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 |
|  |  |  |  |  |  |  |  |
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|  |  |  |  |  |  |  |  |

OTHER PHARMACEUTICAL PRODUCTS (administered in the last 3 months)

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| --- | --- | --- | --- | --- | --- | --- | --- |
| Trademark | International Nonproprietary Name | Pharmaceutical form | Series | Dosage, frequency and route of administration | Indications for use | Start date of administration | End date  of administration |
|  |  |  |  |  |  |  |  |
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### 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: | ❑ assignment of concomitant treatment | | ❑ no treatment | ❑ concomitant treatment cancelling | | ❑ withdrawal of SPP | ❑ non-pharmacological therapy (including surgical treatment) | | ❑ dosage increase of SPP | ❑ other (please specify): | | | |
| Pharmacological therapy of LOE (if any): | | |
| |  |  | | --- | --- | | Result: | ❑ death caused by LOE | | ❑ full recovery without consequences | ❑ death not caused by LOE | | ❑ amelioration | ❑ recovery with any consequences (please specify): | | ❑ no changes | ❑ no information | | | |
| |  |  | | --- | --- | | Measures of the seriousness: | ❑ prolongation of out-patient treatment | | ❑ death of the patient (date \_\_\_/\_\_\_/\_\_\_\_\_\_\_) | ❑ disability | | ❑ danger to life | ❑ congenital abnormality | | ❑ hospitalization or its prolongation | ❑ 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: |  |

SIGNATURE \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ STAMP\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_