Ministry of Healthcare
of the Russian Federation

FEDERAL SERVICE FOR SURVEILLANCE IN HEALTHCARE
(ROSZDRAVNADZOR)

ORDER

Moscow

15 February 2017 No. *1071*

ON APPROVAL OF THE PHARMACOVIGILANCE PROCEDURE

In compliance with Articles 64, 65 of the Federal Law dated 12 April 2010 No. 61-FZ "On Circulation of Medicinal Products" (Legislation Bulletin of the Russian Federation, 2010, N 16, Art. 1815; N 31, Art. 4161; N 42, Art. 5293; N 49, Art. 6409; 2011, N 50, Art. 7351; 2012, N 26, Art. 3446; N 53, Art. 7587; 2013, N 27, Art. 3477; N 48, Art. 6165; 2014, N 11, Art. 1098; N 43, Art. 5797; N 52, Art. 7540; 2015, N 10, Art. 1404; N 27, Art. 3951; N 29, Art. 4359, 4367, 4388; N 51, Art. 7245; 2016, N 1, Art. 9; N 23, Art. 3287; N 27, Art. 4238, 4283), I order:

1. To approve the appended Pharmacovigilance Procedure based on the Appendix.
2. I shall personally supervise the execution of this Order.

Head <*Signature*> M. A. Murashko

[Round seal bearing a coat of arms:
MINISTRY OF HEALTHCARE
OF THE RUSSIAN FEDERATION
FEDERAL SERVICE FOR SURVEILLANCE IN
HEALTHCARE * OGRN 1047796244396]

MINISTRY OF JUSTICE OF THE RUSSIAN FEDERATION

REGISTERED

Registration No. *46039*

20 March 2017

APPROVED BY
Order of the Federal Service for Surveillance in Healthcare,
dated *15.02.17* No. *1071*

PHARMACOVIGILANCE PROCEDURE

1. This Procedure establishes the requirements to conduction of pharmacovigilance.
2. Pharmacovigilance is a type of activity aimed at monitoring of drugs efficacy and safety and identification, evaluation of and prevention from negative consequences of drug usage[1].
3. Pharmacovigilance is carried out by the Federal Service for Surveillance in Healthcare (hereinafter – Roszdravnadzor) by means of analysis of information reported by subjects of circulation of medicinal products regarding side effects of medicinal products, adverse reactions, serious adverse reactions, unexpected adverse reactions associated with administration of drugs, individual intolerance, lack of efficacy of drugs (hereinafter – adverse reactions), as well as other facts and circumstances, which put human's life and health at danger in the course of drugs administration (hereinafter – other safety and efficacy information) revealed at all stages of drug circulation in the Russian Federation and other states in order to identify negative consequences of their use, individual intolerance, warn healthcare professionals and patients thereof and to protect them from such drugs' use.
4. Pharmacovigilance is conducted in compliance with legislation of the Russian Federation in the field of personal data protection.
5. Officers, authorized to carry out pharmacovigilance, include as follows:
    1) Head (deputy heads) of Roszdravnadzor;
    2) Heads of structural subdivisions of Roszdravnadzor, their deputies, which professional duties provide authorities for pharmacovigilance conduction;
    3) Other Roszdravnadzor's state civil officers, which professional duties provide authorities for pharmacovigilance conduction.
6. Pharmacovigilance is carried out by Roszdravnadzor based on the data, received in the form of:
    1) Reports from subjects of circulation of medicinal products (hereinafter- reports);
    2) Periodic Safety Update Reports (hereinafter – PSUR) submitted to Roszdravnadzor by Marketing Authorization Holders or owners of drugs or other legal entities acting on their behalf (hereinafter – MAHs);
    3) Development Safety Update Reports (hereinafter – DSUR) submitted to Roszdravnadzor by legal entities authorized for conduction of clinical trials in the Russian Federation or other authorized legal entities (hereinafter – legal entities authorized for conduction of clinical trials);
    4) Information received in the course of the state control (surveillance) in the sphere of circulation of medicinal products.
7. In order to evaluate scientific and clinical information outlined in documents and data outlined in Paragraph 6 of this Procedure Roszdravnadzor involves Federal State Budgetary Institution, controlled by Roszdravnadzor (hereinafter – the expert organization).

---

[1] Paragraph 52.1, Art. 4 of the Federal Law dated 12 April 2010 No. 61-FZ "On Circulation of Medicinal Products" (Legislation Bulletin of the Russian Federation, 2010, N 16, Art. 1815; N 31, Art. 4161; N 42, Art. 5293; N 49, Art. 6409; 2011, N 50, Art. 7351; 2012, N 26, Art. 3446; N 53, Art. 7587; 2013, N 27, Art. 3477; N 48, Art. 6165; 2014, N 11, Art. 1098; N 43, Art. 5797; N 52, Art. 7540; 2015, N 10, Art. 1404; N 27, Art. 3951; N 29, Art. 4359, 4367, 4388; N 51, Art. 7245; 2016, N 1, Art. 9; N 23, Art. 3287; N 27, Art. 4238, 4283).

8. Evaluation of scientific and clinical information outlined in documents listed in Paragraph 6 of this Procedure, is based on the principles of legalism, protection of human's and citizen's rights and freedoms, protection of legal entities rights, protection of independent expert's rights, objectivity, comprehensiveness and completeness of studies based on novel achievements of science and technology, as well as responsibility of expert organization for expertise and its quality.
9. Reports from subjects of circulation of medicinal products, except for legal entities authorized for conduction of clinical trials in the Russian Federation, are submitted to Roszdravnadzor in compliance with the recommended form "Report on Adverse Reaction or Lack of Therapeutic Efficacy of the Drug" (Appendix No. 1 to this Procedure).
10. Reports of legal entities authorized for conduction of clinical trials are submitted to Roszdravnadzor in compliance with the recommended form "Report on a Serious Unexpected Adverse Reaction to Investigational Medicinal Product" (Appendix No. 2 to this Procedure).
11. If the information outlined in Sub-paragraph 1 of Paragraph 6 of this Procedure is non-compliant with the content of the form fields provided in Appendices No. 1 and No. 2 or if such data was revealed outside the territory of the Russian Federation, those may be presented to Roszdravnadzor in a free format.
12. Reports shall be submitted to Roszdravnadzor through the Automatic Information System of Roszdravnadzor (hereinafter – Roszdravnadzor AIS) or via e-mail pharm@roszdravnadzor.ru PSUR and DSUR shall be submitted to Roszdravnadzor through Roszdravnadzor AIS or by use of electronic data carriers.
13. MAHs shall within the time term not more than 15 calendar days report to Roszdravnadzor data on adverse reactions specified in the Good Pharmacovigilance Practices (GVP EAEU) approved by Decision No. 87[2] of the Council of the Eurasian Economic Commission, dated 03 November 2016 (Paragraphs 7.1.7.1., 7.1.7.3.).
14. Time terms for adverse reaction reporting outlined in the GVP EAEU (Paragraph 7.1.7.1) are calculated according to the GVP EAEU (Paragraph 7.1.2.1).
15. Time terms for other safety and efficacy information reporting outlined in the GVP EAEU (Paragraph 7.1.7.3) are calculated starting from the date when the MAH learns respective facts and circumstances.
16. MAHs shall submit PSUR to Roszdravnadzor using the form outlined in the GVP EAEU (Paragraphs 8.4-8.5).
17. The procedure regarding end date calculation for MAH's collection of data on adverse reactions, other information on safety for subsequent PSUR and frequency of PSUR submission for drugs with various international non-proprietary names or group names are established by Roszdravnadzor.
18. If the PSUR submission time terms and frequencies for particular drugs are not established by Roszdravnadzor, PSUR submission time terms and frequency shall be calculated from the first drug's worldwide registration date and are as follows:
    1) every 6 months from the first drug's worldwide registration date during first 2 years;
    2) annually during next 2 years;
    3) hereinafter – every 3 years.
19. PSUR shall be submitted to Roszdravnadzor within time terms outlined in the GVP EAEU (Paragraph 8.8.1).

[2] Good Pharmacovigilance Practices. Approved by Decision No. 87 of the Council of Eurasian Economic Commission, dated 03 November 2016 (Official website of the Eurasian Economic Union https://docs.eaeunion.org/docs/ru-ru/01411948/cNcd_21112016_87, 21 November 2016).

20. If any adverse reactions and other safety and efficacy information, not included in the instruction for medical use and changing the drug's expected benefit/potential risk ratio, have been revealed, Roszdravnadzor shall have the right to request from the MAH of drug an extra PSUR.
21. An extra PSUR shall be submitted to Roszdravnadzor within time terms outlined in the GVP EAEU (Paragraph 8.8.2).
22. Legal entities authorized for conduction of clinical trials shall report to Roszdravnadzor within the time term not more than 7 calendar days fatal or life-threatening serious unexpected adverse reactions to investigational medicinal product identified in the course of clinical trials approved for conduction in the Russian Federation, unless the clinical trial protocol provides for otherwise.
23. Legal entities authorized for conduction of clinical trials shall report Roszdravnadzor within the time term not more than 15 calendar days serious unexpected adverse reactions, except for reactions outlined in Paragraph 22 of this Procedure.
24. Legal entities authorized for conduction of clinical trials shall report to Roszdravnadzor within the time term not more than 15 calendar days information on investigational medicinal product's safety outlined in Good Clinical Practice of Eurasian Economic Union approved by Decision No. 79 of the Council of the Eurasian Economic Commission dated 03 November 2016 (hereinafter GCP EAEU)[3] (Paragraph 1.5 of the Appendix No. 11).
25. Time terms for reporting of adverse reactions outlined in Paragraphs 22 and 23 of this Procedure are calculated in compliance with the GCP EAEU (Paragraph 1.3.1 of Appendix No. 11).
26. Time terms for reporting of other information on investigational medicinal product's safety as outlined in Paragraph 24 of this Procedure shall be calculated starting from the date when the legal entity authorized for conduction of clinical trial learns respective facts and circumstances.
27. Legal entity authorized for conduction of clinical trial shall disclose a randomization code in reports of adverse reaction outlined in Paragraphs 22 and 23 of this Procedure, unless otherwise specified in clinical trial protocol.

    Adverse reactions of clinical trials' subjects, who received placebo are not subject to reporting in the manner set forth in Paragraphs 22 and 23 of this Procedure.
28. Reports on adverse reactions to comparators, registered in the Russian Federation, revealed on the territory of the Russian Federation, shall be submitted in the manner outlined in Paragraph 12 of this Procedure.
29. Legal entities authorized for conduction of clinical trials shall submit DSUR to Roszdravnadzor in compliance with Paragraph 4 of Appendix No. 12 of the GCP EAEU. Copy of Investigators Brochure regarding trial approved for conduction in the Russian Federation effective at the time of DSUR submission shall be appended to the DSUR.
30. DSUR shall be submitted to Roszdravnadzor on an annual basis within the time term calculated from the date of the beginning of the first clinical trial of investigational medicinal product in the world or from the first drug's worldwide registration date.
31. DSUR for investigational medicinal products studied in the territory of the Russian Federation shall be submitted to Roszdravnadzor within the time term not exceeding 60 calendar days since completion of collection by the MAH of data on adverse reactions for this product.

[3] Good Clinical Practice of the Eurasian Economic Union. Approved by Decision No. 79 of the Council of Eurasian Economic Commission, dated 03 November 2016 (Official website of the Eurasian Economic Union https://docs.eaeuNioN.org/docs/ru-ru/01411924/cNcd_21112016_79, 21 November 2016).

32. In case any data changing the medicinal product's expected benefit/potential risk ratio in the clinical trial is revealed, Roszdravnadzor shall have the right to request an extra DSUR from a legal entity authorized for conduction of clinical trial.
33. An extra DSUR shall be submitted to Roszdravnadzor within the time term not exceeding 60 calendar days since the legal entity authorized for conduction of clinical trial has received Roszdravnadzor's request outlined in Paragraph 31 of this Procedure.
34. Subjects' of circulation of medicinal products (medical organizations) activities aimed at identification of adverse reactions and other safety and efficacy information related to administration of drugs shall be regulated by internal orders of the medical organization.
35. Subjects of circulation of medicinal products (medical organizations) must report to Roszdravnadzor within the time term not more than 3 business days serious adverse reactions with fatal outcome or life-threatening reactions, except for adverse reactions revealed in the course of clinical trials conducted in such medical organization.
36. Subjects of circulation of medicinal products (medical organizations) shall report to Roszdravnadzor within the term not exceeding 15 calendar days the following adverse reactions and other safety and efficacy information revealed by such medical organization, except for adverse reactions revealed in the course of clinical trials:
    1) Serious adverse reactions to drugs, except for serious adverse reactions outlined in Paragraph 35 of this Procedure;
    2) Cases of infectious disease transmission via drug
    3) Lack of efficacy cases – for drugs used for treatment of life-threatening diseases, vaccines for prevention of infection diseases, drugs used for the purpose of pregnancy prevention – when lack of clinical effect is not associated with individual patient's characteristics and/or particular features of the disease;
    4) Adverse reactions which occurred as a result of drug abuse, intended overdose, occupational exposure or for cases when the drug is used intentionally to harm human life and health.
37. Cases of medicinal products' individual intolerance, which served as a basis for prescription of drugs by trade name under the program of preferential provision of drugs shall be reported to Roszdravnadzor by the medical boards in the manner established by the Order of the Ministry of Healthcare of the Russian Federation dated 05 May 2012 No. 502n " On Approval of the Procedure for Establishment and Activity of a Medical Board in a Medical Organization "[4] within the time term not exceeding five business days since the prescription of the particular drug by trade name.
38. Time terms for reporting adverse reactions and other safety and efficacy information outlined in Paragraphs 35-36 of this Procedure shall be calculated starting from the date a subject's of circulation of medicinal products (medical organization) officer responsible for pharmacovigilance has become aware of the following data on an adverse reaction or a special situation:
    1) Information, which allows identifying a legal entity or an individual, revealed an adverse reaction or a special situation;
    2) Information, which allows identifying an individual, in which an adverse reaction occurred;

[4] Order of the Ministry of Healthcare of the Russian Federation dated 05 May 2012, No. 502n "On Approval of the Procedure for Establishment and Activity of a Medical Board in a Medical Organization", (Registered by the Ministry of Justice on 09 June 2012, Registration No. 24516, RG 22 June 2012, No. 141) as amended by Order of the Ministry of Healthcare of the Russian Federation dated 02 December 2013 No. 886n "On making Changes to the Procedure for Establishment and Activity of a Medical Board in a Medical Organization approved by Order of the Ministry of Healthcare and Social Development of the Russian Federation dated 05 May 2012, No. 502n, and to the Procedure of prescription of drugs approved by Order of the Ministry of Healthcare of the Russian Federation dated 20 December 2012 No. 1175n" (registered by the Ministry of Justice of Russia on 23.12.2013 No. 30714).

3) Information, which allows identifying a medicinal product;
4) Information, which allows identifying adverse reaction symptoms.

39. Copies of reports submitted to Roszdravnadzor in compliance with Paragraphs 35-36 of this Procedure are archived in the medical records of patients.
40. Reports, PSUR and DSUR that are entered to Roszdravnadzor AIS as electronic documents are registered automatically.
41. Reports submitted to Roszdravnadzor via e-mail, as well as PSUR and DSUR submitted to Roszdravnadzor through electronic carriers are registered and entered to Roszdravnadzor AIS within 5 business days since the date of receipt.
42. Evaluation of scientific and clinical information contained in reports submitted to Roszdravnadzor AIS is conducted by the expert organization within 5 business days since the date of receipt.
    Evaluation of scientific and clinical information included into PSUR and DSUR are conducted by the expert organization within 60 business days since the date of receipt by the expert organization
43. Results of evaluation of scientific and clinical information contained in reports are sent to Roszdravnadzor by the expert organization as a part of weekly reports.
    Results of scientific and clinical information contained in PSUR and DSUR are sent to Roszdravnadzor as a part of monthly reports of expert organization.
44. In case the expert organization identifies any inconsistencies of a submitted PSUR with Paragraphs 8.4–8.5 of the GVP EAEU, and of a DSUR with Paragraph 4 of Appendix No. 12 of the GCP EAEU, Roszdravnadzor within the time term not exceeding 10 business days since the date of such information receipt, shall send to the MAH of drug or to the legal entity authorized for conduction of clinical trials, a request for making changes to the PSUR or DSUR.
45. MAH of drug or legal entity authorized for conduction of clinical trials shall within the time term not exceeding 30 business days since the receipt of Roszdravnadzor's request specified in Paragraph 44 of this Procedure, submit to Roszdravnadzor a PSUR in accordance with Paragraphs 8.4–8.5 of the GVP EAEU, and DSUR in accordance with Paragraph 4 of Appendix No. 12 of the GCP EAEU.
46. When an expert organization reveals in the course of evaluation of scientific and clinical information contained in reports, PSUR, DSUR data not included in the instruction for medical use or clinical trial documentation, which changes the expected benefit/potential risk ratio of a medicinal product, an expert organization shall send to Roszdravnadzor a conclusion within the time term not more than 5 business days since corresponding data was revealed.
47. If according to the conclusion of the expert organization, the adverse reaction or threat to the human life and health could be resulted from the violation by the subjects of circulation of medicinal products of legislative requirements to pharmacovigilance, or violation of the good clinical practice, Roszdravnadzor shall make a decision regarding a conduction of an inspection of adherence by subjects of circulation of medicinal products to the requirements established by Federal Law dated 12.04.2010 No. 61-FZ "On Circulation of Medicinal Products", and other related approved legislative acts of the Russian Federation, requirements to clinical trials of drugs, storage, transportation, import to the Russian Federation, sale, distribution of drugs and usage of medicinal products in the manner provided in Federal Law dated 26 December 2008 No. 294-FZ "On Protection of Rights of Legal Entities and Individual Entrepreneurs in Conduction of State Control (Surveillance) and Municipal Control"[5].

[5] Federal Law dated 26 December 2008 No. 294-FZ "On Protection of Rights of Legal Entities and Individual Entrepreneurs in Conduction of State Control (Supervision) and Municipal Control", (Legislation Bulletin of the Russian Federation, 2008, No. 52, Art. 6249; 2009, No. 18, Art. 2140; No. 29, Art. 3601; No. 48, Art. 5711; No. 52, Art. 6441; 2010, No. 17, Art. 1988; No. 18, Art. 2142; No. 31, Art. 4160, Art. 4193, Art. 4196, No. 32, Art. 4298; 2011, No. 1, Art. 20; No. 17, Art. 2310; No. 23, Art. 3263; No. 27, Art. 3880; No. 30, Art. 4590; No. 48, Art. 6728; 2012, No. 19, Art. 2281; No. 26, Art. 3446; No. 31, Art. 4320, Art. 4322).

48. If based on the expert organization's conclusion, the reason of an adverse reaction was medicinal product's inconsistency with the quality requirements, Roszdravnadzor shall make a decision on random quality control of a corresponding drug in the manner established by the legislation of the Russian Federation[6].
49. Within 5 business days since the receipt of the conclusion of the expert organization containing information on identification of new safety and efficacy information regarding drugs, not included in the instruction for medical use or clinical trial documentation, which changes the expected benefit/potential risk ratio in drug's usage, Roszdravnadzor shall inform the MAH of drug or a legal entity authorized for conduction of clinical trials.
50. MAH of drug or a legal entity authorized for conduction of clinical trials, within 10 business days since the receipt of Roszdravnadzor's notice specified in Paragraph 49 of this Procedure, shall carry out the check of correctness of the information obtained and submit the information on the check results to Roszdravnadzor.
51. During the period of check specified in Paragraph 50 of this Procedure, the MAH of drug or a legal entity authorized for conduction of clinical trials, shall take necessary measures to prevent from increase of harm associated with circulation of a certain medicinal product.
52. Within 10 business days after the receipt of the results of the check specified in Paragraph 50 of this Procedure, carried out by the MAH, Roszdravnadzor informs the Ministry of Healthcare of the Russian Federation of any new drug safety and efficacy data not included in the instruction for medical use or clinical trial documentation, which changes the expected benefit/potential risk ratio of drug's usage and submits necessary information to review an issue on the need in making changes to the drug registration dossier, cancellation of state registration, conduction of pre-clinical or clinical trials of the drug or any other additional drug quality, efficacy and safety trial (hereinafter – additional trials), as well as the need in or no need in suspension of medicinal product circulation for the period of conduction of additional studies or the period required to make changes to the drug's registration documents.
53. Based on the review of the results of the check outlined in Paragraph 50 of this Procedure, submitted by the MAH of drug, Roszdravnadzor within 30 business days since the receipt of the check results, shall have the right to send to the MAH a request for the need in the development of the Risk Management Plan (hereinafter – RMP) in accordance with Paragraphs 6.2.4–6.2.5 of the GVP EAEU.
54. RMP should be submitted to Roszdravnadzor within 60 working since the receipt of Roszdravnadzor's request specified in Paragraph 52 of this Procedure.
55. If the MAH of drug in the course of the check specified in Paragraph 50 of this procedure reveals any information on inconsistency of the drug with the quality, efficacy and safety requirements, the MAH has a right to develop RMP by itself and submit it to Roszdravnadzor.
56. RMP includes detailed description of pharmacovigilance measures, aimed at identification, assessment and prevention or minimization of risks associated with drugs, including assessment of such measures' efficiency.
57. Roszdravnadzor shall within the time term not exceeding 5 business days since the receipt of the RMP send it to the expert organization to carry out scientific and clinical assessment in order to identify whether measures offered to prevent from harm to citizens' health and lives in usage of the drug are sufficient or not.

[6] Order dated 07 August 2015 No. 5539 of the Federal Service for Surveillance in Healthcare "On Approval of the Procedure of Random Quality Control of Medicinal Products for Medical Use" (Registered by the Ministry of Justice of Russia on 09 August 2015, Registration No. 39263, "Bulletin of Regulations of Federal Executive Bodies, No. 48, 30.11.2015).

58. The conclusion of expert organization regarding the sufficiency of measures contained in the RMP to prevent from harm to citizens' health and lives in usage of the drug shall be sent to Roszdravnadzor within 20 business days since the RMP has been received by the expert organization.
59. Roszdravnadzor shall within 5 business days after the receipt of the expert organization's conclusion outlined in Paragraph 57 of this Procedure, send to the MAH of drug a notice of RMP approval of a notice of the need in making changes to the RMP.
60. If any notice of necessary changes to be made to the RMP has been received the MAH of drug shall within the term not exceeding 20 business days since the receipt of the notice submit to Roszdravnadzor a RMP with all changes made taken into account.
61. Basing on the results of the check specified in Paragraph 50 of this Procedure submitted by legal entity authorized for conduction of clinical trials, Roszdravnadzor shall within 30 business days since the receipt of the check results, review an issue on sending to the Ministry of Healthcare of the Russian Federation and the legal entity authorized for conduction of clinical trials, necessary information to review the need in suspension of a clinical trial, early completion thereof or making changes to the clinical trial protocol.
62. Basing on the results of the pharmacovigilance, Roszdravnadzor shall publish at its Internet web-site data on the decisions made by the Ministry of Healthcare of the Russian Federation based on the results of review of Roszdravnadzor's information specified in Paragraph 52 of this Procedure.

Appendix No. 1 to the Pharmacovigilance Procedure approved by Order of the Federal Service for Surveillance in Healthcare, dated *15.02.17* No. *1071*

Recommended template

REPORT ON ADVERSE REACTION OR LACK OF THERAPEUTIC EFFICACY OF THE DRUG

☐ Initial ☐ Follow up to the report No. _____, dated _____

Patient Information

Patient initials (patient's number)* _____ Sex ☐ M ☐ F Weight _____ kg

Age _____ Pregnancy ☐, gestation period _____ weeks

Allergy ☐ No ☐ Yes, to _____

Treatment ☐ out-patient ☐ in-patient ☐ self-treatment

Suspected Medicinal Product Information

	Medicinal product name (tradename)*	Manufacturer	Batch number	Dose, route of administration	Therapy start date	Therapy end date	Indication
1							
2							
3							

Adverse Reaction

Reaction description* (indicate all details including laboratory test data)

AR resolution date _____

AR onset date _____

AR seriousness criteria:

☐ Death

☐ Life threatening

☐ Involved or prolonged inpatient hospitalization

☐ Disability

☐ Congenital anomaly

☐ Clinically significant event

☐ Not applicable

Actions Taken

☐ No treatment ☐ Suspected medicinal product discontinued ☐ Dose of suspected medicinal product reduced

☐ Non-medicinal treatment (including surgical treatment)

☐ Medicinal treatment_____

Outcome

☐ Recovery without sequelae ☐ Condition improvement ☐ Condition without changes

☐ Recovery with sequelae (indicate) _____

☐ Death ☐ Unknown ☐ Not applicable

Did AR subside after discontinuation of the medicinal product?	☐ No ☐ Yes ☐ Medicinal product was not discontinued ☐ Not applicable
Was the medicinal product restarted? ☐ No ☐ Yes	Result _____ ☐ Not applicable

Other medicinal products administered during last 3 months including medicinal products taken by the patient him/herself (at own discretion)

	Medicinal product name (tradename)	Manufacturer	Batch number	Dose, route of administration	Therapy start date	Therapy end date	Indication
1							
2							
3							
4							
5							

Reporter Information

☐ Physician ☐ Other healthcare professional ☐ Patient ☐ Other

Contact telephone/e-mail:* _____

First name, last name, patronymic _____

Position and place of work _____

Report date _____

* filling of this this field is mandatory

The report may be sent via:

- e-mail: pharm@roszdravnadzor.ru,
- fax: +7(495)698-15-73,
- online at web-site www.npr.roszdravnadzor.ru,
- mailing address: 4 Slavyanskaya Square, Building 1, Moscow 109074.

Appendix No. 2 to the Pharmacovigilance Procedure
approved by Order of the Federal Service
for Surveillance in Healthcare
date *15.02.17* No. *1071*

Recommended template

Report on a Serious Unexpected Adverse Reaction to Investigational Medicinal Product

Clinical trial protocol No.	
Investigational medicinal product name	
Clinical trial protocol title	
Authorization to conduct a clinical trial in the Russian Federation No.	
Name of the medical facility where the adverse reaction was revealed (if occurred in the Russian Federation)	

I. Adverse Reaction Information

1. Patient initials	1a. Country	2. Date of birth	2a. Age	3. Sex	4–6. Adverse reaction onset date (da/mo/yr)	8–12. Check all appropriate to AR ☐ Death ☐ Involved or prolonged inpatient hospitalization ☐ Persistent or significant disability/ incapacity ☐ Life threatening
7–13. Adverse reaction description (including relevant test/lab data)						

II. Suspected Drug(s) Information

14. Suspected drug (including international non-proprietary name or group name)		20. Did the reaction abate after stopping drug? ☐ Yes ☐ No ☐ Not applicable
15. Daily dose(s)	16. Route(s) of administration	21. Did the reaction reappear after reintroduction of the drug? ☐ Yes ☐ No ☐ Not applicable
17. Indication(s) for use:		
18. Therapy dates from to	19. Therapy duration	

III. Concomitant Therapy and Medical History

22. Concomitant drug(s) and dates of administration (exclude those used to treat event)
23. Other relevant medical history data (e. g. diagnoses, allergies, pregnancy with the date of last menstruation specified, etc.)

III. Other Information

24. Name and address of manufacturer	
24a. Case identification number	24b. Date information on adverse reaction received by manufacturer
24c. Adverse reaction report source ☐ Study ☐ Literature ☐ Healthcare professional☐ Authority ☐ Other	
25. Date of this report	
26. Report type ☐ Initial ☐ Follow up	