MINISTRY OF HEALTH OF THE RA
«CENTER OF DRUG AND MEDICAL TECHNOLOGY EXPERTISE» SNCO

Appendix 3
to Order for the Minister of Health of the RA
No. 23-N dated 17 May 2017

Report form
ADVERSE DRUG REACTION, ABSENCE OF THERAPEUTIC EFFECT, QUALITY DEFECT OR SUSPECT ON FALSIFICATION

A. PATIENT DETAILS

1. Name _____ Surname _____	2) Date of birth (date, month, year) __/__/___	3. Sex ☐ Male ☐Female	4. Weight (kg)	5. Height (cm)

B. REASON FOR SUBMISSION OF THE REPORT
☐ Adverse drug reaction ☐ Absence of therapeutic effect ☐Quality defect, ☐suspect on falsification

1. Type of the report; ☐ initial report ☐ subsequent report	2. Treatment ☐ hospital ☐ outpatient ☐ independent	3.) Date of detection (date, month, year) __/__/___	4. Date of the report (date, month, year) __/__/___

5. Description of the adverse reaction (AR)	Event onset date __/_/_
	Event end date __/__/___

6. Patient diagnosis code according to Order No. 871-N dated 13 September 2013, according the which the drug was prescribed	☐ smoking ☐ allergy ☐ alcohol use ☐organ and system dysfunction ☐ concomitant diseases and depression of function (indicate) ☐ genetic factors ☐ other
7. **Pregnancy**: ☐ no, ☐ yes, indicate the period	

C. SUSPECTED MEDICINE (If possible, please enclose a sample with this message card)

Name Manufacturer, country Shelf life Batch number	2. Dosage form	3. Dose single/daily		4. Route of administration	5. start and end of administration
					_____/_____/ _____ _____/_____/ _____

6) Whether event abated after use stopped?
☐ yes ☐ no ☐ unknown

7) Whether event reappeared after reintroduction?
☐ yes ☐ no ☐ unknown ☐there was no reintroduction

8) Did the same event appear in past during the treatment of the patient with the same or any similar medicine?
☐ yes ☐ no ☐ unknown ☐ it was not used earlier

9) Whether event abated after dose reduced?
☐ yes ☐ no ☐ unknown ☐the dose was not reduced

D. ASSOSIATED TREATMENT (except for medicines to eliminate ADR)

1. Name, manufacturer	2. Dosage form	3. Dose single/daily		4. Route of administration	5. start and end date of administration
					____/_____/____ ____/_____/ ___

Outcome of the adverse reaction:	Measures taken to eliminate the adverse reaction:
☐ recovered ☐ did not recover ☐ recovery with sequela ☐ recovering ☐ death related to ADR ☐ unknown ☐ other	☐ no treatment ☐medicine stopped ☐dose changed ☐ concomitant medicines withdrawn ☐ medical treatment ☐ surgery ☐ other

Criteria for classification of an adverse reaction as serious

☐ life-threatening
☐ disability
☐hospitalization/prolongation of hospitalization
☐ congenital-anomaly
☐ death related to ADR
☐ other medically important condition

E. COMMENTS

F. REPORTER DETAILS

Name Surname	Speciality ☐ doctor ☐ pharmacist ☐ other	Address:

G. ANALYSIS (to be filled-in by the Scientific Centre)

1. Relationships between ADR and the drug:

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

2. Type of the adverse reaction:

☐ serious ☐ expected ☐not serious ☐ unexpected

3. Status of the drug
☐registered ☐ not registered ☐ humanitarian aid ☐ at the stage of clinical research

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