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ВСЕМИРНАЯ ОРГАНИЗАЦИЯ ЗДРАВООХРАНЕНИЯ
ЕВРОПЕЙСКОЕ РЕГИОНАЛЬНОЕ БЮРО

Mission to Support the Development of the National Guideline on Surveillance of Adverse Events Following Immunization
Tbilisi, Georgia,
10-13 April 2018

14 March 2018
Original: English

Scope and purpose

A WHO mission to support development of the national policy and guidance on surveillance of adverse events following immunization (AEFI) will take place from 10 to 13 April 2018 in Georgia.

The main purpose of the mission is to provide guidance and technical advice to the Ministry of Health of Georgia in developing the national guideline on surveillance of AEFI. The guideline will be basing on WHO recommendations, available guidance and tools for setting up surveillance systems and causality assessment mechanisms to detect and respond effectively in case of AEFIs.

According to WHO, a minimum capacity to ensure vaccine safety includes detection of AEFIs, investigation of serious AEFIs, assessment of the causes and final classification of events, and vaccine safety communication.

The national AEFI guideline will be based on WHO policy, guidelines and tools in the area of AEFI surveillance and will cover the following key areas:

- Adopting WHO basic concepts, terms and definitions in AEFI surveillance;
- Defining system objectives and methods to monitor AEFIs;
- Defining events to report & case definitions;
- Defining roles, responsibilities, procedures and tools for AEFI reporting, validation and investigation;
- Defining data reporting elements (variables & forms), data processing & management procedures;
- Providing guidance on key data analysis & risk assessment procedures;
- Establishing a national mechanism and procedures for AEFI causality assessment;
- Defining AEFI incident/crisis management responsibilities;
- Outlining AEFI feedback and risk communication mechanisms;
- Defining responsibilities for AEFI Supervision/ Monitoring/ Evaluation.

A national steering committee, established by the Ministry of Health will be engaged in the guideline development process. The steering committee will include experts from key national authorities involved in AEFI surveillance and response, including:

- Representatives from the national immunization programme (national and sub-national level);
- Representatives from the national drug regulatory authority responsible for pharmacovigilance;
- Representatives from primary health care and hospital services, potentially involved in case detection, notification and clinical management;
- Representatives from SES, potentially involved in case investigation;
- Leading clinical experts involved in review, causality assessment and classification of serious AEFI cases.

Key deliverables of the first mission are defined as follows:

- National AEFI surveillance guideline drafted with inputs from key national stakeholders;
- Ministry of Health and partners (WHO CO and UNICEF CO) debriefed on the mission outcomes and further recommendations to adopt and implement the guidelines.