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GSCF World Congress: A New Age Of Regulatory Harmonization In Africa

by [David Ridley](#)

Harmonization of national regulatory frameworks would represent a step change for self-care in Africa, agreed speakers in the final session on day one of the 2022 GSCF World Congress. Panelists also share self-care best practices from countries including South Africa, Egypt and Kenya.

In the final session the first day of the GSCF World Congress in Cape Town, South Africa, panelists outlined a “step change” that has been occurring in the harmonization of Africa’s regulatory frameworks for medicines.

Reckitt’s senior director of regulatory affairs for the AMESA (Africa, Middle East, West & South Asia) region started the session by saying this was a topic “close to her heart.”

However, there are still many barriers to achieving the “self-care revolution” that such harmonization may enable, she noted.

Laws and policies in Africa supporting self-care are limited, she said, “because we don’t keep up with the changes in the environment around us.”

Low general literacy is a particular challenge, she continued, resulting in the misuse and abuse of drugs, increased risk of harmful drug interactions, and the purchase of falsified products.

Nevertheless, ITG chair Deepa Maharaj said the regulatory innovation seen during the pandemic in Africa during the pandemic was “heartening.” (Also see "[Learn From Regulatory Innovation During COVID-19, Urges Global Self-Care Industry](#)" - HBW Insight, 29 Mar, 2022.)

COVID-19 presented African countries with opportunity to “step up and rise to find solutions, no matter how dark the day,” she said.

Regulators in the North-West Africa region, for example, are now looking at how they can widen access to healthcare for their populations, she reported.

Egypt is looking at ways to expedite Rx-to-OTC switch, she continued, as well as how to facilitate digital advertising.

COVID Innovation

COVID-19 prompted the South African Health Products Regulatory Authority to become more agile, and responsive to local needs, while also aspiring to international regulatory standards, noted Tumi Semete.

CEO of SAHPRA, Semete expressed great pride at achieving Status 3 in a recent WHO audit, meaning that the agency is judged to have a “stable, well-functioning and integrated regulatory system.”

Going forward, Semete wants the regulator to be an enabler of self-care innovation and sector growth, and to be open to dialogue with both local and international manufacturers.

Change is also happening at the pan-African level, Semete noted, with the African Medicines Agency currently working on a legal framework for drug regulation across the continent.

Pan-African Harmonization

If established, such a framework would enable drugs approved in one African country to potentially be sold in another, she pointed out – an exciting possibility for both consumers and manufacturers.

Nancy Ngum, program health officer for the African Medicines Regulatory Harmonization (AMRH) initiative, outlined the context of regulatory harmonization in Africa.

African Union ministers of health in 2018 endorsed a draft treaty for the establishment of an African Medicines Agency at the World Health Assembly held in Geneva, Switzerland, Ngum explained. The cabinet of South Africa recently approved the signing of the AMA treaty, which is now with parliament for ratification.

“Harmonization is a critical lever to ensure the efficiency and effectiveness of African national regulatory agencies,” Ngum concluded.

Pharmacy Partners

The final session of the day was brought to a close by GSCF's Africa strategy lead Evah Amwayi, who re-emphasized the importance of pharmacy in expanding self-care across the African

continent.

“We are educators, we talk about your products, about how to self-medicate responsibly,” explained Amwayi, who is also executive secretary of the Kenya Association of the Pharmaceutical Industry (KAPI).

“We are also allies in drug design,” she added, “because we can give you a lot of information on the gaps that need to be addressed.”

Alongside regulatory harmonization and strengthening the role of pharmacists, Amwayi also emphasized the role of digitalization in realizing the future potential of self-care in Africa.

She pointed to Kenya as a model, where pharmacists have become delivery drivers in order to conform to local e-commerce medicines dispensing regulations.

Electronic Information

In Morocco, regulators are exploring augmented reality as a way to make medicines information more engaging, she noted.

In general, electronic product information represents a powerful way to overcome health literacy barriers in Africa, where many different languages are often spoken within a single country. (Also see "[AESGP Annual Meeting, Day 2 \(Part 2\): Can Regulation Be A Catalyst For Innovation?](#)" - HBW Insight, 9 Jun, 2022.)

“In a continent with a thousand tribes, regulators get on top of this to ensure patients get the right information,” she said. “Literacy may be low, but mobile penetration is very high,” she added.

“E-labelling can help us do what we cannot do with paper,” she concluded. “It can help us penetrate and inform African consumers in their native languages.”