|  |  |
| --- | --- |
| **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 |  |