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COVID-19 Legal Insights



Pharma and Medical Services

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Derogating emergency measures directly impacting the pharmaceutical industry and medical services - Decree No. 195/2020 and Military Ordinance No. 1/2020

A state of emergency was declared in Romania on 16 March 2020 by Presidential Decree No. 195/2020 (the “Decree”), published in the Official Gazette No. 212/2020. The Decree institutes a 30-day state of emergency throughout the Romanian territory and establishes first emergency measures of direct and immediate application, as well as measures of gradual applicability with a view to preventing the spread of COVID-19 and handling the consequences of this epidemic. The Decree seeks to protect public health and the right to life, including by exceptional social and economic measures, with direct and immediate impact on the population, economic institutions and undertakings and, naturally, on the pharmaceutical industry and medical services sector.

Also, pursuant to the Decree and to Government Emergency Ordinance No. 1/1999 on curfew and the state of emergency, the Minister of Internal Affairs issued Military Ordinance No. 1/2020 on certain first emergency measures concerning public gatherings and the transboundary circulation of goods, published in the Official Gazette, Part I No. 219 of 18 March 2020 (the “Military Ordinance”).

The Decree

1. What are the main measures in the health sector and how do they depart from the general rules?

More specifically, Chapter III of Appendix No. I to the Decree contains the main first emergency measures ordered with a view to securing the logistical and operational basis to increase the strength, and efficiency and provide financing for the healthcare system in the struggle to prevent and combat COVID-19; these measures are of an exceptional nature, derogating from the provisions of the general rules, as follows:

- **Contract Staff.** Healthcare units, social security services and structures of the Ministry of Internal Affairs (which ensures an integrated coordination of the medical response measures against COVID-19) may hire without a contest, for a limited period of 6 months, medical contract staff, auxiliary staff, pharmacists, laboratory staff and other necessary categories of contract staff. An absolutely necessary measure in the current state of emergency, since the secondments of employees from the private environment to public institutions, including in the medical sector, were prohibited earlier this year, according to Government Emergency Ordinance No. 1/2020, which caused an acute lack of expert contract staff at the level of the institutions and authorities from the medical sector.
- **Facilitating supply and reimbursement of medical services.** Legislative acts concerning the provision of medical services and medicinal products within the social security system (more precisely, the Framework Contract and the laws of the national health programmes) were extended subsequent to 30 March throughout the state of emergency with a view to securing the following objectives:
 - Provision of medical services related to the treatment of COVID-19 cases to all persons on the territory of Romania, the expenses being borne from the budget of the Sole National Health Insurance Fund (FNUASS);
 - Making possible the provision of medical services and medicinal products without validation with the national health insurance card and without a minimum reporting term;
 - For hospitals under contract with the health insurance houses, reimbursement of the amounts contracted from the budgets of FNUASS or the Ministry of Health, even if the number of cases dealt with or the volume of activity conducted exceeds the contracted level;
 - Prescription of medicinal products to patients with chronic conditions by general practitioners, including restricted medicinal products on the List of reimbursable medicinal products (previously prescribed by the specialist doctor only).

- **Direct procurement of materials, equipment and medicinal products.** In essence, by derogation from the public procurement laws, central public authorities and legal entities in which the State is a majority shareholder may directly procure the materials and equipment required to fight the COVID-19 epidemic:
 - With financing from the Ministry of Health's budget, healthcare units and public health directorates may acquire materials and medicinal products required throughout the pandemic by direct procurement procedure;
 - Also, ministries with their own health system may conduct direct procurements for their own healthcare units, both from the budgets of the ministry and from the budget of the healthcare unit.
- **Price of medicinal products.** By derogation from existing rules (set forth under Law No. 95/2006, Order of the Minister of Health No. 368/2017 and secondary laws on the provision of medical services and medicinal products within the health insurance system), the healthcare units may procure medicinal products for the treatment of the patients infected with COVID-19 at a **price which may exceed the maximum price approved by the Ministry of Health**. This is an exceptional measure which requires caution and should only be applied in cases of strict necessity, since the Decree sets forth on the other hand that, throughout the state of emergency, the authorities could cap the prices of medicinal products and medical equipment, and to requisition inventories or facilities for the production and distribution of medicinal products used in the treatment of COVID-19.
- **Clawback tax.** The amount of the percentage related to the clawback tax for Quarter I of 2020 shall be capped at the amount of Quarter IV of 2019 (in any case, quite high); it is a derogation from the method of calculating the quarterly percentage, provided in Government Emergency Ordinance No. 77/2011.
- **Off-label prescription.** Implicitly derogating from the rules of Law No. 95/2006, the Decree permits the prescription of off-label treatments (beyond the scope of permitted indications) for the patients infected with SARS-CoV-2 virus, based on the endorsement of the treatment by the medicinal product policy committee within the healthcare unit.
- **Supplementation of treatments and medical services.** New healthcare programmes and medical services meant to prevent and fight against COVID-19 may be established by order of the Minister of Health.

The Military Ordinance

2. What are the measures implemented in the public health sector by the Military Ordinance throughout the state of emergency?

The Ordinance contains a set of measures implemented throughout the state of emergency in the public health sector, which may be of interest to the pharmaceutical industry, as follows:

- Suspension of all cultural, scientific, artistic, religious, sporting, entertainment or gambling, spa and personal care activities conducted on indoor premises. In case of any doubts or hopes that the usual medical and scientific events, with the participation of healthcare professionals and the maximum number of participants, could still take place, the Ordinance makes it clear that such events are suspended for the duration of the state of emergency;
- Indeed, all indoor events entailing the participation of more than 100 persons are prohibited, whilst for events with lower attendance numbers, measures should be taken so as to secure a distance of at least 1 meter amongst participants.
- Finally, taking over a recent draft regulation of the Ministry of Health, the Ordinance prohibits the transport with a view to being distributed outside Romania of medical devices and healthcare materials used for the prevention and treatment of COVID-19-related ailments, and of the medicinal products listed in Canamed (National Catalogue of Medicinal Products). An exceptional measure for sure, contrary to certain fundamental principles of the European Union, but entirely justified within the context of the COVID-19 pandemic.

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Editors

COVID-19 Legal Insights is our response to the COVID-19 outbreak. We shall keep you informed on the various legal challenges posed by the coronavirus, thanks to a dedicated practice group comprising lawyers with different backgrounds, such as compliance/regulatory, corporate and commercial, insurance, labour and employment, litigation and arbitration, insolvency, public procurement, data privacy, tax and customs. In addition, our taskforce offers strategic advice on crisis-specific matters: corporate restructuring, review and (re)negotiation of agreements (including collective bargaining agreements and individual employment contracts), performance of the contracts which are affected by force majeure and hardship, unblocking pre-litigation relationships, etc. To keep abreast of developments, please feel free to regularly check our dedicated online resource: <http://www.tuca.ro/covid-19/>



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