health
Department: Health
REPUBLIC OF SOUTH AFRICA

SUSPECTED ADVERSE DRUG REACTION REPORT HIV/AIDS AND TB TREATMENT PROGRAMME

TEL NO.		FAX		EMAIL	
SUB-DISTRICT		DISTRICT		PROVINCE	
CLUSTER / FACILITY NAME					

(Please place original form in the patient records and send duplicate to NDoH)

PATIENT DETAILS:

Patient Initials			Age		Date of Birth	
ID Number			Gender	☐M ☐ F	Pregnant	☐ Yes ☐ No
Allergy	Weight (kg)		Height (cm)		Estimated Gestational Age	

MEDICINES (AND CONCOMITANT MEDICINES, INCLUDING HERBAL PRODUCTS, IF KNOWN)

Medicine(s)		Suspect drug (*)	Dose	Interval	Route	Date started	Date stopped	Prescriber/Designation
ARV-FDC (See key below)								
TB (See key below)								
Herbal								
Other								

Key: 1. AZT **2.** 3TC **3.** TDF **4.** FTC **5.** EFV **6.** NVP **7.** ABC **8.** D4T **9.** ATV **10.** ETR **11.** DRV **12.** RAL **13.** LPV/r **14.** ATV/r || **15.**R **16.**H **17.**Z **18.**E **19.**RH **20.**RHZE **21.** Km **22.** Am **23.** Cm **24.** Mfx **25.** Lvx **26.** Gfx **27.** Eto **28.** Trd **29.** Pto **30.** Cs **31.** PAS **32.** Cfx **33.** Axr **34.** Clr **35.** Amx/Clv **36.** Rx **37.** Lzd **38.** Imipenem **39.** Bedaquiline **40.** Delamanid **41.** PA 824 **42.** E **43.** Z **44.** High Dose INH

ADVERSE DRUG REACTION

Date of onset of reaction (dd/mm/yyyy) ______ Date reported (dd/mm/yyyy) ______

Description of reaction or problem (tick all that apply) – Attach additional information as required

☐ Pain/tingling/numbness in extremities
☐ Back pain
☐ Persistent muscle pain
☐ Abdominal pain
☐ Impaired concentration
☐ Unusual fatigue
☐ Insomnia/sleep issues
☐ Hearing loss
☐ Ringing in the ears

☐ Psychosis/hallucinations
☐ Fat gain
☐ Fat loss
☐ Fat redistribution
☐ Weight loss
☐ Constipation
☐ Loss of appetite
☐ Fever
☐ Chills

☐ Unusual bruising
☐ Unusual bleeding
☐ Rash
☐ Dizziness
☐ Problems with breathing
☐ Nausea
☐ Vomiting
☐ Diarrhoea
☐ Vision changes

☐ Enlarged breast(s)
☐ Depression
☐ Heartburn
☐ Headache
☐ Anxiety
☐ Confusion
☐ Pancreatitis
☐ Lactic Acidosis

☐ Hyperpigmentation
☐ Violent behavior
☐ Impotence
☐ Abnormal behavior
☐ Other

LABORATORY RESULTS: SELECT ABNORMAL ONE(S) AND WRITE THE VALUES (BL=BASELINE; CURR=CURRENT)

Hb	ALT	AST	Chol	Lact	K+	Creat	CD4	Viral Load	CMP	GFR	Platelets	other	other
B L													
Cur													

ADVERSE REACTION OUTCOME

Intervention:
☐ Patient counseled
☐ Referred to expert
☐ Additional clinic visit
☐ Discontinued Suspected drug
☐ Additional lab request
☐ Hospitalization
☐ Other

Action Taken:
☐ Discontinued suspected drug
Replaced by ______
☐ Decreased dose
☐ Treated with ☐ Other

Patient Outcome:
☐ Recovering
☐ Died
☐ Other

RELEVANT CLINICAL HISTORY (ATTACH ADDITIONAL INFORMATION)

Date patient initiated ARVs (dd/mm/yyyy)				Initial regimen	
How long has patient been diagnosed with HIV		Years		Months	
How long has patient been on ARV treatment		Years		Months	

Concomitant medical condition(s) (tick all that apply):
☐ HTN ☐Diabetes ☐KS ☐B ☐Hepatitis B ☐PCP ☐Cryp Meningitis ☐Oropharyngeal Candidiasis ☐Other

Additional Information

REPORTED BY:

Name		Qualifications	
Designation	☐ Doctor ☐ Nurse ☐ Pharmacist ☐ Other	E-mail	

Tel		Signature		Date	

COMPLETE ADDITIONAL INFORMATION ON A SEPARATE SHEET