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## **New rules on licensing of the pharmaceutical activity in Russia**

Regulation of the Russian Government dated 22 December 2011 No. 1081 "On licensing of the pharmaceutical activity" ("Regulation on licensing of the pharmaceutical activity") entered into force on 7 January 2012. The Regulation on licensing of the pharmaceutical activity was adopted as a follow-up to Federal law dated 4 May 2011 No. 99-FZ "On licensing of certain types of activities" ("Law on licensing"), thus revoking the previously-effective Regulation of the Russian Government dated 6 July 2006 No. 416 "On approving of the rules on licensing of the pharmaceutical activity". It should be pointed out that under section 4 article 9 of the Law on licensing, a pharmaceutical license has no fixed expiration date.

In this alert we will discuss the following key issues of the Regulation on licensing of the pharmaceutical activity:

- list of activities which constitute pharmaceutical activity;
- licensing authorities;
- licensing requirements;
- documents for obtaining a pharmacy license.

### **List of activities which constitute pharmaceutical Activity**

Regulation on licensing of the pharmaceutical activity provides for a definite normative list of services for rendering of which it is necessary to obtain a pharmacy license:

1. services which relate to circulation of medical products for medical application:

- wholesale and retail trade of medical products;
- storage of medical products;
- carriage of medical products;
- allotment of medical products;
- preparation of medical products.

2. services which relate to circulation of medical products for veterinary application:

- wholesale and retail trade of medical products;
- storage of medical products;
- carriage of medical products;
- allotment of medical products;
- preparation of medical products.

## **Licensing authorities**

Companies or individual entrepreneurs which intend to obtain a pharmacy license should approach one of the following authorities:

- Federal Service on health care and social development supervision– for activity, exercised by companies of wholesale trade of medical products for medical application;
- Federal Service on veterinary and phytosanitary supervision – for activity, exercised with regard to medical products for veterinary application;
- Executive authorities in the constituent parts of Russia – for activity, exercised with regard to medical products for medical application (with the exception of the wholesale trade).

## **Licensing requirements**

Regulation on licensing of the pharmaceutical activity provides for a definite distinction between requirements:

1. Requirements for license applicants, i.e. premises, qualified staff and management;
2. Requirements for the license-holder, i.e. premises, qualified staff, further upgrade of qualification of specialists, compliance with legislation of medical products circulation, trade rules etc.

## **Documents for obtaining a pharmacy license**

The applicant should submit the following documents to the relevant authority:

1. Documents, which are necessary under the Law on licensing (application, constituent documents, documents which confirm payment of the state duty);
2. Documents which relate to the pharmaceutical activity (data on the medical license, copies of documents which confirm the existence of the relevant equipment and premises, data on a hygiene certificate, copies of documents which confirm the relevant qualification and education of the staff, etc.).

## **Conclusion**

On the whole, it should be pointed out that the Regulation on the licensing is more precise and has more definite structure than the previously-effective rules. A positive sign is that there is no obligation to prolong licenses which were issued before.

According to the Law on licensing there is a term within which the competent authority should issue a license (not more than 45 days) and exhaustive grounds for the refuse to issue a license (indication of the false or distorted information, non-compliance with the licensing requirements, decision on annulling the previously issued pharmacy license). Thus, there is possibility to develop the practice of pharmaceutical companies in Russia.