

## Project Appraisal Committee Minutes

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**“Building capacity for Access and Delivery of New Global Health Technologies for TB, Malaria, Neglected Tropical Diseases (NTDs), and other Diseases in Low and Middle Income Countries (LMICs)” and “GHIT: Research and Development (R&D) of New Global Health Technologies for TB, Malaria, NTDs and other Diseases for Patients and Citizens of LMICs”**

25 August 2014

**Written Comments** (see Annex):

Ruby Sandhu-Rojon (RBA)

Christoph Hamelmann (RBEC)

Dafina Gercheva (BOM)

Takeshi Kohno (BERA)

**The project documents were circulated virtually by Magdy Martinez-Soliman, Director a.i. Bureau for Development Policy. The Project Appraisal Committee (PAC) endorsed the project documents with the understanding that comments made by the PAC would be reflected in the final documents.**

**Presentation:**

The four-year projects funded by the Government of Japan are follow-up to the initial phase of the twin projects that commenced on April 2013 and ended on March 2014 (GHIT) and on June 2014 (Access and Delivery) respectively.

These two complementary projects are initiatives aimed at responding to a number of MDGs with particular reference to MDGs 4, 5, 6 and 8 by supporting the development of new global health technologies for TB, Malaria, Neglected Tropical Diseases and other diseases, and strengthening access and delivery for new health technologies by building capacity within LMICs. They also contribute to the fostering of public-private partnerships for development. These projects are anchored in Outcome 3.3 of UNDP’s 2014-2017 Strategic Plan and provide UNDP with the opportunity to increase the participation of LMICs in the process of innovation for new global health technologies. This includes increasing the involvement of LMICs in the early stages of R&D of new global health technologies for TB, Malaria, NTDs and other diseases as well as the subsequent stages of capacity development to improve the optimal and rational adoption of these new global health technologies to the citizens and patients of select LMICs.

The GHIT Project is a partnership between UNDP and GHIT, a Japanese not for -profit grant making organization established in 2013 to support the innovation of new global health technologies for TB, Malaria, NTDs and other diseases. GHIT will provide grants to support

partnerships between research organizations, including Product Development Partnerships (PDPs), for the R&D of global health technologies for TB, Malaria, NTDs and other diseases. In addition to UNDP, the Bill & Melinda Gates Foundation, the Government of Japan and the Japanese pharmaceutical industry support GHIT's grant-making fund.

The Access and Delivery Project is a partnership led by UNDP in collaboration with WHO's Special Programme for Research and Training in Tropical Diseases (TDR) and PATH, a leading global health non-profit with special expertise in delivering new global health technologies to LMICs. The project strengthens the capacity of select LMICs for the access and delivery of new global health technologies. In its first year of operation, the partnership commenced capacity strengthening activities in three countries: Ghana, Indonesia and Tanzania. As outlined in the Access and Delivery Project Document, this project will leverage the comparative strengths of the partners to develop capacity in: legal and policy frameworks; understanding of country needs including potential market size and user perspectives; health sector capacity in monitoring of clinical trials; sustainable health financing; and pricing as well as supply chain management for new global health technologies.

**Key comments:**

The PAC commended the project documents, considering them to be comprehensive and well-written, and in line with UNDP's mandate.

The PAC noted that the alignment and convergence with the new UNDP Strategic Plan was not clearly established, especially with regard to the projects' targets or beneficiaries namely women and young people in light of their greater risk of contracting malaria, TB and neglected tropical diseases.

The PAC also noted that challenges around access and delivery of health technologies should be framed more broadly as a development challenge. Access to health technologies are also issues of poverty, inequality and a lack of availability of services, etc.

The PAC asked why the GHIT project is executed under the NGO modality while the Access and Delivery Project is being implemented under the NIM modality. Both projects will be executed under the NGO modality. When Phase 1 of the GHIT project was initiated, the PCA modality had been recommended as a means of entering into an agreement with GHIT, a local Japanese NGO. As for the Access and Delivery project, PATH, a NGO based in Seattle will be implementing the project, together with WHO/TDR and UNDP as the responsible parties.

The relatively high level of risk was questioned. The PAC stressed that while the risk logs in both projects have identified the management responses for each risk, it is very important that both projects contain robust risk management strategies as both projects are of high value, importance and risk probability.



A second comment on risk from the PAC was the concern that as only UN Member State was funding the GHIT project, the perception could arise among other UN Board Members and LMICs that UNDP was advancing a certain agenda on innovation and access of health technologies, a controversial topic. It was recommended that this perception be carefully managed, which was agreed by all.

The PAC recommended that the Results and Resources Frameworks of both documents be strengthened as some of the outputs and output targets read as activities or the indicators and baselines are missing. The PAC also requested to remove Project Oversight as an output in the RRF of the Access and Delivery project document, as this is UNDP's role. The Project Oversight was kept in the project document as Output 7 because the access and delivery partnership is a multi-country, multi-disciplinary project requiring complex programming and communications commitment by UNDP to ensuring the efficient and effective management of both projects.

The PAC requested the inclusion of annual work plans for each of the 4 years of implementation of both projects. Because the annual work plan will be reviewed and revised on an annual basis to reflect the specific country needs for capacity strengthening before the commencement of each year's activity, it was decided only to include the first year of the AWP (July 2014-June 2015) in both projects.

The PAC requested the strengthening of Management Arrangements and the Monitoring Framework and Evaluation sections of both projects. The PAC commented that the roles of the project partners need to be clarified in both sections in accordance with their roles in the projects.

There was a question about why only two LMICs were chosen as target countries in the Access and Delivery project document as opposed to four LMICs selected in the first phase (April 2013-March 2014). It had been intended that UNDP provide technical and policy advice to strengthen capacity for the access and delivery of new global health technologies for TB, malaria and NTDs in at least two LMICs. The project document was revised to reflect the fact that project activities had commenced in three LMICs with the possibility of activities being undertaken in a fourth country, Thailand.

Finally, the PAC asked for clarification whether the UNDP global HHD director is expected to reserve 30% LoE for the Access and Delivery project as noted in the summary budget table. Although the Director will play a key role in strategically positioning UNDP in this area of work, this staff cost allocation refers to any of the current HHD leadership positions.

Summary of PAC recommendations on Access and Delivery Partnership Project Document:

1. Elaborate the situational analysis section by providing more evidence of current situation regarding the prevalence of TB, malaria and NTDs in LMICS and the current access rate of LMICs to global health technologies.
2. Expand the project strategy section by describing what the project will accomplish, how it will be accomplished, and how this change contributes to the overall outcome.
3. Reflect how the project will support the development of health policy and strategy targeting the issues of poverty, inequality and lack of revenue, and lack of availability of health technologies.
4. Include the respective budget breakdown in the RRF section.
5. Reflect how monitoring and evaluation will be specifically performed by the project partners in accordance with their roles in the project.

Summary of PAC recommendation on GHIT Project Document:

6. Include information on how UNDP will advance funds to the GHIT in the project document

Summary of PAC recommendations applicable to both the GHIT and Access and Delivery Partnership Project Documents:

7. Make sure that the project documents are aligned with the 2014-2017 UNDP Strategic Plan, especially with regard to projects' targets or beneficiaries namely women and youth populations as they are recognized as being vulnerable to Malaria, Tuberculosis and other diseases
8. Include the risk management strategies in both projects
9. Elaborate the Management Arrangement section of both projects by reflecting the roles of the project partners in the projects
10. Strengthen the RRF sections of both documents, as some of the outputs and output targets read as activities or indicators and baselines are missing

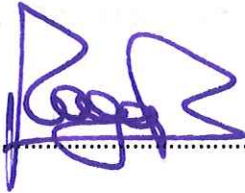
**Follow up required:**

The PAC endorsed the documents with the understanding that the above recommendations would be integrated, while keeping the document clear and concise. The comments above were thoroughly reviewed and incorporated into a revised project document where applicable.

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PAC minutes approved by:

Magdy Martinez-Soliman,  
Director a.i.  
Bureau for Policy and Programme Support



Date. 13 NOV 2014



## ANNEX: Comments received in writing

RBA

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**From:** Ruby Sandhu-Rojon  
**Sent:** Thursday, June 26, 2014 8:47 AM  
**To:** Stan Nkwain; Tenu Avafia  
**Cc:** Ruby Sandhu-Rojon; Priya Gajraj; Linda Maguire  
**Subject:** RE: Invitation to Virtual PAC: Global Health Innovation and Technology (GHIT) and Access and Delivery

Dear Stan,

Please find the consolidated feedback (below and attached) from RBA on the project documents.

Overall, the two projects are in line with UNDP's mandate on capacity building and aid coordination, and its commitment to working with partners to achieve the MDGs. In addition, UNDP has a strong partnership with the Global Fund to Fight AIDS, TB, and Malaria (GFATM). Based on that, UNDP is well positioned and has the capacity to be a leader in partnering with global health organizations to help define and support the delivery of global health products in LMICs.

- ❑ **Programme approach versus project approach:** As both projects are pursuing almost the same objectives of improving health care by providing access and timely delivery of pharmaceutical technologies and drugs for TB and Malaria in developing countries, it could have been more indicated to formulate one programme with two main outcomes. This would also facilitate the reporting, monitoring and evaluation process thereafter.
- ❑ **Results and Resources Framework:** The indicators need to be strengthened to better specify categories of beneficiaries (either institutions or number of particular people) in terms of targets for both projects.
- ❑ **Project implementation modality:** One of the projects is to be executed under NIM modality and the other one under NGO modality. The reason why those two modalities have been chosen needs to be further explained in the projects.
- ❑ **Alignment with 2014-2017 UNDP Strategic Plan:** Alignment and convergence with the new UNDP Strategic Plan is not clearly established, especially with regard to projects' targets or beneficiaries namely women and youth populations as they are recognized as being vulnerable to Malaria, Tuberculosis and other diseases.
- ❑ The issue of access to and delivery of health services requires a more comprehensive response. Beyond the capacity aspect, this matter is also an issue of poverty, inequality and lack of revenue, lack of availability of services, etc. Therefore the project should also reflect how we will support the development of health policy and strategy targeting the above issues.

☐ The participation of communities is crucial, and the projects could better reflect an innovative approach in setting up a strong partnership with direct involvement of the population.

☐ The RRF needs to be completed as the indicators and baselines are missing.

We hope this is helpful.

## **RBEC**

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**From:** Christoph Hamelmann

**Sent:** Wednesday, June 25, 2014 3:25 PM

**To:** Tenu Avafia

**Cc:** Olivier Adam; Elena Panova; Stan Nkwain

**Subject:** FW: Invitation to Virtual PAC: Global Health Innovation and Technology (GHIT) and Access and Delivery

Dear Tenu,

I understand from our discussion that this is an additional phase of these 2 twinning projects after the initial project phase of one year which was previously already approved.

The two projects address very critical topics, access to affordable and quality medicines, innovations in medical technologies and rapid market access.

Through its approach, these projects have a special focus on MDG8.E: "In cooperation with pharmaceutical companies, provide access to affordable essential drugs in developing countries".

It is reassuring to know that our best (and internationally highly acknowledged) people including yourself working on access to affordable medicines in the context of TRIPS, IP and other legal and regulatory frameworks will continue to play a lead role in these 2 projects. We can therefore assume that the UNDP project team is well aware about the main risk associated with these two projects: compromising on UNDP's impartiality and reputation as an advocate for (particularly poor and marginalised) population's rights to affordable medicines in a fair and competitive environment of regulated health sector markets, rights that had and still have to be defended against the dominating profit interests particularly of originators among the pharmaceutical industries.

That due to the funding sources the projects are serving in some of its functions the interests of pharmaceutical companies of only one specific country (citation from LPAC document: In keeping, the GOJ is working with the Japanese research organisations and the BMGF to launch a new initiative: the Global Health Innovation Technology Fund, or GHIT. As a non-profit organization, the GHIT articles of incorporation state that *"The purpose of the association shall be to engage exclusively in activities for the promotion and support of scientific research in the public interest and specifically for the research and development and delivery of medical products and technology for developing countries, and through these activities, to deliver*



*Japanese technologies to the patients and citizens of developing countries making international contributions and as well as rejuvenating innovations in the medical products and technology research and development field* poses an additional concern not only in view of potential concerns of other member states with pharmaceutical production and innovation capacities and interests, but also in view of the potential perception among LMIC beneficiary countries that building national capacities through the projects to deal with medicine regulations and market access maybe a vehicle for preferential consideration of some specific products from a specific country.

Since on the other hand these projects surely offer opportunities of engagement along the lines of UNDP's corporate strategies and of addressing the not easy to handle MDG8.E, one way to control the risks associated with the comments above could be to address them through a special external project advisory group with a particular focus to safeguard and document UNDP's approach and action under these projects. Lessons learnt from this would also be very beneficial for future projects which build on engagement processes with the pharmaceutical companies, whether directly or through the usual vehicles of 'independent' funds or non-profit organisations.

Lastly, I noted that the 'Building capacity....' project provides for a 30% salary of a Director (D1) position. Could you clarify whether this refers to any of the current HHD leadership positions and whether this means that the UNDP global HHD director will from now on reserve 30% LoE to work for one particular project sponsored by one member country?

There are a few additional lower level issues with the projects which I am happy to discuss further internally during the implementation phase.

Overall, I think these projects address important and very relevant development issues and I hope we will be able to handle the risks in a proactive and transparent way.

Best regards  
Christoph



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## BOM

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**From:** Dafina Gercheva

**Sent:** Monday, June 30, 2014 9:38 AM

**To:** Tenu Avafia

**Cc:** Stan Nkwain; Magdy Martinez-Soliman; Emiliana Zhivkova

**Subject:** Invitation to Virtual PAC: Global Health Innovation and Technology (GHIT) and Access and Delivery

Dear Tenu,

Thank you for the opportunity to review and provide comments to the two health technology innovation project documents: Global Health Innovation and Technology (GHIT) and Access and Delivery. As a package the two projects are important tools in supporting the achievement of Outcome 3 of the Strategic Plan that countries have strengthened institutions to progressively deliver universal access to basic services.

Both project documents are good first drafts which will benefit from stronger precision and clarity of presentation. Both projects are high value and high risk: the GHIT project has identified 12 risks, all of which are of high impact and probability, and are of legal, political and operational nature, while the Access and Delivery project has identified 9 risks, of which 5 are of high impact and probability. While the risk logs in both projects have identified the management responses for each risk, as both projects are of high value, importance and risk probability, it is important that both projects contain robust risk management strategies. The risk management strategies in both projects should maximize the probability of achieving planned results of both projects by pursuing opportunities while constraining threats to acceptable levels. The risk management strategies must also ensure a balanced consideration of both the expected gains from project activities and the organization's associated risk exposure. Measures to monitor and respond to the identified risks should be incorporated in the project work plans with adequate resources and clarity regarding responsibilities. During the implementation of the projects, the risks should be monitored to ensure that risk responses remain effective and regular reviews performed to ensure that emerging risks are identified and taken into account in plans as early as possible. The Tips and Guidelines in Conducting the Five Steps of the Risk Management Cycle and the Guidance for Assessment of Probability and Impact of Risks of the Enterprise Risk Management Framework which guide UNDP's overall risk policy are useful practical tools to assist risk mapping and risk management. These two tools are available in the POPP.

As the two projects are linked and build on one another, this strategic linkage should be spelled out more clearly in both documents and reflected accordingly in all sections – from the Situation Analysis, Strategy, Results and Resources Framework Sections and the Management Arrangements Sections. The RRF sections of both documents need to be strengthened, as some of the outputs and output targets read as activities. The RRF section of the Access and Delivery project document should contain the respective budget breakdown and should contain annual

work plans for each of the 3 years of implementation. Project Oversight cannot be an output in the RRF of the Access and Delivery project document, as this is UNDP's role.

The Management Arrangements sections of both projects need further development and must spell out clearly the roles of the project partners included in the project organization structure in managing the project, carrying out the activities and providing oversight. The project organization structures need to be further unpacked with respect to the senior beneficiaries, project assurance and project support. As the GHIT project document is an NGO implementation project, the CSO Capacity Assessment Tool, available in the POPP, should be utilized to assess the capacity of GHIT to implement the project. Additionally, information on how UNDP will advance funds to the GHIT should be included in the project document.

The Monitoring Framework and Evaluation section needs to reflect how monitoring and evaluation will be specifically performed by the project partners in accordance with their roles in the project.

I hope you find these comments useful and I look forward to receiving advanced drafts of both project documents.

Best regards,

Dafina



**Ms. Dafina Gercheva**

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**BERA**

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**From:** Takeshi Kohno

**Sent:** Thursday, June 26, 2014 3:36 PM

**To:** Tenu Avafia

**Cc:** Fadzai Gwaradzimba; Nick Rene Hartmann; Stan Nkwain; Naoki Nihei

**Subject:** RE: Invitation to Virtual PAC: Global Health Innovation and Technology (GHIT) and Access and Delivery

Dear Tenu,

Please find below BERA's comments as our contribution to the Virtual PAC. Thank you for your and your team's outstanding effort. BERA is always here to assist. Good luck for successful implementation!

Best, Takeshi

1. Overall Comments:

BERA commends BPPS colleagues that through this project UNDP can innovatively bring together public, private, and non-profit sectors and their expertise to carry out this project especially because tackling neglected tropical diseases has literally been neglected over many years, despite its seriousness and acute needs for global response. BERA wishes to reiterate that a success of the project depends on a close coordination and collaboration between UNDP and GHIT as a pair.

2. Access and Delivery (A&D):

BERA wishes to note that, as two project documents (A&D and R&D) rightly demonstrate their complementarity to each other's activity, UNDP's global reach and development expertise in A&D will help support GHIT's R&D activities. Hence, BERA strongly supports UNDP's advisory role for the GHIT portfolio and requests to conduct this activity punctually.

On the number of programming countries in A&D, BERA wishes to request qualifications why only two LMICs are chosen in this project document (page 5, para 4) when there were three countries (originally four) in the first phase (April 2013-March 2014), and what would happen to the first phase investment that had been made in a country if dropped. BERA in this connection wishes to add that the donor would be keenly interested in the rationale of the selection of target countries, and the justification of activity cost compared to other similar cases.

3. Research and Development (R&D)

BERA wishes to request BPPS to ensure close collaboration with GHIT so that the phases of health technology development and its applicability can be reflected in the A&D activities when possible and applicable.

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