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Major Russian legislation changes for 2013

Life Sciences

New law on state procurement contract system

On January 1, 2014 Federal Law No. 44-FZ on the Contract System for the Procurement of Goods, Works and Services for State and Municipal Services ("**Contract System Law**"), which had been widely discussed and criticized throughout 2013, entered into force with direct affect on the healthcare sector. The considerable number of new rules that it introduced provide detailed regulation of the obligations and restrictions applicable to customers and contractors and stimulate long-term relationships between them. All stages of state procurement are affected by the regulations: planning, formation, placement and performance of each order. The new state and municipal procurement procedure is expected to be more open and transparent, and to improve the effective use of budget funds.

The new Contract System Law generates a number of corruption risks, in particular, it creates conditions (especially with respect to the means of placing orders) that increase the risk of abuse by the customer, the justification of the starting price of a contract is not sufficiently regulated, and there is no detailed procedure for price adjustments. The new rules concerning amendment and termination of a contract give the customer more rights to unilaterally repudiate or reduce a price, which generally increases the risk of pressure being brought on businesses.

Amendments to various legislative acts concerning healthcare matters for uniformity purposes

Federal Law No. 317-FZ on Amendments to Certain Legislative Acts of the Russian Federation and the Rescinding of Certain Provisions of Legislative Acts of the Russian Federation Concerning Healthcare for Citizens of the Russian Federation ("**Law No. 317-FZ**") entered force on November 25, 2013. The Law makes similar amendments to a range of Russian laws that deal in one way or another with healthcare in order to make them consistent with Federal Law No. 323-FZ on the Principles of Citizens' Healthcare of November 21, 2011 ("**Principles of Healthcare Law**"). In particular, a uniform definition of medical organization has been introduced, as well as types, forms and conditions of medical assistance.

Upon recommendation of the Federal Antimonopoly Service of Russia ("**FAS Russia**"), Law No. 317-FZ empowers the healthcare authority – the Russian Federation Ministry of Health ("**Health Ministry**") – to issue binding instructions to cure healthcare violations, initiate and consider cases involving violations of Russian Federation healthcare law, and determine liability for failure to comply with the instructions of state authorities or obstruction of supervisory authorities. The Russian Federation Government is also empowered to determine a procedure for forming various lists of medicines.

New administrative offenses relating to healthcare

Law No. 317-FZ introduces new administrative offenses: violation of the established rules on the circulation of medical products, failure to comply with obligations to provide information on conflicts of interest in medical and pharmaceutical activities, violations of legislation on the circulation of medicinal products, failure to provide information or the provision of false information to the federal executive authority responsible for supervision and control of healthcare, and others. Notably, the new rules are formulated in a way that enables them to be applied to absolutely dissimilar unlawful acts violating various provisions of the law. However, final judgment on this issue will only be possible as soon as stable enforcement practice is formed in respect of the new articles of Russian Federation Administrative Penal Code No. 195-FZ of December 30, 2001 ("**APeC**").

Mirror restrictions on interaction between pharmaceutical companies and medical and pharmacy workers

The express restrictions on pharmaceutical companies interacting with medical and pharmacy workers introduced by Law No. 317-FZ in Federal Law No. 61-FZ on the Circulation of Medicinal Products of April 12, 2010 mirror those previously imposed on interaction with medical and pharmacy workers by art. 74 of the Principles of Healthcare Law (bans on gifts, paid entertainment, personal meetings, branded prescription forms, etc.).

Nevertheless, at present applicable law does not provide administrative liability for violations of these prohibitions for pharmaceutical companies, their officers, or medical or pharmacy workers, which results in frequent violations in practice.

Additional requirements for professional training events organized by pharmaceutical companies

The amendments introduced by Law No. 317-FZ are based on proposals made by FAS Russia concerning, in particular, ensuring equal opportunities for all producers and distributors of similar medicinal products to inform medical workers of their products during scientific or other events intended to improve the professional skills of medical workers. At the suggestion of FAS Russia a ban on the creation of discriminatory conditions with respect to the participants of such events organized by the producers or distributors

of pharmaceutical products was introduced. Pharmaceutical companies that wish to conduct a scientific or other event intended to improve the professional skills of medical and/or pharmaceutical workers must publish respective notification on their websites at least two months in advance and notify the Health Ministry by the same date. Amendments to the APeC made by Law No. 317-FZ provide that failure to dislose information or the disclosure of false information to the Health Ministry, in particular with respect to scientific and other events, entails a fine for legal entities of up to 70,000 rubles.

VAT on medical products

Law No. 317-FZ also amends Part II of Russian Federation Tax Code No. 117-FZ of August 5, 2000 ("**Tax Code**") to bring the terminology into line with the Principles of Healthcare Law. In particular, the new language uses the term "medical product". The law decreses the rate of VAT to 10% with respect to medical products upon presentation of a registration certificate (until January 1, 2017 upon presentation of a medical-purpose product certificate).

Doctors required to prescribe medicines using international nonproprietary name only

On July 1, 2013, Russian Federation Ministry of Healthcare Decree No. 1175n of July 1, 2013 ("**Decree**") entered into force approving a new procedure for prescribing medicines, which can be performed by medical workers only, and rules on prescription forms. The Decree establishes that a medical worker prescribes medicines by international nonproprietary name ("**INN**"), or absent an INN, by generic name. This condition has been introduced for the purpose of unifying the contents of prescription forms and bringing prescription documents into line with international practices, as well as in the interests of the patient's right to receive information on all medicinal products with a similar INN that may be available in retail outlets to treat his/her illness. However, as yet there is no administrative penalty for violation of this prescription procedure.

Changes to regulation of medical services advertising

As of January 1, 2014, amendments to Federal Law No. 38-FZ on Advertising of March 13, 2006 ("**Advertising Law**") took effect expanding the permissibility of references to therapeutic qualities in advertising of preventative, diagnostic, and rehabilitation methods, and traditional medicine. Previously such reference was admissible solely in respect of medicines, medical services (including treatment methods), and medical products. The restrictions applied to advertisement of medicines (for example, prohibition to create an impression that it is not necessary to visit a doctor, or implying that a healthy person needs to use the advertised product) are expanded to advertising of preventative, diagnostic, and rehabilitation methods, and traditional medicine as well.

The new version of the Advertising Law prohibits all advertising relating to pregnancy termination services.

New rules introduced on state registration of medicinal products for medical use

Healthcare Ministry Order No. 428n of October 22, 2012 entered into force in 2013 approving new Administrative Rules on the provision of the state service of state registration of medicinal products for medical use ("**Rules**"). The Rules have been introduced for the purpose of improving the quality and accessibility of registration, as well as in connection with recent changes in legislation relating to the circulation of medicinal products. In particular, following the introduction of the Rules the state register of medicinal products is now available online, the list of documents required for registration has been revised, and an exhaustive list of grounds for denying registration has been introduced, along with the option of electronic filing and a new application processing period.

The new Rules generally establish a clearer, more transparent procedure for state registration of medicinal products for medical use. We may hope that this procedure will in practice meet the expectations of pharmaceutical companies for the registration of new pharmaceuticals on the Russian market.

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