OncoPharm Egypt S.A.E

Report about a suspected adverse reaction

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☐ **Initial report** ☐ **Follow-up report**

I. PATIENT DATA

Patient initials	Patient date of birth	Patient sex	Weight (kg)	Height (cm)	Country	Clinical trial?
First- Surname	Day Month Year	○ male ○ female				○ no ○ yes, code:

Basic disease:

II. SUSPECTED ADVERSE REACTION

Suspected adverse reaction (term):

Reaction start date: Day Month Year

Reaction stop date: Day Month Year

Further description (diagnostics, laboratory values, therapy, course):

Serious criteria:

- ☐ Results in death
- ☐ Life threatening
- ☐ Caused / prolonged hospitalisation
- ☐ Disabling / incapacitating
- ☐ Congenital anomaly / birth defect

Outcome of suspected adverse reaction:

- ○ recovered / resolved
- ○ recovering / resolving
- ○ not recovered / not resolved
- ○ recovered / resolved with sequelae
- ○ unknown
- ○ fatal, date of exitus: Day Month Year

Autopsy: ○ yes ○ no

III. DRUG(S) GIVEN BEFORE ONSET OF SUSPECTED ADVERSE REACTION

Drug(s) (trade name)	Manufacturer	Dose + Unit	Route of administration	Therapy dates (from/to)	Indication(s)	Suspected causal relationship
I.						○ Yes ○ No
II.						○ Yes ○ No
III.						○ Yes ○ No
IV.						○ Yes ○ No

If „no suspected causal relationship“ with drug(s), please specify other suspected cause (e.g. basic disease, concomitant diseases):

IV. RELEVANT HISTORY AND COMMENTS

Relevant history and comments:

Physician / Pharmacist / Healthcare professional:

Phone:

Address

Date:

Reported also to:

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