

The risk of shortage of medicines - COVID-19

The declared state of emergency by a decision of the National Parliament allowed the Minister of Health to issue an order of 20.03.2020, by virtue of which the export of quinine-based medicines is prohibited. The purpose of the ban is to meet the needs of the Bulgarian market in connection with the complicated epidemiological situation in the country due to the spread of COVID-19.

Meanwhile, the National Parliament voted on explicit provisions entitling the Minister of Health to ban the export of medicinal products, whereas envisioning fines amounting up to BGN 100,000 (EUR 51,000).

At the same time, the European Commission is working to adopt measures aimed at safeguarding the free movement of all goods within the EU and, in particular, guaranteeing the supply of medicines, medical equipment and food.

On 19.03.2020 the European Commission adopted implementing Regulation (EU) 2020/402 making the exportation of certain products subject to the production of an export authorization. Such authorization shall be required for the export outside the Union of personal protective equipment.

The Association of the Research Based Pharmaceutical Manufacturers in Bulgaria and its member pharmaceutical companies (ARPharM) announced that the immediate risk of shortage of medicinal products due to COVID-19 is minimal in the short term and the organization does not expect disruption of the drug supply chains, unless the restrictions due to COVID-19 outbreaks last more than a few months.

The team of Penkov, Markov & Partners, which specializes in the Pharmaceutical Matters has extensive experience in advising pharmaceutical companies affiliated with ARPharM and the European Federation of Pharmaceutical Industries and Associations (EFPIA) and is available for any consultation and assistance.

For more current topics related to the legislation governing the relations in the state of emergency, you can find information on our website: <u>www.penkov-markov.eu</u>. Of course, you can also contact us for further information and assistance at <u>lawyers@penkov-markov.eu</u> The above provides general information related to the adoption of the Emergency Measures and Actions during the State of Emergency Act and it is not exhaustive, whereas it serves only as a guide for interpreting the news as of March 26, 2020.