Investing in the Development & Conservation of New Antibiotic Treatments
Global Antibiotic Research & Development Facility

Vision and Strategy
In cooperation with the public and private sectors:

• develop new antibiotic treatments addressing AMR
• promote their responsible use for optimal conservation
• while ensuring equitable access for all

by setting up a not-for-profit product development partnership that will focus on global health needs, while ensuring any new product is adapted to resource-limited settings.
The context

- Lack of sufficient *investment and incentives* for the development of antibiotic treatments
- WHA GAP requests WHO Secretariat to work on the creation of *new partnership(s) to address R&D gap*
- Many initiatives have been launched, but overall remain insufficient: *complementarity is key*
- Market-driven approaches are not structured to address *responsible use* and some of the unmet needs
The Role of WHO

• Take part in the set-up of the new partnership
• Report on the antibiotic pipeline to feed into the Global Health R&D Observatory
• Provide input on priority setting, target product profiles and overall direction
• Facilitate coordination with other initiatives, e.g. G7 global network meeting of researchers and experts in 2016/17
• Develop and pilot conservation approaches
• Develop options for a global framework for development and conservation (WHA68.7)
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<tbody>
<tr>
<td><strong>Task</strong></td>
<td>Developer</td>
<td>Funder</td>
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<tr>
<td><strong>Main Focus</strong></td>
<td>Product develop.</td>
<td>AMR basic research Prod. Develop.</td>
<td>Early stage research &amp; early stages of product develop.</td>
<td>Product development (market entry rewards)</td>
<td>AMR Basic &amp; preclinical research product develop.</td>
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<td><strong>Specific public health needs</strong></td>
<td>Global health needs &amp; suitability for resource poor settings</td>
<td>Based on WHO’s priority medicines report</td>
<td>Yes</td>
<td>Rewards linked with unmet global needs</td>
<td>JPI AMR Strategic Research Agenda</td>
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<td>Products submitted to conservation strategies?</td>
<td>Yes</td>
<td>No</td>
<td>--</td>
<td>Yes, rewards linked with stewardship</td>
<td>No</td>
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<td>Target product profiles?</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
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<td>Possibility to link with other initiatives?</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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Antibiotic development should be financed partly through a global funding mechanism and should experiment new models for conservation and access.

Sustainable investment should be coordinated at country and international levels.

R&D should focus on the significant bacterial infections with an emphasis on global needs.

Scientific relevance shall guide choices.

New antibiotics must be affordable for all and subject to a global conservation agenda.
Three-Pronged Approach

1. Research and Development
   - Conduct antibacterial research both with academia and the private sector, including paradigm-shifting approaches for antibiotic treatments.
   - Support rapid and (near) point-of-care diagnostics as an essential component of the product development strategy.

2. Conservation
   - Implement and test new incentive models, including de-linkage of R&D cost from price of product, to support responsible use initiatives.

3. Access
   - Promote equitable, responsible access: ensuring access to all in need, while minimizing unnecessary use.
Short-Term Goals

1. Identify needs, gaps, top priorities for development of new antibiotics/antibiotic regimes unaddressed by other actors, ensure complementarity

2. Establish partnerships with existing R&D networks

3. Launch short-term projects to deliver needed therapeutic solutions (e.g. appropriate paediatric formulations or improved regimens of existing antibiotics)

4. In doing so, immediately test existing conservation and access proposals applied to short-term projects.
Long-Term Goals

1. Build, with partners, a solid \textit{antibiotic R&D portfolio} to respond to longer-term needs to address AMR

2. Support the framework for the effective \textit{conservation} (stewardship) of antibiotics, with WHO and countries

3. \textbf{Secure funding sources} to sustain continuous pipeline replenishment and test incentive mechanisms
Deliverables and Timelines

Five-Year Plan
Years 1-2

• Set up a core team and working network of public and private partners
• Finalize a business plan and establish budget for a minimum of five years
• Engage additional founding partners and funders for long-term support

• Establish **priority target product profiles (TPPs)**
Years 1-2 continued

- Establish governance, including scientific advisory board and international network of scientific experts
- Set up a independent legal entity
- Identify short- and long-term research projects
- Initiate 1-3 short term projects, for example:
  - improved paediatric formulations (form, dosage, shelf-life)
  - new formulations of existing drugs (appropriate dosage, administration route)
  - combinations of existing drugs to address AMR
  - establish feasibility of innovative projects (e.g. adjuvants’, anti-virulence, dormancy breakers)
Years 3-5

- Continue initiated short-term projects and implement new projects
- Implement the business plan, including funding of innovative R&D proposals and of pilot conservation projects
- Secure long-term funding
- Launch long-term projects, for example:
  - combination screening platforms
  - platform for improved formulations;
  - support disruptive scientific approaches (e.g. anti-virulence)
Start-up and launch: no time to waste

Seed funding of 3+ million USD is required for:

- Within 2 years, to become an independent organization focused on providing tools to fight AMR

**START-UP PHASE**

People and Projects

- 4-6 FTEs for core team (DNDi to provide 1 FTE and infrastructure)
- Raise further funding for new projects
- Set up initial projects

2 Yrs

3-5 Yrs
What commitments are needed today?

• Financial and political support – steering role
• Contribution of expertise – working groups
• Partnerships with your ongoing initiatives – complementarity!

Thank you!