## **AE/ADR, SAE/SADR, and LOE reporting form**

| **Template for AE/ADR, SAE/SADR, and LOE report** |
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| Date and time of information receipt |  |
| Full name of the person reporting adverse reactions (AR). If the reporter is a physician, include their position and place of work | When contacting the referrer of the message, it is necessary to inform:«Personal data collection will be carried out with confidentiality, the information obtained will be used **solely for pharmacovigilance purposes**, and will not be disclosed to any persons except regulatory authority employees if necessary». |
| Contact information of the reporter of adverse reaction::e-mail, phone | For the possibility of obtaining additional information about the AR/AE case and LOE. |
| Brief description | Suspected drug, presumably causing the adverse reaction AR/AE, SAR/SAE and LOE (trade name, dosage form, strength, route of administration, batch number):\*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Patient details (age, sex, initials):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Adverse reaction description (briefly, e.g. nausea, headache, drug ineffectiveness):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Full name and position of the person who recorded the information |  |
| Date of the form completion |  |

**For reporting all adverse reactions to medications, you may:**

* send the completed form to the pharmacovigilance specialist of ANO NPRC via e-mail: adversereaction@drugsafety.ru or report by any convenient method:
* Fill out the attached form about the adverse event pn the website:

[www.drugsafety.ru](http://www.drugsafety.ru/)

* Call the free 24-hour hotline in Russia: 8 800 777-86-04
* • Send a message via WhatsApp or Viber to the number: +7 903 799-21-86
* • Scan the QR code