Registered with the Ministry of Justice of the Russian Federation dated December 25, 2012, No. 26356

MINISTRY OF HEALTHCARE OF THE RUSSIAN FEDERATION

ORDER
dated September 14, 2012, No. 175n

ON APPROVAL OF THE MEDICAL PRODUCT SAFETY MONITORING PROCEDURE

Pursuant to Article 96, Federal Law dated November 21, 2011, No. 323-FZ, *On Fundamentals of Public Health Protection in the Russian Federation* (Collection of Laws of the Russian Federation, 2011, No. 48, Article 6724; 2012, No. 26, Article 3442; No. 26, Article 3446) and paragraph 5.2.191 of the Regulations on the Ministry of Health of the Russian Federation as approved by resolution of the Russian Federation Government dated June 19, 2012, No. 608 (Collection of Laws of the Russian Federation, 2012, No. 26, Article 3526), I order:

To approve the Medical Product Safety Monitoring Procedure, according to the Appendix.

Minister
V.I. SKVORTSOVA

Appendix to
Order dated September 14, 2012, No. 175n,
of the Ministry of Health of the Russian Federation

MEDICAL PRODUCT SAFETY MONITORING PROCEDURE

1. This Procedure establishes the rules of safety monitoring of the medical products circulating in the territory of the Russian Federation (hereinafter the 'monitoring').

2. The monitoring is aimed at detecting and preventing side effects not specified in the medical product leaflet/ user manual, adverse effects in its application, particular features of medical products' interaction, facts and circumstances threatening life and health of patients and medical professionals during application and operation of registered medical products.

3. Monitoring includes collection, processing, registration and analysis of information on side effects not specified in the medical product leaflet/ user manual, adverse effects in its application, particular features of medical products' interaction, facts and circumstances threatening life and health of patients and medical professionals in application and operation of registered medical products.

4. Monitoring shall be carried out by the Federal Service on Healthcare Surveillance (hereinafter 'Roszdravnadzor') and its territorial offices (hereinafter 'Departments of Roszdravnadzor for the Russian Federation constituents') on the basis of:-

4.1. Reports received from individuals, including patients, individual businessmen and legal pharmaceutical entities, from medical product manufacturers or medical product manufacturer's authorized representatives in particular (hereinafter the 'reports'):-

1) side effects not indicated in the medical product leaflet/ user manual;

2) adverse effect in the medical product application;

3) particular features of medical products' interaction;

4) facts and circumstances threatening life and health of patients and medical professionals in application and operation of medical products.

4.2. Information received in governmental control over medical product circulation.

5. The Reports specified in paragraph 4.1 of this Procedure shall be sent to Roszdravnadzor in

accordance with the Procedure for Reporting by Pharmaceutical Entities of All Instances When Side Effects Not Specified in the Medical Product Leaflet/ User Manual Are Detected, of Adverse Effects in its Application, of Particular Features of Medical Products' Interactions, of Facts and Circumstances Threatening Life and Health of Patients and Medical Professionals in Application and Operation of Medical Products, as approved by Order of the Ministry of Health of the Russian Federation dated June 20, 2012, No. 12n (registered by the Ministry of Justice of the Russian Federation on July 20, 2012, No. 24962).

6. Roszdravnadzor shall register the received Reports specified in paragraph 4.1 of this Procedure within One business day.

7. Based on the received Reports specified in paragraph 4.1 of this Procedure, Roszdravnadzor shall notify the medical product manufacturer or the medical product manufacturer's authorized representative, within Three business days, of the need to confirm or refute this information and to provide the appropriate information on the facts stipulated in the Report to Roszdravnadzor.

8. Based on the obtained Reports containing facts and circumstances threatening life and health of patients and medical professionals in application and operation of medical products, Roszdravnadzor shall make a decision to suspend application of the medical product for a period of time not exceeding Twenty business days and verify the submitted information in accordance with Article 10, Federal Law on Protection of Rights of Legal Entities and Individual Businessmen in Exercising Governmental Control (Supervision) and Municipal Control <1>.

KonsultantPlus: Note.

There must be a misprint in the official document wording: Federal Law dated December 26, 2008, No. 294-FZ, On Protection of Rights of Legal Entities and Individual Businessmen in Exercising Governmental Control (Supervision) and Municipal Control, is meant.

<1>Article 10, Federal Law dated December 26, 2008, No. 294-FZ, *On Fundamentals of Public Health Protection in the Russian Federation* (Collection of Laws of the Russian Federation, 2008, No. 52 (Part I), Article 6249; 2009, No. 18 (Part I), Article 2140; No. 29, Article 3601; No. 48, Article 5711; No. 52 (Part I), 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 (Part I), Article 4590; 2012, No. 19, Article 2281; No. 26, Article 3446; No. 31, Article 4320; No. 31, Article 4322).

9. Following the verification specified in Sections 7 - 8 of this Procedure, Roszdravnadzor shall, within a period of time not exceeding Five business days, make one of the following decisions:-

1) to withdraw the medical product from circulation;

2) to resume application and circulation of the medical product.

10. The decisions specified in Sections 8 and 9 hereof shall be documented in appropriate orders by Roszdravnadzor.

11. The order to withdraw a medical product from circulation shall be made by Roszdravnadzor if the facts and circumstances threatening life and health of patients and medical professionals in application and operation of medical products are proven.

12. The order to resume application and circulation of a medical product shall be made by Roszdravnadzor if the facts and circumstances threatening life and health of patients and medical professionals in application and operation of medical products are not proven.

KonsultantPlut: note.

There must be a misprint in the official document wording: paragraph 4.1 of Section 4, not Section 4.1, is meant.

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13. Following the monitoring, Roszdravnadzor (Department of Roszdravnadzor for the Russian Federation constituents) shall notify, within Three business days, the pharmaceutical entity that has submitted the Report in accordance with paragraph 4.1 hereof of the decision made.

The Notification shall be delivered to the applicant or sent to it by registered mail with receipt confirmation and may also be sent to the applicant using information and communications technologies (electronically).

14. Roszdravnadzor shall post the following monitoring information on its official website in the Internet information and telecommunications network:-

1) medical product name, with indication of the manufacturer's number;

2) medical product state registration date and its registration number; marketing authorization effective period;

3) purpose of the medical product established by its manufacturer;

4) medical product type;

5) class of the potential risk associated with the medical product application;

6) medical product code under the All-Russian Classifier of Products;

7) name and location of the medical product manufacturer or the medical product manufacturer's authorized representative;

8) medical product manufacturing site address;

9) obtained information on:-

(a) side effects not specified in the medical product leaflet/ user manual;

(b) adverse effects in the medical product application;

(c) particular features of medical products' interaction;

(d) facts and circumstances threatening life and health of patients and medical professionals in application and operation of registered medical products;

10) details of the documents based on which the information specified in Section 5 hereof is provided;

11) full and (if any) abbreviated name, including corporate name, and legal form of incorporation of the legal entity, its location address, telephone numbers and (if any) email addresses of the legal entity; last name, first name and (if any) patronymic of the individual businessman or individual, including the patient, his/her residential address as well as telephone numbers and (if any) email addresses, which applies and operates the medical product;

12) details of the order, if Roszdradnadzor makes a decision to suspend application or to withdraw the medical product as well as to resume application of the medical product;

13) details of the verification order by Roszdravnadzor;

14) details of the verification certificate by Roszdravnadzor;

15) information on verification results.

15. The information indicated in Section 14 of this Procedure shall be generally available.

16. The medical product safety data shall be protected against unauthorized access in accordance with the Federal Law On Information, Information Technologies and Information Protection <1>.

<1> Federal Law dated July 27, 2006, No. 149-FZ, On Information, Information Technologies and Information Protection (Collection of Laws of the Russian Federation, 2006, No. 31, Article 3448; 2010, No. 31, Article 4196; 2011, No. 15, Article 2038; No. 30, Article 4600).