Approved by
the Order of the Ministry
of Health of Ukraine as of
26 September 2016 № 996

Regulations of central and regional group of quick response to AEFI/tuberculin diagnostics

1. These Regulations define the activity of central and regional group of quick response to AEFI/tuberculin diagnostics (hereinafter – group of quick response to AEFI).

2. This group of quick response to AEFI includes specialists in "neurology" ("pediatric neurology"), "infectious diseases" ("pediatric infectious diseases"), "allergology" ("pediatric allergology"), "immunology" ("pediatric immunology"), "anesthesiology" ("pediatric anesthesiology"), "epidemiology", "pediatrics"/"therapy" (depending on the chairman's specialty), "forensic-medical examination", "pathologic anatomy".

3. The group of quick response to AEFI is headed by chairman specialized in "pediatrics" or "therapy".

4. The chairman of group of quick response to AEFI:
1) appoints deputy chairman of group of quick response to AEFI and secretary;
2) is responsible for preparing documents for the meeting of group of quick response to AEFI and complying with the terms for their consideration.

5. If the chairman of group of quick response to AEFI is absent the deputy chairman shall organize the work.

6. The decision of group of quick response to AEFI shall be approved by majority vote of members of group of quick response to AEFI provided two thirds of its composition is present at the meeting. In case of equality of votes, the vote of chairman of group of quick response to AEFI is deciding.

7. The task of group of quick response to AEFI is the following:
1) analysis of report forms on adverse event following immunization/tuberculin diagnostics (hereinafter – report form) by form provided in Annex 6 of Pharmacovigilance Procedure approved by MoH Ukraine Order as of 26 September 2016 № 996 (hereinafter – Procedure);
2) establishment of causal association between AEFI and use of vaccine, tuberculin.

8. The group of quick response to AEFI in its activity is governed by the Constitution of Ukraine, Laws of Ukraine, Acts of the President of Ukraine, Supreme Council (Verkhovna Rada) of Ukraine, the Cabinet of Ministers of Ukraine, legal acts of MoH Ukraine and these Regulations.

9. The groups of quick response to AEFI are divided into central and regional.
10. The central group of quick response to AEFI is a standing advisory body of the Ministry of Health of Ukraine.
11. The chairman and composition of the central group of quick response to AEFI are approved by MoH Ukraine Order.
12. The central group of quick response to AEFI:
1) shall analyze:
- information provided in (paper and/or electronic) copies received from Public Enterprise "The State Expert Center of the Ministry of Health of Ukraine" (hereinafter – the Center):
- report forms on AEFI, containing information about clinical manifestations of adverse reactions, not mentioned in instruction for medical use or list of clinical manifestations of adverse reactions after use of vaccine, tuberculin, casual association (if available) between such AEFI and use of batch/batches of vaccine/vaccines, tuberculin;
- report forms which became a basis for signal forming, if there is a casual association between such AEFI and use of batch/batches of vaccine/vaccines, tuberculin;
- report forms on AEFI related to program error of immunization/tuberculin diagnostics when vaccine, tuberculin are used, if there is information according to protocol of investigation and establishment of causal association between serious and/or cluster of AEFI/tuberculin diagnostics and use of vaccine, tuberculin (hereinafter- protocol of investigation) by form provided in Annex to these Regulations conforming the availability of causal association between them and use of vaccine, tuberculin.
2) shall consult if there are questions related to safety and efficacy of use of vaccine, tuberculin, etc.

13. The central group of quick response to AEFI shall be involved in actions within 48 hours after receiving information indicated in subitem 1, item 12 of these Regulations from the Center, if there are questions related to safety and efficacy of use of vaccine, tuberculin, etc.

14. Based on work results the central group of quick response to AEFI shall submit to the Ministry of Health of Ukraine and/or applicant (if necessary) a decision in form of protocol of the meeting which shall be considered as a recommendation.

15. The decision of the central group of quick response to AEFI is legally binding if effect is given by MoH Ukraine Order.

16. The copies of protocols of meeting of the central group of quick response to AEFI shall be submitted to the Center.

17. Regional group of quick response to AEFI is a standing advisory body of the Ministry of Health of Ukraine at healthcare structural unit of Autonomous Republic of Crimea, oblast, Kyiv and Sevastopol City State Administrations (hereinafter – healthcare structural unit).

18. The chairman and composition of the regional group of quick response to AEFI are approved by Order of appropriate healthcare structural unit.

19. Regional group of quick response to AEFI:
1) receives the report forms about all cases of AEFI which occurred in administrative territorial unit;
2) analyzes the report forms related to all cases of AEFI, which occurred in administrative territorial unit, for the purpose to define the category of severity;
3) sends all received report forms to the Center;
4) investigates all serious and cluster of AEFI and establishes a causal association between AEFI and use of vaccine, tuberculin;
5) based on investigation results completes the protocol of investigation and submits it to the Center with a copy of appropriate report form not later than 15 days since registration of AEFI.
6) after receiving the additional data pertinent to serious and/or cluster of AEFI, which require reassessment of causal association between AEFI and use of vaccine, tuberculin, draws up the updated protocol of investigation and submits it to the Center not later than 15 days since the additional data have been received. If this term falls on the day off or holiday, information shall be provided on the first working day after it.

20. The chairman of regional group of quick response to AEFI submits copies of report forms to the main staff/non-staff specialist in “therapy” of appropriate healthcare structural unit.

T. Liaskovskyi

Chief, Pharmaceutical Activity
and Pharmaceutical Product Quality Administration