



Medicines Control Authority of Zimbabwe

PHARMACOVIGILANCE AND CLINICAL TRIALS DIVISION

SUSPECTED ADVERSE DRUG REACTION (ADR) IN-HOUSE REPORT FORM

Reference #	Patient Initials	Patient Details	ADR Summary	Medical History	Suspected Drug(s)	Clinical Findings	ADR Listing in Summary
ADR125/2018	G. F	Age: 06-02-1997 Gender: Female Weight: 56	Onset: 14-03-2018 to -- Outcome: Recovering Stevens Johnson syndrome	Allergic to Sulfur	COTRIMOXAZOLE - COTRIMOXAZOLE- 15-03-2018 - 16-03-2018		Action Taken: Drug withdrawn Relatedness: Probable / Likely
ADR124/2018	TC	Age: 25-11-1960 Gender: Female Weight: 77	Onset: 14-05-2018 to 16-05-2018 Outcome: Recovering esophageal ulcer	peanut allergy	CIMETIDINE 400 FC - - 15-05-2018 - DOXYCYCLINE - - 12-05-2018 - 14-05-2018	metronidazole course for one week GI endoscopy confirmed ulcer	Action Taken: Drug withdrawn Relatedness: Possible
ADR119/2018	Prnts	Age: 11-12-1998 Gender: Unknown Weight:	Onset: 05-04-2018 to 25-04-2018 Outcome: Recovering Pharmacy management information systems		Gen - G- 10-04-2018 - 20-04-2018		Action Taken: Dose not changed Relatedness: Certain
ADR118/2018	LCC	Age: 27-04-2001 Gender: Male Weight:	Onset: 01-03-2016 to 27-04-2018 Outcome: Recovering Allergic rash		Albendazole - albendazole- 19-04-2018 -		Action Taken: Unknown Relatedness: Possible
ADR117/2018	abc	Age: -- Gender: Male Weight: 120	Onset: 13-02-2018 to 20-04-2018 Outcome: Not yet recovered Psychogenic erectile dysfunction		Nifedipine - NIFELAT- 06-04-2017 -		Action Taken: Dose not changed Relatedness: Probable / Likely
ADR114/2018	LCC	Age: -01-2015 Gender: Male Weight: 12	Onset: 16-09-2017 to 20-04-2018 Outcome: Not yet recovered Bullous rash upper chest		AMOXYCILLIN - AMOXEN- 04-04-2018 -		Action Taken: Unknown Relatedness: Possible
ADR113/2018	AT	Age: 02-11-1994 Gender:	Onset: 13-09-2016 to -- Outcome:	None reported	Efavirenz - EFV- 13-09-2016 - Tenofovir - TDF	None reported None reported	Action Taken: Unknown Relatedness:

Reference #	Patient Initials	Patient Details	ADR Summary	Medical History	Suspected Drug(s)	Clinical Findings	Relatedness: ADR Listing in Summary
ADR112/2018	JG	Age: 05-08-1980 Gender: Male Weight: 60	Onset: -09-2016 to -- Outcome: Not yet recovered Gynaecomastia	None reported.	Tenolam - TEN-13-09-2016 Efavirenz - EFV-22-09-2015 - 20-09-2016 Tenolam - TEN-22-09-2015 - 20-09-2016	None reported. None reported.	Action Taken: Drug withdrawn Relatedness: Probable / Likely
ADR111/2018	ATT	Age: 01-05-1988 Gender: Female Weight:	Onset: 19-03-2018 to -- Outcome: Recovered Diarrhoea		metformin - -17-03-2018 -		Action Taken: Dose reduced Relatedness: Possible
ADR110/2018	LCC	Age: 02-02-1995 Gender: Male Weight: 85	Onset: 10-03-2018 to -- Outcome: Not yet recovered Anaphylaxis	penicillin allergy	Amoxicillin - Amoxo-28-03-2018 -	paractemaol all clear	Action Taken: Dose reduced Relatedness: Possible
ADR109/2018	RN	Age: 01-01-1989 Gender: Female Weight: 56	Onset: 10-03-2018 to -- Outcome: Unknown Swollen legs		nifedipine - -01-03-2018 -		Action Taken: Unknown Relatedness:
ADR108/2018	WPNM	Age: 14-12-1989 Gender: Male Weight: 90	Onset: 14-02-2018 to -- Outcome: Recovered Persistant cough	None	amlodipine - amlovar-07-02-2018 - 01-03-2018	None None	Action Taken: Drug withdrawn Relatedness: Possible
ADR107/2018	L C	Age: 14-04-2000 Gender: Male Weight: 92	Onset: 19-01-2018 to -- Outcome: Unknown Cerebellar ataxia	Seizures	Phenytoin - -01-12-2017 - chloramphenicol - -01-01-2018 -	Phenytoin levels were noted to be twice the maximum therapeutic levels. Normalized after withdrawal of chloramphenicol.	Action Taken: Unknown Relatedness:
ADR106/2018	PK	Age: 20-03-1969 Gender: Male Weight: 54	Onset: --2016 to -- Outcome: Not yet recovered Gynaecomastia	None reported.	Efavirenz - EFV-20-03-2016 - 27-09-2016 Tenolam - TEN-20-03-2016 - 27-09-2016	None reported. None reported.	Action Taken: Drug withdrawn Relatedness: Probable / Likely
ADR105/2018	NZ	Age: 11-03-1986 Gender: Female Weight: 55	Onset: 21-09-2015 to -- Outcome: Unknown Rash and Skin irritation	None reported	Efavirenz - EFV-17-08-2015 - Tenolam - TEN-17-08-2015 -	ART None reported	Action Taken: Unknown Relatedness: Probable / Likely
ADR103/2018	BM	Age: 15-03-2011 Gender: Female Weight:	Onset: 17-09-2016 to 20-09-2016 Outcome: Recovered Rash	None provided	Albendazole - ALBE-12-09-2016 - 12-09-2016 Diethylcarbamazine citrate - DC-12-09-2016 - 12-09-2016	None reported None reported	Action Taken: Not applicable Relatedness: Possible
ADR102/2018	Unknown	Age:	Onset: 02-10-	Headache	Zithromax - Azithromycin		Action

ADR102/2018	Unknown	Age: -- 1999	Onset: 09-10- 2017 to --	Headache and flu	Zithromax - Azithromycin- 06-10-2017 - 08-10-2017		Action Taken: Unknown
Reference #	Patient Initials	Patient Details: Gender: Weight: 86	ADR Summary Outcome Rash	Medical History	Suspected Drug(s)	Clinical Findings	ADR Listing in Summary Relatedness: Possible
		Female	Unknown		Cetirizine - Cetirizine- 06-10-2017 - 10-10-2017 Paracetamol, Ibuprofen, Codeine phosphate - Myprodol- 06-10-2017 -		
ADR101/2018	AS	Age: 11- 07-2017 Gender: Male Weight: 64	Onset: -02- 2017 to -- Outcome: Not yet recovered Gynacomastia	None reported	Tenofovir - - 08-03-2011 - 07-07-2017 Efavirenz - - 08-03-2011 - 07-07-2017 Lamivudine - - 08-03-2011 - 07-07-2017 Cotrimoxazole - - 20-03-2018 -	None reported None reported	Action Taken: Drug withdrawn Relatedness: Probable / Likely
ADR51/2018	unknown	Age: -- 1989 Gender: Female Weight:	Onset: 01-03- 2018 to 27-03- 2018 Outcome: Unknown Rash	None given	Nevirapine - - 28-02-2018 -	None given None given	Action Taken: Unknown Relatedness:
ADR50/2018	YTM	Age: 07- 12-2000 Gender: Female Weight:	Onset: 19-01- 2018 to -- Outcome: Unknown Pregnancy	HIV positive	levonogestrel - jadelle- 01-03-2018 - tenofovir/lamivudine/efavirenz - tenolam E- 01-03-2017 -		Action Taken: Unknown Relatedness: