

# Russian government issues first compulsory pharmaceutical licence

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On 5 January 2021, the Russian government published an [ordinance](#)\* on the issuance of a compulsory licence for inventions related to the production of remdesivir, a drug intended for the treatment of COVID-19.

The Russian government has allowed Pharmasintez JSC to use the corresponding invention patents, owned by Gilead Sciences, Inc. and Gilead Pharmasset LLC, for one year. Within three months, the Russian Ministry of Industry and Trade must provide the Russian government with information on the payment of commensurate compensation for the use of patents by Pharmasintez JSC to the right holders.

This ordinance was adopted on the basis of Article 1360 of the Russian Civil Code, which provides for the issuing of a compulsory licence in the interests of the defence and security of the state without the consent of the patent holder, subject to notification as soon as possible and payment to the latter of commensurate compensation.

Taking into account the lack of a clear definition of "state security" in the legislation, the validity of using the compulsory licence mechanism for a pharmaceutical product is controversial. It also raises questions about how the compensation to the right holders will be calculated and to what extent it will correspond to the fair market value of the licence.

The use of the compulsory licence mechanism and the lack of certainty for right holders regarding the calculation of compensation could negatively affect the investment attractiveness of Russia for pharmaceutical companies producing original drugs. A robust intellectual property protection system is recognised by pharmaceutical manufacturers as critical to translating investment and research into innovative life-saving treatments. At the same time, the issuance of compulsory licences by the state actually devalues the unique developments protected by a patent.

In addition, the Russian State Duma is considering a [bill](#)\* on expanding the grounds for issuing compulsory licences. The bill proposes granting the Russian government the right to issue a compulsory licence in case of emergency related to ensuring the defence and security of the state, as well as protecting the life and health of citizens. At the same time, the Russian government will have to approve the methodology for calculating compensation. At the moment, the bill has been adopted in the first reading. (For the bill to become law, it must be passed in three readings in the State Duma, approved by the Federation Council and signed by the President). We will keep you updated on further changes.

For more information on this eAlert, please contact CMS Russia experts [Vsevolod Tyupa](#), [Alexey Shadrin](#) or your regular contact at CMS Russia.

\* *In Russian*

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