INVESTING IN THE DEVELOPMENT OF NEW ANTIBIOTICS AND THEIR CONSERVATION:  
A PROPOSAL FOR A GLOBAL ANTIBIOTIC RESEARCH AND DEVELOPMENT FACILITY

TECHNICAL CONSULTATION JOINTLY HOSTED BY THE
WORLD HEALTH ORGANIZATION AND THE DRUGS FOR NEGLECTED DISEASES INITIATIVE

GENEVA, SWITZERLAND
13 NOVEMBER 2015

REPORT

Introduction

The Sixty-eighth World Health Assembly in 2015 adopted a Global Action Plan on Antimicrobial Resistance (GAP-AMR), which requires the WHO Secretariat to propose options for the establishment of new partnerships to identify priorities for new treatments, diagnostics, and vaccines to fight resistant pathogens; to act as the vehicle for securing and managing investment in new medicines, diagnostics, vaccines and other interventions; to establish open collaborative models of research and development facilitating access to the outcomes of such research; and to provide incentives for investment (WHA68.7). As part of the implementation of this mandate, WHO and the Drugs for Neglected Diseases initiative (DNDi) jointly organized a one-day technical consultation on 13 November 2015 in Geneva. This consultation built on an earlier meeting hosted by WHO on 13 May 2014 that discussed innovative models to foster discovery and development of new antibiotics to address antimicrobial resistance. It also follows an 8 - 9 December 2014 meeting co-hosted by WHO and DNDi to explore the need for a product development partnership to promote innovation and responsible use and access to new antibiotics.¹

The technical consultation aimed at obtaining specific feedback on the proposal for the set-up of a Global Antibiotic R&D Facility, referred to hereafter as the ‘Partnership’. Feedback was sought on key issues, including complementarity of the proposed Partnership, the role of WHO, and the scientific strategy for short- and long-term R&D projects. Ultimately, the meeting aimed to determine the level of country and stakeholder support for the proposal. Attendance included over 70 representatives from 22 countries and key stakeholder groups from civil society, academia, and industry. The agenda of the meeting, the expanded concept note, a list of participants, and all presentations that were delivered during the meeting are available on the WHO website.²

¹ For further information on these meetings see: http://www.who.int/phi/implementation/consultation_inn nadp/en/
² Ibid.
Summary of the discussions

The discussions focused on the following main issues:

1. **The respective roles of WHO and DNDi** – Participants raised the question about the division of work between DNDi, the Partnership, and WHO, expressing the need for a clear division of roles. WHO explained that the GAP-AMR requests the WHO Secretariat to explore the possibility of setting up new partnership(s) to foster R&D of new antibiotics. WHO will facilitate the creation of the new product development partnership, but will not have an operational role. While WHO will not be part of the governance, it could serve as observer. WHO will provide technical input where necessary (for example, into the development of the Partnership’s target product profiles). WHO will also lead the establishment of a global framework for development and stewardship as requested in WHA68.7. This will not be part of the mandate of the Partnership although it is a vital element for its future work. As requested by the GAP-AMR, WHO is also planning to track the antibiotic development pipeline and ensure that this activity will feed into the WHO Global Health R&D Observatory. Subject to an agreement by its Board, DNDi will incubate the Partnership by lending its facilities and infrastructure until the project is viable on its own and will become its own legal entity.

2. **Complementarity and focus of the Partnership** – One of the main subjects of discussion was the relationship of the Partnership to existing and planned initiatives in the area of research and development in the field of AMR. Participants pointed out that there is a need to clearly define the role of the Partnership in developing antimicrobial treatments that industry and other players are not developing. Participants saw a strong added value and competitive advantage if the Partnership focuses on short- and medium-term goals targeting antibiotic treatments (for example, combinations or reformulations of existing antibiotics) and on specific long-term projects that other actors are not taking up (for example, high risk technological approaches or candidates for unaddressed TPPs). The focus should be on global health needs, ensuring that products are suited for resource-limited settings. While conservation aspects should be embedded in the design of the projects, the development of a global framework for development and stewardship will be dealt with by WHO outside the Partnership. Participants emphasized the need for collaboration among the different actors in the AMR R&D field and pointed out that the Partnership should avoid duplicating efforts (for example, by the use of existing networks) instead of creating parallel networks. It was also clarified that the Partnership will not be a funder of R&D, but rather an implementer.

3. **Other important issues raised included the need to:**
   - ensure that data produced will feed into the WHO Global Observatory on Health R&D;
   - develop an appropriate governance structure;
   - include actors from all countries;
   - develop target product profiles;
   - link the development of new treatments to a global conservation framework;
   - work closely with partners on developing new diagnostics that will allow for more focused use of antibiotics; and
   - develop an access-oriented intellectual property policy.
Main conclusions

Participants welcomed the Partnership initiative and saw a strong added value in a product development partnership focusing on the development of new antibiotic treatments. Such a partnership would have to ensure its complementarity to existing initiatives and focus on treatments that other actors will not develop. The proposed Partnership should:

- work with partners in both developing and developed countries;
- focus on product development;
- play a complementary role to other initiatives by exploring the potential of different partners such as the Joint Programming Initiative on Antimicrobial Resistance (JPIAMR), Biomedical Advanced Research and Development Authority (BARDA), and the Innovative Medicines Initiative (IMI);
- ensure complementarity and collaboration with pharmaceutical companies, including generic and biotechnology companies;
- collaborate closely with diagnostic developers;
- define specific targets and specific target product profiles;
- rapidly define and launch short- and mid-term projects, but continue to explore long-term gaps and projects that are too risky for pharmaceutical partners and investors;
- collaborate with WHO on questions concerning conservation and ensure that projects undertaken by the Partnership pilot developing conservation approaches; and
- develop an appropriate governance model.

Next steps

- The expanded concept note will be reviewed to reflect the input received during the discussions and will be posted on the WHO website.
- The DNDi Board will discuss the proposal on 1 December 2015 and render a decision.
- Seed funding will need to be raised from donors in the next three months.
- A small core team will be constituted.
- A working group will be set up.
- As soon as the seed money is available, the implementation phase will start.
- A full business plan will be developed during 2016.