Annex 5
of Pharmacovigilance Procedure
(subitem 1 of item 1 of section IV)

# Report
## on cases of adverse reactions to medicinal products, vaccines, tuberculin and/or lack of efficacy of medicinal products and/or adverse events following immunization/tuberculin diagnostics

**_____ for 20__**

(health facility, healthcare structural unit)

| To be submitted by/to | Submission date | Form N 69<br><br>Annual<br>To be sent by mail |
|---|---|---|
| 1. Health facilities irrespective of form of property – to healthcare structural unit of the Autonomous Republic of Crimea, Oblast, Kyiv and Sevastopol City State Administrations<br><br>2. Healthcare structural unit of the Autonomous Republic of Crimea, Oblast, Kyiv and Sebastopol City State Administrations – to Pharmacovigilance Department, PE "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) | 20 January<br><br>30 January | |
| Name of health facility | | |
| Location | | |

| Codes of organization | | | | | |
|---|---|---|---|---|---|
| EDRPOU | Territory (KOATUU) | Economic activity (KVED) | Form of ownership (KFV) | Organizational and legal form of management (KOPFG) | Ministry, other central executive authority, which the organization is subordinate to (KODU) |
| 1 | 2 | 3 | 4 | 5 | 6 |
| | | | | | |
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**Table 1000. Cases of adverse reactions (AR) to medicinal products, vaccines, tuberculin and/or lack of efficacy (LE) of medicinal products and/or adverse events following immunization (AEFI)/tuberculin diagnostics at health facility**

| N Sequence number | Full name (initials) | Gender (M/F) | Age | Number of case history or medical history | Suspected MP (trade name, pharmaceutical form, manufacturer, country) | Description of manifestations of AR, indication of LE, description of AEFI | Main clinical and concurrent diagnoses (indicating ICD -10 code) |
|---|---|---|---|---|---|---|---|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| | | | | | | | |
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| | | | | | | | |

**Table 1001. Cumulative data about cases of adverse reactions (AR) to medicinal products, vaccines, tuberculin and/or lack of efficacy (LE) of medicinal products and/or adverse events following immunization (AEFI)/tuberculin diagnostics at health facilities of administrative territorial unit**

| Number of health facilities | Number of health facilities, which submitted case reports on AR/LE/AEFI | Number of doctors (excl. those not involved in medical care) | Population size (average annual) | Including children (up to 18 years inclusive) | Number of report forms on cases of AR/LE/AEFI |
|---|---|---|---|---|---|
| 1 | 2 | 3 | 4 | 5 | 6 |
| | | | | | |
| | | | | | |
| | | | | | |

| | | | |
|---|---|---|---|
| Head of facility | _____ (signature) | _____ (full name) | Chief of Department/the Oblast (City) Health Department |

| | | | |
|---|---|---|---|
| Date | __ _____ _____ (in numbers) | _____ (signature) | _____ (full name) |

| | | |
|---|---|---|
| Executor | _____<br>(signature) | _____<br>(full name) |
| Place of stamp (if available) | | Place of stamp (if available) |

## REQUIREMENTS FOR COMPLETING REPORT

1. Table 1000 of report shall be completed by the person responsible for pharmacovigilance at health facility irrespective of form of ownership and person in charge at healthcare structural unit of the Autonomous Republic of Crimea, Oblast, Kyiv and Sevastopol City State Administrations. The report shall include all revealed during the year cases of adverse reaction to medicinal products, vaccines, tuberculin and/or lack of efficacy of medicinal products and/or adverse events following immunization/tuberculin diagnostics at health facility irrespective of form of ownership as follows: data on all revealed cases of adverse reactions to medicinal products, vaccines, tuberculin and/or lack of efficacy of medicinal products and/or adverse events following immunization/tuberculin diagnostics at health facilities of the oblast (city) in consecutive order by facilities (of oblast, city, district importance) shall be entered into every column of table. Every next case shall be entered into the new line of the table 1000.

2. Columns of the table 1000:

1 - Sequence number;

2 - Full name (first name, patronymic, last name shall be indicated by initials);

3 - Gender (female or male).

If the report deals with the medicinal product taken by pregnant woman, and adverse reaction and/or lack of efficacy of medicinal product, vaccine, tuberculin and/or adverse events following immunization have developed in fetus, provide all data (except for adverse reactions) about mother indicating the pregnancy trimester;

4 - Age (for patients aged 3 years and over indicate the number of years; for patients aged under 3 years indicate the number of months; for patients aged under one month indicate the number of days);

5 - Number of case history or medical history;

6 - Suspected medicinal product (trade name, pharmaceutical form, manufacturer (full name), country);

7 - Description of manifestations of AR, indication of LE, description of AEFI (indicate negative clinical manifestations associated with prevalent or combined effect on digestive system, skin, central nervous system, cardiovascular system, respiratory system, urogenital system, immune and other systems because of the prescription of suspected medicinal product or combination of medicinal products, vaccines, tuberculin, that result in certain body dysfunction. In case of lack of efficacy, indicate “lack of efficacy”. In case of AEFI, describe AEFI).

8 - Main clinical and concurrent diagnoses with indication of ICD -10 code (indicate main clinical and concurrent diagnoses of the patient who developed AR to medicinal product, vaccine, tuberculin and/or LA of medicinal product and/or AEFI/tuberculin diagnostics and ICD 10-code).

3. Table 1001 of report shall be completed by the person in charge from healthcare structural unit of the Autonomous Republic of Crimea, Oblast, Kyiv and Sevastopol City State Administrations. The report shall include all revealed during the year cases of adverse reaction to medicinal products, vaccines, tuberculin and/or lack of efficacy of medicinal products and/or adverse events following immunization/tuberculin diagnostics at health facility irrespective of form of ownership (i.e. absolute indices related to certain administrative territorial unit (oblast (city)).

4. Columns of table 1001:

1 - Number of health facilities (indicate number of all functioning health facilities regardless of forms of ownership located at the territory of administrative territorial unit (oblast, city));

2 - Number of health facilities, which submitted report forms on AR/LE/AEFI (indicate number of all functioning health facilities regardless of forms of ownership located at the administrative territorial unit, which during the reporting year submitted report forms about adverse reactions and/or lack of efficacy of medicinal products, vaccines, tuberculin and/or AEFI);

3 - Number of doctors (excl. those not involved in medical care) (indicate total number of doctors, excluding those not involved in medical care (pathologists, laboratory doctors, doctor-statisticians, etc.));

4 - Population size (average annual) (indicate total average annual size of population in the administrative territorial unit (oblast, city) in the reporting year (according to the Department of Statistics));

5 - Including children (up to 18 years inclusive) (indicate average annual number of children (0-18 years inclusive) in the total population in the administrative territorial unit specified in column 4);

6 - Number of report forms on AR/LE/AEFI (indicate total number of report forms about adverse reactions to medicinal products, vaccines, tuberculin and/or lack of efficacy of medicinal products and/or AEFI/tuberculin diagnostics sent from the administrative territorial unit (oblast, city). This index shall coincide with total number of report forms specified in table 1000).