A first step to develop a good access to medicines practice
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Access to medicines has been on the global health policy agenda in many forms - World Health Assembly resolutions, high level technical and political commissions, and the Access to Medicines Index among its many iterations. Despite all these, access however defined remains an elusive goal. Fueled by hope to reach the SDGs by 2030, the Global Action Plan on Healthy and Well -being For All (GAP) has adopted three strategic approaches, "align, accelerate, and account." Within the GAP Accelerator 5 on innovation, the approach of alignment that includes harmonization of operational practice, has been translated into the action of developing "global good access practices". This idea of committing to the development of good access practices is to be commended and should be urgently undertaken not only by the GAP signatories but also by all other stakeholders, notably and importantly to include research funders, product developers, clinical trial operators, industry, academics and critically important manufacturers who understand markets.

However, to do this it will be necessary to confront one of the key challenges to an access practice and that is the lack of a common definition or even agreement on how access is to be assessed. Those that use the term have differing understandings of its content. From the perspective of developers, industry, manufacturers, and others in the medicines field, this lack of a clear definition is a primary source of our communal failure to achieve the elusive goal of access however it might be defined. While the definition of access is not the only dimension of an access practice in need of development, finding a way towards a functional definition is fundamental. Other aspects of an access practice that need attention are the mechanisms to engage manufacturers of low-cost products, funding all the stages of product life cycle especially when a product is not commercially viable, data on disease prevalence and on the size and nature of national and regional markets for priority diseases, and improving pooled and national procurement, among others. But the first step towards an access practice is to corral agreement on a definition of access that is actionable and functional in relation to the different actors for use in planning and implementation of activities from a forward perspective so that it is a defined target to achieve rather than a retrospective measurement.

There are numerous ways stakeholders describe access. Fortunately, a closer look reveals some common elements that can be a starting point for an accord on definition. First access is often defined by the nature of a beneficiary of access but this beneficiary is described in too many ways; as persons across the income pyramid, vulnerable populations, or the base of the pyramid, or the public sector which can be defined to mean just national public health systems or include NGO purchasers, or LMICs, by economic quintiles, or graduating MICs where many of the world's poor reside, or priority populations, or by disease categories; or those on the WHO priority list, or those suffering from neglected or tropical diseases. Sometimes access is described in terms of the product such as one that satisfies "unmet global health needs" or products with "significant global health value." None of these are clear or similar enough to rely upon for a market analysis, a step that is essential to a commercialization strategy that optimally integrates an access strategy. Without an integrated strategy, neither a commercialization partner or a not for profit producer can determine if a strategy is sustainable and thus choose to make and market a product. A diversity of meaning is also unworkable especially when the concept of access changes across the life cycle of products. It is a well-known and unfortunate reality that there are products that have been developed but sit on shelves because they cannot

or will not be produced by a manufacturer. This is avoidable if funders, donors, and all other stakeholders organize themselves to define the targets of access with enough clarity and similarity for all actors in the product life cycle, thus the wisdom of the GAP principle of alignment.

Thus, there is effort necessary to identify, align and harmonize the common elements of the definition of access such as the nature of the beneficiary and other parameters. GAP signatories should not act independently of all other stakeholders to do this. However, those that have undertaken the lead on Accelerator 5 can convene the different stakeholders to share on how each defines access and build agreement on the nuances, dimensions and particulars of access relative to each participant and how it might change given the stage of a product development, or disease or population or other factors to be decided. This blog is not intended to define the nuances and parameters but rather to urge that stakeholders convene to decide these. This proposal of a multi-stakeholder approach to defining access is supported by global consensus as represented by the WHO statement that rightly says that "Access to medicines and vaccines is a multidimensional problem." [1] Thus, when considering the who should be involved in the definition discussions, it is essential to agree that no sector or actor should be excluded.

Another consequence of the multidimensionality of the problem, is that the pathway to an access practice can only be navigated through a systems approach with all actors engaged and committed to finding meanings that work for everyone along the entire product lifecycle. This will require all the actors in the system to coordinate with each other and integrate solutions in a way they are not currently doing. In this respect, this approach will be disruptive to the current status quo in which stakeholders act in silos even though together they comprise the medicines system. This approach is not serving humanity as it could. The current system is failing many and will need to be revised, but that is not going to happen in the absence of real effort to build a firm foundation. Establishing a good access practice will require an institutionalization process, by which some behaviors and concepts become the norm; they are reinforced through repeated use and adopted because the process to create the access practice has legitimacy given its inclusiveness.

January 2020 is the dawn of new decade, one that was declared during the UN General Assembly High Level Meeting on Universal Health Coverage as "the decade of implementation". The question is implement what? This opinion proposes that an access practice is what needs to be implemented but it first must be designed. To do so will require some new ways of working together for the good of humanity and it starts with establishing functional definition of access.

[1] http://apps.who.int/gb/ebwha/pdf_files/EB144/B144_17-en.pdf?ua=1 Road map p 3