Registered with the Ministry of Justice of the Russian Federation on July 25, 2012, No. 25013

MINISTRY OF HEALTH OF THE RUSSIAN FEDERATION

ORDER
dated June 15, 2012, No. 7n

ON APPROVAL OF THE PROCEDURE FOR IMPORT OF MEDICAL PRODUCTS TO THE RUSSIAN FEDERATION FOR STATE REGISTRATION

Pursuant to Article 38, 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, *Concerning the Structure of Federal Executive Bodies* (Collection of Laws of the Russian Federation, 2012, No. 22, Article 2754), I order:

To approve of the Procedure for Import of Medical Products to the Russian Federation for State Registration in accordance with the Appendix below.

Minister
V.I. SKVORTSOVA

Appendix
to Order of the Ministry of Health
of the Russian Federation
dated June 15, 2012, No. 7n

PROCEDURE
FOR IMPORT OF MEDICAL PRODUCTS TO THE RUSSIAN FEDERATION FOR STATE REGISTRATION

1. This Procedure was developed to regulate import of medical products to the Russian Federation for state registration.

2. Medical products are imported to the Russian Federation for state registration based on the permit for import of medical products for state registration (hereinafter 'the medical product import permit'), which is issued by the Federal Service on Healthcare Surveillance (hereinafter 'Roszdravnadzor').

3. Medical products are imported to the Russian Federation for state registration by a medical product manufacturer or the manufacturer's authorized representative being a legal entity or an individual businessman registered in the Russian Federation and authorized by the medical product manufacturer to represent its interests in connection with the medical product circulation in the Russian Federation, in particular, with the product-related procedures of compliance assessment and state registration, and in which name the medical product registration certificate can be issued (hereinafter 'the applicant').

4. The quantity of medical product samples imported to the Russian Federation for state registration is determined by the applicant with allowance for recommendations of the companies performing technical tests, toxicological studies, clinical trials as well as tests for approval of the metering device type (with respect to the medical products classified as metering devices in state regulation of the uniformity of measurements), depending on the category of the potential risk associated with the medical product application and the scope of required tests (studies).

5. A medical product import permit is a one-off document and entitles the applicant to import medical products to the Russian Federation for state registration. The medical product import permit is valid for six months from its issue date.

6. A medical product import permit indicates:

1) the medical product name, its quantity, manufacturing date and/or useful life;

2) information on the applicant:

a) full and (if any) abbreviated name, in particular, corporate name, legal form of incorporation of the legal entity, its location address, state registration number of the entry on the legal entity establishment;

b) last name, first name and (if any) patronymic name of the individual businessman, his/her residential address, identification document data, state registration number of the entry on the individual businessman registration;

3) effective period of the medical product import permit.

7. To obtain a medical product import permit, the applicant shall submit an application signed by CEO of the legal entity (another person entitled to act on behalf of this legal entity) or by the individual businessman (his/her authorized representative) to Roszdravnadzor, specifying:

1) the medical product name, the complete set, quantity, manufacturer's number, series number or batch number, medical product manufacturing rate, useful life and/or service life;

2) the medical product purpose as established by the manufacturer;

3) the applicant's full and abbreviated (if any) names, legal form of incorporation, location address, state registration number of the entry on the legal entity establishment or the individual businessman registration, his/her residential address, ID document data, state registration number of the entry on state registration of the individual businessman, telephone number and (if any) email address;

4) information on the companies where technical tests, toxicological studies, clinical trials as well as tests for approval of the metering device type (with respect to the medical products classified as metering devices in state regulation of the uniformity of measurements) are planned to be held.

8. The Application shall be accompanied by:

1) copies of the contracts for holding the necessary tests (studies, trials), indicating the necessary quantity of medical products;

2) a copy of the document evidencing powers of the manufacturer's authorized representative.

9. Within five business days from acceptance of the application and the documents specified in Section 8 hereof, Roszdravnadzor shall issue the medical product import permit or the notice of refusal to issue the medical product import permit, giving reasons for the refusal, to the applicant.

10. The reason for refusal to issue a medical product import permit may be as follows:

1) the applicant's failure to provide or to fully provide the documents indicated in Section 8 of this Procedure;

2) limitation on import of the medical product to be imported to the Russian Federation in accordance with an international treaty <*> or a resolution of the Russian Federation Government <**>.

<*> 'Uniform List of Goods to Which Prohibitions or Limitations on Import/Export by the Customs Union Member States within the Eurasian Economic Community Apply in Trade with Third Parties and the Regulations on Application of the Limitations (approved by the EurAsEC Inter-Governmental Board Resolution dated November 27, 2009, No. 19, by Resolution of the Customs Union Commission dated November 27, 2009, No. 132) (The Rossiyskaya Gazeta, 2009, No. 227/1).

<**> Articles 21 and 22, Federal Law dated December 8, 2003, No. 164-FZ, *On Fundamentals of State Regulation of Foreign Trade Activities* (Collection of Laws of the Russian Federation, 2003, No. 50, Article 4850).

3) availability to Roszdravnadzor of the information obtained as a result of a medical product safety monitoring <*>, on detection of side effects not specified in the leaflet or the operation manual for the medical product, on adverse effects in application of the medical product, on particular drug interaction features, on facts and circumstances threatening life and health of patients and medical professionals in application and operation of the medical products.

<*> 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.

11. Roszdravnadzor records the issued medical product import permits.

The information on the issued medical product import permits is posted on Roszdravnadzor's official website in the Internet (information and telecommunications network).

12. No fee is charged for the medical product import permit issue.