Annex 3
of Pharmacovigilance Procedure
(subitem 4 of item 2 of section III)

List*
of clinical manifestations of adverse reactions after use of vaccine, tuberculin

Codes	Clinical manifestations of adverse reactions after use of vaccine, tuberculin
1	Increase of temperature < 39° C
2	Increase of temperature ≥ 39° C
3.1	Pain at injection site
3.2	Swelling of soft tissues at injection site < 50 mm
3.3	Hyperaemia at injection site < 80 mm
3.4	Infiltrate at injection site < 20 mm
4.1	Swelling of soft tissues at injection site □ 50 mm
4.2	Hyperaemia at injection site □ 80 mm
4.3	Infiltrate at injection site □ 20 mm
5	Lymphadenopathy
6	Headache
7	Irritability
8	Somnolence
9	Skin rash of non-allergic genesis
10.1	Nausea
10.2	Abdominal pain
10.3	Dyspepsia
10.4	Diarrhoea
11	Catarrhal events
12.1	Myalgia
12.2	Arthralgia
13	Mumps-like symptoms
14	Thrombocytopenia
15	Post-injection abscess
16.1	Anaphylactic shock
16.2	Anaphylactic reaction
17	Allergic reaction
18.1	Vaccine-associated paralytic poliomyelitis
18.2	Acute flaccid paralysis
19	Febrile convulsions

20	Afebrile convulsions
21	Apnoea
22	Subcutaneous cold abscess
23	Superficial ulcer > 10 mm
24	Regional lymphadenitis
25	Keloid cicatrix
26.1	Generalized BCG-infection
26.2	Osteomyelitis
26.3	Osteitis

_____

* The list is not comprehensive; also it is necessary to use instruction for medical use of appropriate vaccine, tuberculin registered in Ukraine.

Cumulative data
about cases of adverse reactions after use of vaccine, tuberculin

_____ **for period _____**

(health facility, healthcare structural unit)

Trade name	**Name of enterprise-manufacturer**	**Batch**	**Number of administered doses**	**Number of immunized persons**	**Adverse reactions (according to codes of clinical manifestations of adverse reactions)***		
					code	**clinical manifestations of adverse reactions**	**number**
1	2	3	4	5	6	7	8
					1	Increase of temperature < 39° C	
					2	Increase of temperature ≥ 39° C	
					3.1	Pain at injection site	
					3.2	Swelling of soft tissues at injection site < 50 mm	
					3.3	Hyperaemia at injection site < 80 mm	
					3.4	Infiltrate at injection site < 20 mm	
					4.1	Swelling of soft	

						tissues at injection site ≥ 50 mm	
					4.2	Hyperaemia at injection site ≥ 80 mm	
					4.3	Infiltrate at injection site ≥ 20 mm	
					5	Lymphadenopathy	
					6	Headache	
					7	Irritability	
					8	Somnolence	
					9	Skin rash of non-allergic genesis	
					10.1	Nausea	
					10.2	Abdominal pain	
					10.3	Dyspepsia	
					10.4	Diarrhoea	
					11	Catarrhal events	
					12.1	Myalgia	
					12.2	Arthralgia	
					13	Mumps-like symptoms	
					14	Thrombocytopenia	
					15	Post-injection abscess	
					16.1	Anaphylactic shock	
					16.2	Anaphylactic reaction	
					17	Allergic reaction	
					18.1	Vaccine-associated paralytic poliomyelitis	
					18.2	Acute flaccid paralysis	
					19	Febrile convulsions	
					20	Afebrile convulsions	
					21	Apnoea	
					22	Subcutaneous cold abscess	
					23	Superficial ulcer > 10 mm	
					24	Regional lymphadenitis	
					25	Keloid cicatrix	
					26.1	Generalized BCG-	

						infection	
					26.2	Osteomyelitis	
					26.3	Osteitis	

_____

* The list is not comprehensive; also it is necessary to use instruction for medical use of appropriate vaccine, tuberculin registered in Ukraine.

INSTRUCTIONS FOR COMPLETING CUMULATIVE DATA

1. Cumulative data about cases of adverse reactions after use of vaccine, tuberculin shall be completed by responsible person in the following order:

1) in the heading of cumulative data the health facility, healthcare structural unit and reporting period shall be specified;

2) trade name of vaccine and tuberculin;

3) name of enterprise-manufacturer, country;

4) batch of vaccine and tuberculin (the batch shall be indicated correctly with all available letters (Latin or Cyrillic) and digits, mentioned on the package of vaccine or toxoid, or tuberculosis allergen (e.g.: AD12CN234DE – the correct variant of indicating the batch, АД12СН234DE – incorrect variant of indicating the batch));

5) number of actually administered doses of appropriate batch of vaccine, tuberculin;

6) number of persons immunized or having tuberculin diagnostics conducted by specific batch of vaccine, tuberculin;

7) information about adverse reactions according to the list of clinical manifestations of adverse reactions after use of vaccine, tuberculin, given in Annex 1 of the Pharmacovigilance Procedure, approved by MoH Ukraine Order as of 26 September 2016 N 996 (hereinafter – the List). If the clinical manifestations of adverse reactions are not indicated in the List, but stated in the instruction for medical use of appropriate vaccine, tuberculin, this adverse reaction shall be specified in free line without code;

8) if there are no adverse reactions during the reporting period, specify "0" in appropriate column of cumulative data.

2. Cumulative data about cases of adverse reactions after use of vaccine, tuberculin shall be submitted to:

- Pharmacovigilance Department, PE "State Expert Center of the Ministry of Health of Ukraine" (40, Ushynskyi St., Kyiv, 03151; tel./fax: +38 (044) 498-43-58; e-mail: vigilance@dec.gov.ua);

- the appropriate healthcare structural unit in paper format with cover letter (to the address of appropriate healthcare structural unit. In e-form to e-mail of the appropriate healthcare structural unit).