



CHANGES IN RULES FOR RETAIL SALES OF MEDICAL DEVICES

For the attention of manufacturers and importers of medical devices as well as wholesale and retail traders and pharmacies

Pepeliaev Group advises that the Russian Government has adopted a Resolution which changes the Rules for selling certain types of goods¹.

Main changes

Resolution No. 6 of the Russian Government dated 5 January 2015 “On amending the Rules for selling certain types of Goods” introduces restrictions connected with retail trading in medical devices.

In particular, 7 days after this Resolution is officially published it is prohibited to trade in medical devices at *the place where the buyer is located, outside permanent trading places*: in homes, places of work or study, in transport, in the street or other places. Previously the Rules for Selling Certain Goods prohibited door-to-door sales of certain categories of pharmaceuticals, but these restrictions did not affect medical devices.

Additionally, a duty has been imposed on sellers to sell medical devices based on proper medical prescriptions as well as over the counter, in accordance with the product labels. The previous version of the Rules for Selling Certain Goods had no provisions regarding medical devices being sold on prescription.

Please note that these changes also affect how the requirement should be performed to provide information about medical devices. After the Regulation comes into force, the information about medical devices should contain *the date and number of the registration certificate* issued by the Federal Service on Surveillance in Healthcare in relation to the medical device. Previously the Resolution required the number and date of *the permission for such medical devices to be used*.

At the same time, the Resolution *has cancelled* the seller's obligation to provide to the buyer information *about the rules for selling* medical devices, which previously was mandatory. At present it applies only to pharmaceuticals.

What to think about and what to do

The most important consequence of this Resolution is that door-to-door trading in medical devices will be prohibited, as will trading in medical devices without a doctor's prescription when such a prescription is required. Retailers and pharmacies, as well as manufacturers and distributors, should take these restrictions into account as they make their business plans.

¹ Approved by Resolution No. 55 of the Government of the Russian Federation dated 19 January 1998 “On approving the Rules for selling certain types of goods, the list of durable goods regarding which the buyer may not demand that similar goods be provided to him/her for the period of repairs or replacement, and the list of non-food goods of proper quality which may not be returned or exchanged for a similar product of another size, form, dimensions, design, colour or batching”.

Help from your adviser

Pepeliaev Group's lawyers have considerable experience of advising and representing clients with regard to trading in medical devices. They are ready to provide comprehensive assistance and legal support in respect of the above issues.

Contact details



Vladimir Sokov
Senior Partner,
Head of Corporate Division
Pepeliaev Group
T.: +7 (495) 967-00-07
v.sokov@pgplaw.ru



Oxana Migitko
Head of Commercial Practice
Pepeliaev Group
T.: +7 (495) 967-00-07
o.migitko@pgplaw.ru



Sergey Klimenko
Senior Associate,
Project coordinator for the
pharmaceutical and medical
industry
Pepeliaev Group
T.: +7 (495) 967-00-07
s.klimenko@pgplaw.ru



Sergey Spasennov
Partner (St Petersburg)
Pepeliaev Group
T.: +7 (812) 640-60-10
s.spasennov@pgplaw.ru



Egor Lysenko
Head of Siberian office
in Krasnoyarsk
Pepeliaev Group
T.: +7 (391) 277-73-00
e.lysenko@pgplaw.ru