



Prague, 3 April 2020

Ref. No.: MZDR 14994/2020-1/LEG

MZDRX019T00F

## **DECISION**

The Ministry of Health, as the competent administrative authority pursuant to Section 11(a) of Act No. 378/2007 Coll., on Medicinal Products and on the amendment of certain related laws (Act on Medicinal Products), as amended, has decided on the following measure:

In the interest of protecting public health in relation to the current spread of the source of the disease, the SARS-CoV-2 coronavirus which causes the COVID-19 disease, and in order to ensure the availability of medicinal products important to providing medical care, the Ministry of Health in accordance with Section 8(6) of the Act on Medicinal Products

### **temporarily permits**

- 1) the distribution and use of medicinal oxygen, exclusively for the purpose of ensuring the covering of healthcare services in the Czech Republic, as concerns medicinal oxygen filled, contrary to the marketing authorisation, into pressurised bottles, bundles of bottles and portable vaporization stations with valves, which are designated for filling technical oxygen, provided that the filling and preparation of the primary packaging is conducted under the conditions of best production practices and the manufacturer ensures their traceability,
- 2) the holders of permits to manufacture medicinal products - medicinal gases to use the medicinal product of medicinal oxygen taken from a location other than that stated in the registration documentation, if such location is listed in the different registration documentation of a medicinal product containing medicinal oxygen approved in another European Union member state, which has valid certification for best production practices.

This measure comes into effect on the date of its publication in the official bulletin of the Ministry of Health, and expires on the last day of the sixth calendar month following the date of termination of the state of emergency.

### **Rationale:**

This decision has been issued in connection with the adverse development of the epidemiological situation in terms of the occurrence of the COVID-19 disease caused by the new coronavirus designated as SARS-CoV-2 in the Czech Republic and the future need to satisfy the demand for medicinal oxygen used in intensive care at healthcare facilities. In the

case of a critical rise in its consumption for the purpose of coping with the COVID-19 epidemic, it is essential to ensure its availability even in a situation when medicinal oxygen is not available in the packaging approved within the marketing authorisation for these medicinal products.

Given the fact that, based on available findings from the course of the COVID-19 epidemic, there is a rising demand for medicinal oxygen, it is necessary to secure a crisis alternative of distributing medicinal oxygen.

Mgr. et Mgr. Adam Vojtěch, MHA,  
Minister of Health

*Signed electronically*