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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.