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)

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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 |
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|  |  |
| --- | --- |
| 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): |

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|  Pharmacological therapy of LOE (if any): |
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|  |  |
| --- | --- |
| 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  |

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| 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): |

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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\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_