FOSTERING THE DEVELOPMENT AND RATIONAL USE OF NEW ANTIBIOTICS:
HOW A PRODUCT DEVELOPMENT PARTNERSHIP COULD PROMOTE INNOVATION AND RESPONSIBLE ACCESS TO NEW ANTIBIOTICS

Technical Consultation jointly hosted by WHO and DNDi

Geneva, 8-9 December 2014

MEETING REPORT
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INTRODUCTION

The World Health Organization (WHO) and the Drugs for Neglected Diseases initiative (DNDi) jointly organized a two-day technical consultation on 8–9 December 2014 in Geneva. The objective of the meeting was to explore the potential need for a product development partnership (PDP) to promote innovation and responsible access to new antibiotics.

The first day was divided into two sessions. The first, “Framing the challenge”, allowed participants to discuss the current research and development (R&D) landscape in relation to antibiotics and antibiotic resistance. The second session, “Aspirations in needs driven innovation: past, present and future”, moved the discussion forward, with DNDi and WHO presenting lessons learned and a potential framework as a basis to kick-start further conversation. The participants also discussed issues of financing. On the second day, the group further discussed possible models and next steps.

All presentations as well as the agenda can be found on the WHO website.¹

SUMMARY OF DISCUSSIONS

The meeting began with introductory remarks from Marie-Paule Kieny, Assistant Director-General, Health Systems and Innovation, WHO, and Bernard Pécoul, Executive Director, DNDi, followed by a round of introductions from participants around the table.

SESSION 1: FRAMING THE CHALLENGE

CHAIR: MANICA BALASEGARAM, MÉDECINS SANS FRONTIÈRES (MSF) ACCESS CAMPAIGN

The session began with a presentation by Anthony So, Director, Program on Global Health and Technology Access, Duke University, on the current antibiotics research landscape – including R&D pipelines, funders and funding, prizes, research institutions, private companies, current role of PDPs, global markets, scientific variables, and issues of stewardship and accountability.

Following Anthony So’s presentation, the group discussed the importance of understanding and effectively leveraging the current political, scientific and funding landscape for antibiotics and antibiotic resistance. Some members added more information to the basic landscaping presented. An effective model should incentivize R&D upstream while ensuring responsible access and rational use downstream, and the participants discussed potential characteristics of a mechanism or PDP that would be effective on both fronts. The participants also discussed sustainable financing and coordination and pooling of incentives, as well as how the issue of antibiotic resistance fits into the larger global policy picture and the political dimensions of the global discussion. Participants pointed out that, unlike the area of neglected diseases, there are very few “low hanging fruits” in the area of antibiotics. Over the past decade, industry has largely failed to discover new classes of antibiotics, and as a result efforts in this area cannot be limited to the screening of existing compound libraries. It was also pointed out that, apart from the discovery of novel classes of antibiotics, products such as paediatric versions of many existing antibiotics are still missing. The latter could potentially be picked up by a publicly financed research mechanism.

¹ All meeting-related documents available online at: http://www.who.int/phi/implementation/consultation_imnadp/en/ (last visited 20 January 2015).
SESSION 2: ASPIRATIONS IN NEEDS DRIVEN INNOVATION: PAST, PRESENT AND FUTURE
CHAIR: ZAFAR MIRZA, WHO

Marie-Paule Kieny began the session with an introduction to the principles and objectives underlying the WHO Global Action Plan on antimicrobial resistance (AMR-GAP) as well as an overview of key areas that need to be addressed. These included the use of medicines (factors such as variability in consumption between countries, lack of information systems, self-medication, underuse and overuse), quality of antibiotics, and R&D. She presented the outline for a potential model for R&D financing and how such a model could function in the current environment, including options on how to manage the intellectual property involved, how to take products from the innovation stage through to development and registration, and how to ensure rational use through a managed market.

Bernard Pécoul presented DNDi’s perspective on how a PDP could promote innovation and rational use of new antibiotics. He drew upon DNDi’s experience functioning as a PDP in the sphere of neglected disease to highlight the lessons learned from the changes in the global public health R&D and access landscape over the last 10-15 years. He identified fundamental challenges, including prioritizing R&D and patients’ needs in relation to low and middle income countries, linking scientific innovation with equitable access, and addressing gaps where market incentives aligned with intellectual property are insufficient to address health needs. The presentation also touched upon how DNDi could potentially serve as an “incubator” for a new research mechanism on antibiotics.

Following a brief discussion, John-Arne Røttingen, Director, Division of Infectious Disease Control, Norwegian Institute of Public Health, presented an overview of potential sources of financing for a PDP or other such mechanism for innovation and promotion of rational use of antibiotics. He identified the failures of global governance and markets and outlined policy options of varying levels of difficulty and commitment. He then presented the tools available: country contributions, international taxation, innovative financing, investments, payments, and philanthropy. This was followed by a detailed analysis of the ways in which countries could innovatively finance such a mechanism and the recommendations of the Report of the Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG)2 in this area.

The group then discussed the type of mechanism required and whether a PDP would address both the upstream and downstream dimensions of the problem. It was agreed that it was important to draw upon lessons learned from current PDPs, but that the nature of the antibiotics challenge required an updated, innovative model different from the classic PDPs for neglected diseases. While recognizing the complexity of the problem as laid out in the WHO AMR-GAP and the wide variety of actions that will be required for sustainable solutions at the global level, the group felt that the concept of a publicly financed research initiative would fit in the current political landscape. The consensus was that any initiative should be sufficiently ambitious while remaining practical and incremental/modular in approach. The group further discussed the feasible scope of such a mechanism, including whether to include all anti-infectives or whether to focus on antibiotics only, and other factors, such as sustainable financing and potential governance structure.

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Manica Balasegaram, MSF, and Jean-Pierre Paccaud, DNDi, presented a concept for a virtual model with staggered modular implementation based on the concept note. It was pointed out that a virtual model would offer benefits in terms of flexibility, lower overheads and decreased levels of immobilized capital as well as facilitating collaborations with external actors. While the European Organisation for Nuclear Research (CERN) was mentioned as a potential model, it was noted that for financing research into antibiotics huge infrastructure is not required. The group debated the business model (not-for-profit as against for-profit models), the benefits of a modular versus integrated approach, as well as the three suggested modules:

Module 1: Upstream discovery long term and downstream projects short term
Module 2: Economic frameworks and business models
Module 3: Responsible access strategies and rational use strategies

Further discussion centered on governance structures as well as varying models for full or partial de-linkage, management of IP, and the potential coordinating role such a mechanism could play in leveraging existing initiatives, building partnerships and increasing awareness. In this context, the key role and experience of the industry was discussed with respect to the management of the development of new products, worldwide registration and marketing. Any new model will have to include industry as one of the key players in drug development. However, investment of public money would need to go hand in hand with affordable prices and rational use of any new antibiotics.

While the group recognized the need for an initiative to finance R&D into new antibiotics and diagnostics, it felt that it would be misleading to label such an initiative a “PDP” due to the inherent differences in function from the PDPs that currently exist in other areas. In this context, it was also noted that gaining insight on lessons learned by industry, including those companies who no longer operate in this space, is crucial.

The group discussed what added value a new initiative could bring in comparison to existing programmes such as the United States Biomedical Advanced Research and Development Authority (BARDA) and the Innovative Medicines Initiative (IMI). A number of points were made during this discussion, including that:

• any new initiative should focus on research that is driven by public health needs. For that purpose any new initiative would need to work on target product profiles established on identified needs;
• new classes of antibiotics are needed and consequently a new initiative should not only focus on translational research and clinical development, but also on basic long term research in new mechanisms of action;
• a new research initiative would have to be linked to the development of a global preservation framework to prevent rapid development of resistant strains; and
• new antibiotics would need to be accessible and affordable to all people in need.

In relation to the development of a global framework for preservation, participants pointed to a number of potential forms such a framework could take, including the establishment of a global charter for preservation as well as a WHO regulation under article 21 of the WHO Constitution.
Participants then discussed the way forward and the importance of leveraging political momentum through several key upcoming events such as the WHO Executive Board and World Health Assembly, as well as the G7 and G20 summits. It was pointed out that it is important to include countries from all regions and all income levels since preservation needs to be addressed on a global level. Participants also noted that any initiative should be presented as addressing AMR not only as a health problem, but also as a threat to global health security and economic development. Participants also highlighted the need for WHO to take a leading role in this field.

**AGREED NEXT STEPS**

- Revise draft concept note based on discussions
- DNDi and WHO to explore avenues for seed funding
- Organize outreach at WHO Executive Board, G7, G20 and other Member States to engage policymakers
- Interested Member States to explore a possible side-event at WHA
- Coordinate with WHO AMR-GAP efforts

Continue to work with the group, including participants who could not join the meeting; consider re-convening the group in 2015 to discuss the concept further.