**NOTIFICATION OF SIDE EFFECT OF A MEDICINAL PRODUCT BY PATIENTS AND THEIR FAMILIES/CARETAKERS**

* *CONFIDENTIAL –*

NOTIFICATION APPLIES TO: □ You

 □ Your child

 □ Other person ………………………………

**INFORMATION ABOUT THE PATIENT**:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Initials | Date of birth | Age | Sex:□ F□ M | Weight | Height |
| Day | Month | Year |  |  |  |  |

**INFORMATION ABOUT SIDE EFFECT:**

|  |  |
| --- | --- |
| Date of side effects: | ClassificationHas the side effect been serious□ Yes□ NoMark appropriate reaction:□ death□ life threatening□ permanent or significant disability or impairment of performance□ hospitalization or prolonged stay in hospital□ other |
| Description of side effects: |
| Result:□ Recovery without permanent effects□ Recovery with permanent effects□ During the treatment of symptoms□ Other ……………………………. |
| Were you pregnant while taking medicines:□ No□ Yes; if yes, please indicate the week of pregnancy ………………………. |

**INFORMATION ABOUT MEDICINES:**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Name of medicine | Mark “P” if you suspect the medicine to cause symptoms | Dosage (*eg. 20 mg twice a day)* | Route of administration (*eg. oral*) | Date you started taking the medicine | Date you stopped taking the medicine | Reason for taking the medicine *(eg. hypertension)* |
|  |  |  |  |  |  |  |

|  |
| --- |
| **ADDITIONAL INFORMATION:** eg. earlier reactions to the medicine, allergies, other diseases, results of additional tests |

**DOCTOR’S PARTICULARS:**

Do you agree to contact your doctor in order to obtain more information­?

 □ No

 □ Yes; if yes, please give contact data of your doctor

Name and surname …………………………………………………………….. Telephone ………………………………

Address ………………………………………………………………………………………………………………………………….

E-mail: …………………………………………………………………………………………………………………………………….

**DATA OF THE NOTIFYING PERSON:**

Name and surname …………………………………………………………….. Telephone ………………………………

Address ………………………………………………………………………………………………………………………………….

E-mail: ……………………………………………………………………Date and signature ………………………………..

Side effect of a medicinal product is understood as any adverse and unintentional effect of the product.

For the notification to be valid it must contain at least:

1. Identification data of the notifying person
2. Identification data of a patient
3. Name of the medicinal product/active substance, the usage of which caused suspected side effect.
4. Side effect (one or more)

Completion of other fields in the form will make evaluation of the case easier.

*We inform that Your personal data will be processed by Przedsiębiorstwo Farmaceutyczne LEK-AM Sp. z o.o. with the seat in Zakroczym at ul. Ostrzykowizna 14A in accordance with an Act of 29 August 1997 on personal data protection (Dz.U. from 2002 No 101, item 926, as amended), exclusively for the purposes of complying with an obligation of monitoring safety of medicinal products.*

*Any person shall be entitled to have an access to the content of his/her personal data and the right to correct them. Giving personal data is not obligatory but is a prerequisite to accept the notification.*

**NOTIFICATION OF SIDE EFFECT OF A MEDICINAL PRODUCT BY PROFESSIONAL HEALTHCARE WORKERS**

* *CONFIDENTIAL –*

**INFORMATION ABOUT THE PATIENT**:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Initials | Date of birth | Age | Sex:□ F□ M | Weight | Height |
| Day | Month | Year |  |  |  |  |

**INFORMATION ABOUT SIDE EFFECT**:

|  |  |
| --- | --- |
| Date of side effects: | ClassificationHas the side effect been serious□ Yes□ NoMark appropriate reaction:□ death□ life threatening□ permanent or significant disability or impairment of performance□ hospitalization or prolonged stay in hospital□ other, which a doctor at his/her discretion considers as seriousStatistical number of the reason of death ……………………………………………. |
| Description of side effects: |
| Result:□ Recovery without permanent effects□ Recovery with permanent effects□ during the treatment of symptoms□ Unknown |
| Pregnancy:□ No□ Yes; if yes, please indicate the week of pregnancy ………………………. |

**INFORMATION ABOUT MEDICINES:**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Name of medicine | Mark “P” if you suspect the medicine to cause symptoms | Dosage (*eg. 20 mg twice a day)* | Route of administration (*eg. oral*) | Date the administration of the medicine started  | Date the administration of the medicine finished  | Reason for taking or statistical number of the disease  |
|  |  |  |  |  |  |  |
| **ADDITIONAL INFORMATION**: eg. previous reactions to the medicine, risk factors, results of additional tests |

**DATA OF THE NOTIFYING PERSON:**

Name and surname ……………………………………………………………Specialization ……………………………

Address ………………………………………………………………………………………………………………………………….

Telephone …………………………………………………….. Fax: ……………………………………………………………….

E-mail: ……………………………………………………………………Date and signature ………………………………..