

## RUSSIA CRIMINALIZES COUNTERFEIT MEDICINES

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On Dec. 25, 2014, the Russian Parliament adopted new legislation aimed at the criminalization of (1) pharmaceutical counterfeiting and (2) distribution of counterfeited and falsified medicines and medical devices. The law became effective on Jan. 23, 2015.

Several articles of the Russian Criminal Code were amended to include the following new provisions:

- Under article 235 of the Russian Criminal Code, the penalty for unauthorized manufacturing of medicines and medical devices (for which authorization is required) is 3-5 years imprisonment and a fine in the amount of 500,000 to 2,000,000 rubles (at today's exchange rates, that equals about USD \$8,000-\$31,000). If the crime was committed by a criminal organization or on a large scale (exceeding 100,000 rubles or USD \$1,500), the penalty is 5-8 years imprisonment and a fine in the amount of 1,000,000 to 3,000,000 rubles (approximately USD \$15,500-\$46,000).
- Under article 238 of the Criminal Code, the penalty for the circulation of falsified, defective, unregistered medicines, medical devices and circulation of falsified biologically active supplements is 3-5 years of compulsory labour, deprivation of the right to hold certain positions or carry out certain activities for up to 3 years, or 3-5 years imprisonment and a fine in the amount of 500,000 to 2,000,000 rubles (approximately USD \$8,000-\$31,000). If the crime was committed by a criminal organization or the crime committed caused grievous bodily harm or death, the penalty will be 5-8 years imprisonment and a fine in the amount of 1,000,000 to 3,000,000 rubles (approximately USD \$15,500-\$46,000).
- Under article 6.33 of the Russian Administrative Code, the circulation of falsified, counterfeit, defective and unregistered medicines, medical devices and circulation of falsified biologically active supplements will lead to an administrative fine in the amount from 1,000,000 to 5,000,000 rubles (approximately USD \$15,00-\$77,000) or

suspension of activities for a term of 90 days. Circulation is defined as:

- manufacturing, sale or import of falsified medicines in Russia;
  - manufacturing, sale or import of falsified medical devices in Russia;
  - sale or import into Russia of counterfeit medicines;
  - sale or import into Russia of counterfeit medical devices or;
  - circulation of falsified biologically active supplements.
- Under article 327 of the Criminal Code, forgery of documents for medicines and medical devices or packages of medicines or medical devices will lead to a fine in the amount of 500,000 to 1,000,000 rubles (or approximately USD \$8,000-\$16,000).

Prior to the enactment of this new law, the trading in counterfeit drug products was treated no differently than for luxury goods, where the sanctions are primarily seizure of the offending goods and a trivial fine. The much harsher sanctions under the new law reflect the serious public health concerns associated with the distribution of fake and potentially dangerous drugs to innocent consumers.

Contributions to this article were also made by Meldir Erbulekova, Student-at-Law at our Moscow office.

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