

## DECISION

The Ministry of Health, as the competent administrative authority pursuant to Section 11(a) of Act No 378/2007, on pharmaceuticals and on the amendment of certain related laws (hereinafter referred to as the “Act on Pharmaceuticals”), as amended, has decided on the following measure:

In the interest of protecting public health in relation to the current spreading of the causative agent of the novel SARS-CoV-2 coronavirus which causes COVID-19 disease, and in order to ensure the availability of medicinal products needed for the provision of medical care, the Ministry of Health, in accordance with Section 8(6) of the Act on Pharmaceuticals,

### temporarily permits

the distribution, dispensing and use of the non-registered human medicinal product **Avigan, 200 mg tablets**, active substance favipiravir (200 mg favipiravir per tablet), 1 package containing 100 tablets, **manufacturer: FUJIFILM Toyama Chemical Co., Ltd.**, 14-1, Kyobashi 2-Chome, Chuo-Ku, Tokyo 104-0031, Japan (hereinafter referred to as the “medicinal product Avigan”). This medicinal product is registered in Japan.

The following conditions must be fulfilled for the distribution, dispensing and use of the said medicinal product:

- The medicinal product Avigan is designated for hospitalised patients in the Czech Republic who have confirmed COVID-19 infection, and based on their informed consent.
- The distributor authorised to import and distribute this medicinal product is **Astro-Pharma Vertrieb und Handel von pharmazeutischen Produkten GmbH**, registered office **Allerheiligenplatz 4, 1200 Vienna, Austria**, potentially through **Astro Pharma GmbH, Wolfgang-Pauli-Gasse 5, 1140 Vienna, Austria**. The distributor is authorised to distribute based on a license from another EU Member State, namely Austria, distribution license No INS-481358-0009-006.
- Based on this decision, the distributor is authorised to perform the one-off distribution of 100 packages (10,000 tablets) of the respective medicinal product to: **Všeobecná fakultní nemocnice v Praze, Nemocniční lékárna, U Nemocnice 499/2, 128 00 Prague 2**.

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

### Justification:

This temporary measure 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 novel coronavirus designated as SARS-CoV-2, in the Czech Republic.

With a view to the fact that, according to available medical knowledge, the medicinal product Avigan, active substance favipiravir, seems potentially effective in the treatment of the

COVID-19 disease, it is necessary to ensure a critical supply thereof to treat patients with COVID-19.

The conditions stated in the decision were stipulated by the Ministry of Health to ensure the safety of the use of the medicinal product Avigan, in particular because this medicinal product is not registered in the EU.

Given that this is a medicinal product which has no alternative on the market in the Czech Republic, and the matter concerns the procurement of a medicinal product to treat serious health conditions, the Ministry of Health is temporarily permitting the distribution, dispensing and use of the medicinal product Avigan with the requisite that the conditions specified above are met and for the stipulated period of time, based on the unforeseeable development of the epidemiological situation around the COVID-19 disease. When handling this medicinal product, it is necessary to observe the applicable provisions of the Act on Pharmaceuticals, with the exception of the foregoing particularities.

Mgr. et Mgr. Adam Vojtěch, MHA

Minister of Health