

# SUSPECTED ADVERSE REACTION REPORT

**CONFIDENTIAL**

## 1. PATIENT DETAILS

Patient initials	Case number	Age	Weight	Height	sex
			Kg	cm	Male <input type="checkbox"/> Female <input type="checkbox"/>

## 2. Adverse Drug Reaction (ADR)

Describe the diagnosis or the symptoms

### Date

Start

End

### Outcome

In the column on the left enter 1 to 6, depending on the ADR outcome:

- 1 = Death
- 2 = Not yet recovered
- 3 = Cure without damage
- 4 = Cure with permanent damage
- 5 = Still recovering
- 6 = Unknown

Do you consider any of the above ADRs to be serious?  Yes  No

If Yes note why you consider the ADR to be serious (note all which apply):

Death

Life Threatening

Cause / Prolong Hospitalization

Disabling

Congenital Anomaly

Significant Medical Event







In case of death, indicate the cause:

Date of death:

(If medical examiner is available, please attach)

## 3. Medicines:

Brand name / Active substance

Batch Number  
(Lot No.)

Route of administration

Dose (Units & Frequency)

### Date

START

END

Indication

Suspect

Concomitant

4. **Supplementary Remarks** e.g. Relevant medical History (Allergy, Previous ADR,, Environmental data, Smoking, Drug abuse), Symptoms outcome, Laboratory test, Correlation, Treatment.

## 5. Reporter Details

Full Name:

Speciality of Reporter

Address:

Hospital doctor, *speciality:*

Hospital Pharmacist

Hospital:

Signature:

Private Doctor, *specialist:*

Private Pharmacist

Tel.:

Date:

Other, *clarify:* \_

PHARMACEUTICAL SERVICES, MINISTRY OF HEALTH

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ΣΦΡΑΣΙΣΤΕ ΜΕ ΣΥΓΚΟΜΜΗΤΙΚΗ ΤΑΙΝΙΑ Η ΣΥΡΡΑΠΤΗΚΟ

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**ANSWERING SERVICE**  
**LICENCE No. 131**

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**PHARMACEUTICAL SERVICES**  
**MINISTRY OF HEALTH**  
**Pharmacovigilance and Clinical Trial**  
**Department**  
**Polyfimou 15, 2033 Strovolos**

### **INSTRUCTIONS FOR COMPLETING THE FORM**

- Table 1: PATIENT DETAILS  
Complete all the details you have available.
- Table 2: Adverse Drug Reaction (Adr)  
Report ALL the ADRs, even if you are unsure whether related to the medicine.  
DO NOT FORGET THE START DATE.
- Table 3: MEDICINE  
Complete all the details you have available.
- CAUTION! The minimum data required for the evaluation of the yellow card are:  
SUSPECT MEDICINE - ADVERSE DRUG REACTION with START DATE -  
PATIENT and REPORTER DETAILS