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| **Form of notice of adverse drug reactions (ADR) and / or lack of efficacy (LOE) of the medicinal product (MP) under its medical use** | **Medical documentation form**  |

І. GENERAL INFORMATION

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1. Patient's initials | 2. Number of case-record/outpatient medical record | 3. Date of birth | 4. Sex | 5. Consequences of adverse drug reaction (ADR) or lack of efficacy (LOE) |
| day | month | year |  recovery recovering unchanged  unknown |  recovery with sequelae death not caused by ADR death possibly caused by ADR death caused by ADR |
|  |  |  |  |  |  |
| **6.** **Beginning of ADR or LOE** (date, time) | **7.** **Ending of ADR or LOE** (date, time) | **9. Category of ADR / LOE** |
| **/\_\_\_\_/\_\_\_\_/\_\_\_\_\_\_/, /\_\_\_\_/\_\_\_\_/** | **/\_\_\_\_/\_\_\_\_/\_\_\_\_\_\_/, /\_\_\_\_/\_\_\_\_/** |
| **8**. **Description of ADR. Indication of  LOE** (including laboratory and instrumental survey concerning ADR) |  patient's death /\_\_\_/\_\_\_/\_\_\_\_\_/ threat to life  hospitalization for an outpatient  prolongation of hospitalization  long-term disability, disability congenital developmental anomalies other important medical assessment none of the above |

## ІІ. INFORMATION ABOUT THE SUSPECT DRUG (SD), MANUFACTURER OF THE SD (for vaccines see additional information on the reverse side of the form)

|  |  |  |
| --- | --- | --- |
| **10. SD (**trade name, dosage form **)** | **11. Manufacturer, country** | **12. Batch number** |
|  |  |  |
| **13. Indications for use** (where possible indicate the auto-coding of medical record data) | **14. Single dose** | **15. Dosage frequency** | **16.** **Method of administration** | **17. Start of therapy with the SD** | **18. End of therapy with the SD** |
|  |  |  | **/\_\_\_/\_\_\_/\_\_\_\_/** | **/\_\_\_/\_\_\_/\_\_\_\_\_/** |

**ІІІ. INFORMATION ABOUT THE CONCOMITANT MEDICATION (excluding drugs that have been used to correct the effects of ADR)**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **19. Concomitant drug** (trade name, dosage form, manufacturer ) | **20. Indications for use** (where possible indicate the auto-coding of medical record data) | **21. Single dose** | **22. Dosage frequency** | **23. Method of administration** | **24. Start of therapy** | **25. End of therapy** |
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| **26. Other important information** (diagnoses, allergies, pregnancy, indicating duration, etc.) |

**ІV. MEANS OF CORRECTION THE ADR**

|  |
| --- |
|  **Cancellation of the SD** |
| Has the cancellation of the SD lead to the ADR? yes no  |
|  **Rechallenge of SD**Has the ADR reappeared after rechallenge of the SD? yes no  |
|  **Change of the SD dose regime** (decrease/increase, *indicate how much*)*:*Has the ADR/LOE been indicated after changing the dose regime of the SD? yes no  |
|  **Correction of ADR/LOE has not been performed** |
|  **Drug therapy of ADR/LOE** *(specify drug, dosage regime, duration of use)* |

**V. CAUSE-EFFECT RELATIONS BETWEEN CLINICAL SIGNS OF ADR AND SD**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  **defined** |  **likely** |  **possible** |  **questionable** |  **not defined** |  **is beyond classification** |

**VІ. INFORMATION ABOUT THE NOTIFIER**

|  |  |  |
| --- | --- | --- |
| **27. Name of the notifier, phone/fax, email** | **28. Notification is provided** **by** | **29. Name and address of the institution of healthcare or the notifier** |
|  |  doctor  pharmacist pharmacy technician nurse paramedic  obstetrician notifier |
|  |
| **30. Source of notification****(30-32 only for the notifier**)  doctor  patient research      literature      other | **31. Notification number assigned by the notifier** | **32. Notifier's receipt date** | **33. Notification type** | **34. Date of completion** |
|  |  |  primary following final |  |