GOVERNMENT OF THE RUSSIAN FEDERATION

RESOLUTION
dated June 19, 2012, No. 615

ON APPROVAL OF THE RULES OF MAINTAINING THE STATE REGISTER OF MEDICAL PRODUCTS AND MEDICAL PRODUCT MANUFACTURERS/MAKERS

Pursuant to Article 38, Federal Law *On Fundamentals of Public Health Protection in the Russian Federation,* the Government of the Russian Federation resolves:

1. To approve of the attached Rules of Maintaining the State Register of Medical Products and Medical Product Manufacturers/Makers.

2. The information on medical products and medical equipment that had been registered in the Russian Federation before this Resolution took effect is to be included into the State Register of Medical Products and Medical Product Manufacturers/Makers.

3. The powers envisaged in this Resolution shall be exercised within the maximum headcount of the central staff of the Federal Service on Healthcare Surveillance, as established by the Government of the Russian Federation, and the budget allocations envisaged in the federal budget for administration and management in the indicated functional area.

4. This Resolution shall take effect on July 1, 2012.

D. MEDVEDEV
Chairman of the Government
of the Russian Federation

Approved by the Resolution of the Government
of the Russian Federation
dated June 19, 2012, No. 615

RULES OF
MAINTAINING THE STATE REGISTER OF MEDICAL PRODUCTS AND MEDICAL PRODUCT MANUFACTURERS/MAKERS

1. These Rules shall govern the procedure for maintenance of the State Register of Medical Products and Medical Product Manufacturers/Makers.

2. The State Register of Medical Products and Medical Product Manufacturers/Makers (hereinafter the 'Register') is a federal information system that contains information on medical products and medical product manufacturers/makers.

3. The Register shall operate on the following principles:

(a) single input and multiple use of the source information;

(b) use of electronic documents relevant in law, as evidenced by the electronic signature;

(c) use of the 'software as a service' (SaaS) model.

4. The Register shall be maintained by the Federal Service on Healthcare Surveillance electronically, by making Register entries, with assigning the unique register entry number in the Register.

5. The Register shall be maintained in the accordance with the uniform organizational, methodological, software/ hardware principles that ensure compatibility and interoperability of this Register with other federal information systems and the information and telecommunications networks.

6. The Register shall be accessible by authorized access to the information source posted in the Internet information and telecommunications network.

7. The Register shall contain the following information:

(a) medical product name;

(b) medical product state registration date and number; marketing authorization effective period;

(c) manufacturer-assigned medical product purpose;

(d) medical product type, according to the nomenclature classification of the medical products as approved by the Ministry of Health of the Russian Federation;

(e) category of the potential risk associated with the medical product application, in accordance with the nomenclature classification of the medical products as approved by the Ministry of Health of the Russian Federation;

(f) code in the All-Russian Classifier of Products for the medical product;

(g) name and location of the medical product applicant;

(h) name and location of the medical product manufacturer/maker;

(i) medical product manufacturing/ making address;

(j) information on interchangeable medical products.

8. Information shall be entered into the Register within one business day from making the decision on the state registration of the medical product or on making amendments to the medical product marketing authorization.

When the medical product marketing authorization is modified, it is necessary to preserve the unique number of the Register entry and the history of changes.

9. The information contained in the Register shall be posted on the official website of the Federal Service on Healthcare Surveillance in the Internet information and telecommunications network and shall be provided upon request sent to the Service. The information contained in the Register shall be updated daily, with preservation of all of the Register versions.

10. The backup copy of the Register shall be created to protect the information contained in it twice a month.

11. The information contained in the Register shall be protected against unauthorized access in accordance with the Federal Law on Information, Information Technologies and Information Protection.

12. The information contained in the Register is publicly available and is provided to federal and local authorities, other legal entities as well as individuals.

13. The information contained in the Register shall be provided free-of-charge.

14. The request for data contained in the Register shall be submitted to the Federal Service on Healthcare Surveillance in a free form, in hard copy or electronically, via the official website of the Service in the Internet information and telecommunications network or to the federal information system Uniform Portal of Federal and Municipal Services (Functions).

The information contained in the Register shall be provided within five business days from receipt of the respective request, in particular, through the inter-departmental electronic exchange system.

Urgent (on the date when the respective request is received) provision of the information contained in the Register shall be carried out upon requests of federal and local authorities.