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World Local Production Forum 2023: Industry experts confirm regulatory challenges affecting equitable access to medicine & healthcare products in Africa

Industry experts at the World Local Production Forum (WLPF) in The Hague, Netherlands, have confirmed the urgent need to address the regulatory challenges affecting the equitable access to medicine and healthcare products in Africa today. Citing conditions affecting the development of Africa's new public health order, it was agreed that a global regulatory standard would remain a critical undertaking to decrease Africa's reliance on foreign healthcare products and imports.

The WLPF, which comes to a close this evening, provided a platform for participating members to call on global health organizations to play a key role in developing an enabling ecosystem for the local production of medicine, vaccines and diagnostic test kits in Africa.

At present, pharmaceutical manufacturers based on the continent have faced major regulatory challenges to supply international donor funders, ultimately limiting their growth and ability to support demand in their region. This is due to donor funders insisting on regulatory standards that differ from those of the regional authorities.

Having a globally recognised regulatory standard would provide local pharmaceutical manufacturers in Africa with a unilateral standard that may expedite their access to the donor-funded market. This instrumental undertaking would assist local producers with the compliance required to supply institutions like the Global Fund and PEPFAR, within the next 6 months.

Industry experts at the WLPF believe that we can use the Global Benchmarking Tool to measure the maturity level of different regulatory authorities, in order to assess their ability to qualify as a WHO Listed Authorities (WLAs). At present, only 3 countries have WLA status, including the Republic of Korea, Singapore and Switzerland. It is suggested that WLA status be adopted by donor funders as an acceptable pre-requisite for procurement.

As such, all regulatory authorities in Africa with a maturity level 3 or 4, including South Africa, should be recognised as a WHO Listed Authority (WLA) without delay.

With WLA status, local pharmaceutical manufacturers will be able to supply donor funders and ultimately unlock significant resources ring-fenced by DFI's for the manufacture of healthcare products in Africa today. Dr. Tedros Ghebreyesus, Director General of the World Health Organisation (WHO) added that governments require policies and regulations to streamline approval processes in order to foster an enabling ecosystem for local production.

With access to appropriate funding, and sound off-take agreements from donor funders and the public sector, local manufacturers can build sustainable business models to ensure the long-term production of medicines and vaccines in Africa, for Africa. The Federation of African Pharmaceutical Manufacturers Associations (FAPMA) supports this initiative and recently called on the Global Fund and US government to procure 30% of their products from African manufacturers, over the next 3-5 years, at a 15-20% price premium.

If we can recognise WLA status as our new global regulatory standard, manufacturers based in Africa can mobilize the resources made available by international financial institutions and development banks, towards playing an indelible role in securing a new public health order for Africa. This would ensure our collective and continued, sustainable and equitable access to medicine and vaccines in Africa, improving our pandemic preparedness while significantly decreasing our reliance on foreign imports.

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Note to the Editors: *Kindly attribute quotes to Michael Mynhardt, Co-Founder & CEO at MMH & Partners (Pty) Ltd, panelist at the World Local Production Forum in The Hague.*