Government Decree 67/2020 (26 March)

on measures related to the supply of medicinal products during the period of state of danger declared for the prevention of the human epidemic endangering life and property and causing massive disease outbreaks, for the elimination of its consequences, and for the protection of the health and lives of Hungarian citizens

The Government,

acting within its original legislative power laid down in Article 53 (2) of the Fundamental Law,

acting within its function laid down in Article 15 (1) of the Fundamental Law,

orders as follows:

Section 1 During the period of state of danger declared by Government Decree 40/2020 (11 March) on the declaration of state of danger, in authority proceedings to be conducted in cases of COVID-19 coronavirus, connected to epidemic control, the existence of a patient care interest deserving special consideration defined in point 23 of section 1 of Act XCV of 2005 on medicinal products for human use and amending other Acts regulating the market for medicinal products (hereinafter "Gytv.") shall be presumed.

Section 2 The pharmaceutical state administration organ may, on the basis of any information it learns in connection with performing its tasks specified in law, even in the absence of a notification under section 16 (2) of the Gytv., establish a shortage of medicinal products or its risk.

Section 3 (1) The pharmaceutical state administration organ shall publish on its webpage the list of active substances of the medicinal products indicated in the authorisations issued under section 25 (6) and (6a) of the Gytv. for the treatment of COVID-19 coronavirus cases.

(2) By way of derogation from section 25 (6) and (6a) of the Gytv., no authorisation shall be required for prescribing or using, for the treatment of COVID-19 coronavirus cases, medicinal products containing an active substance indicated in the list under paragraph (1) otherwise than for the indications contained in the summary of product characteristics approved in the marketing authorisation.

(3) The treating doctor shall notify the pharmaceutical state administration organ of any prescription or use of medicinal products that is not subject to authorisation under paragraph (2) subsequently, but not later than 90 days following the end of the period of state of danger. Such a notification may include all the cases that occurred at the healthcare provider concerned.

(4) The pharmaceutical state administration organ shall assess the applications under section 25 (6) and (6a) of the Gytv. that are related to COVID-19 coronavirus cases as a matter of priority.

(5) In its proceedings under section 11/D of Government Decree 217/1997. (1 December) on the implementation of Act LXXXIII of 1997 on compulsory health insurance benefits, if an authorisation by the pharmaceutical state administration organ is not available, the National Health Insurance Fund shall request directly the pharmaceutical state administration organ's opinion concerning the eligibility of applications.

Section 4 This Decree shall enter into force on the day following its promulgation.