FIJI

ADVERSE DRUG REACTION REPORT

(**Note:** Identities of Reporter, Patient and Institution will remain Confidential)

Demographic Details:

Patient (Initials or Identity Number) : AA

Age : 4 days

Weight : 2820 g

Height : 45cm

Race :

Adverse Drug Reaction Description (include date of onset):

Baby g born at Term. Develops seizures, poor feeding and cries a lot 4 days p.p.
Mother has long standing history of drug abuse and has been on methadone and benzodiazepines (diazepam 25 mg bd) throughout pregnancy

Drug Therapy Prior to Reaction. Asterisk Suspected Drugs Use Generic Names	Daily Dosage and Route	Date Begun	Date Stopped	Reason for Use
Child: none				
Mother Methadone		Dose unknown, long Term		
Diazepam	25 mg bd	Long Term		

Treatment of Reaction:

Outcome: Recovered ☒ Not Yet Recovered ☐ Unkown ☐ Fatal ☐

Date of Death / /

Comments (e.g. relevant history, allergies, previous exposure to this drug):

Dechallenge
Rechallenge (if available)

Reporting Person Name: Dr. MOCK

Institution: DOWNHILL Hospital

Signature:

Date:

GHANA 2015

FDB/ADR 17994
FOOD AND DRUGS BOARD
in Strict Confidence

ADVERSE REACTION REPORTING FORM

(A) PATIENT DETAILS:

Age/Date of Birth (dd/mm/yyyy): / 56 / Gender: M ( ) F (X) Wt: 65 kg
Name/Folder Number ..... Telephone No.: .....
Hospital/Treatment Centre ..... DOWNTOWN .....

(B) DETAILS OF ADVERSE REACTION AND ANY TREATMENT GIVEN (Attach a separate sheet when necessary)

56 yr old lady treated for hypertension for several months, developed a dry cough not responding to codein

Date reaction started (dd/mm/yyyy): 2017/05/31 Date reaction stopped (dd/mm/yyyy): / / ongoing

(C) OUTCOME OF ADVERSE REACTION:

Recovered ( ) Not yet recovered (X) Unknown ( )
Did the adverse reaction result in any untoward medical conditon? Yes ( ) No (X) If yes, specify .....
SERIOUSNESS: Death ( ) Life threatening ( ) Disability ( ) (Specify) .....
Hospitalization ( ) Others (specify) .....

(D) SUSPECTED PRODUCT(S) (Attach sample or product label if available)

Brand name	Generic name	Batch no.	Expiry date	Manufacturer
AMLODIPIN – LISINOPRIL				
Reason(s) for use (Indication)		**Daily dose:**	**Route of Administration:**	
HYPERTENSION		5mg/5mg	PO	
Date started: (dd/mm/yyyy)		**Date stopped: (dd/mm/yyyy)**		
Did the adverse reaction subside when the drug was stopped (de-challenge)? Yes ( ) No ( )				
Was the product prescribed? [X] **Yes** [ ] **No)**		**Source of Drug:**		

Was product re-used after detection of adverse reaction (re-challenge)? Yes ( ) No ( )
Did adverse reaction re-appear upon re-use? Yes ( ) No ( )

(E) CONCOMITANT DRUGS INCLUDING HERBAL MEDICINES TAKEN PRIOR TO THE ADVERSE REACTION

(Attach a separete sheet when necessary)

Name of Drug	Daily dose	Date started	Date stopped	Reason(s) for use
Amoxicillin/clavulanic acid	625mg	2017/05/20	2017/05/30	chest infection

Attach all relevant laboratory tests/data

(F) REPORTER DETAILS

Name of Reporter: Dr HOCK Profession .....
Address: .....
Signature: ..... Tel: ..... E-mail: mock@training.com
Date (dd/mm/yyyy): / /

REPUBLIC OF RWANDA

MINISTRY OF HEALTH

National Center for Pharmacovigilance and Medicine Information

ADVERSE EVENT NOTIFICATION FORM

A. INFORMATIONS ON THE PATIENT

Patient address	Village :		Sector:		
	Cell :		District:		
Other available address (cell phone/email,...)					
N° of patient file/dossier X3 A4	Date of birth ...../...../..... or Age 68		weight (Kg) 100	height(cm)	Sexe ☐ F ☒ M
Pregnancy? ☐ yes ☐ No ☐ don't know	If yes, precise the age of the pregnancy (amenorrhea weeks):		The pregnant woman is : ☐ primiparous ☐ multiparous		
The patient has any chronicle diseases? ☒ yes ☐ No ☐ don't know If yes, precise these diseases in the follow place (you can add another paper if needed)			1 chronic renal failure		
2 Angina pectoris	3		4		
Associate risk factors (tick on the following ones): tobaccos, alcohol, clinical background, familial history, allergies ... Describe any other risk factors if applicable (*you can add a new paper on this if needed*):					

B. INFORMATIONS ON ADVERSE EVENTS RELATED TO SUSPECTED HEALTH PRODUCT

Description of the adverse event : Patient had severe angina attack and was hospitalized. Diagnosis of MI next day			
Date and time of when Adverse reaction start 2006/11/12 at .....h..... min	Time to onset of reaction (hours/days): 3 months	Date and time when reaction has stopped ...../...../..... at .....h.....min ongoing	
INFORMATION ON THE SUSPECTED HEALTH PRODUCT			
Name of the product en INN or local name (if plant medicine), form and dosage : IRBESARTAN 300 mg/cp	Brand name/manufacture :		
Manufactured date :	Expired date :	Batch N° :	
The product was prescribed? ☒ yes ☐ No	If the product was prescribed, indicate the reason why : hypertension		
Dosage Prescribed : 300 mg Dosage taken :	Frequency of daily dosing prescribed : 1x/d Frequency of daily dosing use by patient:	Treatment duration	
Date, if possible the time of the starting taking the suspected product: 2006/8/31	Date, if possible, the time the suspected product was stopped: 2006/11/13		
The administration route used by patient : PO	Details on the dilution (if applicable) :		
Where patient has been provided with this product?			
Is it the first time the patient has taken the suspected product? ☐ yes ☐ No If no, did he experiment the same reactions the last time he take this product ☐ yes ☐ No			
Is there any measure taken to manage /treat t this adverse event? ☒ yes ☐ No			
If yes, indicate these measures (pharmaco-therapy, refer the patient, stop the treatment, change the treatment, etc....) CARDIAC INTENSIVE CARE, NITROGLYCERIN, β BLOCKERS			
Evolution of adverse event			
☐ Recovery without sequelae ☒ Not recovery	☐ Hospitalization ☒ hospitalization prolonged	☐ Life threatening ☐ Permanent incapacity	☐ Deceased ☐ Unknown ☐ others : specify

C. OTRHER PRODUCT USED: Is there any other product used by patient? ☐ yes ☐ No If yes fill the table below

(Add a new page if needed be)

	1	2	3
Name of the Product	CRESTOR	SERENOA REPENS	
Indication			
Dosage used by patient	10 mg	1 per day	
Administration route used by patient	po		
Date (time if applicable) of start to take the product			
Date (time if applicable) of stop to take the product			

D. INFORMATIONS ON THE NOTIFICATOR

Name * Dr Nock	
Qualification * :	Place of Works/Health Facility*
PO box* :	Phone number/yours or for the Health Facility*
Email :	Date*

Your support in this Pharmacovigilance program is appreciated.

Submission of a complaint does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to an event.
All information is held in strict confidence and programme staff is not expected to and will not disclose reporter's identity in response to any public request.
Information supplied by you will contribute to the improvement of medicine safety and therapy in Rwanda.
Once completed **please send to: National Pharmacovigilance and Medicine Information Center or to the Drug and Therapeutic Committee (DTC) of the hospital which is near of you**

Food Medicine and Health Care Administration and Control Authority of Ethiopia (FMHACA)

Adverse Drug Event reporting form

Patient Name (abbreviation) AE	Card No	Age, Date of birth baby	Sex F	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)
POVIDONE IODINE			Jan 2006	Feb 2006		

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

Three months old baby undergoing surgery for necrotizing enterocolitis. Skin scrubbed and intraabdominal rinsing with povidone-iodine. Diagnosis of thyroid dysfunction 10 days later

TSH 201 mUI/L T3 1.3 nmol/L T4 TOT 22 nmol/L

therapy provided unknown. Recovered.

Reaction necessitated:
Discontinuation of drug/s ☒ YES ☐ No
Hospitalization prolonged ☒ YES ☐ No

Reaction subsided after D/C of suspected drug?
☐ YES ☐ No ☐ Information not available
Reaction reappeared after restart of suspected drug?
☐ YES ☐ No ☐ Information not available

Treatment of reaction: unknown

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

Squelae:

Relevant medical conditions such as allergies, renal disease, liver disease, other chronic diseases, pregnancy etc pre-term delivery

Reported by: Name Dr MOCK	Profession: Neonatologist	Email address: mock@training.edu	Telephone
Name of health institution:			Date

2015

SUSPECTED ADVERSE REACTIONS FORM v 5 (4/2012)
"Saving Lives Through Vigilant Reporting"
***FIELDS MUST BE COMPLETED.**

For FDA use only
AER No. 2012-0001
Date received: _____

All reports are confidential.

PATIENT'S PARTICULARS

*Patient's Name or Initials XY * Sex: ☒ Male ☐ Female Weight _____Kg Height (cm) _____

Address or Contact Number: _____ *Age 75 Date of Birth (mm/dd/yr)_____

Medical History/Admitting Diagnosis: hypertension, coronary disease Ethnic group: ☐ Filipino ☐ Chinese ☐ Caucasian

Any Known Allergy: ☐ No ☒ Yes, Specify: Wasp venom Pregnancy Status: ___ No

Hospital/facility , if admitted: Uplift Hospital ___ Yes (1st, 2nd, 3rd trimester)

*DETAILS OF THE ADVERSE REACTION

Date of onset: 2017/1/13; ____am, ____pm

Do you consider the reaction to be serious? ☒ Yes, if yes indicate why: ☐ No

Describe the reaction, including pertinent laboratory data:

Patient cannot pass urine, weak, vomiting, diarrhoea. Wife says he must have been eating some thing that did not agree with him

☐ Patient died due to reaction
☒ Involved or prolonged in-patient hospitalization
☐ Life threatening
☐ Involved persistent or significant disability
☐ Congenital anomaly in the newborn
☐ Other outcome, please give details:

Can this be due to Medication Error? ☐ No
☐ Yes, if yes, which type:
___Prescribing
___Transcription
___Dispensing
___Administration

Can the adverse reaction be due to :

1. **Product quality defect** ___No ___**Yes, Specify, encircle:** color change ; caking; powdering ; counterfeit; odor change; defective container; contaminants; separation of components; undissolved suspension/powder
2. **Therapeutic failure:** ___No ___**Yes, Specify, encircle:** antimicrobial resistance, drug interaction, poor compliance, counterfeit, expired; improper storage; under-dosing, inappropriate medication; inappropriate route of administration; excipients/preservatives

*Suspected drug product(s) Indicate brand name	Daily Dose	Route	Date started	Date stopped	Reason (s) for using the product (Indication)	Manufacturer and Batch/Lot #
ALFUZOSIN	7.5 mg	po	2016/11/20	—		

List all other drug/s taken at the same time and/ or 3 months before. If none, check box. ☐ *No Other drug/s taken*

Brand name of the drug	Daily Dose	Route	Date started	Date stopped	Reason/s for using the drug	Manufacturer and Batch & Lot No.
FRUSEMIDE	40 mg	po	long	Term	hypertension	
Nitroglycerin	1 puff	sl	long	Term		

*MANAGEMENT OF ADVERSE REACTION

Was treatment given? ☐ No ☒ Yes (If yes, please specify): _____

Outcome:
☒ Recovered (Date of recovery): 2017/1/17 ☐ Unrecovered Other diseases: _____liver _____renal _____HPN
☐ Fatal (Date of death):_____ ☐ Unknown _____ Diabetes _____CVS ____Endocrine ____Cancer

Sequela/e: (any permanent complications or injuries as a result of the ADR) Re-challenge? ☐ Yes Result_____
☐ Yes (Please specify)_____ ☐ No ☐ Unknown ☐ No

* REPORTER'S PARTICULARS

*Printed Name of Reporter: Dr MOCK

Signature of reporter: _____

Date reported (mm/dd/yr): _____

*Contact no:_____

Email address: _____

*Profession: __MD ___ RPh ___RN___Patient ___Dentist ___other
*Facility: ___Clinic ____Trial site _____Other