THE MINISTRY OF HEALTH Palackého náměstí 375/4, 128 01 Prague 2

Prague, 23 March 2020

Ref. No.: MZDR 12756/2020-2/MIN/KAN

MZDRX019LQHW

EXTRAORDINARY MEASURE

The Ministry of Health, as the competent administrative authority pursuant to Section 80(1)(g) of Act No. 258/2000 Coll., on public health protection and amending certain related acts, as amended (hereinafter referred to as "Act No. 258/2000 Coll."), orders, proceeding pursuant to Section 69(1)(i) and (2) of Act No. 258/2000 Coll., in protecting the population and preventing the occurrence and spread of the COVID-19 disease caused by the new SARS-CoV-2 coronavirus, this Extraordinary Measure:

I.

- 1. All physicians, with the exception of those with specialised expertise in the disciplines of allergology and clinical immunology, dermato-venerology, infectious medicine or rheumatology, or special expert competence or special specialised competence in paediatric dermato-venerology, paediatric rheumatology, or corrective dermatology, are prohibited from prescribing the pharmaceutical product Plaquenil, registration number 25/209/00-C. This prohibition shall not apply to prescriptions on the basis of request forms for use in the provision of in-patient care to patients with the COVID-19 disease and to prescriptions written in electronic or paper form by a physician with specialised expertise in the disciplines of pulmonology and phthisiology for patients who are already being treated for the indication of sarcoidosis.
- 2. All veterinarians are prohibited from prescribing the humane pharmaceutical product Plaquenil, registration number 25/209/00-C.
- 3. All physicians with specialised expertise in the disciplines of allergology and clinical immunology, dermato-venerology, infectious medicine or rheumatology, or special expert competence or special specialised competence in paediatric dermato-venerology, paediatric rheumatology, or corrective dermatology, are prohibited from prescribing the pharmaceutical product Plaquenil, registration number 25/209/00-C, in therapeutic indications, other than those stated in the applicable product data summary, for a treatment period in excess of 2 months, more than 2 packages. Furthermore, this ban shall apply to physicians with specialised expertise in the disciplines of pulmonology and phthisiology when writing a prescription in electronic or paper form for patients who are already being treated for the indication

of sarcoidosis.

- 4. All physicians referred to in paragraph 3 are ordered to always state the main diagnosis when prescribing the pharmaceutical product Plaquenil, registration number 25/209/00-C.
- 5. All pharmacists are prohibited from dispensing the pharmaceutical product Plaquenil, registration number 25/209/00-C, if the specialisation of the prescribing physician is not stated in the prescription, if the main diagnosis related to the prescribed pharmaceutical product is not stated, if the specialisation of the prescribing physician does not correspond to the specialisations stated in the prescription restrictions for the product, or if the product has been prescribed in a therapeutic indication other than that stated in the applicable product data summary. This prohibition shall not apply to dispensing on the basis of request forms for use in the provision of in-patient care to patients with the COVID-19 disease.

II.

The pharmaceutical product Plaquenil, registration number 25/209/00-C, prescribed prior to 23 March 2020 by a physician with specialised expertise in the disciplines of allergology and clinical immunology, dermato-venerology, infectious medicine or rheumatology, or special expert competence or special specialised competence in paediatric dermato-venerology, paediatric rheumatology, or corrective dermatology, may be dispensed during the term of validity of the medical prescription in which the pharmaceutical product was prescribed, even if the main diagnosis is not stated in the prescription.

III.

This Extraordinary Measure shall take effect on 23 March 2020 at 20:00 hours.

IV.

This Extraordinary Measure rescinds Extraordinary Measure Ref. No. MZDR 12756/2020-1/MIN/KAN of 23 March 2020.

Rationale:

This Extraordinary 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 pharmaceutical product Plaquenil seems to be potentially effective in the treatment of the COVID-19 disease, its unavailability for the treatment of patients in the registered indications as well as patients with COVID-19 must be prevented. With a view to the issue of validity of medical prescriptions, however, the dispensing of the pharmaceutical product shall be permissible even if the prescription does not meet all of the requirements for the dispensing of the product set in

Extraordinary Measure MZDR 12756/2020-1/MIN/KAN, provided it was issued prior to 23 March 2020.

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

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