HEALTH R&D DEMONSTRATION PROJECTS – A SCOPING DOCUMENT

Executive Summary

Apart from their obvious value in terms of development of new products to address unmet health needs of developing countries, demonstration projects would be useful tools to validate key principles and approaches outlined in the CEWG report so that they are indeed demonstrating new approaches to finance and conduct R&D.

Implementation is envisaged to take place in two phases.

Goal & Background

The draft resolution prepared during the open-ended meeting of the Member States, 26-28 November 2012, in the follow-up of WHA65.22, requests the Director-General in operative paragraph 4.4:

to facilitate through regional consultations and broad engagement of relevant stakeholders the implementation of a few health R&D demonstration projects to address identified gaps that disproportionately affect developing countries, particularly the poor, and for which immediate action can be taken;

1 In order to deepen the analyses presented in the Background document prepared for the open-ended meeting of Member States in November 2012 - where the report and the feasibility of the recommendations proposed by the Consultative Expert Review Group’s report were discussed - the WHO Secretariat has developed draft Working Papers focusing on four main elements: the global observatory for health research and development (R&D); R&D coordination and prioritization; R&D financing; and options for demonstration projects. The Working Papers are drafts and will be revised based on feedback received.
In the operative paragraph 4.8 of the same draft resolution, the Director General is requested:

to report on the implementation of health R&D demonstration projects (referred to in subparagraph 4(4) above) to the Sixty-eighth World Health Assembly, through the Executive Board at its 136th session;

Understanding the request

The WHO Secretariat is requested to “facilitate”, i.e. to convene and facilitate this work through “regional consultations”.

“Broad engagement of relevant stakeholders”, i.e. inclusive engagement is also requested. There are many relevant stakeholders in the area of health R&D, including policy makers; relevant public sector organizations such as R&D institutions; academic institutions; pharmaceutical and health technology manufacturers and their associations; international organizations including United Nations agencies; not-for-profit organizations; product development partnerships; researchers; clinicians and patients.

The ultimate objective of this exercise is “implementation of a few health R&D demonstration projects to address identified gaps that disproportionately affect developing countries, particularly the poor, and for which immediate action can be taken”.

“Implementation” can be interpreted as any effort that can lead to effectively filling the gaps for the benefit of people in developing countries, especially the poor. Obviously, it is not possible to have a start-to-end product development in the short time allocated for this work in the Draft Resolution (see Timelines section below). In this context, we interpret “Implementation” as having two phases:

- **Phase 1** - on which the Director-General of WHO is requested in OP 4.8 to report to the WHA would correspond to the development, through “broad engagement of relevant stakeholders”, of a comprehensive and fully financed project plan for each of the identified demonstration projects, for which responsibilities have been mapped out to relevant actors who have accepted to own this responsibility.

- **Phase 2** – which could span several years - would correspond to the conduct of the demonstration project up to the registration and availability in developing countries of a new product adapted to their needs, or to the validation of a new approach, as appropriate.

In the time frame prescribed by the draft resolution, success with a demonstration project would correspond to the successful completion of Phase 1.

From discussions held during the November 2012 open-ended meeting, “few” is understood as more than 3 and less than 10 projects, to be determined by the World Health Assembly in 2014, should the draft resolution be endorsed as it is in May 2013.
Nature of the Demonstration projects

From discussions held in many fora on the demonstration projects, the following principles have emerged. The demonstration projects would validate key principles and approaches to support R&D. They would also feed into the development of norms and standards for health R&D which incorporate the principle of de-linkage of costs of research and price of product. In addition, the demonstration projects would try to explore the following ideas:

1) New push and pull mechanisms:
   a. Open approaches to research and development and innovation
   b. Pooled funds
   c. Direct grants to companies
   d. Milestone prizes and end prizes
   e. Patent pools
2) New forms of coordination
3) A focus on GSPA PHI priorities i.e. diseases of the poor in developing countries
4) Regional and/or global priorities
5) Capacity strengthening at country level to improve sustainability of R&D efforts including through technology transfer agreements
6) Delivery of a new health technology or strategy/policy/method within 4-5 years

The demonstration projects may be taken forward at regional or global levels, and may be managed and implemented by different actors (academia, private sector, PDPs, civil society or multinational agencies). Priority may be given to products/technologies that need a “final push” to get registered and become available.

Timelines

The draft resolution requests the Director-General to report to the Sixty-eighth World Health Assembly which will take place in May 2015 through the 136th Executive Board, to be held in January 2015. The deadline for submitting a report for consideration by the EB is November 2014. Should the draft resolution be adopted in May 2013 as currently formulated, and the shortlist of demonstration projects validated by the WHA in May 2014, 5 months is the time available to implement Phase 1 of the demonstration projects.
**ACTION PLAN**

**Exploration phase**

This phase is to explore and prepare a portfolio of possible Demonstration Projects for consideration by WHO Governing Bodies. This includes three broad types of activities:

1. Identification of relevant technical resources in terms of existing work on R&D gaps and analysis of their strengths and weaknesses. An outreach to stakeholders is being executed. The contacts include: WHO staff at regional offices and headquarters (specific disease departments); major international organizations involved in the R&D agenda (TDR; ANDI; ASEAN-NDI; PDPs; MSF; COHRED; BVGH; IFPMA etc.); Member States experts.

2. Desk analysis by the WHO Secretariat of major priority R&D gaps: This activity will build on efforts to date to map health R&D and identify gaps by different organizations. Most of these mapping exercises are limited to neglected diseases i.e. Type III and Type II diseases and there is hardly any systematic effort to map “developing countries’ specific research and development needs in relation to Type I diseases”. Some of these efforts occurred one-time and others were for a few years and only some are continuing. Moreover, according to a report released jointly by Global Health Technologies Coalition and Policy Cures in April 2012, *Saving lives and Creating Impact: Why investing in global health research works*, between 2000 and 2010, 45 new global health products were registered to tackle a wide variety of health problems and neglected diseases. According to the same report there are currently over 360 medicines, vaccines, contraceptives, insecticides, diagnostics, and microbicides in development which is “the largest pipeline ever of new global health products”. In 2012, DNDi and MSF conducted a study to reassess the state of R&D for neglected diseases in the last 12 years. According to this study, of the 756 new drugs approved between 2000 and 2011, 29 (3.8%) were indicated to be for neglected diseases. This study estimates from the current pipeline that an average of 4.7 new products each year (excluding vaccines) could be delivered for neglected diseases through 2018 – a significant improvement, if realized, compared with the 2.4 new products averaged each year for the period 2000-2011 and the 0.6% to 1.3% new products per year for 1975-1999.
For all these reasons, the WHO Secretariat will prepare a report which takes stock of the existing R&D gap analysis in view of improving the pipeline. Apart from presenting a synthesis of the existing work, such a report can add value to the existing debate in two important ways: one, by including special R&D needs of developing countries in relation to Type I diseases; and two, by proposing a framework for priority setting for R&D once the gaps have been identified.

3. Regional consultations:

PAHO/AMRO has already undertaken an R&D gap analysis and they are in the process of finalizing a report.

SEARO is holding a regional consultation from 26 to 27 July 2013 in Bangkok, Thailand to discuss various deliverables in the draft resolution from a regional perspective. Part of the discussions during this meeting would be dedicated to unmet R&D needs in the region.

AFRO organized a regional consultation from 14 to 15 May 2013, in Brazzaville, Congo. This meeting is intended to provide a unified view of the African Region Member States on financing and coordination of health R&D. Part of the discussions during this meeting will be dedicated to the identification of unmet R&D needs in the region.

Other regional offices may choose to hold formal consultations, or decide to take advantage of recent R&D prioritization exercises.

Annex I lists only a few examples of emerging potential projects for incorporation into the portfolio to be presented to the WHA in May 2014.

**WHA selection of a shortlist of projects:**

A Secretariat report will be prepared containing the portfolio of possible demonstration projects collected through the process outlined above and presented to the Sixty-seventh WHA in 2014 through 134th EB in January 2014 for discussion and final selection of a shortlist of projects for implementation.

**Demonstration projects – Phase 1**

Assuming the WHA endorses all or some of the proposed demonstration projects, Phase 1 of the implementation can begin in June 2014. Facilitation by WHO would vary from project to project. It would involve convening the potential partners, agreeing on working together, developing descriptions of their respective roles and responsibilities, estimating resource needs and approaching Member States and their donor agencies for resource mobilization.

The end-point of Phase 1 would be a Secretariat report submitted to the sixty-eighth World Health Assembly, through the 136th session of Executive Board in January 2015. The report would include the description of a comprehensive and fully financed project plan (proofs of concept) for the ideas (health technologies or approaches) that were endorsed by the Sixty-seventh World Health
Assembly. The demonstration itself would be considered a success if at least 75% of the project plans are fully financed.

Phase 2 would begin after the Sixty-eighth World Health Assembly, in 2015.
Annex 1

A few examples of potential demonstration projects.

Demonstration projects, for which an immediate action can be taken, can cover any health technology for instance medicines, vaccines, diagnostics, medical devices and so forth.

Projects can potentially be selected at any stage of R&D innovation cycle, i.e. discovery, development and delivery.

<table>
<thead>
<tr>
<th>Disease</th>
<th>R&amp;D gap / need for health technology development</th>
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<tbody>
<tr>
<td>Chagas disease</td>
<td>- Point of care diagnostic is needed</td>
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<td></td>
<td>- Paediatric formulation for nifurtimox for acute disease is required.</td>
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<tr>
<td>Human African trypanosomiasis</td>
<td>- Safer and reliable diagnostic tests are required instead of lumbar puncture;</td>
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<td></td>
<td>- Oral drug formulations are required</td>
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<tr>
<td>HIV</td>
<td>- Paediatric liposomal formulations of ARVs are required</td>
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<tr>
<td>Infectious diseases</td>
<td>- New classes of antibiotics are needed</td>
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<tr>
<td>Diabetes Mellitus</td>
<td>- Heat stable insulin is needed</td>
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</tbody>
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<more to be added>