Adverse Drug Reaction Reporting Form

REPORTER: ☐ Med. Professional ☐ Other	**Reference number** (to be filled in by Swyssi)	**DATA ON THE REPORTER:** **Name:** **Position** (if it is a med. professional) **Address:** **Phone:**
Report: ☐ Initial ☐ Follow - up	**Date:**	Is the reporter a GP? ☐ Yes ☐ No Does he give consent for additional contact? ☐ Yes ☐ No Consent to contact the doctor ☐ Yes ☐ No (it is filled if the reporter is not a medical person)
Country:		

DATA ON THE PATIENT

Initials:

Sex: ☐ M ☐ F **Age:** _____ **Weight (kg):** _____

Pregnancy: ☐ (date of last monthly cycle) _____

Impaired liver function: ☐ Yes ☐ No ☐ Unknown

Impaired kidney function: ☐ Yes ☐ No ☐ Unknown

Allergy (please specify):

DRUG INFORMATION

Trade name/(INN)	**Route of administration**	**Dose**	**Duration of treatment**		**Therapeutic indication**
			Starting date	**End date**	
Concomitant treatment	**Route of administration**	**Dose**	**Duration of treatment**		**Therapeutic indication**
			Starting date	**End date**	

DATA ON THE Adverse drug reaction (ADR)

Description of the ADR:	**Beginning of the ADR:** _____/_____/_____ **End of the ADR:** _____/_____/_____

Outcome of the ADR:

☐ Recovered

☐ Recovered with consequences

☐ Improvement of the condition

☐ The condition does not change

☐ Deterioration

☐ Death

☐ Unknown

Severity criteria:

Is the reaction serious? ☐ Yes ☐ No

If yes, please indicate which of the following severity criteria characterize the adverse reaction:

☐ Recovered without consequences

☐ Hospitalization

☐ Life-threatening condition

☐ State without change

☐ Disability

☐ Congenital abnormalities

☐ Death - date (____/_____/_____)

☐ Unknown

☐ Other (please specify) _____

Connection between the medicinal product and the adverse reaction:

☐ Certain

☐ Probable

☐ Possible

☐ Unlike

☐ Cannot assess

☐ Unknown

☐ Other (please specify) _____

MEASURES TAKEN FOLLOWING THE ADR

Measures taken as a result of the ADR:	**Drug therapy following the ADR (if necessary):**
☐ None ☐ Cessation of the suspected drug ☐ Dose reduction of the suspected drug ☐ Cessation of concomitant treatment ☐ Drug therapy ☐ Non medicinal treatment (including surgery) ☐ Other (please specify) _____	

Did the adverse reaction recur after second administration of this medicine? ☐ Yes ☐ No ☐ The medicine was not being re-assigned ☐ Other (please specify) _____	**Measures taken:** ☐ None ☐ Cessation of the suspected drug ☐ Dose reduction of the suspected drug ☐ Cessation of concomitant treatment ☐ Drug therapy ☐ Non medicinal treatment (including surgery) ☐ Other (please specify) _____

CONCOMITANT DISEASES

(Anamnestic data, suspected drug interactions. Please specify if there are congenital abnormalities; administration of other drugs during pregnancy; date of last menstrual cycle. Please add additional page if necessary)	**Risk factors:** ☐ Alcohol ☐ Smoking ☐ Medicinal abuse ☐ Pacemaker ☐ Allergy ☐ Congenital / genetic abnormalities

IMPORTANT ADDITIONAL INFORMATION

Laboratory tests (type; result; date; values - normal, abnormal)

COMPLAINS REGARDING PRODUCT QUALITY

Is the adverse reaction related to a complaint or no effect? ☐ Yes ☐ No

Batch number:	Drug form:	Expiration date:	Quantity:

To be completed by the Marketing Authorisation Holder

Date on which the ADR was reported to the representative of Swyssi AG:	**Date and signature:**
Date on which the employee forwarded the report on the ADR:	