Registered with the Ministry of Justice of the Russian Federation dated July 20, 2012, No. 24962

MINISTRY OF HEALTH OF THE RUSSIAN FEDERATION

ORDER
dated June 20, 2012, No. 12n

ON APPROVAL OF THE PROCEDURE FOR DISCLOSURE BY PHARMACEUTICAL ENTITIES OF ALL INSTANCES WHEN THE SIDE EFFECTS NOT SPECIFIED IN THE MEDICAL PRODUCT LEAFLET / USER MANUAL ARE DETECTED, OF ADVERSE EFFECTS ASSOCIATED WITH THE MEDICAL PRODUCT APPLICATION, OF THE PARTICULAR FEATURES OF MEDICAL PRODUCTS' INTERACTION, OF THE FACTS AND CIRCUMSTANCES THREATENING LIFE AND HEALTH OF PATIENTS AND MEDICAL PROFESSIONALS IN APPLICATION/ OPERATION OF MEDICAL PRODUCTS

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), and the Decree of the Russian Federation President dated May 21, 2012, No. 636, *On the Structure of Federal Executive Bodies* (Collection of Laws of the Russian Federation, 2012, No. 22, Art. 2754), I order:

To approve the Procedure for Disclosure by Pharmaceutical Entities of All Instances when the Side Effects not Specified in the Medical Product Leaflet / User Manual Are Detected, of Adverse Effects Associated with the Medical Product Application, of the Particular Features of Medical Products' Interaction, of the Facts and Circumstances Threatening Life and Health of Patients and Medical Professionals in Application/ Operation of Medical Products.

Minister
V.I. SKVORTSOVA

Appendix to
Order dated June 20, 2012, No. 12n,
of the Ministry of Health
of the Russian Federation

PROCEDURE FOR DISCLOSURE BY PHARMACEUTICAL ENTITIES OF ALL INSTANCES WHEN THE SIDE EFFECTS NOT SPECIFIED IN THE MEDICAL PRODUCT LEAFLET / USER MANUAL ARE DETECTED, OF ADVERSE EFFECTS ASSOCIATED WITH THE MEDICAL PRODUCT APPLICATION, OF THE PARTICULAR FEATURES OF MEDICAL PRODUCTS' INTERACTION, OF THE FACTS AND CIRCUMSTANCES THREATENING LIFE AND HEALTH OF PATIENTS AND MEDICAL PROFESSIONALS IN APPLICATION/ OPERATION OF MEDICAL PRODUCTS

1. This Procedure establishes the rules of disclosing by pharmaceutical entities of all instances when the side effects not specified in the medical product leaflet / user manual are detected, of adverse effects associated with the medical product application, of the particular features of medical products' interaction, of the facts and circumstances threatening life and health of patients and medical professionals in application/ operation of medical products (hereinafter the 'Procedure').

2. Companies duly established in the Russian Federation or representative offices of foreign companies, which are duly accredited in the Russian Federation, or individual businessmen registered in

the Russian Federation or individuals that carry out technical tests, toxicological studies, clinical trials, medical product quality, efficiency and safety review, medical product state registration, manufacturing, making, import to/ export from the Russian Federation, conformity assessment, governmental control, storage, transportation, sales, assembly, commissioning, application, operation, including the maintenance envisaged in the manufacturer's regulatory, technical and/or utilization documents, as well as repairs, disposal or destruction (hereinafter the 'Pharmaceutical Entities'), shall, within Twenty business days from detecting the side effects not specified in the medical product leaflet / user manual, the 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/ operation of medical products, send a Report containing the said information (hereinafter the 'Report') to the Federal Service on Healthcare Surveillance.

3. The Report shall be sent in writing or electronically via the official website of the Federal Service on Healthcare Surveillance in the Internet information and telecommunications network and also via the information system 'Uniform Portal of Federal and Municipal Services (Functions)'.

4. The Report shall contain the following information:-

1) data on the pharmaceutical entity:

(a) full name and legal form of incorporation, registered address, for legal entities;

(b) last name, first name and patronymic (the latter, if any), residential address, for individuals, including individual businessmen;

(c) telephone number;

(d) email address (if any);

2) name of the medical product, with respect to which any side effects not specified in the leaflet/ user manual, any adverse effects in its application, particular features of interaction with other medical products, facts and circumstances threatening life and health of patients and medical professionals in application and operation are detected, with indication of the manufacturer's number;

3) medical product manufacturer's name;

4) description of the medical product's side effects (if such information is available) not specified in the leaflet/ user manual, the adverse effects in its application, the particular features of the medical products' interaction, facts and circumstances threatening life and health of patients and medical professionals in application/ operation of medical products.

5. A written Report provided by a legal entity shall be signed by the legal entity CEO or authorized representative and certified with the legal entity's seal.

A written Report provided by an individual, including an individual businessman, shall be certified with his/her signature.

6. Information included into the Report shall be processed and registered in accordance with the Procedure for Medical Product Security Monitoring, as approved by the Ministry of Health of the Russian Federation <*>.

<*>Article 95, 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).

7. For failure to disclose or for concealing the information envisaged in Section 4 hereof, the persons to whom it becomes known by the nature of their professional activities shall be liable in accordance with Russian law.