Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits (PIP Framework)

Influenza Antiviral Donation Agreement under PIP Framework Section 6.8 ("Agreement")

Article 1. Parties to the Agreement

F. Hoffman-LaRoche Ltd (hereinafter the "Company")
Grenzacherstrasse 124,
4070 Basel,
Switzerland

and

The World Health Organization (hereinafter "WHO")
20 avenue Appia
1211 Geneva 27
Switzerland

hereinafter together the "Parties" and each a "Party"

Article 2. Subject Matter of the Agreement

2.1 The PIP Framework was adopted by the World Health Assembly on 24 May 2011, and its key goals are to improve and strengthen the sharing of influenza viruses with human pandemic potential, and to increase the access of developing countries to pandemic products such as vaccines, diagnostic tests and antivirals. Section 6.8 of the PIP Framework directs the Director-General of WHO to seek commitments from pharmaceutical manufacturers to secure influenza antiviral medicines for use in the containment of outbreaks of H5N1 and other influenza viruses with human potential.

2.2 Through this Agreement, the Company agrees to donate to WHO influenza antiviral Treatment Courses (as defined in the Term Sheet) from the Company for distribution to countries in need during the next influenza pandemic, subject to the pre-conditions, time frames and quantities specified herein. The donation of influenza antiviral Treatment Courses by the Company to WHO includes the maintenance by the Company of a global emergency response stockpile of influenza antiviral Treatment Courses to enable immediate access to some in connection with the emergence of a virus with human pandemic potential.

Article 3. Definitions

3.1 Terms defined in Section 4 of the PIP Framework have the same meaning when used in the context of this Agreement.
3.2 "**Term Sheet**" mean the terms and conditions describing the rights and obligations of each Party with regard to the Commitment (as defined below).

**Article 4. Commitments of WHO**

WHO agrees to provide the influenza antiviral Treatment Courses supplied pursuant to this Agreement to countries in need, as determined by WHO and will provide them to those countries on a donation basis, to treat the civilian population in those countries. WHO agrees not to provide the Medicine to active members of the military or armed forces as specifically designated or intended end-users in any country.

**Article 5. Commitments of the Company**

5.1 The Company agrees to comply with the commitment below (the "**Commitment**"), in accordance with the terms set out hereunder and in the Term Sheet in annex to this Agreement and forming an integral part thereof, including with respect to timetables established thereunder.

5.2 The Company commits to the following, subject to, and in accordance with, the terms of the Term Sheet:

The Company shall donate influenza antiviral Treatments Courses to WHO, in an amount not to exceed 5 million Treatment Courses in total under this Agreement, as follows:

1) For the first three months following the date of declaration of, or characterization of an event as, an influenza pandemic by WHO, the Company will provide to WHO 100,000 (one hundred thousand) influenza antiviral Treatment Courses;

2) On or about the beginning of the fourth month following declaration of, or characterization of an event as, a pandemic by WHO, the Company will provide a percentage of its Production as follows:
   (i) 8% of its Production in months 4-12 of pandemic year 1;
   (ii) 5% of its Production in pandemic year 2 (see Annex 1).

**Article 6. Term Sheet**

6.1 The Term Sheet specifies the terms for the Commitment in Article 5 above and shall form the Annex to this Agreement. The Annex shall be an integral part of this Agreement.

6.2 At the request of either Party at any time, but at a minimum every four (4) years from the signature of this Agreement, the Parties will review the provisions contained in the Term Sheet
to evaluate if modifications are necessary and the Term Sheet may be adapted by mutual agreement of the Parties as a result of such review. Any modification requested by either Party shall be discussed by the Parties in good faith and the Parties shall use best reasonable efforts to agree on such modifications within three months of starting such discussions.

6.3 In case of an imminent risk of an influenza pandemic, and at the latest upon declaration by WHO of an influenza pandemic, the Parties will review (and, if necessary, adapt) the Term Sheet with the objective of ensuring that all mechanisms are in place to enable the speedy implementation of the Commitments once an influenza pandemic is declared. The Parties will also conduct an after-action review of the Term Sheet after the end of the pandemic event.

Article 7. Dispute Resolution

7.1 If a dispute cannot be resolved after three-months from its beginning, through negotiations or other amicable, non-binding means of the Parties' choice, including conciliation, disputes shall be subject to, and finally settled under, binding arbitration on conditions that are mutually agreed by the Parties. The Parties agree that such conditions include use of the Rules of Arbitration of the International Chamber of Commerce by a panel of three arbitrators appointed in accordance with the said Rules. The seat of the arbitration shall be in Geneva, Switzerland. The arbitral proceedings shall be conducted in English.

7.2 Any matter relating to the interpretation or application of this Agreement which is not covered by its terms will be resolved by reference to the laws of Switzerland.

Article 8. Liability and Indemnity

Provisions on liability and indemnity are contained in the Term Sheet.

Article 9. Privileges and Immunity

Nothing in or relating to these clauses shall imply the obligation of WHO to submit to any national legislation or jurisdiction, or be deemed a waiver of any of the privileges and immunities of WHO in conformity with the Convention on the Privileges and Immunities of the Specialized Agencies approved by the General Assembly of the United Nations on November 21, 1947 or otherwise under any national or international law, convention or agreement.

Article 10. Name and Emblem and Provision of Information

10.1 Except as otherwise explicitly provided in this Agreement, neither Party shall, in any statement or material of an advertising or promotional nature, refer to the relationship of the Parties under this Agreement, or otherwise use the other Party's name, acronym and/or emblem,
without the prior written consent of that other Party. Notwithstanding the foregoing, the Parties shall however be free to inform the public that they have entered into this Agreement. Either Party will send the planned communication to the other Party five (5) days prior to its publication. Within that time frame, the other Party can provide feedback.

10.2 When information provided in the context of this Agreement is described by the Party providing it as confidential, the receiving Party will treat the information as strictly confidential and will only use the information for the purpose for which it was provided. The receiving Party undertakes to disclose any such confidential information only to persons who have a need to know and who are bound by like obligations of confidentiality and restrictions on use as contained herein.

10.3 However, there will be no obligation of confidentiality or restriction on use where:
   (a) the information is publicly available, or becomes publicly available, otherwise than by action of the receiving Party; or
   (b) the information was already known to the receiving Party (as evidenced by its written records) prior to its receipt; or
   (c) the information was received from a third party not in breach of an obligation of confidentiality; or
   (d) the receiving Party is required by law to disclose the information, provided that the receiving Party will immediately notify the disclosing Party in writing of such obligation and provide adequate opportunity to the disclosing Party to object to such disclosure or request of confidential treatment thereof.

Article 11. Warranties

Each Party warrants to the other Party that it has the full power to enter into this Agreement, to carry out its obligations under this Agreement and to grant the rights and benefits granted by it to the other Party under this Agreement.

Article 12. Duration of Agreement

This Agreement will become effective upon the signing by both Parties and shall remain in effect until 31 December 2026, unless terminated by either Party in accordance with Article 13 below.

Article 13. Termination

Either Party shall have the right to terminate this Agreement at any time with one hundred and eighty (180) days written notice to the other Party. If an influenza pandemic occurs during such notice period, all obligations under this Agreement will survive and termination will take effect only after both fulfilment of the obligations by the Parties under the Term Sheet and the announcement of the end of the pandemic.
Article 14. Force Majeure

No Party shall be liable for any delay in the performance of or failure to perform its obligations under this Agreement, where such delay or failure is caused by Force Majeure ("Force Majeure" is defined and further detailed in the Term Sheet).

Article 15. Miscellaneous

15.1 Any notice to be given between the Parties shall be effectively given if sent by letter, fax or similar means of communication, postage prepaid or charged to the sender and addressed to the other Party at the address shown below:

(a) If to WHO:

World Health Organization,
20 Avenue Appia
1211 Geneva 27
Switzerland

Attention: PIP Framework Secretariat, with copy to pipframework@who.int

(b) If to the Company:

F. Hoffmann-La Roche Ltd
Group Legal Department
Grenzacherstrasse 124
4070 Basel
Switzerland

Attention: Robert Ferraro

15.2 This Agreement, including any current or future Annexes, contains all the rights, obligations and terms made by the Parties in connection with the subject matter detailed herein. Any amendment of this Agreement, including any amendment of this Section 15.2, is only valid if made in writing as an amendment to this Agreement and signed by authorized signatories of the Parties.

15.3 Should any part of this Agreement, including its Annex, be or become void, ineffective or unenforceable for any reason, the validity of the remaining sections of this Agreement shall not be affected. In such a case, the ineffective section or sub-section shall be deemed as replaced by provisions achieving the purpose of this Agreement as far as possible.
Article 16. Signature and Acceptance

In WITNESS whereof, this Agreement has been duly executed by the Parties.

SIGNED for and on behalf of WHO

Signature
Name: Dr Michael J. Ryan
Title: Executive Director
WHO Health Emergencies Programme and Deputy Director-General
Date: 17 MAI 2024

SIGNED for and on behalf of F. Hoffmann-La Roche Ltd

Signature
Name: Teresa Graham
Title: CEO Roche Pharmaceuticals

Signature
Name: Dr. Isabel Boissonnas
Title: Legal Counsel
Date: 27 May 2024