Registered in the Ministry of Justice of Russia on December 25, 2012, N 26356

MINISTRY OF HEALTH OF THE RUSSIAN FEDERATION

ORDER
Dated September 14, 2012, N 175n

ON APPROVAL OF
MEDICAL DEVICE SAFETY MONITORING PROCEDURE

In accordance with Clause 96 of the Federal Law dated November 21, 2011, N 323-FZ "On Fundamentals of Health Protection of Population in the Russian Federation" (Collection of Legislative Acts of the Russian Federation, 2011, N 48, Cl. 6724; 2012, N 26, Cl. 3442; N 26, Cl. 3446) and paragraph 5.2.191 of the Regulations on the Ministry of Health of the Russian Federation approved by Decree of the Government of the Russian Federation dated June 19, 2012, No. 608 (Collection of Legislative Acts of the Russian Federation, 2012, N 26, p 3526), it is hereby ordered:

To approve the Medical Device Safety Monitoring Procedure according to the enclosure.

Minister
V. I. SKVORTSOVA

Appendix
to the Order of the Ministry
of Health of the Russian Federation
dated September 14, 2012, N 175n

MEDICAL DEVICE SAFGETY MONITORING PROCEDURE

1. This Procedure sets the rules for monitoring safety of medical devices in circulation in the territory of the Russian Federation (hereafter - monitoring).

2. The goal of monitoring is to identify and prevent side effects that are not mentioned in the instructions for use or in user manuals of a medical device, adverse reactions during its use, peculiarities of interaction of medical devices between each other, facts and circumstances endangering the life and health of population and health professionals at application and operation of registered medical devices.

3. Monitoring includes the collection, processing, recording and analysis of information about side effects that are not mentioned in the instructions for use or user manual of a medical device, adverse reactions at during its use, peculiarities of interaction of medical devices between each other, facts and circumstances endangering the life and health of population and health professionals at application and operation of registered medical devices.

4. Monitoring is carried out by Federal Service on Surveillance in Healthcare ("Roszdravnadzor") and its territorial bodies (further - Roszdravnadzor offices in the constituent entities of the Russian Federation) on the basis of:

4.1. Reports received from individuals, including patients, individual entrepreneurs and legal entities engaged in circulation of medical devices, including manufacturers of medical devices or from authorized representatives of manufacturers (hereafter - Reports):

1) on side effects that are not mentioned in the instructions for use or user manual of a medical device;

2) on adverse reactions during application of medical devices;

3) on the peculiarities of interaction of medical devices between each other;

4) on the facts and circumstances endangering the life and health of population and health professionals during application and operation of medical devices.

4.2. Information obtained in the exercise of state control over circulation of medical devices.

5. Reports specified in subparagraph 4.1 of paragraph 4 of this Procedure shall be addressed to the Ministry of Health in accordance with the Procedure of reporting by entities involved in circulation of medical devices about all cases of revealing of side effects not specified in the instructions for use or user manual of a medical device, about adverse reactions during its use, peculiarities of interaction of medical devices between each other, facts and circumstances endangering the life and health of population and health professionals at application and operation of registered medical devices approved by the Order of the Ministry of Health of Russia dated June 20, 2012, N 12n (registered by the Ministry of Justice of July 20, 2012, No. 24962).

6. Roszdravnadzor within one business day registers the report indicated in subparagraph 4.1 of paragraph 4 of this Order that it received.

7. On the basis of the received reports specified in subparagraph 4.1 of paragraph 4 of this Order, the Ministry of Health within three working days notify the manufacturer of a medical device or an authorized representative of the manufacturer of the need to confirm or refute this information and submission to Roszdravnadzor of relevant information by facts contained in the report.

8. On the basis of the received reports containing the facts and circumstances endangering the life and health of population and health professionals at application and operation of medical devices, Roszdravnadzor decides on the suspension of the application of the medical device for a period not exceeding twenty working days, and checks the provided information in accordance with Clause 10 of the Federal Law "On protection of rights of legal entities and individual entrepreneurs when exercising state control (supervision) and municipal control" <1>.

ConsultantPlus: note.

In the official text of the document there is apparently a misprint: this refers to the Federal Law dated 26.12.2008 N 294-FZ "On protection of rights of legal entities and individual entrepreneurs when exercising state control (supervision) and municipal control".

<1> Clause 10 of the Federal Law dated December 26, 2008 N 294-FZ "About fundamentals of health protection of population in the Russian Federation" (Collection of Legislative Acts of the Russian Federation, 2008, N 52 (h. I), Cl. 6249; 2009, N 18 (part I), Cl. 2140; N 29, Cl. 3601; N 48, Cl. 5711; N 52 (h. I), Cl. 6441; 2010, N 17, Cl. 1988; N 18, Cl. 2142; No. 31, Cl. 4160, Cl. 4193, Cl. 4196; N 32, Cl. 4298; 2011, N 1, Cl.20; N 17, Cl. 2310; No. 23, Cl. 3263; N 27, Cl. 3880; N 30 (part I), Cl. 4590; 2012, N 19, Cl. 2281; N 26, Cl. 3446; N 31, Cl. 4320; N 31, Cl. 4322).

9. According to the results of the audit indicated in paragraphs 7 and 8 of this Order, the Ministry in a period not exceeding five working days takes one of following decisions:

1) to withdraw from circulation of the medical device;

2) to resume the use and circulation of the medical device.

10. The decisions referred to in paragraphs 8 and 9 of this Order are executed by relevant orders issued by Roszdravnadzor.

11. The order to withdraw a medical device from circulation is accepted by the Roszdravnadzor in case of confirmation of facts and circumstances endangering the life and health of population and health professionals at application and operation of medical devices.

12. The order to resume the use and circulation of medical devices is accepted by the Roszdravnadzor in case of non-verification of facts and circumstances endangering the life and health of population and health professionals at application and operation of medical devices.

ConsultantPlus: note.

In the official text of the document there is apparently a misprint: this refers to subparagraph 4.1 of paragraph 4 and not paragraph 4.1.

13. Roszdravnadzor (Roszdravnadzor office in the constituent entities of the Russian Federation) by results of monitoring within three working days notifies about the decision taken the entity involved in circulation of medical devices that submitted the report in accordance with paragraph 4.1 of this Order.

The notification is given to the applicant or sent to him by registered mail, with return receipt requested, and can also be sent to the applicant through information and communication technologies (in an electronic form).

14. The Ministry publishes on its official website in information and telecommunications network "Internet" the

following information for monitoring:

1) name of a medical device with indication of the number;

2) date of state registration of the medical device and its registration number, validity of the registration certificate;

3) intended use of the medical device established by a manufacturer;

4) a type of the medical device;

5) class of potential risk of the medical device;

6) the code of the Russian classifier of products for the medical device;

7) the name and location of the manufacturer of a medical device or an authorized representative of the manufacturer;

8) the address of the place of production of the medical device;

9) information received:

a) about side effects that are not mentioned in the instructions for use or user manual of a medical device;

b) adverse reactions at application of medical devices;

c) peculiarities of interaction of medical devices between each other;

d) facts and circumstances endangering the life and health of population and health professionals at application and operation of registered medical devices;

10) particulars of documents based on which the information referred to in paragraph 5 of this Order was received;

11) full and (if available) abbreviated name, including corporate name and legal form of the legal entity, address of its location, as well as phone numbers and (if available) email address of the legal entity, surname, name and (if available) patronymic of the individual entrepreneur or physical person, including the patient, the address of his place of residence and phone number and (if available) e-mail address, that use and operate of the medical device;

12) details of the order, in case of Roszdravnaadzor takes a decision to suspend or to withdraw from circulation the medical devices, as well as on the resumption of the use of the medical device;

13) details of the order of Roszdravnadzor on inspection;

14) details of the inspection performed by Roszdravnadzor;

15) information on the inspection results.

15. The information specified in paragraph 14 of this Order is publicly available.

16. Protection of data of medical device safety monitoring from unauthorized access is implemented in accordance with the Federal Law "On information, information technologies and information protection" <1>.

<1> Federal Law dated July 27, 2006, N 149-FZ "On information, information technologies and information protection" (Collection of Legislative Acts of the Russian Federation, 2006, N 31, Cl. 3448; 2010, N 31, Cl. 4196; 2011, N 15, Cl. 2038; No. 30, Cl. 4600).