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B2B: New Procedure for Registration of Medical Products

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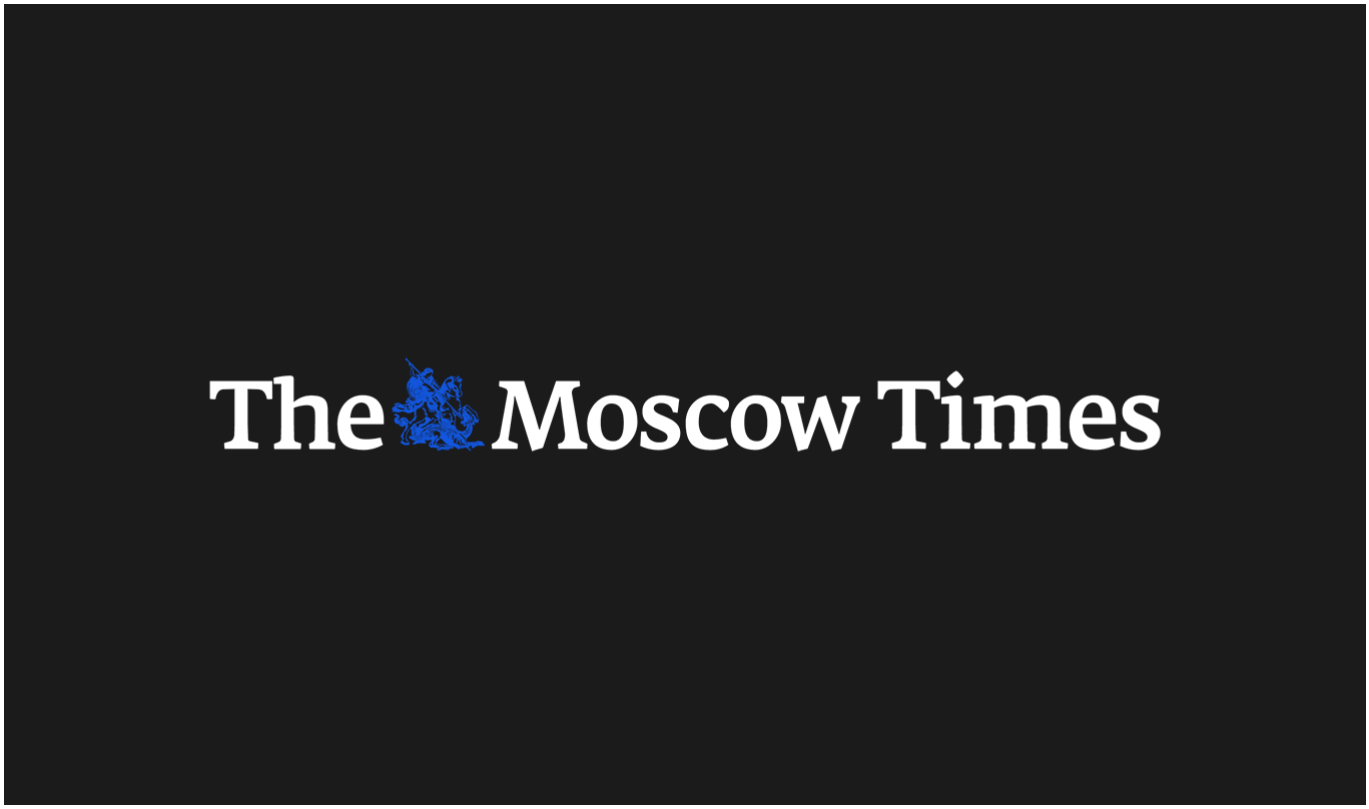

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Russian Health Ministry ("Health Ministry") Order of October 22, 2012. No. 428n on Approval of the Administrative Rules for Provision of the State Service of State Registration of Medical Products for Medical Use has entered into force. This order introduces a new procedure ("Rules") for registration of medical products for medical use.

Summary of changes

The new Rules were drafted to improve the quality and accessibility of registration and in connection with changes in law affecting the circulation of medicines in the last few years.

In particular, the following amendments were made:

• the state register of medicines is now available online;

• the list of documents required for registration has been revised;

• an exhaustive list of grounds for refusal of registration has been provided; and

• electronic document filing has been introduced.

These and certain other changes are considered below.

New filing procedure

The registration of medical products will now be handled by the Health Ministry and was previously performed by the Russian Healthcare Supervisory Service (Roszdravnadzor). One significant change is the creation of a state register of medicines, which can be accessed at http://grls.rosminzdrav.ru.

The Rules stipulate that the product developer or any other legal entity that it authorizes can apply for registration. Previously, only organizations could apply, and it was unclear whether a developer's representatives could register a medical product. The rules now clearly define who can apply. The new Rules also provide for the electronic filing of the documents necessary for registration of a product.

The new Rules introduce a clearer procedure for filing registration documents and establish an exhaustive list of such documents. Registration of a medical product now requires the submission of draft layouts of the primary and secondary (consumer) packaging of the medicine, instructions for use, and the clinical trials report. Registration also requires a chart of the production process for the preparation/pharmaceutical substance, investigator's brochure, patient information sheet, and other documents. The Rules also set out requirements for the content of the documents mentioned above and abolish the previous requirement to state the future price of the product in question.

Grounds for denying registration

The following list provides the grounds for denying Registration:

• a document package is not submitted;

• if the Health Ministry findings during amendments to the registration dossier establish a possible reduction in the safety, quality and effectiveness of the product;

• if different medical products are submitted for registration under a single trade name; and

• if a medical product is submitted for registration under different trade names.

Registration timing

The Rules introduce new processing times for registration of medical products, which were previously provided for in Federal Law No. 61-FZ on the Circulation of Medicines.
The decision to either register or reject is made within 210 business days of the application being accepted (the previous processing time was around 180 days, or 90 days for the expedited procedure). The new Rules establish a 90 day period for amendment of the registration dossier. Previously, this period was from one to six months, depending on the nature of the amendments.

State duty

The new Rules reiterate the state duties already established in the Russian Tax Code. The cost of state registration of medical products may range from 30,000 rubles to 225,000 rubles, depending on the service. The state duty is charged for state services such as expert examination of documents, of quality medical product and expected benefits, certification of state registration of the medical product, amendments to instructions for use of a medical product, and changes in the ingredients of a medical product.

On the whole, the new Rules establish a clearer and more transparent state registration procedure. It only remains to be seen if this procedure can be implemented quickly and meets

the expectation of pharmaceutical companies in the Russian market with respect to registration of new products.

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