Context and objectives of the workshop on platform technologies

21 July 2016
David Wood and Virginia Benassi
Platform Technologies Consultation launched in Oct 2015

Public consultation on ideas for potential platforms to support development and production of health technologies for priority infectious diseases with epidemic potential.

The epidemic of Ebola in West Africa showed that the world is unable to develop effective interventions in a timely manner for control of severe emerging infectious diseases using current approaches to vaccine, drug and diagnostics development.

The World Health Organization (WHO) is inviting submission of structured ideas on how to improve R&D readiness for priority infectious disease threats. Specifically, propositions are requested for flexible development and production platform technologies.

Submission of platform ideas by Friday 5 February 2016, 17:00 Geneva time.

Read more...pdf, 220kb

Vaccines

- Trials progressing

Treatments

- Trials continue

Diagnostics

- Novel tests
Objectives of production platform consultation

• Ideas were requested for flexible development and production platform technologies to manufacture candidate products for evaluation in Phase 1 clinical trials before any confirmed epidemic threat

• Also to cover manufacture of candidate products for Phase 2 and 3 clinical evaluations during a potential epidemic
Scope

• Vaccines, therapeutics (drugs and blood products), and diagnostics

• Targeted against the priority pathogens defined through the R&D Blueprint process

• Only proposals that can address more than three priority pathogens were considered
Access

• Candidate products developed through this process should be **affordable for use in populations in which they are tested** and/or needed

• The priority pathogens may affect any country but options to address affordability in low and middle income countries (LMICs) needed to be included in each proposal

• The submissions should explain how IP issues will be managed to ensure fair and equitable access, especially for LMICs, to any product(s) developed through the proposed platform(s).
Public health use

• Candidate products developed through this mechanism and that are found to have a favorable benefit-risk profile should be available in sufficient quantity to enable potential use in disease control efforts.

• Therefore submissions should include strategies to assure readiness for production at an appropriate scale to contribute to epidemic control.
Response to the consultation

- By the closing date in February 2016 **35 responses** were received
- After an initial screening by WHO, **33 ideas** were determined to be in scope
- A first round of review was conducted by an ad hoc Advisory Group, informed by a 3-day **technical workshop** where the 33 ideas were presented (Geneva, April 4-6 2016)
Ad hoc Advisory Group
(SAG representative Dr Chris Wilson)

Professor Miles Carroll
National Infections Service
Public Health England, UK

Professor Stephan Günther
Bernhard-Nocht-Institute of Tropical Medicine, Germany

Doctor Karen Midthun (Chair)
Biological Drug Development,
USA

Professor Rosanna Peeling (Co-Chair)
International Diagnostics Centre, London School of Hygiene and Tropical Medicine, UK

Doctor Isao Hamaguchi
Department of Safety Research on Blood and Biological Products, Japan

Professor Helen Rees
Wits Reproductive Health and HIV Institute,
South Africa

Professor Ahmad Hersi
Cardiac Sciences Department, Faculty of Medicine King Saud University, KSA

Professor Larisa Rudenko
Department of Virology, Institute of Experimental Medicine RAMS, Russia

Professor Surinder Singh
National Institute of Biologicals, Ministry of Health and Family Affairs, India

Doctor Graeme Bilbe
Drugs for Neglected Diseases Initiative,
Switzerland

Doctor John Horton
Tropical Project, UK

Professor Junzhi Wang
Institute of Biological Product Control, National Institutes for Food and Drug Control, China
Objectives of the April workshop

• To **review and assess** the proposed ideas;
• To enable WHO to identify the promising ones for further development; and
• To **create an enabling environment** where the presenting groups could initiate bilateral and/or multilateral discussions around potential future collaboration, as appropriate.
# Round 1 outcomes

<table>
<thead>
<tr>
<th>PLATFORM TECHNOLOGIES*</th>
<th>Accepted for round 2</th>
<th>Not accepted for round 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 or more product streams</td>
<td>1</td>
<td>4</td>
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<tr>
<td>Vaccines</td>
<td>4</td>
<td>4</td>
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<tr>
<td>Monoclonal antibodies</td>
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<td>Polyclonal immunoglobulin</td>
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<td>Antivirals</td>
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<td>Diagnostics</td>
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<td>3</td>
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<tr>
<td>Enabling technologies</td>
<td>1</td>
<td>5</td>
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</tbody>
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Round 2 process and outcomes

• 30 June - **13 groups were accepted into round 2** and invited to submit more detailed proposals
• 5 July - Advisory Group met by teleconference for initial discussions
• 8 July - reviews completed and **top 6 proposals agreed**; 3 vaccines, 1 diagnostics, 1 immunotherapy, 1 covering all product streams
• Successful groups invited to **present to potential funders and interested Member States** in today's meeting
Objectives of today's workshop

• To present the most meritorious ideas emerging from the WHO Public Consultation on ideas on how to improve R&D readiness against priority infectious disease threats to interested Member States and relevant R&D funders

• To create an enabling environment for bilateral and/or multilateral discussions around potential future collaborations, or support, as appropriate
2nd Technical workshop on platform technologies
Geneva, Switzerland, 21 July 2016

thank you!