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Online Sale of Medicines and Greater Liability for Circulating Fake Medicines

Bryan Cave Leighton Paisner (Russia) hereby advises that amendments have been made to the regulations on circulation of medicines in Russia.

1. The law on distance selling of medicines enacted.

On 3 April 2020, Russian President Vladimir Putin signed Federal Law No. 105-FZ (the "**Law**") amending certain legislative acts of the Russian Federation concerning distance selling of medicines.

Under the Law, the right to engage in distance selling of medicines is granted to pharmacies licensed to sell medicines to the public and *authorised to engage in distance* selling of medicines by the federal healthcare watchdog (Roszdravnadzor).

The procedure for granting an authorisation to engage in distance selling of medicines to the public, the requirements on pharmacies authorised to conduct such sales, the distance selling procedure and the regulations on home delivery of medicines will be subsequently determined by the Russian Government.

Distance selling of the following medicines is not permitted:

- prescription medicines;
- o narcotic drugs and psychotropic medications; and
- medicines containing over 25 per cent ethyl alcohol by volume.

The Law permits distance selling of prescription medicines (apart from narcotic drugs or alcohol-containing medicines) during the emergency regime and/or when there is a threat of a dangerous disease spreading. Appropriate procedures and requirements on pharmacies may be established by the Russian Government, *as required*.

It should be noted that distance selling of prescription medicines is an extreme measure so the relevant provision of the Law (introduced by Part 9, Article 55 of Federal Law No. 61-FZ dated 12 April 2010 "On Circulation of Medicines") will be effective until 31 December 2020.

2. Greater liability for circulating fake, unregistered or substandard medicines

In addition to the above, on 1 April 2020, the Russian President signed two Federal Laws dated 1 April 2020 No. 95-FZ "On Amending Article 238-1 of the Criminal Code of the Russian Federation" and No. 89-FZ "On Amending the Code of Administrative Offences of the Russian Federation" stepping up liability for distributing fake, infringing, unregistered or substandard medicines via the media or information and telecommunications networks, including the Internet.

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	Liability		
Elements of the offence/crime	Individuals	Officials	Legal entities and sole traders
Part 3, Article 6.33 of the Russian Code of Administrative Offences			
Online sale of fake, infringing, substandard or unregistered medicines or BAFS (unless they involve criminal wrong-doing)	RUB 75,000 to RUB 200,000	RUB 150,000 to RUB 600,000	Legal entities: RUB 2,000,000 to RUB 6,000,000 or administrative suspension of operations for up to 90 days Sole traders: RUB 150,000 to RUB 600,000 or administrative suspension of operations for up to 90 days
Part 1.1, Article 238.1 of the Russian Criminal Code			
Production, distribution or importation into Russia of fake medicines or medical devices, or distribution or importation into Russia of substandard medicines or medical devices, or illegal production, distribution or importation into Russia of unregistered medicines or medical devices for distribution, or production, distribution or importation into Russia of fake BAFS containing pharmaceutical substances not declared during state registration committed on a large scale via the media or information and telecommunications systems, including the Internet	- Forced work for four to five years, with or without disqualification from certain positions or certain activities for two to three years; or - imprisonment for four to six years, with or without a fine of RUB 750,000 to RUB 2,500,000 or in the amount of the salary or other income of the convicted person for one to two years, with or without disqualification from certain positions or certain activities for up to four years.		

Get in touch

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