

Registered in the Ministry of Justice of Russia on July 20, 2012, N 24962

MINISTRY OF HEALTH OF THE RUSSIAN FEDERATION

ПРИКАЗ

Dated June 20, 2012, N 12n

ON APPROVAL OF REPORTING

BY ENTITIES INVOLVED IN CIRCULATION OF MEDICAL DEVICES OF ALL CASES OF DETECTION OF SIDE EFFECTS NOT MENTIONED IN THE INSTRUCTIONS FOR USE OR IN USER MANUALS OF A MEDICAL DEVICE, ABOUT ADVERSE REACTIONS DURING ITS USE, ABOUT PECULIARITIES OF INTERACTION OF MEDICAL DEVICES BETWEEN EACH OTHER, ABOUT FACTS AND CIRCUMSTANCES ENDANGERING THE LIFE AND HEALTH OF POPULATION AND HEALTH PROFESSIONS AT APPLICATION AND OPERATION OF MEDICAL DEVICES

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) and Decree of the President of the Russian Federation dated May 21, 2012, N 636 "On the Structure of Federal Bodies of Executive Power" (Collection of Legislative Acts of the Russian Federation, 2012, N 22, Cl. 2754) it is hereby ordered:

To approve the Procedure of reporting by entities involved in circulation of medical devices about all cases of [Par36](#) detection of 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 medical devices in accordance with the appendix.

Minister
V. I. SKVORTSOVA

Appendix
to the Order of the Ministry
of Health of the Russian Federation
dated June 20, 2012, N 12n

PROCEDURE OF REPORTING

BY ENTITIES INVOLVED IN CIRCULATION OF MEDICAL DEVICES OF ALL CASES OF DETECTION OF SIDE EFFECTS NOT MENTIONED IN THE INSTRUCTIONS FOR USE OR IN USER MANUALS OF A MEDICAL DEVICE, ABOUT ADVERSE REACTIONS DURING ITS USE, ABOUT PECULIARITIES OF INTERACTION OF MEDICAL DEVICES BETWEEN EACH OTHER, ABOUT FACTS AND CIRCUMSTANCES ENDANGERING THE LIFE AND HEALTH OF POPULATION AND HEALTH PROFESSIONS AT APPLICATION AND OPERATION OF MEDICAL DEVICES

1. This Procedure sets the rules for reporting by entities involved in circulation of medical devices about all cases of [Par36](#) detection of 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 medical devices (hereafter – the Procedure).

2. Organizations established in the prescribed manner in the territory of the Russian Federation or

representative offices of foreign organizations accredited in the established procedure in the territory of the Russian Federation or individual entrepreneurs registered in the territory of the Russian Federation, or individuals engaged in technical tests, toxicological researches, clinical tests, examination of quality, efficacy and safety of medical devices, their state registration, production, manufacture, importation into the territory of the Russian Federation, export from the territory of the Russian Federation, conformity assessment, state control, storage, transportation, implementation, installation, commissioning, application, operation, including maintenance of specified regulatory, technical and (or) operational documentation of the manufacturer, as well as repair, recycling or disposal (hereinafter – entities involved in circulation of medical devices) within twenty working days from the date of detection of the side effects 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 medical devices send a report containing information specified below (hereinafter - the report) to the Federal Service on Surveillance in Healthcare of the Russian Federation (Roszdravnadzor).

3. The report will be sent in a written form or in an electronic form through the official website of the Federal Service on Supervision in Healthcare in the information-telecommunication network "Internet" and also through Federal state information system "Common Government Services Portal of Russian Federation".

4. The report must contain the following information:

1) information on the entity involved in circulation of medical devices:

a) full name and legal form, location address - for legal entities;

b) surname, name and patronymic (the latter – if any), residence address - for physical persons, including individual entrepreneurs;

c) contact telephone number;

d) e-mail address (if available);

2) the name of the medical product in relation to which the identified 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 medical devices, with specification of the factory number;

3) name of the manufacturer of the medical device;

4) description of side effects of a medical device (if such information is available) 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 medical devices.

5. A written report submitted by a legal person is signed by the head of the legal entity or the authorized representative of the legal person and the seal of the legal entity.

A written report submitted by a physical person, including individual entrepreneur, certified by his signature.

6. The information specified in the report is processed and recorded in accordance with the Procedure of medical device safety monitoring approved by the Ministry of Health of the Russian Federation <*>.

<*> Clause 95 of the Federal Law dated November 21, 2011, N 323-FZ "About fundamentals of health protection of population in the Russian Federation" (Collection of Legislative Acts of the Russian Federation, 2011, N 48, Cl. 6724).

7. Persons who failed or hid information under paragraph 4 of this Order who became aware of it due to their professional activity shall be liable in accordance with the legislation of the Russian Federation.
