

Why the ongoing harmonisation of regulation of medicines in Africa should be patient-centric

Kawaldip Sehmi argues the case for the patients' voice to be heard

Cases of expired drugs quite often go unreported not only because of limited awareness and enforcement of patients' rights but also due to inadequate access to vital information, such as medicine side effects. Access to quality drugs remains a particular challenge as costs remain at exorbitant levels.

Across Africa, media reports frequently highlight issues, such as expired drugs that are reported to have been imported by governments or donations. In some countries, National Drug Authorities have limited capacity to test drugs due to inadequate laboratory analysis facilities, with most countries relying on certificates of authorisation to manufacture drugs that run the risk of potentially being forged.

It is against this backdrop that the creation of the African Medicines Agency (AMA) in 2018 – a process spearheaded by the New Partnership for Africa's Development (NEPAD) under the African Union (AU) and the World Health Organization (WHO) – is a timely development.

Optimism is high as the initiative aims to strengthen patient access to safe, efficacious and quality assured medicines across Africa by pursuing stronger regulatory harmonisation amongst the AU member states.

At the International Alliance of Patients' Organizations (IAPO), as strong advocate for patient-centred healthcare globally, we are actively campaigning to ensure that AMA engages patients as key partners. We believe patient engagement in regulatory harmonisation must take place as early as possible and be nurtured over time.

The question of how to ensure that the future AMA is truly patient-centric was the core focus of IAPO's African Regional Meeting, held in Entebbe, Uganda, in July 2017. This was an opportunity for the community of IAPO's African patient advocates to come together



and discuss how patients can engage with the African Medicines Agency.

A key outcome of the meeting was the drafting of a joint statement – the Entebbe Statement – calling for a patient-centric African Medicines Agency. The statement highlights the importance of ensuring that patients are placed at the centre of regulatory harmonisation processes for medicines in Africa.

Patient groups, therefore, have an unprecedented opportunity to be part of the conversation right from the start, and to be co-drivers in the harmonisation process, even before the birth of the AMA. Early engagement would enable patients to have a meaningful say, not only on medicines regulation, but also on the strategic direction and practical functioning of the entire harmonisation journey.

It is crucial that every patient has a real opportunity to access high-quality health services. At the same time, patients cannot truly take responsibility as equal healthcare stakeholders if they are left behind in key decision-making processes.

Patient involvement must not be seen as a concession that other stakeholders grant to patients on a discretionary basis. Rather, genuine patient involvement is a key way of empowering patients to take their share of responsibility, and become key partners, with an equal seat at the table.

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