Annex 2
of Pharmacovigilance Procedure
(subitem 5 of item 1 of section III)

REPORT FORM
ON ADVERSE REACTION TO MEDICINAL PRODUCT, VACCINE, TUBERCULIN AND/OR LACK OF EFFICACY OF MEDICINAL PRODUCT (MP) AND/OR ADVERSE EVENT FOLLOWING IMMUNIZATION (AEFI)/TUBERCULIN DIAGNOSTICS TO BE SUBMITTED BY PATIENT AND/OR HIS/HER REPRESENTATIVE

1. Patient information	First name _____ Patronymic _____ Last name _____ Address _____ _____ Tel./fax _____
2. Information about the suspected MP, vaccine, tuberculin	Trade name_____ Presentation_____ Manufacturer_____
3. Information on prescribing the suspected MP, vaccine, tuberculin	Suspected MP, vaccine, tuberculin were prescribed to patient by doctor ☐yes ☐no Patient used suspected MP, vaccine, tuberculin without medical prescription ☐yes ☐no
4. Describe manifestations of adverse reaction to MP, vaccine, tuberculin and/or AEFI/tuberculin diagnostics and/or indicate the MP lack of efficacy	
5. Information about reporter	First name _____ Patronymic _____ Last name _____ Address _____ _____ Tel./fax _____
6. Information about doctor, health facility and address of patient who experienced adverse reaction to MP, vaccine, tuberculin and/or MP lack of efficacy and/or AEFI/tuberculin	First name _____ Patronymic _____

diagnostics	Last name _____ Address of health facility _____ _____ Tel./fax _____ Name of health facility, where doctor works _____ _____ Patient's address _____ _____

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: *bezpecapacienta*@dec.gov.ua). See e-report form at www.dec.gov.ua.

INSTRUCTIONS FOR COMPLETING REPORT FORM TO BE SUBMITTED BY PATIENT

1. Patient information (specify the full name of patient, who experienced the adverse reaction at using MP, vaccine, tuberculin and/or MP lack of efficacy, and/or AEFI/tuberculin diagnostics; the address and telephone number).

2. Information about the suspected MP or vaccine, or tuberculin (specify the trade name, presentation and manufacturer).

3. Information on prescribing the suspected MP or vaccine, or tuberculin (the appropriate position shall be ticked).

4. Describe manifestations of adverse reaction to MP, vaccine, tuberculin and/or AEFI/tuberculin diagnostics, and/or indicate the MP lack of efficacy (adverse reaction, AEFI/tuberculin diagnostics shall be described in detail, including immediate manifestation of adverse reaction, AEFI/tuberculin diagnostics, as well as a brief description of all clinical data shall be given, which may relate to the observed adverse reaction, AEFI/tuberculin diagnostics, or information about the MP lack of efficacy shall be provided).

5. Information about the reporter (specify the full name, address, telephone number of person submitting the report form).

6. Information about doctor, health facility and address of patient who experienced adverse reaction to MP, vaccine, tuberculin and/or MP lack of efficacy, and/or AEFI/tuberculin diagnostics (the full name of doctor, address of place of work, telephone number, name of health facility, where doctor works, address of patient who was observed the adverse reaction to MP, vaccine, tuberculin and/or MP lack of efficacy, and/or AEFI/tuberculin diagnostics).