

REPORT OF LACK OF EFFICACY OF PHARMACEUTICAL PRODUCT

ALL PROVIDED INFORMATION IS CONFIDENTIAL AND NON-DISCLOSURE WITH THE EXCEPTION OF THE CASES STIPULATED BY LAW

INFORMATION ABOUT REPORTER (person, who reports about ADR)

Name:	Professional belonging:
Place of employment:	Address:
Telephone/Mobile:	E-mail:

INFORMATION ABOUT PATIENT (CONSUMER)

Initials:	Sex: <input type="checkbox"/> male <input type="checkbox"/> fem <input type="checkbox"/> unknown	Weight (кг):	Age: <input type="checkbox"/> unknown
Liver disease: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> unknown	Kidney disease: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> unknown	Pregnancy: <input type="checkbox"/> Yes Term _____ weeks <input type="checkbox"/> No <input type="checkbox"/> unknown	
Allergy: <input type="checkbox"/> Yes (specify the allergen) <input type="checkbox"/> No <input type="checkbox"/> unknown	Additional information:		

SUSPECTED MEDICINAL PRODUCT (-S)

Product (trade name, dose, pharmaceutical form)	Batch	Frequency and method of administration	Indication	Date of start	Date of stop

OTHER MEDICINES

Medicine (trade name, pharmaceutical form, dose, active substance)	Batch	Frequency and method of administration	Indication	Date of start	Date of stop

INFORMATION ABOUT LACK OF EFFICACY (LOE)

Detailed description of LOE	Start date: (____/____/____)	Date of stop: (____/____/____)
Did the LOE disappear after the drug was stopped? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Drug was not stopped		
Did the LOE reappear after the drug was reintroduced? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Drug was not reintroduced		
Actions taken to treat the ADR: <input type="checkbox"/> Drug withdrawal <input type="checkbox"/> Dose reducing <input type="checkbox"/> Co-treatment cessation <input type="checkbox"/> None <input type="checkbox"/> Medicinal therapy <input type="checkbox"/> Non-medicinal therapy <input type="checkbox"/> Other (indicate):		
Treatment of LOE:		
Outcome: <input type="checkbox"/> Recovering without consequences <input type="checkbox"/> Improvement of state <input type="checkbox"/> State without changes <input type="checkbox"/> Death <input type="checkbox"/> Unknown <input type="checkbox"/> Recovering with the consequences (indicate):		
Criterion of seriousness: <input type="checkbox"/> Death (date ____/____/____) <input type="checkbox"/> Life threatening <input type="checkbox"/> Hospitalization – initial or prolonged <input type="checkbox"/> Disability <input type="checkbox"/> Congenital malformations <input type="checkbox"/> Important medical event (indicate):		<input type="checkbox"/> None

Employee name: _____ Position: _____ Region: _____

Information receive date: _____ Date sent in company: _____ Signature: _____