Registered by Minjust (the Ministry of Justice) of Russia under No. 46039 on 20 March 2017

MINISTRY OF HEALTH OF THE RUSSIAN FEDERATION

FEDERAL SERVICE FOR SURVEILLANCE IN HEALTHCARE

ORDER

No. 1071 dated 15 February 2017

(as amended by Order No. 6252 dated 16 July 2020)

CONCERNING APPROVAL OF PHARMACOVIGILANCE PROCEDURE

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

1. The attached [Procedure](#P29) for pharmacovigilance activities be approved according to the appendix.

2. Monitoring of fulfillment of this order be my responsibility.

Head

M. A. MURASHKO

Approved

by Order of Federal Service

for Surveillance in Healthcare

No. 1071 dated 15 February 2017

PHARMACOVIGILANCE PROCEDURE

1. This Procedure shall set requirements to pharmacovigilance activities.

2. Pharmacovigilance shall mean the activity of monitoring of efficacy and safety of medicinal products aimed at identification, assessment and prevention of adverse consequences caused by use of medicinal products. <1>.

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<1> Clause 52.1, article 4 of Federal Law No. 61-FZ On Circulation of Medicines dated 12 April 2010 (Corpus of Legislative Acts of the Russian Federation 2010, No. 16, article 1815; No. 31, article 4161; No. 42, article 5293; No. 49, article 6409; 2011, No. 50, article 7351; 2012, No. 26, article 3446; No. 53, article 7587; 2013, No. 27, article 3477; No. 48, article 6165; 2014, No. 11, article 1098; No. 43, article 5797; No. 52, article 7540; 2015, No. 10, article 1404; No. 27, article 3951; No. 29, article 4359, 4367, 4388; No. 51, article 7245; 2016, No. 1, article 9; No. 23, article 3287; No. 27, article 4238, 4283).

3. Pharmacovigilance shall be exercised by the Federal Service for Surveillance in Healthcare (hereinafter referred to as “Roszdravnadzor”) by analyzing the information provided by the subjects of circulation of medicines on side effects of medicines, adverse reactions, serious adverse reactions, unexpected adverse reactions occurred during the use of medicinal products, on individual intolerance, lack of efficacy of medicinal products (hereinafter referred to as “adverse reactions”) as well as on other cases and circumstances constituting a threat to life or health of a person during the use of medicinal products (hereinafter referred to as the “other safety and efficacy information”) identified at all stages of circulation of medicines in the Russian Federation and other countries to identify potential adverse consequences of their use, individual intolerance, to warn healthcare professionals and patients thereof and protect them from use of such medicinal products.

4. Pharmacovigilance shall be exercised in compliance with the legislation of the Russian Federation on personal data protection.

5. The following official persons shall be authorized to exercise pharmacovigilance:

1) head (his deputies) of Roszdravnadzor;

2) heads of Roszdravnadzor structural subdivisions, their deputies if their job descriptions provide for authority to exercise pharmacovigilance;

3) other civil officers of Roszdravnadzor if their job descriptions provide for authority to exercise pharmacovigilance.

6. Pharmacovigilance shall be exercised by Roszdravnadzor on the basis of the data received in the form of:

1) Reports from subjects of circulation of medicines (hereinafter referred to as “reports”);

2) Periodic safety update reports for medicinal products (hereinafter referred to as “PSUR”) submitted to Roszdravnadzor by holders or owners of marketing authorizations for medicinal products or other legal entities authorized by them (hereinafter referred to as “marketing authorization holders”/”MAH”);

3) Development safety update reports for investigational medicinal products (hereinafter referred to as “DSUR”) submitted to Roszdravnadzor by legal entities authorized to conduct a clinical trial in the Russian Federation *[comment by translator:* *hereinafter referred to as “clinical trial approval holders”/“CTAH”]* or by other authorized legal entities (hereinafter referred to as “legal entities approved to conduct clinical trials in the Russian Federation”);

4) Information received in the course of state control (surveillance) of circulation of medicines.

7. To assess the scientific and clinical information contained in the documents and the data specified in [clause 6](#P42) hereof Roszdravnadzor shall engage the Federal State Budgetary Institution under Roszdravnadzor’s supervision (hereinafter referred to as the “expert institution).

8. Assessment of the scientific and clinical information contained in the documents and the data specified in [clause 6](#P42) hereof shall be based on the principles of legality, observance of human and civil rights and freedoms, rights of legal entities, of the expert’s independence, impartiality, comprehensiveness and completeness of investigations held in view of the latest achievements in science and technology, responsibility of the expert institution for carrying of expert assessment and its quality.

9. Reports from subjects of circulation of medicines, unless such subjects are CTAH, shall be submitted to Roszdravnadzor according to the recommended form “Notification of Adverse Reaction or Lack of Therapeutic Effect of Medicinal Product” provided in [Appendix No. 1](#P146) hereto.

10. Reports from CTAH shall be submitted to Roszdravnadzor according to the recommended form “Report of Serious Unexpected Adverse Reaction to Investigational Medicinal Product” provided in Appendix No. 2 hereto.

11. If the nature of data stated in [sub-clause 1, clause 6](#P43) hereof does not correspond to the contents of fields in the forms provided in [Appendices No. 1](#P146) and [No. 2](#P299) hereto or if the stated data have been received outside the Russian Federation, these data may be submitted to Roszdravnadzor in any form.

12. The reports shall be submitted to Roszdravnadzor using the Automated Information System of Roszdravnadzor (hereinafter referred to as the “Roszdravnadzor AIS”) or via electronic mail to pharm@roszdravNadzor.ru. PSURs and DSURs shall be submitted to Roszdravnadzor using the Roszdravnadzor AIS or electronic media.

13. Marketing authorization holders shall report adverse reactions defined in the Good Pharmacovigilance Practice approved by decision of the Council of the Eurasian Economic Commission No. 87 dated 3 November 2016 *[comment by translator: hereinafter referred to as EAEU GVP]* <2> (clauses 7.1.7.1., 7.1.7.3) to Roszdravnadzor within 15 calendar days.

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<2> Good Pharmacovigilance Practice. Approved by decision of the Council of the Eurasian Economic Commission No. 87 dated 3 November 2016 (Official website of the Eurasian Economic Union: https://docs.eaeunion.org/docs/ru-ru/01411948/cNcd\_21112016\_87, 21 November 2016).

14. The timelines for submission of adverse reactions defined in the EAEU GVP (clause 7.1.7.1) shall be calculated according to the EAEU GVP (clause 7.1.2.1).

15. The timelines for submission of other safety and efficacy information defined in the EAEU GVP (clause 7.1.7.3) shall be calculated from the date a marketing authorization holder has identified respective facts and circumstances.

16. Holders of marketing authorizations for medicinal products shall submit PSUR to Roszdravnadzor according to the form defined in the EAEU GVP (clauses 8.4 — 8.5).

17. Roszdravnadzor shall be responsible for approval of the procedure on calculation of PSUR data lock point (for inclusion of adverse reactions and other safety findings) and for approval of PSUR submission frequency in respect of medicinal products with various international non-proprietary names or group names.

18. For PSURs for medicinal products which do not have DLP and frequency approved by Roszdravnadzor, such frequency and DPL shall be calculated starting from the date of the first state registration of the medicinal product in any country in the world *[comment by translator: based on the international birth date, IBD]* and shall be determined as follows:

1) Every 6 months from IBD during the first 2 years;

2) on an annual basis during the next 2 years;

3) And every 3 years subsequently.

19. PSURs shall be submitted to Roszdravnadzor within the timelines defined in the EAEU GVP (clause 8.8.1).

20. Roszdravnadzor has authority to request ad-hoc PSUR from MAH in case of identification of adverse reactions and other safety and efficacy information not labeled in the prescribing information of the medicinal product, changing the balance between expected benefit and potential risk associated with the use of the medicinal product.

21. Ad-hoc PSUR shall be submitted to Roszdravnadzor within the timelines defined in the EAEU GVP (clause 8.8.2).

22. CTAHs shall submit to Roszdravnadzor reports on fatal or life threatening unexpected serious adverse reactions to investigational medicinal product, which have been identified in the course of the clinical trials approved in the Russian Federation unless otherwise provided by the approved protocol of the clinical trial within 7 calendar days.

23. CTAHs shall submit to Roszdravnadzor reports on serious unexpected adverse reactions except for those defined in [clause 22](#P68) hereof within 15 calendar days.

24. CTAHs shall provide Roszdravnadzor with the safety information concerning investigational medicinal product defined by the Good Clinical Practice of the Eurasian Economic Union approved by decision of the Council of the Eurasian Economic Commission No. 79 dated 03 November 2016 (hereinafter referred to as the “EAEU GCP”) <3> (clause 1.5 of Appendix No. 11 of EAEU GCP) within 15 calendar days from identification of respective facts.

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<3> Good Clinical Practice of the Eurasian Economic Union. Approved by decision of the Eurasian Economic Commission No. 79 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).

25. The timelines for submission of adverse reactions defined in [clauses 22](#P68) and [23](#P69) hereof shall be calculated according to the EAEU GCP (clause 1.3.1 of Appendix No. 11).

26. The timelines for submission of other safety information on investigational medicinal product defined in [clause 24](#P70) hereof shall be calculated starting from the date CTAH has identified respective facts and circumstances.

27. CTAHs shall unblind adverse reactions defined in [clauses 22](#P68) and [23](#P69) hereof unless otherwise provided by the clinical trial protocol.

The adverse reactions occurred in clinical trial subjects receiving placebo shall not be reported within the procedure set in [clauses 22](#P68) and [23](#P69) hereof.

28. Reports on adverse reactions to comparators, authorized for marketing in the Russian Federation, shall be submitted within the procedure established in [clause 12](#P52) hereof.

29. CTAHs shall submit DSURs to Roszdravnadzor according to clause 4 of Appendix No. 12 of the EAEU GCP. DSUR shall be accompanied with a copy of Investigator’s Brochure of the clinical trial approved in the Russian Federation which is in effect at the time of the DSUR submission.

30. DSUR shall be submitted to Roszdravnadzor annually within the term calculated starting from the date of the first clinical trial of the medicinal product held in any country of the world or from the IBD.

31. DSURs for medicinal products studied in the Russian Federation shall be submitted to Roszdravnadzor within 60 calendar days from the data lock point.

32. Roszdravnadzor has the authority to request ad-hoc DSUR from CTAH in case of identification of any data changing the balance between the expected benefit and potential risk of the medicinal product in the clinical trial.

33. Ad-hoc DSUR shall be submitted to Roszdravnadzor within 60 calendar days from the date of receipt of Roszdravnadzor’s request defined in [clause 31](#P81) hereof by the CTAH.

34. Subjects of circulation of medicines (medical institutions) shall have internal governing directives to identify adverse reactions and other safety and efficacy information associated with use of medicinal products.

35. Subjects of circulation of medicines (medical institutions) shall provide Roszdravnadzor with data on fatal or life threatening serious adverse reactions, except for the adverse reactions identified in the course of the clinical trials carried out in this medical institution, within 3 business days from identification of respective facts.

36. Subjects of circulation of medicines (medical institutions) shall provide Roszdravnadzor with data on the following adverse reactions and with other safety and efficacy information identified by such medical institution, except for the adverse reactions identified in the course of the clinical trials, within 15 calendar days from identification of the respective facts:

1) Serious adverse reactions to medicinal products, except for the serious adverse reactions defined in [clause 35](#P85) hereof;

2) Cases of transmission of infectious agents via medicinal product;

3) Cases of lack of the claimed efficacy of medicinal products used to treat life threatening diseases, vaccines used to prevent infectious diseases, medicinal products used to prevent pregnancy unless absence of clinical effect is caused by the patient’s individual characteristics and (or) by specifics of his (her) disease;

4) Adverse reactions occurred due to abuse of the product, in case of intended overdose, in case of professional occupational exposure or use of the medicinal product for intended harm to life and health of a person.

37. Cases of individual intolerance to medicines which resulted in prescribing of medicinal products according to their trade name within the scope of the medicine assistance programs shall be reported to Roszdravnadzor by medical panels according to the procedure established by order of Minzdrav (Ministry of Health) of Russia No. 502н On Approval of the Procedure for Establishment and Activity of a Medical Panel in a Medical Institution dated 05 May 2012 <4> and within the term not exceeding 5 business days from the date on which a prescription has been issued for the respective medicinal product according to its trade name.

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<4> Order of the Ministry of Health of the Russian Federation No. 502н On Approval of the Procedure for Establishment and Activity of a Medical Panel in a Medical Institution dated 05 May 2012 (Registered by Minjust of Russia on 9 June 2012, registration number 24516, Rossiyskaya Gazeta (Russian Newspaper), issue No. 141 dated 22 June 2012) as amended by Order of the Ministry of Health of the Russian Federation No. 886н “On Amendment of the Procedure for Establishment and Activity of a Medical Panel in a Medical Institution Approved by Order of the Ministry of Healthcare and Social Development of the Russian Federation No. 502н Dated 05 May 2012 and of the Procedure for Prescribing and Issuing Prescriptions for Medicinal Products Approved by Order of the Ministry of Health of the Russian Federation No. 1175н dated 20 December 2012” dated 02 December 2013 (Registered by Minjust of Russia on 23 December 2013 under No. 30714).

38. The timelines for submission of data on adverse reactions and other safety and efficacy information defined in [clauses 35](#P85) — [36](#P86) hereof shall be calculated starting from the date on which the official PV responsible person of the subject of circulation of medicines (medical institution) has received the following data on the adverse reaction or the special case:

1) Identifiable reporter (legal entity or the individual);

2) Identifiable patient (individual who has suffered the adverse reaction);

3) Identifiable medicinal product;

4) Identifiable symptoms of the adverse reaction.

39. Copies of reports submitted to Roszdravnadzor according to [clauses 35](#P85) — [36](#P86) hereof shall be retained in the patient’s medical records.

40. The reports *[comment by translator: ICSRs]*, PSURs, DSURs submitted to Roszdravnadzor AIS in electronic form shall be registered automatically.

41. The reports, PSURs, DSURs submitted to Roszdravnadzor via the electronic mail as well as the PSURs and DSURs submitted to Roszdravnadzor on electronic media shall be registered and entered into the Roszdravnadzor AIS within 5 working days from receipt.

42. Scientific and clinical information contained in the reports submitted to the Roszdravnadzor AIS shall be assessed by the expert institution within 5 working days from the date of their receipt.

Scientific and clinical information contained in PSURs and DSURs shall be assessed by the expert institution within 60 working days from the date of their receipt by the expert institution.

43. The results of assessment of scientific and clinical information contained in the reports shall be sent by the expert institution to Roszdravnadzor as part of weekly reports.

Results of assessment of scientific and clinical information contained in PSURs and DSURs shall be sent to Roszdravnadzor as part of monthly reports by the expert institution.

44. If the expert institution has identified that the provided PSUR does not comply with clauses 8.4 — 8.5 of the EAEU GVP or the DSUR does not comply with clause 4 of Appendix No. 12 of the EAEU GCP, Roszdravnadzor shall request amendment of such PSUR or DSUR from MAH or CTAH within 10 working days from the date of receipt of such information.

45. MAH or CTAH shall provide Roszdravnadzor with the PSUR complying with clauses 8.4 - 8.5 of the EAEU GVP or the DSUR complying with clause 4 of Appendix No. 12 of the EAEU GCP within 30 working days from the date of receipt of Roszdravnadzor’s request defined in [clause 44](#P107) hereof.

46. If the assessment of the scientific and clinical information contained in the reports, PSURs and DSURs by the expert institution results in identification of any data not included in the prescribing information or the clinical trial documents, changing the balance between expected benefit and potential risk of the medicinal product, the expert institution shall send this conclusion to Roszdravnadzor within 5 working days from the date of identification of respective data.

47. If, according to the conclusion of the expert institution, the adverse reaction or the threat to human life or health may have been caused by violation of the PV legislative requirements committed by subjects of circulation of medicines or by violation of the good clinical practice, Roszdravnadzor shall decide to inspect compliance of subjects of circulation of medicines with the requirements to clinical trials of medicinal products, storage of medicines, their transportation, import to the Russian Federation, dispensing and sale, use of medicinal products, which requirements have been set by Federal Law No. 61-FZ On Circulation of Medicines dated 12 April 2010 and other legal regulations of the Russian Federation adopted in compliance therewith; the inspection shall be held within the procedure set by Federal Law No. 294-FZ On Protection of Rights of Legal Entities and Individual Entrepreneurs within the Scope of State Control (Surveillance) and Municipal Control dated 26 December 2008 <5>.

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<5> Federal Law No. 294-FZ On Protection of Rights of Legal Entities and Individual Entrepreneurs within the Scope of State Control (Surveillance) and Municipal Control dated 26 December 2008 (Corpus of Legislative Acts of the Russian Federation, 2008, No. 52, article 6249; 2009, No. 18, article 2140; No. 29, article 3601; No. 48, article 5711; No. 52, article 6441; 2010, No. 17, article 1988; No. 18, article 2142; No. 31, article 4160, article 4193, article 4196, No. 32, article 4298; 2011, No. 1, article 20; No. 17, article 2310; No. 23, article 3263; No. 27, article 3880; No. 30, article 4590; No. 48, article 6728; 2012, No. 19, article 2281; No. 26, article 3446; No. 31, article 4320, article 4322).

48. If according to the conclusion of the expert institution the adverse reaction may have been caused by medicinal product not meeting the quality requirements, Roszdravnadzor shall make a decision to carry out a selective quality control of the respective medicinal product within the procedure established by the legislation of the Russian Federation. <6>

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<6> Order of the Federal Service for Surveillance in Healthcare No. 5539 On Approval of the Procedure for Selective Control of the Quality of Medicines for Medical Use dated 7 August 2015 (Registered by Minjust on 9 August 2015, registration number 39263, Bulleting of Regulations of Federal Executive Bodies, No. 48, 30 November 2015).

49. Within 5 working days from the date of receipt of the conclusion of the expert organization containing information on the identification of new data on the safety and efficiency of medicinal products that are not contained in the package leaflet for human use or clinical trial documentation changing the risk-benefit ratio of using medicinal products, Roszdravnadzor notifies the holder of the registration certificate of the medicinal product or the legal entity, in whose name the approval for conducting clinical trials was issued, electronically through the Roszdravnadzor AIS, or by posting an information letter on the [website](http://ivo.garant.ru/document/redirect/990941/1454) of Roszdravnadzor on the Internet, or in writing (hard copy).

(clause 49 as amended by Order No. 6252 dated 16 July 2020)

50. Within 10 working days from receipt of Roszdravnadzor’s notification defined in [clause 49](#P118) hereof, MAH or CTAH shall verify the information for correctness and shall provide the results of verification to Roszdravnadzor.

51. During the course of verification defined in [clause 50](#P119) hereof, MAH or CTAH shall implement measures required to prevent aggravation of the harm related to circulation of the respective medicinal product.

52. Within 10 working days from the date of receipt of the results of the inspection specified in [Clause 50](#P119) hereof, carried out by the holder of the registration certificate, or within 10 working days from the date of receipt by Roszdravnadzor of the results of sampling quality control of the medicinal product in accordance with [Clause 48](#P118) hereof, Roszdravnadzor shall notify the Ministry of Health of the Russian Federation (hereinafter — the Ministry) on the identification of new data on the safety and efficiency of medicinal products that are not contained in the package leaflet for human use or clinical trial documentation changing the risk-benefit ratio of using medicinal products, including when identifying the need to amend the package leaflet for human use of the medicinal product in relation to information on indications for use and contraindications for the medicinal product use, identified side effects, adverse reactions when using the medicinal product, and sends the relevant information to consider the need to amend the registration dossier of the medicinal product, cancel state registration, conduct preclinical or clinical trials of the medicinal product, or other additional studies of the quality, efficiency and safety of the medicinal product (hereinafter — additional studies), as well as the need or the absence of need to suspend the circulation of the medicinal product for the period of additional studies, or for the period required to amend the registration documentation of the medicinal product.

(clause 52 as amended by Order No. 6252 dated 16 July 2020)

53. Following review of the results of verification defined in [clause 50](#P119) hereof and submitted by MAH, Roszdravnadzor has authority to request the development of a Risk Management Plan (hereinafter referred to as the “RMP”) according to clauses 6.2.4 — 6.2.5 of the EAEU GVP from MAH within 30 working days from the date of receipt of the verification results.

54. RMP shall be submitted to Roszdravnadzor within 60 working days from the date of receipt of Roszdravnadzor’s request defined in [clause 52](#P121) hereof.

55. If during the verification defined in [clause 50](#P119) hereof MAH identifies the product does not meet quality, safety, and efficacy requirements, MAH has the right to develop a RMP and submit it to Roszdravnadzor by its own decision.

56. The RMP shall include a detailed description of pharmacovigilance activities aimed at identification, assessment and prevention or minimization of risks related to medicinal products, including assessment of efficiency of such measures.

57. Within 5 working days from receipt of the RMP Roszdravnadzor shall provide it to the expert institution for scientific and clinical assessment to identify whether proposed measures are sufficient to prevent harm to life and health of the public during the use of medicinal product.

58. The conclusion of the expert institution concerning sufficiency of the measures proposed in RMP to prevent harm to life and health of the public shall be sent to Roszdravnadzor within 20 working days from the date of receipt of the RMP by the expert institution.

59. Within 5 working days from the date of receipt of the conclusion from the expert institution defined in [clause 57](#P126) hereof, Roszdravnadzor shall send a notice on the RMP approval or a notice to amend the RMP to MAH.

60. In case of receipt of the notice to amend the RMP, MAH shall submit updated RMP to Roszdravnadzor within 20 working days from the date of receipt of such notice.

61. Following review of the results of verification defined in [clause 50](#P119) hereof which was submitted by CTAH, Roszdravnadzor shall consider sending respective information to the Ministry and CTAH within 30 working days from the date of receipt of the verification results so that the following alternatives could be considered in respect of the medicinal product: the need to suspend the clinical trial, the need of early termination of the clinical trial or introduction of changes into the clinical trial protocol.

(clause 61 as amended by Order No. 6252 dated 16 July 2020)

62. Based on the results of pharmacovigilance, Roszdravnadzor publishes information on its website on the Internet about:

1) identification of new confirmed data about side effects, adverse reactions, serious adverse reactions, unexpected adverse reactions during the medicinal product use, including the data that affect the risk-benefit ratio of the medicinal product use;

2) decisions made by the Ministry on amending the package leaflet of the medicinal product, on suspension of the medicinal product use, on withdrawal from circulation of the medicinal product or on resumption of the medicinal product use, information about which is submitted by the Ministry in electronic format signed with an enhanced electronic qualified signature to Roszdravnadzor within three working days from the date of the relevant decision.

(clause 62 as amended by Order No. 6252 dated 16 July 2020)

Appendix No. 1

to the Pharmacovigilance Procedure

approved

by order of the Federal Service

for Surveillance in Healthcare,

No. 1071 dated 15 February 2017

Recommended form

NOTIFICATION

OF ADVERSE REACTION OR LACK OF THERAPEUTIC EFFECT

OF MEDICINAL PRODUCT

|  |  |  |  |
| --- | --- | --- | --- |
|  | Initial |  | Follow-up to reportNo. \_\_\_\_\_\_\_\_\_ dated \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

|  |
| --- |
| Patient |
| Initials (patient ID) [<\*>](#P278) \_\_\_\_\_\_\_\_ | Sex M F | Weight \_\_ kg |
| Age \_\_\_\_\_\_\_\_\_\_ Pregnancy , term \_\_\_ weeks |
| Allergy None Yes, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Treatment outpatient inpatient self-treatment |
| Suspect medicinal product |
|  | Name (trade) <\*> | Manufacturer | Batch number | Dose, route | Start Date  | Stop date  | Indication |
| 1 |  |  |  |  |  |  |  |
| 2 |  |  |  |  |  |  |  |
| 3 |  |  |  |  |  |  |  |
| Adverse reaction | Date of AR onset \_\_\_\_\_ |
| Description of reaction <\*> (provide all details, including the laboratory findings) | AR seriousness criteria: |
|  Death |
|  Life-threatening |
|  Hospitalization/its prolongation |
|  Disability |
|  Congenital anomaly |
|  Medically significant |
| Date of AR resolution \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  Not applicable |
| Measures taken |
|  No treatment Withdrawal of suspect medicine Dose reduction |
|  Non-medicine treatment (including surgery) |
|  Medicine treatment \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Outcome |
|  Recovery without consequences Improvement of condition Condition unchanged |
|  Recovery with consequences (specify) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  Death Unknown Not applicable |
| Did AR abate after product withdrawal? |  No Yes The medicine was not withdrawn Not applicable |
| Was the medicine prescribed again? No  | Yes Result \_\_\_\_\_\_\_\_\_\_\_\_\_\_ Not applicable |
| Other medicines used during the last 3 months, including those used by the patient at his (her) own discretion (on his (her) own accord) |
|  | Name (trade) | Manufacturer | Batch number | Dose, route | Start date  | Stop Date  | Indication |
| 1 |  |  |  |  |  |  |  |
| 2 |  |  |  |  |  |  |  |
| 3 |  |  |  |  |  |  |  |
| 4 |  |  |  |  |  |  |  |
| 5 |  |  |  |  |  |  |  |
| Reporter |
|  Physician Other healthcare professional Patient Other |
| Contact telephone number/e-mail address: <\*> \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Name.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Position and place of employment \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Date of notification \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  |

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<\*> Mandatory field.

The notification may be sent via:

- e-mail: pharm@roszdravnadzor.ru;

- fax: +7(495)698-15-73,

- online: www.npr.roszdravnadzor.ru

- post: 4 Slavyanskaya ploshchad, stroenie (bldg.) 1, Moscow, 109074

Appendix No. 2

to the Pharmacovigilance Procedure

approved

by order of the Federal Service

for Surveillance in Healthcare,

No. 1071 dated 15 February 2017

Recommended form

Report

of Serious Unexpected Adverse Reaction

to Investigational Medicinal Product

|  |  |
| --- | --- |
| No. of the clinical trial protocol |  |
| Medicine name |  |
| Protocol name |  |
| CT authorization No. (in Russia) |  |
| Name of the healthcare facility in which the adverse reaction was identified (if the reaction occurred in the Russian Federation) |  |

I. Information On Adverse Reaction

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| 1. Patient’s initials | 1a. Country | 2. Date of birth | 2a. Age | 3. Sex | 4 - 6. Date of the adverse reaction onset | 8 - 12. Tick all applicable boxes in respect of the ADR |
|  Death |
| (date/month/year) |  Hospitalization/its prolongation |
| 7 - 13. Description of the adverse reaction (including the laboratory findings and instrumental examination data) |  Persistent incapacity or disability  |
|  Life-threatening |

II. Information on Suspect Medicinal

Product (Products)

|  |  |
| --- | --- |
| 14. Suspect medicinal product (including its international non-proprietary name or group name) | 20. Did the reaction abate after withdrawal? |
|  Yes No |
|  Not applicable |
| 15. Daily dose(s) | 16. Route(s) | 21. Did the reaction recur after re-challenge? |
| 17. Indication(s): |
|  Yes No |
|  Not applicable |
| 18. Treatment dates from | to | 19. Treatment duration |

III. Concomitant Medicine Treatment and Medical History

|  |
| --- |
| 22. Concomitant medicinal product(s) and dates of administration (except for those used for treatment of the adverse reaction) |
| 23. Other relevant medical history (i. e. diagnoses, allergies, pregnancy with dates of recent period, etc.) |

ConsultantPlus: note.

The sections are numbered according to the official document version.

III. Other Data

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| 24. Name and address of the manufacturer |
| 24a. Case identification number | 24b. Date of receipt of the information on the adverse reaction by the manufacturer |
| 24c. Source of information on the adverse reaction Trial Literature Healthcare professional Regulatory agency Other |
| 25. Date of this report |
|  |
| 26. Type of report |
|  Initial Follow-up |