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Legal Alert

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Draft Law Envisages New Punishments for Healthcare Violations

A draft law either establishing or strengthening administrative liability for certain violations in the field of healthcare is currently under review.

The draft federal law "On Amendments to the Code of Administrative Offences of the Russian Federation to Improve Regulation of Administrative Liability in the Field of Healthcare"[1] (the "Draft Law") was introduced to the State Duma by the Russian Government. The Draft Law was passed by the State Duma in the first reading on 21 June 2016. Amendments to the Draft Law should be submitted for consideration by the responsible committee by 21 July 2016.

This alert only covers provisions that may be especially relevant for pharmaceutical companies, but it should be noted that the Draft Law also establishes liability for medical organizations and medical and pharmaceutical professionals for other violations of applicable rules and regulations in the field of healthcare (e.g., violation of the rules on rendering medical treatment, violation of the rules on performance of medical examinations, violation of civil rights in the field of healthcare, violation of the rules on administration and prescription of medicinal preparations, etc.).

In accordance with the Draft Law administrative sanctions will be introduced for pharmaceutical companies for the following violations:

- Non-compliance with the restrictions imposed by Russian legislation on interactions with medical and pharmaceutical professionals (i.e., Article 67.1. of Federal Law No. 61-FZ “On the Circulation of Medicines”, dated 12 April 2010):

Penalty: an administrative fine of from RUB 300,000 to RUB 500,000 for medicines’ manufacturers, developers, distributors, wholesale organizations, pharmacies and organizations authorized to use the medicines' trade name.

In its current version the Draft Law does not establish any specific punishment for violations of the rules on interactions with healthcare professionals envisaged by Federal Law No. 323-FZ “On the Fundamentals of Citizens’ Health Protection in the Russian Federation” for medical devices companies.

- Violation of the procedure for conduct of clinical trials and pre-clinical trials of medicines:

(i) violation of the rules of good clinical practice (GCP) during performance of clinical trials of medicines;

[1] Available at: http://asozd.duma.gov.ru/main.nsf/%28Spravka%29?OpenAgent&RN=1093620-6

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(ii) violation of the rules of good laboratory practice (GLP) during performance of pre-clinical trials of medicines.

Penalty: warning or an administrative fine for officers - from RUB 5,000 to RUB 10,000; for legal entities - from RUB 20,000 to RUB 30,000.

- Violation of the licensing requirements:

(i) violation of the requirements of the license for the performance of medical and/or pharmaceutical activity.

Penalty: warning or an administrative fine for officers - from RUB 20,000 to RUB 30,000; for legal entities - from RUB 50,000 to RUB 200,000.

(ii) serious violation of the requirements of the license for the performance of medical and/or pharmaceutical activity.

Penalty: an administrative fine for officers - from RUB 25,000 to RUB 35,000; for legal entities - an administrative fine of from RUB 200,000 to RUB 300,000 or an administrative suspension of activity for up to 90 days.

- Violation of the legislation on the circulation of medicines:

(i) violation of the requirements on wholesale and retail trade:

Penalty (increased): an administrative fine for officers - from RUB 20,000 to RUB 30,000; for legal entities - an administrative fine of from RUB 100,000 to RUB 150,000 or an administrative suspension of activity for up to 90 days.

(ii) sales of medicines on the list of essential and most important medicinal preparations ("EDL") in violation of the maximum retail mark-ups:

Penalty: an administrative fine for officers - from RUB 100,000 to RUB 150,000; for legal entities - an administrative fine of from RUB 250,000 to RUB 500,000 or an administrative suspension of activity for up to 90 days.

(iii) sales of medicines on the EDL in violation of the maximum wholesale mark-ups:

Penalty: an administrative fine for officers - from RUB 150,000 to RUB 200,000; for legal entities - an administrative fine of from RUB 500,000 to RUB 1,000,000 or an administrative suspension of activity for up to 90 days.

According to the general rules the penalties are applied for each violation.

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