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ADVANCING GLOBAL EQUITABLE ACCESS TO VACCINES: INTELLECTUAL PROPERTY, TECHNOLOGY TRANSFER AND CONTRACTS

Panel Discussion
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Comments by Dr. Isaac T. Chikwanha

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1. Please describe the Global Health Innovative Technology Fund (GHIT) equitable access policies and contracts?

- GHIT funds R&D for health technologies (diagnostics, therapeutics and vaccines) for neglected tropical diseases (NTDs), tuberculosis and malaria across different stages of development—from early discovery to clinical trials, field validation and regulatory approval.
- The GHIT Access Policy (AP) sets out the expectations in terms of access considerations that any applicant for GHIT funding should expect, particularly ensuring access for Low Income Countries (LICs) and Low and Middle-Income Countries (LMICs).
- Because of the multiple diseases, multiple technologies and different stages of R&D we fund, it brings a different set of challenges in developing an Access Policy that captures all the requirements. For example, while we need to have affordability embedded very early on in R&D, we probably can't talk about actual pricing until we get to later stages of product development. However, we try to ensure that applicants understand our expectation of affordability for products in certain targeted territories.
- The AP itself is just a guideline and not legally binding. We have Investment Agreements (IA) where we have more specific access considerations depending on the product and stage of development. The Investment Agreements are legally binding contracts we have with the developers.
- The AP's focus areas are data and product access; and addresses issues of data sharing, IP and affordability.
- On data and IP, the AP defines how GHIT expects data to be shared. It determines that any IP obtained from data generated with GHIT funding should be used to promote open innovation, collaborative research and access, which are GHIT's founding principles. At the same time, it also recognizes the value of IP to innovators.
- On affordability, the AP sets outs guidance on how product developers could set pricing strategies that consider the socioeconomic status of end users while simultaneously ensuring sustainability of production. There are different ways to achieve this for which the AP provides guidance.

2. As a funder, how does GHIT ensure access to the products that you fund?

- I am not sure we can actually ensure access. The best we can claim is that we lay out the groundwork for reasonable endeavours to facilitate access because there are multiple other actors and factors at play that as a funder we probably cannot control.
- One of these reasonable endeavours is that our Investment Agreements oblige GHIT grantees to develop access plans or launch strategies guided by our Access Policy. We require our grantees to start thinking about how their product is going to get to patients, particularly in LICs, very early on during R&D, and this is reflected in our terms on affordability, adaptability, and access. As an R&D funder, we ensure access considerations are integrated in the R&D as early as possible but the actual access plans start from Phase II/field validation stage.
- The access plans should set out the manufacturing plans (to meet estimated demand), regulatory plans, pricing strategies (and any proposed plans for ensuring that the products are accessible and affordable for targeted territories), planned use of IP (for example, tech transfer, voluntary licensing etc.) In the case of NTDs (where there is not much funding for procurement) we also expect the product developer to have plans showing how their product will reach the last mile. Once we receive the initial launch plans we review them—sometimes with external expertise—and advise on areas that require further thinking or more concrete plans. We then link the grantees with the relevant stakeholders who could help in those areas.
- The launch plans are reviewed annually as R&D evolves. The plans are then adapted accordingly.
- These access considerations survive beyond GHIT funding and basically follow the product.

3. How does GHIT enforce the access policies and how does it deal with any breach of the agreements?

- That is the question. It's not easy. But I guess the first step is really to use our Access Policy as a filter and also as we review the R&D partners, we try to work with those who have the same mission as us.

- The second step is to negotiate. While we have our expectations as to what IP should be used, how data should be shared and what affordability means, the grantees also have their own expectations (recall that in most cases we are trying to get a public good out of private goods) and we need to acknowledge that. Through negotiations, what we eventually put in the IA should be agreeable to both parties and the assumption is that if you sign, you agree to honor the obligations.
- But things do happen and we have many examples, COVID vaccines being one of them. If for any reason, there is an egregious breach and a grantee fails to meet the obligations, while we have potential legal recourse, it's not our first course of action and we try to negotiate other options. For example, if the cost of goods sold are too high, we ask them to consider other options, such as technology transfer to another more affordable location, generic manufacturing or pricing negotiation tied to volume commitments.