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Report № _____/_____
❑ initial ❑ final
(filled by Pharmacovigilance service)

REPORT OF LACK OF EFFICACY OF PHARMACEUTICAL PRODUCT

ALL THE INFORMATION GIVEN BY YOU IS CONFIDENTIAL AND NON-DISCLOSABLE EXCEPT AS OTHERWISE PERMITTED BY LAW

INFORMATION ABOUT PATIENT

Full name:		**Hepatic disease**	❑ yes ❑ no ❑ no information
№ of medical treatment record / case history:		**Renal disease**	❑ yes ❑ no ❑ no information
Sex:	❑ male ❑ female	**Pregnancy**	❑ yes **Duration**_____ weeks
Age (at the moment of reaction):		**Allergy** (please specify):	❑ yes ❑ no
Weight (kg):			

SUSPECTED PHARMACEUTICAL PRODUCT (-S) (SPP)

Trademark	International Nonproprietary Name	Pharmaceutical form	Series	Dosage, frequency and route of administration	Indications for use	Start date of administration	End date of administration

OTHER PHARMACEUTICAL PRODUCTS (administered in the last 3 months)

Trademark	International Nonproprietary Name	Pharmaceutical form	Series	Dosage, frequency and route of administration	Indications for use	Start date of administration	End date of administration

LACK OF EFFICACY (LOE)

Description of lack of efficacy signs (including data of laboratory-instrumental examinations)	Start date of LOE	End date of LOE

Did changing of SPP result in LOE disappearance? ❑ yes ❑ no ❑ no withdrawal of SPP

Did rechallenge of SPP cause repeated LOE? ❑ yes ❑ no ❑ no rechallenge of SPP

Measures taken:
- ❑ no treatment
- ❑ withdrawal of SPP
- ❑ dosage increase of SPP
- ❑ assignment of concomitant treatment
- ❑ concomitant treatment cancelling
- ❑ non-pharmacological therapy (including surgical treatment)
- ❑ other (please specify):

Pharmacological therapy of LOE (if any):

Result:
- ❑ full recovery without consequences
- ❑ amelioration
- ❑ no changes
- ❑ death caused by LOE
- ❑ death not caused by LOE
- ❑ recovery with any consequences (please specify):
- ❑ no information

Measures of the seriousness:
- ❑ death of the patient (date ___/___/_____)
- ❑ danger to life
- ❑ hospitalization or its prolongation
- ❑ prolongation of out-patient treatment
- ❑ disability
- ❑ congenital abnormality
- ❑ clinically significant event (please specify):

INFORMATION ABOUT REPORTER (person that informs about LOE)

Full name:			
Occupation:	❑doctor ❑ pharmacist ❑ medical representative ❑ other (please specify):		
Address:			
Phone:		**E-mail:**	
Date of LOE information receiving:		**Filling date:**	