Annex 6
of Pharmacovigilance Procedure
(subitem 3 of item 1 of section IV)

REPORT FORM ON ADVERSE REACTION TO MEDICINAL PRODUCT, VACCINE, TUBERCULIN AND/OR LACK OF EFFICACY OF MEDICINAL PRODUCT AND/OR ADVERSE EVENT FOLLOWING IMMUNIZATION/ TUBERCULIN DIAGNOSTICS (AEFI)	**MEDICAL DOCUMENTATION** Form № 137/o
Report to be filled in and submitted to: Pharmacovigilance Department, PE "The State Expert Center of the Ministry of Health of Ukraine" (40, Ushynskyi St., 03151, Kyiv, tel./fax: +38 044 498-43-58; e-mail: vigilance@ dec.gov.ua. **Please find e-report form at** https://aisf.dec.gov.ua	

I. PATIENT INFORMATION

Full name (initials)	Case history/ medical card №	Date of birth/ age	Sex	Weight (kg)	Height (cm)
			☐ male ☐ female		

II. SUSPECTED AR/LE/AEFI

Suspected AR/AEFI *(describe each clinical manifestation of AR/AEFI with date and time of onset and end, and outcome/indication of LE)* Date and time of onset of AR/LE/AEFI _____ Date and time of end of AR/LE/AEFI _____ **Correction of AR/LE/AEFI:** ☐ without treatment ☐ non-drug treatment ☐ drug therapy ☐ surgery ☐ dialysis	**AR/LE/AEFI sequela** ☐ recovery without sequela ☐ recovering ☐ no changes ☐ recovery with sequela ☐ death ☐ unknown

Whether these AR/AEFI manifestations are considered serious (relate to AR/AEFI case in whole)

☐ yes ☐ no
If yes, specify, why AR/AEFI is considered serious (indicate one or several reasons):

☐ patient died /___/___/_____/(date of death)
☐ life-threatening
☐ hospitalization/prolonged hospitalization
☐ long-term disability
☐ congenital malformations
☐ other important medical evaluation
☐ invalidity
☐ cluster of AEFI

III. INFORMATION ABOUT SUSPECTED MP, VACCINE, TUBERCULIN

Suspected MP, vaccine, tuberculin (trade name, pharmaceutical form, manufacturer)	Batch №	Indications (if possible by ICD-10)	Strength	Single dose	Frequency of use	Method of administration	Date and time of start of therapy	Date and time of end of therapy

***Measures taken related to suspected MP, vaccine, tuberculin for correcting* AR/LE/AEFI**

☐ withdrawal of suspected MP ☐ unknown
☐ not applicable *(e.g., if suspected MP, vaccine, tuberculin for single use)*
☐ drug therapy of AR/LE/AEFI *(specify MP, strength, duration of prescription)*

Repeated prescription of suspected MP, vaccine ☐ yes ☐ no
If yes, specify whether:
☐ a dose of suspected MP was reduced (how much)
☐ a dose of suspected MP was raised (how much)
☐ a dose was not changed

Did the AR/LE reappear after reintroduction of suspected MP
☐ yes ☐ no

IIIa. ADDITIONAL INFORMATION IN CASE OF AEFI TO VACCINES OR TUBERCULIN

Category of immunization or tuberculin	Category of AEFI

diagnostics ☐ mass campaign ☐ vaccination by age ☐ preschool ☐ school ☐ immunization of travelers ☐ tuberculin diagnostics ☐ other	☐ vaccine/tuberculin-related reaction ☐ program error ☐ accidental event ☐ reaction to injection/anxiety-related reaction to injection/tuberculin diagnostics ☐ unknown

Dose number (for vaccine)		Site of vaccine/tuberculin injection		Method of administration of vaccine/tuberculin
☐ first ☐ second ☐ third	☐ fourth ☐ fifth ☐ > fifth	☐ left shoulder ☐ right shoulder ☐ shoulder (not specified) ☐ left hip ☐ right hip	☐ hip (not specified) ☐ left forearm ☐ right forearm ☐ forearm (not specified)	☐ peroral ☐ intramuscular ☐ intracutaneous ☐ subcutaneous ☐ other _____
Shelf life /___/___/_____/				

Data of patient history, who was conducted immunization/tuberculin diagnostics (vaccination history, occurrence of reaction to previously administered vaccine, tuberculin, availability of acute or exacerbation of chronic disease within 1 - 1,5 months before immunization/tuberculin diagnostics, use of immunosuppressive therapy within 1 month and blood products within 3 months before immunization/ tuberculin diagnostics, etc.)

_____
_____
_____
_____

IV. INFORMATION ABOUT CONCOMITANT MP

(except for products used to correct AR/LE/AEFI sequela)

Concomitant MP, (trade name, pharmaceutical form, manufacturer, batch №)	Indications (if possible by ICD-10)	Strength	Single dose	Frequency of use	Method of administration	Date of start of therapy	Date of end of therapy

Other important information (concomitant diagnoses, data of laboratory and instrumental studies, allergy

history, pregnancy with term of pregnancy, mode of conception, pregnancy outcome indicated (if pregnancy ends, indicate date of delivery, type of delivery, etc.))
_____
_____
_____
_____

V. INFORMATION ABOUT REPORTER	**VI. INFORMATION ABOUT MEDICAL/ PHARMACEUTICAL PROFESSIONAL** (if not the reporter)
Full name _____	Full name _____
Specialty _____	Specialty _____
Health facility _____	Health facility _____
_____	_____
Location _____	Location _____
_____	_____
E-mail _____	E-mail _____
Tel. _____ Date _____	Tel. _____ Date _____

INSTRUCTIONS FOR REPORT FORM COMPLETING

I. Patient information

Patient's full name (patient's last name, first name and patronymic shall be indicated by first letters. If the report relates to medicinal product, vaccine taken by pregnant woman and the adverse reaction had occurred in fetus, all data (except for adverse reaction) should be given about mother.

Case history/medical card № (Patient's case history/medical card № shall be indicated).

Date of birth/age (Indicate day, month and year of birth. For patients aged 3 years and over indicate the number of years (e.g. 4 years); for patients aged under 3 years indicate the number of months (e.g. 24 months); for patients aged under one month indicate the number of days (e.g. 5 days)).

Sex (indicate either F or M. If the report relates to medicinal product, vaccine taken by pregnant woman and the adverse reaction had occurred in fetus, all data (except for adverse reaction) should be given about mother, indicating the trimester of pregnancy).

Weight (indicate patient's weight in kg).

Height (indicate patient's height in cm).

II. Suspected AR/LE/AEFI

Suspected AR/AEFI *(describe each clinical manifestation of AR/AEFI with dates and time of onset, end and sequela)*/Indication of LE (indicate each AR/AEFI with dates and time of onset, end and sequela of AR/LE/AEFI. In report related to fetus congenital malformations indicate date of childbirth and term of pregnancy).

Sequela of AR/LE/AEFI (tick the appropriate).

Correction of AR/LE/AEFI (tick the appropriate).

Manifestations of AR/AEFI (relate to AR/AEFI in whole) (tick the appropriate. In case of cluster of AEFI the report forms should be completed for each patient who had a registered AEFI and who was conducted immunization/tuberculin diagnostics).

III. Information about suspected MP, vaccine, tuberculin

Suspected MP, vaccine, tuberculin (trade name, pharmaceutical form, manufacturer) (indicate trade name of medicinal product, vaccine, tuberculin suspected to cause AR/LE/AEFI, pharmaceutical form, manufacturer).

Batch № (indicate batch № of suspected medicinal product, vaccine, tuberculin).

Indications: (specify indications for prescribing suspected medicinal product, vaccine, tuberculin (if possible by ICD-10)).

Strength (indicate the quantity of active substance(s) per dosage unit or volume unit, or mass unit according to pharmaceutical form of suspected medicinal product, vaccine, tuberculin).

Single dose (indicate single dose of suspected medicinal product, vaccine, tuberculin).

Dose frequency (indicate dose frequency of suspected medicinal product, vaccine, tuberculin).

Method of administration (indicate method of administration of suspected medicinal product, vaccine, tuberculin).

Date and time of start of therapy (indicate day, month, year and time of prescribing the suspected medicinal product, vaccine, tuberculin).

Date and time of end of therapy (indicate day, month, year and time of end of therapy with suspected medicinal product, vaccine, tuberculin).

Measures taken related to suspected medicinal product, vaccine, tuberculin for correcting AR/LE/AEFI (tick the appropriate).

IIIa. Additional information in case of AEFI to vaccines or tuberculin

Category of immunization or tuberculin diagnostics (tick the appropriate box of immunization or tuberculin diagnostics category).

Category of AEFI (tick the appropriate box of AEFI category).

Dose number (for vaccine) (tick the appropriate box of dose number of vaccine complex).

Site of administration of vaccine/tuberculin (tick the appropriate box of site of vaccine/tuberculin administration).

Method of administration of vaccine/tuberculin (tick the appropriate box of method of vaccine/tuberculin administration).

Data of patient history, who was conducted immunization/tuberculin diagnostics (vaccination history, occurrence of reaction to previously administered vaccine, tuberculin, availability of acute or exacerbation of chronic disease within 1 - 1,5 months before immunization/tuberculin diagnostics, use of immunosuppressive therapy within 1 month and blood products within 3 months before immunization, etc.) (indicate information related to vaccination history, occurrence of reaction to previously administered vaccine, tuberculin, availability of acute or exacerbation of chronic disease within 1 - 1,5 months before immunization/tuberculin diagnostics, use of immunosuppressive therapy within 1 month and blood products within 3 months before immunization/tuberculin diagnostics, etc.).

IV. Information about concomitant medicinal products (except for products used to correct AR/LE/AEFI sequela).

Concomitant medicinal products, vaccine, tuberculin (trade name, pharmaceutical form, manufacturer, batch №) (indicate trade name of concomitant medicinal products prescribed, their pharmaceutical form, manufacturer, batch №).

Indications (specify indications for prescribing concomitant medicinal products, vaccine, tuberculin (with code of ICD-10, if possible).

Strength (indicate the quantity of active substance(s) per dosage unit or volume unit, or mass unit according to pharmaceutical form of concomitant medicinal product, vaccine, tuberculin).

Single dose (indicate single dose of concomitant medicinal product, vaccine, tuberculin).

Dose frequency (indicate dose frequency of concomitant medicinal product, vaccine, tuberculin).

Method of administration (indicate method of administration of concomitant medicinal product, vaccine, tuberculin).

Date of start of therapy (indicate day, month and year of prescription of concomitant medicinal product, vaccine, tuberculin).

Date of end of therapy (indicate day, month and year of end of therapy with concomitant medicinal product, vaccine, tuberculin).

Other important information (concomitant diagnoses, data of laboratory and instrumental studies, allergy history, pregnancy with term of pregnancy, mode of conception, pregnancy outcome indicated (if pregnancy ends, indicate date of delivery, type of delivery, etc.)) (indicate data, which may cause the development of adverse reaction/lack of efficacy but not directly related to it).

V. Information about reporter

Reporter’s full name, specialty, organization (health facility), postal address of organization, e-mail telephone and date of completing shall be indicated.

VI. Information about medical/pharmaceutical professional (if not the reporter)

Full name of medical/pharmaceutical professional, specialty, health facility, location, e-mail telephone and date of completing shall be indicated.