

# Press-release of 12.08.2010

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On 9th August 2010, the Federal Antimonopoly Service (FAS Russia) found that the Federal Service for Supervision over Health Care and Social Development (Roszdravnadzor) and the Federal Agency for Technical Regulation and Metrology (Rosstandart) violated Part 1 Article 15 of the Federal Law “On Protection of Competition”.

Earlier FAS Russia received a petition of “Pravovoi Departament” Ltd., which faced excessive administrative barriers. According to the petitioner, actions of Roszdravnadzor created additional difficulties for importers of lenses and frames for eye glasses in customs clearance of these goods as well as registration of compliance declarations with Rosstandart.

Investigating the petition, FAS Russia established that Roszdravnadzor has issued letters, which introduced state registration of corrective glasses<sup>1</sup> and use of registration certificates issued by Roszdravnadzor for customs clearance. Rosstandart sent letters about mandatory state registration of eyewear items with Roszdravnadzor in order to register a compliance declaration.

Currently there are no legal definitions of “medical products” and “medical equipment”, which enabled Roszdravnadzor to classify corrective lenses and eye glasses frames as products subject to mandatory registration.

The FAS Russia’s Commission discovered that in order to register compliance declarations Rosstandart required importers of eyewear to have mandatory registration with Roszdravnadzor, which was contrary to the existing legislation. Under the established procedures for accepting and registering compliance declarations, a declaration submitted for registration must be accompanied by copies of the documents required for such products under the relevant federal laws. No federal law obligates to register corrective lenses and frames for eye glasses classified as medical equipment.

Having investigated the case, FAS Russia found that Roszdravnadzor and Rosstandart violated Part 1 Article 15 of the Federal Law “On Protection of Competition” as they unreasonably prevented activities of economic entities, particularly, by setting requirements to the goods or economic entities, which are not provided for by the law of the Russian Federation.

FAS Russia issued a determination to Roszdravnadzor requesting to withdraw the letters introducing state registration of corrective lenses and frames for eye glasses. FAS Russia also has given recommendations that it is unacceptable to apply the Rules for registering medical products to the above items. The FAS Russia’s Commission issued a determination to Rosstandart requesting to withdraw the letters about mandatory state registration of eyewear with Roszdravnadzor.

According to the Head of the Department for Control over the Authorities Vladimir Mishelovin, the problems raised in course of the case investigation are much broader. It appears that registration and subsequent mandatory declaration of compliance are duplicating procedures, which create additional barriers for economic entities. Also product registration does not guarantee that non-registered products are not present in retail. Vladimir Mishelovin believes that “absence of clear concepts of “medical products” and “medical equipment”, defined by the federal laws, is like a

chronic illness, which can have any consequences. In 2009 FAS Russia already inspected activities of Roszdravnadzor and pointed out that this situation could result in violations of the Federal Law “On Protection of Competition”, but things aren’t moving...”

*\*Corrective glasses is the most popular optical instrument aimed at improving and assisting human eyesight in case of optical eye defects or protecting eyes from various harmful impacts.*