# The rise of the African Medicines Agency

## NEPAD and WHO are working on the African Medicine Regulatory Harmonisation programme. Bryan Pearson reports on progress

Science has produced some remarkable advances in recent decades. New vaccines, diagnostics and devices have saved millions of lives. But for Africans, the benefits have not been felt as widely as they should because in Africa it can take four to seven years longer for a new product to jump through the required regulatory procedures than it takes in, say, Europe. This delay in getting products to market, costs lives.

Put another way, Africa has a similar population to India and China who each have one regulatory agency. Africa has more than fifty countries and a regulator in each capital. It is a bottleneck that needs unblocking.

In January 2016, recognising that there was a major challenge that needed to be addressed, the African Union Heads of State adopted the Model Law on Medical Products Regulation, and set in motion a major programme of regulatory harmonisation that is intended to end up with the establishment of an African Medicines Agency (AMA).

It is an undertaking so large that many fear it is too ambitious. But it has heavyweight support from key donors who recognise the benefits that can accrue if reform is successfully negotiated. The AU has appointed NEPAD (the New Economic Programme for African Development) to be the expediting agency. WHO has now also formally joined the process making it a Joint NEPAD/WHO Secretariat Key funding agencies include the World Bank, the Bill and Melinda Gates Foundation, Swiss Development Assistance and DFID.

The 4th Meeting of the Steering Committee on Regulatory Systems Strengthening and Harmonisation Initiatives in Africa took place in Kigali, Rwanda in early December 2018. It treads a delicate path. Ownership of the process has to be retained by member states, and NEPAD/WHO has to help keep a coherence and alignment across its geographic spread, in bringing forward the harmonisation process, even though sometimes there is significant disparity between in-country regulatory agencies.

Significant progress is reported in developing Monitoring and Evaluation guidelines and tools, so that progress at both country and regional levels, can be measured. NEPAD had initially concentrated on country level M&E, and its efforts are now being consolidated alongside WHO's Global Benchmarking Tool to work in tandem.

A Needs and Investment Gaps tool has also been developed to help provide information on MRH activities that need to be funded; who is funding what and where; and what is not funded. This provides core partners – governments, Regional Economic Communities, donors, multilateral agencies and NGOs – with the information they need to decide on future funding commitments.

Africa has too many countries for the NEPAD/WHO secretariat to oversee all the programmes, so the Regional Economic Communities (RECs) such as ECOWAS and the ECA, have taken on the role, albeit delegating to their specialist health agency such as WAHO, and ECSA where possible. SwissMedic, working with WHO has taken on the key capacity building role for the Case and Project Management element of the programme. Initial pilot work in East Africa has led to the development of six components: medicines evaluation and registration; good manufacturing practices; quality management systems; and information management systems.

Beyond this, ten areas for study have been identified and Joint Action Groups established to cover the ground. These range across thematic areas from dossier review and registration, to post-marketing surveillance.

And as if these areas don't seem enough, eight Technical Working Groups have been formed as pillars of the new governance framework. Each will be covering areas of work which are of a continental nature or value, and will be supported by different AMRH partners (depending on scope and nature of the work). These TWGs are at different stages of development but cover: The African Vaccines Regulators Forum (AVAREV) for the regulation of clinical trials; the Pan African Harmonisation Working Party for regulation of Medical Devices (including in vitro diagnostics); the African Medicines Quality Forum for market surveillance; the African Blood Regulators Network for the regulation of blood and blood products; and the African PV Advisory Group (APAG) in the area of pharmacovigilence, to coordinate the many fragmented PV initiatives on the continent and help develop a coherent framework to move forward with.

This might all sound like a lot of committees and talk, but progress is being made and although much work still needs to be done before an AMA can be properly launched, the AMA Treaty has been cleared by the AU Specialised Technical Committee on Legal and Justice Affairs and will be presented for consideration for adoption at the AU Summit in February 2019.

And value? A group from the Johns Hopkins Bloomberg School of Public Health did a study to estimate the potential impact of accelerating access to essential medicines. The study in East and Southern Africa using amoxicillin dispersible tablets and carbetocin estimated that a one-year acceleration to market (over the status quo) saved 11,778 lives, and a two-year acceleration saved 23,391 lives.

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