1 November 2018

Dear Dr Balasegaram,

The World Health Organization (WHO) has collaborated closely on the establishment of the Global Antibiotics Research & Development Partnership (GARDP) over the past years and is a co-founder of the GARDP Foundation now established under the laws of Switzerland. WHO continues to closely work and support GARDP in achieving its mission based on the WHO - GARDP Collaboration Agreement.

WHO believes that obtaining a special status on the basis of the Federal Host State Act will help GARDP in achieving its mission through discovering, developing and delivering new and improved antibacterial treatments in line with the WHO Global Action Plan for Antimicrobial Resistance. Thus, WHO strongly supports GARDP’s application to the Swiss Federal Council to be granted the status as an international organization.

Yours sincerely,

Dr Mariângela Simão
Assistant Director-General
Access to Medicines, Vaccines and Pharmaceuticals
Collaboration Agreement

between

the World Health Organization
20, Avenue Appia
1211 Geneva 27
Switzerland
(hereinafter referred to as “WHO”)
on the one side

and

GARDP Foundation
15, Chemin Louis-Dunant
1202 Geneva
Switzerland
(hereinafter referred to as “GARDP”)
on the other side

Whereas DNDi and WHO have collaborated on the establishment of the GARDP (Global Antibiotic R&D Partnership) Foundation, a foundation established under the laws of Switzerland.

Whereas GARDP is part of the implementation of the WHO Global Action Plan for Antimicrobial Resistance.

Now therefore, the parties agree to collaborate on the development of new affordable antimicrobial treatments, their appropriate use and how to make them accessible to those in need.

1. Objective
The collaboration between the parties pursues three parallel objectives:

Research and product development: collaborate on the development of new antibiotics as well as new or improved formulations and combination treatments; working with partners on rapid and (near) point-of-care diagnostics to support appropriate use and stewardship; and support innovative and paradigm-shifting approaches to the development and commercialization of new antibiotics.

Conservation and appropriate use: ensure that conservation strategies are built in the R&D process; and develop strategies to ensure appropriate use for those antibiotics developed by GARDP, taking into account use in animals and plants.
Access: collaborate on the development and testing of new incentive models enabling the delinkage of the cost of R&D from the price of the product and volume-based returns; and promote access for all in need, while promoting appropriate use.

2. **Collaboration**

2.1 The parties shall collaborate on the activities as described in the Annex attached hereto, which forms an integral part of this Agreement and any other ad-hoc projects.

2.2 The implementation of any activities undertaken by a party is subject to that party’s regulations, rules and administrative practices.

3. **Funding**

3.1 Each party hereto shall be fully responsible for the funding of its activities under this Agreement, except as otherwise expressly agreed to in this Agreement or in any sub-agreement or amendment thereto. The implementation of each activity is subject to the availability of sufficient human and financial resources.

3.2 Each party shall administer the funds handled by it in accordance with its financial regulations, rules and administrative practices. The accounts shall be subject to audit in accordance with the party’s audit rules and procedures and a copy of the report of the external auditor shall be sent to the other party, if so requested, as soon as it becomes available.

3.3 Any transfer of funds between the parties shall be made under an appropriate separate agreement, to be negotiated in good faith between the parties.

4. **Copyright**

4.1 As a general rule, the parties shall decide jointly what works/publications shall be produced under the Agreement and who shall be responsible for the preparation of such works/publications.

4.2 For joint works/publications, GARDP will hold the copyright and will grant WHO a perpetual, irrevocable royalty free, world-wide, sub-licensable licence to use, publish, copy, circulate, translate any such works/publications. Any joint works and publications will be published by GARDP under the Creative Commons Attribution-Non-commercial-Share Alike IGO licence (http://creativecommons.org/licenses/by-nc-sa/3.0/igo/legalcode). Any revision of the work shall be decided jointly.

4.3 Copyright of any work prepared by one of the parties on its own under this Agreement shall be vested in that party, who may publish the work provided that the other party has been given the opportunity to comment on the work and any references to that other party and such comments are given due consideration by the publishing party.
4.4 Both parties shall be duly acknowledged in any work resulting from activities conducted under this Agreement and the wording of such acknowledgement shall be agreed between the parties.

5. Reporting and Governance
GARDP and WHO will keep each other informed on a regular basis on progress of relevant activities. WHO will participate as an Observer in GARDP’s governance mechanisms, specifically its Board of Directors and Scientific Advisory Committee in line with the GARDP Charter and GARDP By-Laws.

6. Relationship and responsibility of the parties
6.1 Nothing in this Agreement shall be construed as creating a relationship of joint venturers, partners, employer/employee or agent. Neither party has the authority to create any obligation for the other.

6.2 Without the prior written consent of the other party, 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 use the other party’s name and emblem. Notwithstanding the foregoing, each party may refer to the relationship of the parties in any material directly related to the work conducted under this Agreement or in the framework of reporting on the activities of WHO or GARDP respectively, e.g. on the respective WHO and GARDP and DNDi websites, annual reports, reports to governing bodies and donors.

6.3 Each party shall be solely responsible for the manner in which it carries out its part of the collaborative activities under this Agreement. Thus, a party shall not be responsible for any loss, accident, damage or injury suffered or caused by the other party, or that other party’s staff or sub-contractors, in connection with, or as a result of, the collaboration under this Agreement.

7. Notices
All notices to be given under this Agreement must be in writing and sent to the address or fax number of the intended recipient set out hereinafter or to any other address or fax number which the intended recipient may designate by notice given in accordance with this Article. Any notice may be delivered personally or sent by first class pre-paid registered mail or by fax, and it will be deemed to have been served: if by hand, when delivered; if by first class registered mail, 48 hours after posting; and if by fax when despatched provided the sender’s fax machine produces automatic receipt of error free transmission to the intended recipient’s fax number.

If to WHO: World Health Organization
Attention: Peter Beyer
20, Avenue Appia
CH-1211 Geneva 27
Tel.: 41 22 791 12507
beyerp@who.int
7. **General provisions**

7.1 This Agreement comes into force upon its signature by both parties and expires after three years unless renewed.

7.2 This Agreement may be modified by mutual written consent of the parties. The Agreement may be terminated by either party with one month's notice, subject to the orderly conclusion of any ongoing activities and the settlement of any outstanding obligations.

7.3 Any dispute relating to the interpretation or application of this Agreement shall, unless amiably settled, be subject to conciliation. In the event of failure of the latter, the dispute shall be settled by arbitration. The arbitration shall be conducted in accordance with the modalities to be agreed upon by the parties or, in the absence of agreement, in accordance with the UNCITRAL Arbitration Rules. The parties shall accept the arbitral award as final.

7.4 Nothing contained herein shall be construed as a waiver of any of the privileges and immunities enjoyed by WHO under national or international law, and/or as submitting WHO to any national court jurisdiction.

Agreed and signed on behalf of the World Health Organization

[Signature]

Mariângela Simão
Assistant Director-General

Date

Agreed and signed on behalf of GARDP

[Signature]

Manica Balasegaram
Executive Director

Date 09/11/2018

Ramanan Laxminarayan
GARDP, BOARD CHAIR

DATE
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**Agreed and signed on behalf of the World Health Organization**

[Signature]

Malangela Sibila
Assistant Director-General

Date

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**Agreed and signed on behalf of GARDP**

[Signature]

Manica Balasegaram
Executive Director

09/11/2018

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[Signature]

Ramanathan Lakshmikanthan
GARDP, Board Chair

November 14, 2018

DATE
Annex: Roles and activities

**COLLABORATION BETWEEN WHO AND GARDP**

To help GARDP fulfil its mission as described in the Business Plan 2017-2023 and to implement the Global Action Plan on Antimicrobial Resistance, WHO and GARDP will closely collaborate on the following areas:

- identifying R&D priorities, including regular analyses of the pre-clinical and clinical pipeline
- developing target product profiles and R&D roadmaps
- supporting research implementation and introduction and appropriate use of new treatments involving WHO Regional and Country Offices, Ministries of Health and National Regulatory Authorities
- building networks with clinical and academic groups and experts to support research implementation and introduction and appropriate use of new treatments
- developing clinical trial protocols, including identification of trial sites and analysis
- conducting supplementary research to inform the research and development process, how to build in conservation, appropriate use and access policies, including through convening specific expert meetings
- develop appropriate use and access strategies for new products
- working through the WHO prequalification programme and WHO collaborative registration procedure to ensure early access and appropriate use in countries and target populations
- exploring alternative R&D incentive and funding models that support conservation of and access to new antibiotics
- lending mutual support to expanding the GARDP donor base and to make it a truly global partnership
- coordinating advocacy positions
- providing any other mutually agreed support

The collaboration will be led by the WHO Department of Essential Medicines and Health Products with close involvement of the WHO AMR Secretariat, the Department of Maternal, Newborn, Child and Adolescent Health, the Department of Reproductive Health and Research, UNDP/UNFPA/UNICEF/WHO/WB Special Human Reproduction Programme – HRP, other relevant WHO Departments and Regional and Country Offices.

WHO will not get involved in negotiating collaboration agreements with other entities or pharmaceutical companies, nor will it be involved in the management of GARDP personnel or funds.