Report on suspected adverse drug reaction (ADR)

Case no. (filled in by APOGEPHA):

Report to:

APOGEPHA Arzneimittel GmbH
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Phone: 0351 3363-3
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E-Mail: pharmacovigilance@apogepha.de

I. PATIENT DATA

initials:	date of birth:	sex:	height:	weight:	pregnant:	study/observational study
first name / last name	day | month | year	☐ f ☐ m	cm	kg	☐ no ☐ yes, week	☐ no ☐ yes, number

Relevant medical history

(e.g. Allergies, smoking, alcohol, liver-/kidney insufficiency):

II. ADVERSE EVENT (AE)

Description of adverse event (diagnosis, if available):

start date: _____ (day | month | year) end date: _____ (day | month | year)

Relevant examination results (e.g. lab results with date)

Actions taken to treat AE

Results/outcome of the AE:

- ☐ death
- ☐ life threatening
- ☐ hospitalization
- ☐ prolongation of hospitalization
- ☐ not recovered
- ☐ significant incapacity/disability
- ☐ recovering
- ☐ completely recovered
- ☐ other, please specify below

Did the adverse event abate after the drug was stopped?
☐ yes ☐ no ☐ not applicable

Did the same adverse event reappear after the drug was re-introduced?
☐ yes ☐ no ☐ not applicable

III. DRUGS (suspect drug and concomitant drugs)

Drug name/active substance/ if applicable batch number	Indication(s)	daily dose (__ x__ daily)	therapy data (from / to)
I.		____ x ____	____ (day | month | year) to ____ (day | month | year)
II.		____ x ____	____ (day | month | year) to ____ (day | month | year)
III.		____ x ____	____ (day | month | year) to ____ (day | month | year)
IV.		____ x ____	____ (day | month | year) to ____ (day | month | year)

I suspect a causal relationship between the adverse event(s) and the following drug:
☐ I, ☐ II, ☐ III, ☐ IV,

Other possible explanations for the adverse event(s): (e.g.: diseases)

I herewith agree that this data may be transmitted to the responsible authorities in the context of drug safety obligatons of the marketing authorisation holder (MAH).

name: _____ address: _____

phone/fax: _____

date/signature: _____

additionally reported to: _____

stamp:

If the space is not sufficient, please use page 2 additional notes.

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Additional notes