

PA-086 **A REVIEW OF REGULATORY CAPACITY STRENGTHENING IN AFRICA IN HIV RESEARCH: THE NEED FOR A NEW PARADIGM**

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10.1136/bmjgh-2016-000260.118

**Background** Recent African initiatives suggest the need for new direction in capacity building and support for regulatory review of HIV prevention research. The African Vaccine Regulatory Forum recently harmonised practices to strengthen regulatory oversight and helped create the African Medicines Agency scheduled to be launched in 2018. The African Union, working through the New Partnership for Africa's Development, took a major step in 2016 adopting the African Union Model Law on Medical Product Regulation. These steps, as well as the work of the African Medicines Regulatory Harmonisation Programme, raise the question of how best to effect regulatory capacity building in this new environment.

**Methods** This paper assesses the evolving role of support for African regulatory systems using a desk review of various regulatory strengthening activities currently underway or planned, with focus on Africa. This review was supplemented by interviews with key informants related to activities intended to support regulatory capacity building in low- and middle-income countries focused upon efforts that were of potential assistance to HIV vaccine development. This analysis supplements findings

from a Regulatory Capacity Building Workshop held in Rwanda in 2015.

**Results** External capacity building efforts need to be responsive to new and/or recent priorities and mechanisms by African entities regarding the strengthening and coordination of regulatory systems. Current capacity building efforts will benefit from coordination and information sharing geared toward new initiatives, as well as focus around ethics review.

**Conclusions** Remarkable progress is being made towards the development of a safe and effective HIV prevention options, and several HIV vaccine efficacy trials are planned over the next few years. Recent ambitious African regulatory initiatives hold the potential to expedite review. It is time for capacity building efforts to consider how best to support the new coordinated and regional regulatory systems being developed and launched over the next few years.