

DONATION AGREEMENT WITH GENERAL CONDITIONS FOR THE SUPPLY OF PRODUCT (non-patient specific) for requests from institutions in the context of COVID-19 ("AGREEMENT")

This AGREEMENT shall govern the relation between:

Sandoz AG, with its registered office at Lichtstrasse 35, 4056 Basel, Switzerland, Registration number CHE-103.977.765. (hereinafter "Sandoz AG")

Sandoz s.r.o., with its registered office at Na Pankráci 1724/129, Nusle, 140 00 Praha 4, Czech Republic, Identification number 41692861 (hereinafter "Sandoz CZ")

(Sandoz AG and Sandoz CZ hereinafter jointly referred to as "Sandoz")

and

**Česká republika** - Ministerstvo zdravotnictví with its registered office at Palackého náměstí 375/4, 128 01 Prague, Czech Republic, Identification number 00024341 (hereinafter the "Institution") who has requested the supply of Sandoz hydroxychloroquine (hereinafter the "Product") as a potential treatment option for patient(s) suffering from COVID-19 related conditions (hereinafter "Patient(s)").

Whereas and by receiving the supply of the requested Product as a donation, the Institution agrees to adhere to the following requirements:

Sandoz AG administrates an initiative of donating of hydroxychloroquine (HCQ) to fight COVID-19 outbreak.

Sandoz CZ, a Sandoz AG affiliate based in the Czech Republic, will, as instructed by Sandoz AG, donate 80 000 tablets (200mg) of the Product to the Institution according to the below conditions, without any requirement for compensation and without any past or future purchase requirement.

Sandoz CZ will import the Product to the Czech Republic (including fulfilment of all necessary regulatory requirements) and deliver the Product to up to ten designated points of receipt determined by the Institution in mutual agreement (also per email) with Sandoz CZ.

The Institution shall ensure that:

1. It provides to Sandoz CZ the name of designated points of receipt for the Product complying with relevant provisions of Act No. 378/2007 Coll. and Good Distribution Practice to which Sandoz will deliver the Product and which will be responsible for further dispensing of the Product within the Czech Republic.
2. Only a physician with a valid medical licence is entitled to administer the Product (hereinafter "Treating Physician"). The Product may only be administered in a hospital (hospital health care providers) and in alignment with an up-to-date COVID-19 treatment guidance, which has been endorsed according to all applicable laws and regulations.
3. This supply is in compliance with all applicable local laws and regulations.
4. The Product shall not be sold or marketed to or by hospitals, Treating Physicians, Patients or any other party. This Agreement is not intended to encourage the use or consumption of Product or any other product of Sandoz.
5. As the Product is of U.S. origin, its transfer must comply with US export control and sanctions laws. The Product shall not be transferred to any entity, individual, Institution or Government that is subject to a U.S. embargo or U.S. sanctions. And, further transfers of the Product for distribution shall be made only to those recipients who agree to be bound by this obligation.
6. The parties of this Agreement are aware that the Product is not registered in the Czech Republic. However, the Product is being donated subject to the needs and request of the competent authorities of the Czech Republic, where competent authority has issued a decision that import of the Product and use of such is in accordance with applicable laws.
7. The Institution shall ensure that Treating Physician and/or his/her Employing Institution shall:
  - a. Ensure that each Patient has been well informed prior to any treatment with the Product (including execution of an Informed Consent), in particular, but not limited to the fact that the Product has not been authorised for the market of the Czech Republic, in accordance with applicable local laws.
  - b. Manage personal information of each Patient in compliance with all applicable local privacy laws and regulation.

- c. Take medical responsibility for the use of the Product and treatment of the Patient to the extent of the applicable laws and regulations.
- d. Take medical responsibility for the appropriate monitoring and follow-up of the Patient to the extent of the applicable laws and regulations.
- e. Not use the Product for any purpose other than stated herein.
- f. Not make the Product available to any third party other than hospital health care providers without Sandoz AG's prior written approval.
- g. If applicable, obtain all relevant authorization from local health authorities and from the local ethics committees as per applicable local laws and regulations.

#### Safety reporting requirements

The State Institute for Drug Control (SUKL) shall to the extent of applicable laws and regulations provide to Sandoz any relevant information, which will be submitted by the Treating Physicians about the safety of the Product, including, but not limited to (a) any Serious Adverse Events, and (b) any additional safety reports.

Such safety reporting shall be made to the Sandoz Local Patient Safety Department (email: farmakovigilance.cz@novartis.com, fax number(s): +420 225 775 445).

#### Limitation of liability

The Treating Physician and his/her Employing Institution (hereinafter "Employing Institution) and/or the Czech Republic shall be responsible to the extent of the applicable laws and regulations for any liability to the extent arising out of (1) the administration of the Product (except for damages resulting from physical or manufacturing Product defects, Sandoz' failure to manufacture the Product in accordance with the applicable GMP requirements and/or Sandoz' failure to comply with applicable handling and shipment regulations); (2) a material breach of this AGREEMENT; and/or (3) any negligent act or omission, including without limitation, failure to comply with applicable laws or regulations.

Except as expressly stated herein, no representation, condition or warranty whatsoever is made or given by or on behalf of Sandoz and its affiliates.

#### Intellectual Property

Neither the Institution nor the Treating Physician nor his/her Employing Institution hereby acquire, or shall acquire the right to file, file, or cause a third party to file (1) any patent application on any invention that relates to the Product and resulting from the Institution's or the Treating Physician's use and/or his/her employee's or agent's use of the Product, and/or (2) any patent application containing or based upon any information provided by or on behalf of Sandoz or any of its affiliate, as a result of the Institution's or the Treating Physician's use and/or his/her employee's or agent's use of the Product or provided information pursuant to this AGREEMENT. The Institution, Treating Physician and his/her Employing Institution hereby do not, and shall not acquire any rights of any kind in the Product or any use thereof, as a result of the Treating Physician's use and/or his/her employee's or agent's use of the Product pursuant to the Institution's or the Treating Physician's request for the Product, except for the rights expressly granted herein. The Institution, Treating Physician and his/her Employing Institution and Sandoz and its affiliates hereby do not transfer or otherwise grant any licenses or rights to the other to any inventions, patent applications, patents, trademark applications, trademarks, copyright applications, copyrights, or data or any other proprietary rights, except as expressly set forth herein.

To the extent of the applicable laws or regulations Sandoz shall have access to the data and work products relating to the Institution's use of the Product. Sandoz shall comply with applicable privacy laws and regulations if it is given access to personal information or personal health information.

Sandoz and its affiliates are hereby granted the right to use all data resulting from the Institution's use of the Product for all purposes, including for submission to regulatory agencies, filing and prosecuting patent applications worldwide, marketing and/or sales of any therapeutic agent (including the Product) or formulation. For the use of data or work products relating to use of the Product resulting from the activities of other subjects Sandoz will enter into separate agreements with the proper subject.

#### Confidentiality

All information provided to the Institution and the Treating Physician or his/her Employing Institution by Sandoz or its affiliates and/or any information developed by the Treating Physician or Employing Institution, alone or together with other persons, in connection with this AGREEMENT (collectively "Information") is regulated by the applicable laws, and where applicable shall be held strictly confidential. The Institution and the Treating Physician or his/her Employing Institution, as applicable, shall not disclose (orally or in writing) any Information to any third party, unless such information developed by the Institution or the Treating Physician or his/her

Employing Institution is published pursuant to the process required in this AGREEMENT, or needs to be disclosed by law or court order. The Institution shall ensure the Treating Physician or his/her Employing Institution as applicable shall not use the Product or any Information provided by Sandoz or its affiliates for any purpose except for the purpose described herein. This obligation of non-disclosure and non-use shall not apply to: (1) Information available to the public through no breach of this AGREEMENT by the Institution and the Treating Physician or his/her Employing Institution; (2) Information already known to the Treating Physician or his/her Employing Institution as shown by their written records; or (3) Information disclosed to the Institution and the Treating Physician or his/her Employing Institution by a third party who is not bound to obligations of confidentiality or non-use to Sandoz or its affiliates (4) Information disclosed by the Institution and the Treating Physician or his/her Employing Institution under the applicable laws or regulations. To the extent the Institution and the Treating Physician or his/her Employing Institution, as applicable are required by law or court order to disclose any Information, the Institution or the Employing Institution as applicable shall give Sandoz written notice of such requirement sufficiently prior to disclosure to permit Sandoz to seek a protective order or other remedy, and the Institution and the Treating Physician or his/her Employing Institution shall disclose only that portion of Information that the Treating Physician or his/her Employing Institution are legally required to disclose.

#### Publication

Institution hereby notifies Sandoz, that this AGREEMENT shall be published according to the Czech legislation, Act No. 340/2015 Col., in the Registry of Contracts.

The Institution and/or the Treating Physician and/or his/her Employing Institution may publish the data (incl. their analysis and interpretation), which are arising from their use of the Product. In case of such publication, the Institution will provide to Sandoz the manuscript and aggregated data from the use of the Product in their respective population if it was made available to Institution.

Sandoz may publish summary data and/or analysis, using only anonymized and aggregated data.

#### Term and termination

This AGREEMENT shall become effective as of signing of the AGREEMENT and shall continue to be effective until either the last Patient is treated pursuant to the Institution's request, or until the last Patient no longer meet(s) established eligibility criteria for the Product administration or the Product has been fully administered, at which time it shall expire. Nothing in this AGREEMENT shall obligate Sandoz to supply the Product or continue to supply Product.

Within thirty (30) days following termination or expiration of this AGREEMENT, Sandoz CZ will provide the Institution with relevant instructions on the management of unused Product.

Provisions in this AGREEMENT, which by their nature are intended to survive the termination or expiration, shall survive.

#### Applicable Law

This AGREEMENT shall be governed, construed, and interpreted pursuant to and in accordance with the laws of the Czech Republic, except for provisions governing compliance with U.S. export control and sanctions laws which shall be governed by the laws of the United States. Any dispute arising from or in connection with this AGREEMENT shall be resolved under the jurisdiction of the courts of the Czech Republic.

This AGREEMENT constitutes a donation agreement according to Section 20/8 of the Act No. 586/1992 Coll., on Income Tax.

#### Severability

Except for provisions governing compliance with U.S. export control and sanctions laws, in the event any provision of this AGREEMENT is held to be illegal, invalid or unenforceable, such provision shall be limited or eliminated to the minimum extent necessary so that this AGREEMENT otherwise remains in full force and effect.

#### Modification and Waiver

No waiver or modification of this AGREEMENT shall be binding upon either party unless made in writing and signed by the parties, and no failure or delay in enforcing any right shall be deemed a waiver.

#### Counterparts and Signature

This AGREEMENT may be executed in three counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

Electronic signature: The Parties agree that this Agreement as well as any Amendments or ancillary documents thereto may be drafted in electronic form and signed with an electronic signature (e. g. simple electronic signature within the DocuSign tool or more advanced electronic signature standard). "Electronic signature" shall mean data in electronic form which is attached to or logically associated with other data in electronic form and which is used by the signatory to sign. Such electronic signature shall be deemed an original signature of the signatory and a document signed in such a way shall be deemed legally valid, binding and enforceable for all Parties. Furthermore, the Parties agree that any electronically signed document (including this Agreement) shall be deemed (i) to fulfil the condition "written" or "in writing," (ii) to have been duly signed and (iii) to constitute a record established and maintained in the ordinary course of business. Electronic copies of such electronically signed documents, if introduced as evidence in any judicial, arbitral, mediation or administrative proceeding, will be admissible as between the parties to the same extent and under the same conditions as other original business records created and maintained in printed form.

#### Notices

Any notice required or authorized to be served hereunder shall be deemed to have been properly served if delivered by hand, or sent by registered or certified mail, or sent by facsimile transmission or electronic mail confirmed by registered or certified mail, to the party to be served at the address specified by such party for that purpose, or, if no such address is specified, at the address given at the head of this AGREEMENT. Notices sent by post shall be deemed to have been delivered within fourteen days after the date of posting. Notices sent by facsimile or electronic mail shall be deemed to have been delivered within 24 hours of the time of transmission.

Sandoz AG

Signature: \_\_\_\_\_

Name: Georg Rieder

Title: CFAO 30-Apr-20 | 6:52:16 PM GMT

Date: \_\_\_\_\_

Sandoz s.r.o.

Signature: \_\_\_\_\_

Name: Jiří Hanzlík

Title: Executive Director 01-V-20 | 7:13:03 dop. GMT

Date: \_\_\_\_\_

**Česká republika** - Ministerstvo  
zdravotnictví

Signature: \_\_\_\_\_

Name: Roman Prymula

Title: Deputy Minister 04-V-20 | 3:45:13 dop. EDT

Date: \_\_\_\_\_