

AEFI/ ADR SURVEILLANCE AND REPORTING PROCESS

Results of assessment will be shared to the relevant parties at the discretion of the MOHMS. Recommendations for implementation will be shared to MOHMS as well.

Notifier (*Client/ Caregiver/ Relative/ Colleague/ Friend/ Health Care Worker*) suspects the occurrence of an AEFI/ ADR and informs a Health Care Professional

Feedback and Resolution

ADR/AEFI Detection

Notification

Causality Assessment

HCP receives the complaint and fills in the relevant form and submission to the **subdivisional, divisional and PV Officer** within 24 hours

Reporting

Analysis

Investigation

AEFI/ ADR Report is received by the PV Officer who uploads the information to the VigiFlow (as soon as possible), verifies the reports, and awaits results of investigation.

***Vigiflow is the PV database which supports the collection, processing, analyzing, and sharing of ADR and AEFI reports*

Carried out at the health facility/community, within a week
Investigation team members:
1. Divisional Medicine Specialist
2. SDMO
3. Other personnel nominated by SDMO
4. SDNM
5. IPC
6. Zone Nurse/ MCH Nurse

Reports are classified into:

- I. **SERIOUS:** results in hospitalization OR disability/ permanent damage OR life-threatening OR results in congenital defect/ birth defect OR results in death
- II. **IMPORTANT MEDICAL EVENT:** are events that occur in clusters OR cause significant parental/ public concern OR events not reported earlier/ unknown for a given drug
- III. **MINOR:** all other reports

The National Committee that will be tasked with carrying out Causality Assessment to be determined by the Chief Medical Advisor

