GOVERNMENT OF THE RUSSIAN FEDERATION

RESOLUTION
No. 1314 of December 3, 2015

On Determination of Compliance of Medicinal Product Manufacturers with the Requirements of the Good Manufacturing Practice

Pursuant to Article 45 of the Federal Law On the Circulation of Medicines, the Government of the Russian Federation resolves to:

1. Approve the attached Rules for Arrangement for and Performance of Examinations of Medicinal Product Manufacturers for Compliance with the Requirements of the Good Manufacturing Practice as well as Issue of Statements on Compliance of the Medicinal Product Manufacturer with the Said Requirements.

2. Add paragraph 36 to the list of services which are required and mandatory for provision by federal executive authorities of government services, and are rendered by entities involved in provision of government services as approved by Resolution No. 352 of the Government of the Russian Federation of May 6, 2011, On Approval of the List of Services which are Required and Mandatory for Provision by Federal Executive Authorities of Government Services and are Rendered by Entities Involved in Provision of Government Services, and Determination of the Amount of Payment for Their Provision (Collected Legislation of the Russian Federation, 2011, No. 20, Article 2829; 2012, No. 14, Article 1655; No. 36, Article 4922; 2013, No. 49, Article 6421; No. 52, Article 7207; 2014, No. 21, Article 2712) as follows:

“36. Examination of Manufacturers of Medicinal Product Manufactured outside of the Russian Federation for Compliance with the Requirements of the Good Manufacturing Practice to Issue Statements on Compliance of the Medicinal Product Manufacturer with the Requirements of the Good Manufacturing Practice”.

3. Establish that the payment for issue of an opinion on compliance of the medicinal product manufacturer with the good manufacturing practice shall amount to RUB 7,500.

4. Powers specified herein shall be exercised by relevant federal executive authorities within the limit sizes and their labor compensation funds set by the Government of the Russian Federation, and budgetary appropriations provided for by the federal budget for administration and management in the specified fields.

Chairman of the Government of the Russian Federation
D. Medvedev
RULES
for Arrangement for and Performance of Examinations of Medicinal Product
Manufacturers for Compliance with the Requirements of the Good Manufacturing Practice
as well as Issue of Statements on Compliance of the Medicinal Product Manufacturer with
the Said Requirements

I. General Provisions

1. These Rules shall establish the procedure for arrangement for and performance of examinations
of medicinal product manufacturers for compliance with the requirements of the good
manufacturing practice, and issue of statements on compliance of the medicinal product
manufacturer with the requirements of the good manufacturing practice (hereinafter referred to as
the Statement).

2. Notions used herein shall have the following meanings:

“Examination” shall mean activity of the Ministry of Industry and Trade of the Russian Federation
(as related to medicinal products for medical use) and the Federal Service for Veterinary and
Phytosanitary Surveillance (as related to medicinal products for veterinary use) (hereinafter referred
to as the Authorized Bodies) or a federal state budget-funded institution subordinate to the
authorized body (hereinafter referred to as the Authorized Institution) aimed at confirmation of
compliance of the medicinal product manufacturer with the requirements of the good manufacturing
practice;

“Inspector” shall mean an employee of an Authorized Body or an Authorized Institution performing
the examination, and having at least 5-year work experience in the field of production and/or quality
control of medicinal products, and higher education in one of specialities (directions of training)
such as biology, biotechnology, veterinary medicine, clinical medicine, radiation, chemical and
biological protection, pharmacy, fundamental medicine, chemical technology and chemistry;

“Basic Dossier of the Production Site” shall mean a document executed by the medicinal product
manufacturer and containing information on arrangements for production and quality control of
medicinal products at the production site.

Other notions used herein shall be used within the meanings as determined by the laws of the
Russian Federation on turnover of medicinal products.

3. Following the results of the examination, the Authorized Body shall issue a Statement in the form
approved by it.
4. For the purpose of issue of the Statement, the manufacturer of medicinal products manufactured within the Russian Federation (hereinafter referred to as the Manufacturer), or the manufacturer of medicinal products manufactured outside of the Russian Federation (hereinafter referred to as the Foreign Manufacturer), or their authorized representative shall submit an application for issue of Statement (hereinafter referred to as the Application) in the form approved by the Authorized Body including details of the document confirming payment of the fee for issue of the Statement directly to the Authorized Body in hard copy or send the same by registered mail with return receipt requested and list of contents or in the form of an electronic document signed using an electronic signature.

Bank details for transfer of payment for issue of the Statement shall be published on the official website of the Authorized Body on the Internet information and telecommunications network (hereinafter referred to as the Internet) and in the federal state information system Unified Portal of State and Municipal Services (Functions).

5. The following documents shall be attached to the Application:

a) a copy of a document confirming powers of the authorized representative of the Manufacturer or the Foreign Manufacturer;

b) a copy of the Basic Dossier of the Production Site;

c) information on detected non-conformity of quality of the medicinal products with the specified requirements including information on withdrawal of the medicinal products from the civil turnover over the period of at least 2 years prior to submission of the Application;

d) a list of medicinal products manufactured at the production site of the Manufacturer or the Foreign Manufacturer with regard to which the examination is performed;

e) a copy of a license issued by the Authorized Body of the country of the Foreign Manufacturer (or a documents on the grounds of which the Foreign Manufacturer performs its activity for manufacture of medicinal products), and its translation into Russian certified in accordance with the established procedure (in case availability of this document is provided for by the laws of the country of the Foreign Manufacturer); and

f) a letter of consent of the Foreign Manufacturer to the examination.

6. Should the medicinal product be manufactured at the production sites located at different addresses, applications and documents listed in paragraph 5 hereof (hereinafter referred to as the documents) shall be submitted for each production site.

7. The Statement shall be issued for each production site. The Statement shall be valid for 3 years, and its period of validity shall be calculated since the date of completion of the examination.

8. Should it be necessary to send the Statement (notice of refusal to issue the Statement) by mail, fax and/or e-mail, a relevant note shall be made in the Application.
9. Within 10 business days since the date of receipt by the Authorized Body of the Application and the documents, the Authorized Body shall check the Application for correct filling in, completeness of the package of documents and reliability of data contained in them.

10. In the event the Application and/or the documents contain incomplete and/or unreliable data, the Authorized Body shall hand over to the authorized representative of the Manufacturer or the Foreign Manufacturer a notice of need to remedy the specified violations within 20 business days since the date of its receipt, or it shall send the same notice to the Manufacturer or to the Foreign Manufacturer by registered mail with return receipt requested or by e-mail. In case of a failure to remedy these violations within the specified period, the Authorized Body shall make a decision to refuse to issue the Statement.

11. Should the details contained in the Application and the documents comply with the specified requirements, and should the violations be remedied within the time period specified in paragraph 10 hereof, the Authorized Body shall make a decision to perform the examination.

12. Should the Authorized Body decide to perform the examination, the Authorized Body shall arrange for and perform the examination of the Manufacturer in accordance with paragraph 18 hereof, or to perform the examination of the Foreign Manufacturer, it shall submit the Application and the documents to the Authorized Institution within 3 business days since the date of decision to perform the examination.

13. Following the results of the examination of the Manufacturer, the Authorized Body, or following the results of the examination of the Foreign Manufacturer, the Authorized Institution shall execute an inspection report in the form approved by the Authorized Body (hereinafter referred to as the Inspection Report).

14. Within 10 business days since the date of signing of the Inspection Report or since the date of its receipt from the Authorized Institution, the Authorized Body shall make a decision to issue (refuse to issue) the Statement. The decision to issue (refuse to issue) the Statement shall be documented in the form of an order of the Authorized Body.

15. The following shall serve as the grounds for refusal to issue the Statement:

a) a failure to remedy the violations in accordance with paragraph 10 hereof and/or lack of confirmation of the actual payment of the fee for issue of the Statement;

b) a decision of the Authorized Institution to refuse to perform the examination of the Foreign Manufacturer in case of a failure to pay the expenses relating to performance of the examination within the time limits specified in paragraph 25 hereof;

c) non-compliance of the Manufacturer or the Foreign Manufacturer with the requirements of the good manufacturing practice.

16. If during the period of validity of the issued Statement, name and/or address of location of the Manufacturer or the Foreign Manufacturer, the list of medicinal products specified in the Statement and manufactured at the same production site and under the same conditions change, the Authorized Body shall make a decision to issue a new Statement without performance of the examination; herewith the new Statement shall expire on the expiry day of the previously issued Statement.
17. Within 5 business days since the date of the relevant decision, information on issue (refusal to issue) of the Statement shall be entered into the State Register of Statements on Compliance of the Manufacturer with the Requirements of the Good Manufacturing Practice and published on the official website of the Authorized Body on the Internet.

II. Procedure for Arrangement for and Performance of the Examination of the Manufacturers and the Foreign Manufacturers

18. The examination of the Manufacturers shall be arranged for and performed by the Authorized Body within the framework of the license supervision of performance of the activity for manufacture of medicinal products performed by the Authorized Body in the manner established by the Federal Law On Protection of the Rights of Legal Entities and Self-Employed Entrepreneurs upon Performance of State Control (Supervision) and Municipal Control with due account for peculiarities as specified in the Federal Law On Licensing of Some Types of Activity.

19. The examination of the Foreign Manufacturers shall be performed by the Authorized Institution. Expenses relating to performance by the Authorized Institution of the examination of the Foreign Manufacturer shall be paid by the Foreign Manufacturer.

20. The examination shall be performed within 160 business days since the date of the Authorized Body’s decision to perform the examination.

The term for performance of the examination may not exceed 10 business days without account for the time of trip to the examination site.

21. Within 20 business days since the date of receipt of the Application and the documents from the Authorized Body, the Authorized Institution shall add the Foreign Manufacturer to the schedule of examinations (hereinafter referred to as the Schedule) which shall be approved by the Authorized Body.

22. Information on the Schedule and amendments thereto shall be published on the official websites of the Authorized Body and the Authorized Institution on the Internet within 3 business days since the date of its preparation or amendment.

23. To perform the examination, the Authorized Institution shall form a Commission of Inspectors and approve its head.

24. Members of the Commission of Inspectors shall be informed of responsibility in accordance with the laws of the Russian Federation for groundless or false conclusions contained in the Inspection Report executed following the results of the examination of the Foreign Manufacturer, and for disclosure of information constituting a trade secret which they may obtain in the course of the examination of which they shall execute a written undertaking.
25. Within 3 business days since the date of approval of the Schedule, the Authorized Institution shall inform the Foreign Manufacturer or its authorized representative of the terms for performance of the examination and the need to conclude an agreement specifying the examination procedure and expenses relating to the examination, and rights and obligations of the Inspectors and the Foreign Manufacturer (hereinafter referred to as the Agreement), and the need to pay within 20 business days since the date of the Agreement the expenses relating to performance by the Authorized Institution of the examination in the amount specified in the Agreement; however, not exceeding the limit amount of the fee for examination approved by the Authorized Body and calculated on the basis of the method approved by the Authorized Body.

26. The following provisions shall be specified in the Agreement:

a) on sending by the Foreign Manufacturer or its authorized representative to the Authorized Institution of a notice including details of the documents confirming the actual payment of expenses relating to performance by the Authorized Institution of the examination by registered mail with return receipt requested and/or by e-mail;

b) on adoption by the Authorized Institution of a decision to refuse to perform the examination in case of a failure to pay these expenses within the specified time period and on notice of it to be given to the Authorized Body, and the Foreign Manufacturer or its authorized representative within 3 business days since the date of this decision;

c) on sending by the head of the Commission of Inspectors to the Foreign Manufacturer or its authorized representative of the examination plan within 10 business days prior to its performance;

d) on the right of the Commission of Inspectors to examine the production site in accordance with the examination plan, to interview responsible officers of the Foreign Manufacturer and to watch its employees as they work at their working places as well as to review record maintenance upon performance of the examination;

e) on taking, if necessary, by the Commission of Inspectors of samples of the medicinal product (medicinal products) in compliance with the requirements of the laws of the Russian Federation including as related to import of medicinal products into the Russian Federation.

27. Within 30 calendar days since the date of completion of the examination, the Commission of Inspectors shall execute the Inspection Report on the letterhead of the Authorized Institution (in 3 copies) to be signed by all members of the Commission of Inspectors. Within 3 business days since the date of signing of the Inspection Report, one of its copies shall be sent to the Foreign Manufacturer or handed over to its authorized representative; the second copy shall be sent to the Authorized Body, and the third copy shall be kept by the Authorized Institution.

28. Should samples of the medicinal product (medicinal products) be taken in the course of the examination, a deed of sampling shall be attached to the Inspection Report executed following the results of the examination of the Foreign Manufacturer.