Annex to the Resolution of the Government dated March 23, 2020 No. 285

In Prague, on March 22, 2020 Ref. No.: MZDR 12717/2020-1/MIN/KAN

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EMERGENCY MEASURE

The Ministry of Health as the administrative body relevant under Section 80 (1) letter g) of the Act No. 258/2000, on protection of the public health and on amendment of other relevant acts, as amended (hereinafter referred to as "Act No. 258/2000 Coll."), under Section 69 (1) letter i) and (2) of the Act No. 258/2000 Coll., to protect the population and to prevent the danger of occurrence and spreading of the COVID-19 illness caused by the new coronavirus SARS-CoV-2, hereby issues its measure:

I.

- 1. Any and all doctors with the exception of doctors with specialised competence in the fields of allergology and clinical immunology, dermatovenerology, infectious medicine or rheumatology, or with specific competence or specific specialisation in the fields of child dermatovenerology, paediatric rheumatology or corrective dermatology shall be prohibited from prescribing medicinal product Plaquenil, registration number 25/209/00-C. This prohibition does not apply to the prescription on a demand for use when providing inpatient care to patients with COVID-19 disease.
- 2. Any and all veterinarians shall be prohibited from prescribing human medicinal product Plaquenil, registration number 25/209/00-C.
- 3. Any and all doctors with specialised competence in the fields of allergology and clinical immunology, dermatovenerology, infectious medicine or rheumatology, or with specific competence or specific specialisation in the fields of child dermatovenerology, paediatric rheumatology or corrective dermatology shall be prohibited from prescribing medicinal product Plaquenil, registration number 25/209/00-C, in therapeutic indications other than those listed in the applicable summary of product characteristics, for a treatment period exceeding 2 months, or in amount exceeding 2 packages.
- 4. All doctors referred to in point 2. shall be ordered to always indicate the main diagnosis when prescribing medicinal product Plaquenil, registration number 25/209/00-C.
- 5. All pharmacists shall be prohibited from dispensing the medicinal product Plaquenil, registration number 25/209/00-C, if the medical prescription does not specify the prescribing doctor's expertise, if the main diagnosis relating to the

prescribed medicinal product is not provided, if the expertise of the prescribing doctor does not correspond to the expertise as stated in the prescribing restriction of the product and if it is prescribed in a different therapeutic indication than specified in the applicable summary of product characteristics. This prohibition shall not apply to the dispense on demand for use when providing inpatient care to patients with COVID-19 disease.

II.

This emergency measure is effective as of March 22, 2020, 18:00 p.m.

Reasoning:

The emergency measure is issued in connection to unfavorable development of the epidemiologic situation in occurrence of the COVID-19 illness, caused by the new coronavirus SARS-CoV-2 in the Czech Republic.

Given the fact that, according to the available scientific knowledge, the medicinal product Plaquenil appears to be potentially effective for the treatment of COVID-19 disease, it is necessary to prevent its unavailability for both patients in registered indications and COVID-19 patients.

Mgr. et Mgr. Adam Vojtěch, MHA

Minister of Health

Signed electronically