Ethiopian Food and Drug Authority (EFDA)
Suspected Adverse Drug Event (ADE) reporting form

Patient Name (Initial)	Card no/MRN	Age, Date of birth	Sex	Weight	Height
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Report type □ Initial □ Follow up		Substance of abuse			
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Information on suspected drug/vaccine

Drug name(write all information including brand name, batch no and manufacturer)	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)

Information on concomitant drug/vaccine, including herbal medicines

Drug name(write all information including brand name, batch no and manufacturer)	Dose/dosage form, route, frequency	Date drug taking was 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)

Was the reaction serious? □ YES □ No

Reason for seriousness

□ Death □ Hospitalization/prolonged □ Disabling

□ Congenital anomaly □ Life threatening

□ Other medically important conditions

Reaction subside after D/C of suspected drug

□ YES, Date_____ □ No □ Unknown

Reaction reappear after restart of suspected drug

□ YES □ No □ Information not available

Treatment of reaction

_____

Outcome: □ Died due to the adverse event □ Died, drug may be contributory □ Not yet recovered

□ Recovered without sequelae □ Recovered with sequelae* □ Unknown

*Sequelae

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

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Reported by: Name	Profession:	Email address:	Telephone
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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 name	Batch No	Manufacturer	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
Unexpected therapeutic effects
All suspected drug interactions
Product quality problems
Treatment failures
Medication errors

This ADE reporting form is prepared and printed by EFDA in collaboration with the USAID Global Health Supply Chain Program- Procurement and Supply Management (GHSC-PSM) project

NB. Drugs includes

Conventional drugs
Herbal drugs
Traditional medicines
Biologicals
Medical supplies
Medicated cosmetics

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EFDA
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ETHIOPIAN FOOD AND DRUG AUTHORITY

Other means of Reporting
Electronic Reporting form on our website: www.efda.gov.et

P.O. Box 5681-Tel.0115-523142