

# PROJECT COLLABORATION AGREEMENT

between

**the World Health Organization**

20, Avenue Appia

1211 Geneva 27

Switzerland

(hereinafter referred to as “WHO”)

on the one side

and

**Drugs for Neglected Diseases initiative**

15, Chemin Louis-Dunant

1202 Geneva

Switzerland

(hereinafter referred to as “DNDi”)

on the other side

## 1. The Project

1.1 The parties agree to collaborate on the incubation of an initiative called “Global Partnership for Antibiotic Research and Development” (“Partnership”). The aim of the initiative is to develop new antibiotic treatments, promoting responsible use of antibiotics and ensuring their access for all. The Partnership incubation is a joint WHO/DNDi project, incubated within DNDi and contributing to achieving some of the objectives set in the WHO Global Action Plan for Antimicrobial Resistance (hereinafter referred to as the “Project”).

1.2 The objective of the Partnership incubation is to ultimately create the conditions for the establishment of a legal entity that would be independent from WHO and DNDi. This Agreement covers the incubation phase. The arrangements under this Agreement do not pre-empt any aspects of the set-up of the new legal entity, its objectives, activities and its governance structure.

1.3 The parties shall collaborate on the Project as described in the Annex attached hereto, which forms an integral part of this Agreement. The activities to be carried out by each party under the Project are also described in the Annex.

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

## **2. Funding**

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

2.2 Any fund-raising for the Project will be directed primarily to governments, non-profit organizations and foundations. Any fund-raising from commercial entities or their foundations, or organizations funded mainly from commercial sources, shall be made in accordance with the rules of both parties in order to avoid any perceived conflict of interest.

2.3 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.

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

## **3. Copyright**

3.1 As a general rule, the parties shall decide jointly what works/publications are to be prepared under the Project and who shall be responsible for the preparation of such works/publications.

3.2 For joint works/publications, DNDi will hold the copyright and WHO will grant DNDi a licence to use, publish, copy, circulate, modify, translate any WHO contribution. Any joint works and publications will be published by DNDi 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.

3.3 Copyright of any work prepared by one of the parties on its own under this Project 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 before publication, which comments shall be given due consideration by the publishing party.

3.4 Both parties shall be duly acknowledged in any work resulting from the Project and the wording of such acknowledgement shall be agreed between the parties. In general, the project should be referred to as a *“joint WHO/DNDi initiative, incubated by DNDi in line with the Global Action Plan for Antimicrobial Resistance.”*

#### **4. Reporting**

DNDi and WHO will keep each other informed on a regular basis on progress in the implementation of the Project.

#### **5. Relationship and responsibility of the parties**

5.1 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.

5.2 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 and the Project in any material directly related to the Project or in the framework of reporting on the activities of WHO or DNDi respectively, e.g. on the respective WHO and DNDi websites, annual reports, reports to governing bodies and donors.

5.3 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 Project.

#### **6. 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

If to DNDi: Drugs for Neglected Diseases *initiative*  
Attention: Jean-Pierre Paccaud  
15, chemin Louis-Dunant  
CH-1202 Geneva  
Tel: +41 22 906 92 66  
jppaccaud@dndi.org

**7. General provisions**

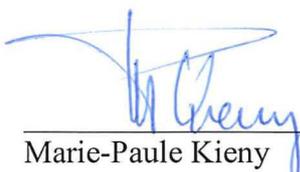
7.1 This Agreement comes into force upon its signature by both parties and expires with the end of the incubation phase after two years.

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 amicably 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

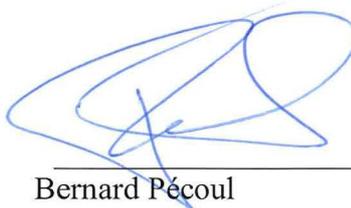


Marie-Paule Kieny  
Assistant Director-General

Date

6/7/2016

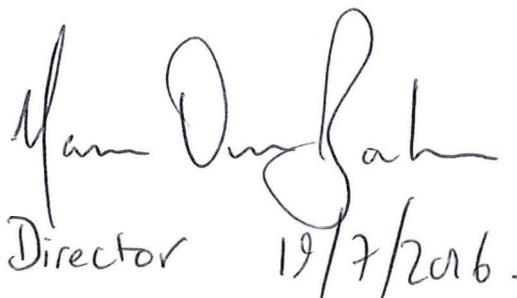
Agreed and signed on behalf of DNDi



Bernard Pécoul  
Executive Director

Date

18/7/2016



Director 19/7/2016.

## **Annex: Project Description**

### **INCUBATION PHASE OF THE GLOBAL PARTNERSHIP FOR ANTIBIOTIC RESEARCH AND DEVELOPMENT**

The parties will create the conditions for the establishment of a legal entity that will be known as the Global Partnership for Antibiotic Research and Development as outlined below. The Project, as described in this document, covers the start-up phase (or incubation phase) of the Partnership.

#### **OUTLINE**

There is general agreement that no single measure will solve the lack of R&D for new antibiotics. A partnership model for product development based on the experience with neglected diseases is an important element of the overall strategy. Such a partnership can test alternative incentives that also contribute to conservation of and access to new antibiotics such as milestone prizes, buy-outs, and staggered end-stage prizes/payments. By doing so, a product development partnership will provide an important alternative to the traditional profit-oriented pharmaceutical approach.

#### **VISION**

In cooperation with the public and private sectors, develop new antibiotic treatments addressing antimicrobial resistance and promote their responsible use for optimal conservation while ensuring equitable access for all by setting up an international public-private partnership that will focus on global health needs.

#### **THREE-PRONGED APPROACH**

The Partnership will pursue three parallel objectives:

- 1. Research and product development:**
  - 1.1. develop improved formulations or combinations that may prolong the life of existing antibiotics through short-term product development projects;
  - 1.2. work with partners on rapid and (near) point-of-care diagnostics; and
  - 1.3. support innovative and paradigm-shifting approaches to the development of new antibiotics.
- 2. Conservation:**
  - 2.1. directly build in conservation strategies in the R&D process; and
  - 2.2. propose conservation strategies for antibiotic treatments, taking into account issues related to animal husbandry.
- 3. Access:**
  - 3.1. implement and test new incentive models enabling the de-linkage of the cost of R&D from the price of the product; and
  - 3.2. promote access for all in need, while minimizing unnecessary and non-rational use.

## **GUIDING PRINCIPLES**

1. The Partnership work of the will be based on the following principles:
2. New antibiotics have to be affordable and should be subject to a global conservation agenda.
3. There is a need for a global mechanism to finance and conserve new antibiotics. Public investment into development of new antibiotics should come with appropriate obligations to governments, regulators, producers, and distributors with respect to the marketing and responsible use of these new products to avoid the rapid build-up of drug resistance.
4. Sustainable investment should be coordinated at country and international level to avoid dispersion of resources.
5. R&D should focus on the most significant drug-resistant bacterial infections to answer global priority public health needs.
6. Science shall be the sole driver and determine the fate of supported projects to promote highly innovative approaches.
7. The governance model shall ensure appropriate representation of all relevant stakeholders and preserve the necessary independence of the Partnership.

## **THE ROLE OF DNDI**

On 1 December 2015, the DNDi Board of Directors agreed to facilitate the set up and hosting of the Partnership for the start-up phase (initial two years) and to provide the scientific environment and infrastructure to ensure an effective incubation period. DNDi will host, for the incubation period, the Project's personnel and provide necessary infrastructure to set up activities rapidly. An initial start-up team will be constituted at DNDi, reporting through the Executive director of DNDi to the DNDi Board of Directors, as well as to the countries and institutions accepting to finance or otherwise support the start-up phase and that will form the Steering Committee. DNDi will thus manage the Partnership's incubation, including management of financial and human resources, setting up the R&D portfolio and collaboration with external partners, including industry.

## **THE ROLE OF WHO**

WHO will provide input on issues around stewardship and R&D priorities and provide technical input where needed, including on the identification of global health needs, financing strategies, target product profiles, identification of R&D portfolio, governance structure of the future entity and conservation strategies. It will support the incubation through outreach to its Member States and other stakeholders. WHO will not get involved in the actual research and development, e.g. negotiating collaboration agreements with other entities or pharmaceutical companies, the management of personnel or management of funds. WHO will designate a focal point to act as the liaison for this collaboration. WHO will also be represented on the Project Steering Committee. Under the GAP-AMR, WHO will develop options for a global framework for development and stewardship of new antibiotic treatments in line with Resolution WHA68.7. As part of the implementation of the GAP-AMR, WHO – subject to funding – will report on the R&D pipeline and current R&D initiatives in the area of antibiotics. The data will feed into the WHO Global Observatory on Health R&D.

## **WORK STREAMS AND DELIVERABLES**

During the start-up phase of two years, the initial team hosted by DNDi is going to focus on the priority work streams listed below.

### **WORKSTREAM 1. SCIENTIFIC**

- 1.1 Identify short-, medium-, and long-term projects (see examples below) to develop antibiotic treatments that industry or others will not undertake due to high risks of failure or lack of commercial incentive, taking into account the need for appropriate diagnostic approaches.
- 1.2 Identify global priority needs and develop priority target product profiles (TPPs), taking into account work already done. TPPs will prioritize infections threatening large populations worldwide, assure suitability in resource-limited settings and attempt to anticipate AMR evolution.
- 1.3 Constitute a working group of experts in basic and applied microbiology, clinical microbiology, antibiotic development, patient care, diagnostics, and public health to provide advice.

### **WORKSTREAM 2. BUSINESS DEVELOPMENT**

- 2.1 Secure initial partnerships with start-ups, universities, research agencies, biotechnology and pharmaceutical companies, and contract research organizations to initiate collaboration on specific projects.
- 2.2 Connect and coordinate activities with existing scientific and business networks and advocacy groups to ensure complementarity and identify synergies.
- 2.3 Explore alternative incentive models that support conservation of and access to new antibiotics.
- 2.4 Identify and establish the appropriate legal form of the Partnership.
- 2.5 Develop strategies to build conservation into the R&D of new products.
- 2.6 Develop an access-driven intellectual property policy.
- 2.7 Establish a full business plan for the Partnership.

### **WORKSTREAM 3. ADVOCACY AND FINANCING**

- 3.1 Engage in advocacy to support conservation, responsible use, new R&D models, and incentives.
- 3.2 Engage with all possible donors and investors, and develop and test innovative financing mechanisms to secure financial support.
- 3.3 Define the financial needs to support the initial product portfolio and related activities and the longer term financial needs (business plan).

### **WORKSTREAM 4. GOVERNANCE STRUCTURE**

- 4.1 Develop a governance model that prioritizes a global health approach, represents patients' needs, obtains the support of governments, and ensures independence.
- 4.2 Identify potential individuals or entities, as appropriate, for the Board of Directors and Scientific Advisory Board.