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| 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 |

I. PATIENT INFORMATION

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

**II. SUSPECTED AR/LE/AEFI**

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| 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 long-term disability  /\_\_/\_\_/\_\_\_\_/(date of death)  life-threatening congenital malformations  hospitalization/prolonged hospitalization other important medical evaluation  invalidity cluster of AEFI | |

**III. INFORMATION ABOUT SUSPECTED MP, VACCINE, TUBERCULIN**

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| 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 |
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| 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**

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| **Category of immunization or tuberculin**  **diagnostics** | | | **Category of AEFI** | | |
| mass campaing  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.)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | |

**ІV.** **INFORMATION ABOUT CONCOMITANT MP**

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

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| 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 |
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| 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.)) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

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

**The notice is filled in and provided at the location:**

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