MINISTRY OF HEALTH OF THE REPUBLIC OF ARMENIA

Scientific Centre of Drug and Medical Technology Expertise after academic E. Gabrielyan

REPORT

OF ADVERSE REACTION OR MANUFACTURING PROBLEM OF MEDICINAL PRODUCT

À. INFORMATION ABOUT PATIENT

1. Name, surname	2. Age or date of birth	3. Sex ☐ Ì ☐ F	4. Weight (KGs)	5. Height(cm)

B. ADVERSE REACTION OR MANUFACTURING PROBLEM

1. ☐ Adverse reaction ☐ Manufacturing problem	2. Date of event (day/mo/yr)	3. Date of report (day/mo/yr)

4. Description of adverse reaction or manufacturing problem

5.Adverse reaction diagnosis methods used

6. Short description and peculiarities of disease , laboratory data	☐ smoking ☐ allergy ☐ alcohol use ☐ concomitant diseasec _____ _____ _____	☐ pregnancy ☐ genetic factors ☐ organ and system dysfunction ☐ other

7. Outcome of adverse reaction

☐ Recovery without sequela	☐ Life-threatening	☐ Congenital anomaly/Birth defect
☐ Recovery with sequela	☐ Disability or incapacity	☐ Outcome is unknown
☐ Not recover yet	☐ Required intervention of medical personnel	☐ Other
☐ Death related to ADR	☐ Hospitalization- initial or prolonged	

C. SUSPECTED MEDICINAL PRODUCT(S)

1. Name, manufacturer, batch number , expiry date	2. Dosage form	3. Dose single/daily	4. Route of administration	5. Indications for use	6. Therapy dates (duration) from / to

D. ASSOSIATED TREATMENT (exclude those used to treat adverse reaction)

1. Name, manufacturer, batch number , expiry date	2. Dosage form	3. Dose sngle/daily	4. Route of administration	5. Indications for use	6. Therapy dates (duration) from / to

E. INFORMATION ABOUT REPORTER

1. Name, address, phone	2. Profession ☐ Doctor ☐ Pharmacist ☐ Other	3. Occupation

F. ADDITIONAL INFORMATION

1. Whether the same medicinal product was administered before? If yes, what kind of adverse reactions were observed?

☐ not administered before ☐ same reactions ☐ unknown

☐ other ----------

2. Whether event abated after use stopped?

☐ yes ☐ no ☐ unknown

3. Whether event reappeared after reintroduction?

☐ yes ☐ no ☐ unknown ☐ there was no reintroduction

4. Whether event abated after dose reduced?

☐ yes ☐ no ☐ unknown ☐ there was no dose reduction

G. ANALYSIS OF REPORT

1. Relation between adverse reaction and suspected medicinal product

☐ definite ☐ probable ☐ possible ☐ doubtful ☐ conditional ☐ impossible to classify

2. Adverse reaction type

☐ serious ☐ expected

☐ not serious ☐ unexpected

3. Status of medicinal product

☐ registered ☐ not registered ☐ humanitarian aid ☐ clinical trial

Reports can be send to Scientific Center of Drug and Medical Technology Expertise department of monitoring of side and adverse effect of medicinal products by the following address:

0051, Yerevan, 49/4 Komitas av.
Tel: (374 10) 23 16 82, 23 08 96 # 123
Fax: (374 10) 23 21 18
Hot line: (374 10) 23 72 65, (374 98) 77 33 68
e-mail: vigilance@pharm.am
Online version of this report can be found at:
web: http://www.pharm.am

You can help million of patients by reporting about suspected side and adverse effects of medicinal products.