Food Medicine and Health Care Administration and Control Authority of Ethiopia (FMHACA)
Adverse Drug Event reporting form

Patient Name (abbreviation)	Card No	Age, Date of birth	Sex	Weight	Height

Ethnic group _____ Substance of abuse _____

Information on suspected drug/vaccine S=suspected drug C=concomitantly used drugs

Drug name(write all information including brand name batch no and manufacturer	S/C	Dose/dosage form, route, frequency	Date drug taking was started (D/M/Y)	Date drug reaction started (D/M/Y)	Date drug taking was stopped (D/M/Y)	Indication (Reason for drug use)

Adverse drug event description(include all available laboratory test results)

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Reaction necessitated:	Reaction subsided after D/C of suspected drug?
Discontinuation of drug/s ☐ YES ☐ No	☐ YES ☐ No ☐ Information not available
Hospitalization prolonged ☐ YES ☐ No	Reaction reappeared after restart of suspected drug? ☐ YES ☐ No ☐ Information not available

Treatment of reaction:

_____

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Outcome: ☐ Died due to the adverse event ☐ Died, drug may be contributory ☐ Not yet recovered
☐ Recovered without sequelae ☐ Recovered with sequelae ☐ Unknown

Squelae:

Relevant medical conditions such as allergies, renal disease, liver disease, other chronic diseases, pregnancy etc_____

Reported by: Name	Profession:	Email address:	Telephone

Name of health institution: Date

Product quality problem: Color change, separating of components, powdering, crumbling, caking, molding, change of odor, incomplete pack, suspected contamination, poor packaging/poor labeling, etc (Write if anything different than given above)

Drug trade name	Batch No	Registration no	Dosage form and strength	Size /type of package

For office use only

Received on: Registration no:

Key: D/M/Y ; Date /Month/Year D/C: Discontinue treatment Y:YES N:NO

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what to report

All suspected reactions to drugs
Unknown or unexpected reactions
Serious adverse drug reactions
Unexpected therapeutic effects
All suspected drug interactions
Product quality problems
Treatment failures
Medication errors

This ADE reporting form was prepared by FMHACA in collaboration with MSH/SPS and financial support from USAID

NB. Drugs includes

Conventional drugs
Herbal drugs
Traditional medicines
Biologicals
Medical supplies
Medicated cosmetics

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From _____

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And Control Authority of Ethiopia

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