Ethics, regulatory and pharmacovigilance

OC - (8715) - GOING FURTHER TOGETHER: THE ROLE OF THE EU IN SUPPORTING REGULATORY HARMONISATION OF HEALTH TOOLS IN AFRICA

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Background

On May 20 2018, African governments adopted the Treaty for the establishment of the African Medicines Agency (AMA) as a stepping stone in the strengthening and harmonising of medical products regulation on the continent. Many countries in Africa lack robust and comprehensive regulatory systems supporting the research and registration of health products, hampering the translation of health research and innovation into public health impacts. The AMA could substantially improve the access to quality-assured, safe and effective health solutions and technologies in Africa and around the world. As the main trade partner and donor to Africa, the EU has a key role to play in supporting this effort.

Method

Desk research and case-study analyses of key medicines regulatory strengthening initiatives in Africa were conducted. Specifically, the EDCTP, the African Vaccine Regulatory Forum (AVAREF), the African Medicines Regulatory Harmonisation Programme (AMRH) and the Zazibona Process; to assess the gaps, needs and opportunities for EU collaboration using actual and reconfigured EU-Africa funding and policy cooperation mechanisms.

Results and conclusions

This presentation will explore initiatives aimed at regulatory strengthening and harmonisation in Africa and propose policy recommendations on how to improve EU efforts in order to support these initiatives in a more systematic and synergetic manner. The recommendations fall into four categories: EU-Africa priority-setting, coordination, funding and capacity-building actions. Recommendations explore, for instance, advancing in the domestication of the African Union Model Law on Medical Products Regulation by all African countries, enlarging the scope of EDCTP regulatory strengthening actions to include Africa’s Regional Centres of Regulatory Excellence (RCOREs) or improving the attractiveness and incentive system of the EMA’s article 58 procedure for African governments, researchers and manufacturers.