local: abscess at the injection site, lymphadenitis, severe local reaction;

2) a condition resulting from errors in violation of the rules for conducting prophylactic vaccinations (storage, transportation, administration of vaccines and other immunobiological preparations), which is regarded as a software error;

3) an increase in body temperature with febrile convulsions after immunization with inactivated vaccines, manifested in the first 3 days after vaccination;

4) allergic reactions of immediate type, developing in the first hours after vaccination;

5) reactions to live vaccines that appear later than the 4th day and 12-14 days after measles, 20-25 days after rubella, 30 days after polio, mumps and combined vaccines with a mumps component;

6) meningeal phenomena developing after the mumps vaccine and on the 42nd day after the measles-containing vaccine;

7) catarrhal syndrome, which is a specific reaction to the vaccine against measles, rubella and mumps or combined vaccines containing one or more of these components, occurring not earlier than the 4th day and not later than 12-14 days after vaccination;

8) vaccine-associated paralytic poliomyelitis (hereinafter referred to as VAPP), which developed from 4 to 30 days after immunization with a live oral polio vaccine (hereinafter referred to as OPV) in vaccinated and up to 60 days in contacts. At the same time, 80% of all cases of VAPP are associated with the first OPV vaccination, the risk of developing the disease in immunodeficient individuals (risk group) is 3-6 thousand times higher than that in healthy people. VAPP is accompanied by residual effects (flaccid peripheral paresis and (or) paralysis and muscle atrophy).

35. All cases of AEFI are subject to mandatory registration and investigation in order to establish the immediate cause of its development in accordance with the instructions for the vaccine.

36. AEFI does not include random events that are a coincidence in time (intercurrent disease in the post-vaccination period) or indirectly associated with the introduction of the vaccine, as well as provoked by the vaccine reaction:

1) meningeal phenomena that are not typical for complications after the administration of inactivated vaccines, toxoids and live vaccines, with the exception of the mumps vaccine;

2) encephalopathy, not characteristic of reactions to the introduction of mumps and polio vaccines and toxoids;

3) the diagnosis of "post-vaccination encephalitis", which requires the exclusion of diseases with cerebral symptoms - tumor formations of the central nervous system (hereinafter referred to as the CNS), influenza, pneumonia, meningococcal infection;

4) intestinal, renal symptoms, heart and respiratory failure, not typical for complications and are signs of concomitant diseases;

5) catarrhal syndrome of acute respiratory disease that occurs earlier than the 4th day and later than 12-14 days after inoculation with a live vaccine;

6) paralysis developed as a result of neurological pathology and not associated with the introduction of a vaccine, except for VAPP;

7) reaction to the vaccine injection, associated with the psycho-emotional state of the vaccinated, caused by fear of pain due to the injection (injection).

37. Each case of suspected AEFI is subject to investigation with the preparation of an act of epidemiological investigation of the AEFI case, containing information about the state of health of the vaccinated person, about the vaccination, about the drug, the AEFI clinic, and the organization of medical care in the event of AEFI.

38. The investigation of AEFI cases is carried out by the health worker who has identified a case of AEFI in a vaccinated individual.

39. The composition of the commission of independent experts for the investigation of AEFI includes a pediatrician (general practitioner), immunologist, epidemiologist, neurologist, allergist, phthisiatrician, infectious disease specialist, pathologist, and, if necessary, specialized specialists.

40. The composition of the NDPI investigation commission is approved by order of the head of the territorial subdivision. If necessary, leading specialists of the republican level and medical higher educational institutions are involved in the investigation of the NPPI.

41. An epidemiological investigation should include the following sections:

1) analysis of anamnestic data:

allergy status of the vaccinated person (reactions to drugs, food, previous vaccines);

the state of health of the vaccinated person, taking into account the assessment of the results of questionnaires, medical examinations, including screening ones;

2) the dynamics of the development of AEFI (type of AEFI, timing of manifestation, duration, course and nature of the first symptoms);

3) measures to provide emergency and pre-medical care to a vaccinated person;

4) diagnostic and therapeutic measures taken regarding the case of AEFI before investigation;

5) the outcome of the development of AEFI;

6) establishing a causal relationship between vaccination and the development of AEFI:

the presence of similar reactions and the frequency of registration of AEFI from this vaccine in other vaccinated persons within the same medical organization;

the presence of similar reactions and the frequency of registration of AEFI from this vaccine in vaccinated persons within several medical organizations (district, city, region);

registration of similar clinical manifestations among unvaccinated persons (family members, kindergarten, school, organizations), frequency of registration, group reaction;

time sequence of AEFI symptoms after vaccine administration;

the interval between the introduction of the vaccine and the appearance of clinical symptoms, taking into account the timing of the expected manifestations of various types of AEFI and according to the instructions for the vaccine;

the likelihood of developing clinical manifestations as a result of vaccination or due to another disease (concomitant or newly diagnosed);

constancy of cases - the similarity of all cases of AEFI;

7) conditions of storage, transportation of the vaccine;

8) qualification of a nurse and (or) brother of the vaccination room in order to identify a program error;

9) compliance of the vaccination station for preventive vaccinations of the population with sanitary and epidemiological requirements;

10) differential diagnosis of AEFI with intercurrent and other diseases based on laboratory and instrumental studies:

mandatory: complete blood count and biochemical analysis in order to exclude a coincidence;

additional: on the recommendation of experts who are members of the commission.

11) investigation in case of death in the post-vaccination period:

pathoanatomical autopsy with histological and virological examination to establish the true causes of death;

analysis of the patient's medical record;

12) investigation in case of suspected low-quality vaccine:

link the AEFI to the quality of the vaccine used;

taking measures to suspend the use of a vaccine (a certain batch of vaccine) and sending vaccine samples for re-examination;

transfer information to the state expert organization in the field of circulation of medicines and medical devices, then to the manufacturer and supplier of the vaccine.

42. If the development of AEFI is confirmed due to a programming error or a reaction to an injection (shot), the vaccine is not subject to investigation as being of poor quality.

43. After the completion of the epidemiological investigation of the case of AEFI, the data are analyzed, the final diagnosis is established and a conclusion is made about the possible causes of the development of AEFI.

44. The results of the investigation with the identified causes of the development of AEFI are brought to the attention of every medical worker involved in the vaccination case at all levels of the health care system.

45. Information about NPPI is entered in the history of the development of the newborn, the history of the development of the child, the card of preventive vaccinations, the medical record of the child, the medical record of the outpatient, approved in accordance with subparagraph 31) of Article 7 of the Code.

46. With the development of neurological diseases (encephalitis, myelitis, polyradiculoneuritis, meningitis), in order to exclude intercurrent diseases, serological studies of paired sera are carried out (the first - in the early stages of the disease, the second - after 14-21 days) to determine the titers of antibodies to influenza viruses, parainfluenza , Coxsackie, ECHO (entericcytopathichumanorphan), tick-borne encephalitis, adenoviruses.

47. When an AEFI is registered after a life-threatening rabies vaccination, the introduction of the rabies vaccine is temporarily suspended by the AEFI case investigation commission, for the period of investigation and decision on the issue of continuing this vaccination.

48. If a connection between the AEFI and the quality of the used vaccine is established, the information is transferred to the manufacturer and supplier of the vaccine.

49. Vaccine samples are sent to an independent laboratory to confirm its quality. Until the results of the study are received, the state body in the field of circulation of medicines and medical devices decides on the temporary suspension of the use of this vaccine.

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|  | Appendix to the Rules  for Registration and Investigation,  Record Keeping and Reporting  of Cases of Infectious,  Parasitic Diseases and  (or) Poisoning,  Adverse Events  after Immunization |

**List of infectious and parasitic diseases among the population subject to registration and accounting in the Republic of Kazakhstan**

1. Infectious diseases subject to individual registration in medical organizations and in territorial divisions:

1) cholera (A00);

2) typhoid fever (A01.0);

3) paratyphoid A, B, C, unspecified (A01.1-A01.4);

4) other salmonella infections (A02);

5) shigellosis (bacterial dysentery) (A03);

6) other bacterial intestinal infections (A04.0-A04.5; A04.7-A04.9);

7) enteritis caused by Yersinia enterocolitica (yersiniosis) (A04.6);

8) other bacterial food poisonings, not elsewhere classified (A05);

9) amoebiasis (A06);

10) viral and other specified intestinal infections (A08);

11) rotavirus enteritis (A08.0);

12) tuberculosis (A15-A19);

13) plague (A20);

14) tularemia (A21);

15) anthrax (A22);

16) brucellosis (A23);

17) leptospirosis (A27);

18) pasteurellosis (A28.0);

19) listeriosis (A32);

20) tetanus (A33-A35);

21) diphtheria (A36);

22) whooping cough (A37);

23) scarlet fever (A38);

24) meningococcal infection (A39);

25) legionnaires' disease (A48.1);

26) ornithosis, psittacosis (A70);

27) rickettsiosis (A75-A79);

28) acute poliomyelitis (A80);

29) acute paralytic poliomyelitis, other and unspecified (A80.3);

30) rabies (A82);

31) viral meningitis (A87.0; A87.1; A87.8; A87.9);

32) viral fevers transmitted by arthropods and viral hemorrhagic fevers (A92-A99);

33) yellow fever (A95);

34) chicken pox (B01);

35) measles (B05);

36) rubella (B06);

37) foot and mouth disease (B08.8);

38) viral hepatitis (B15-B18);

39) mumps (B26);

40) Streptococcus pneumoniae as the cause of diseases classified elsewhere (B95.3);

41) Haemophilus influenzae (Haemophilus influenzae) as the cause of diseases classified elsewhere (B96.3);

42) bacterial meningitis, unspecified (G 00.9);

43) medical abortion (O 04.0; O 04.5);

44) complications associated mainly with the postpartum period (O85; O86; O90.0; O90.1; O91);

45) infectious diseases specific to the perinatal period (P35.0; P35.3; P35.8; P36-P39);

46) complications of surgical and therapeutic interventions, not classified elsewhere (T80.2; T81.3; T81.4; T82.6; T82.7; T83.5; T83.6; T84.5-T84.7; T.85.7; T88.0; T88.1;);

47) coronavirus infection COVID-19 (U07.1; U07.2)

48) rat bite (W53);

49) bite or blow inflicted by a dog (W54);

50) bite or blow from other mammals (W55);

51) carriage of the causative agent of typhoid fever (Z22.0);

52) carriage of pathogens of other gastrointestinal diseases (Z22.1);

53) carriage of the causative agent of diphtheria (Z22.2);

54) carriage of pathogens of other specified bacterial diseases (Z22.3).

2. Parasitic diseases subject to individual registration in medical organizations and in territorial divisions:

1) giardiasis (A07.1);

2) Lyme disease (A69.2);

3) tick-borne viral encephalitis (A84);

4) dermatophytosis, including epidermophytosis, trichophytosis, microsporia, favus (B35);

5) malaria (B50-B54);

6) leishmaniasis (B55);

7) toxoplasmosis (B58);

8) helminthiases (B65-B83);

9) pediculosis (B85);

10) scabies (B86);

11) carriage of the causative agent of another infectious disease (malaria) (Z22.8).

3. Infectious diseases subject to individual registration in medical organizations and summary registration in territorial divisions:

1) infections transmitted predominantly sexually (A50-A53);

2) gonococcal infection (A54);

3) chlamydial infection (A55; A56);

4) disease caused by the human immunodeficiency virus (HIV) (B20-B24);

5) viral infection of unspecified localization (B34.0; B34.1; B34.2);

6) acute infections of the upper respiratory tract of multiple or unspecified localization (J06);

7) flu (J10-J11);

8) other functional intestinal disorders (K59.1; K59.9);

9) asymptomatic infectious status caused by the human immunodeficiency virus (HIV) (Z21).

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