AU Model Law on Medical Products Regulation

7 Things you need to know about the African Union (AU) Model Law on Medical Products Regulation

1. Officially endorsed by African Heads of State and Government at the African Union (AU) Summit in Addis Ababa, Ethiopia in January 2016
2. Legislative framework aimed at guiding AU Member States and Regional Economic Communities (RECs) in harmonising medical products regulatory systems
3. Developed as a result of the partnership between the African Union Commission (AUC), NEPAD Agency, Pan-African Parliament (PAP) and other key cooperating partners
4. Contributes to the AU Pharmaceutical Manufacturing Plan for Africa (PMPA) and the Roadmap for Shared Responsibility and Global Solidarity for the AIDS, TB and malaria response in Africa
5. Satisfies World Health Organization (WHO) best practices on medical products regulation and is aligned with WHO recommendations and international safety and quality standards
6. Strengthens national Laws on medical product regulation and promotes autonomous National Regulatory Authorities (NRAs). AU Member States are at liberty to domesticate and adapt the AU Model Law to ensure alignment with their Constitutional principles and legal systems
7. The AU Model Law is available in four (4) different languages; English, French, Portuguese and Arabic to ensure that it is appreciated across African countries that speak different languages

NEPAD
TRANSFORMING AFRICA

AMRH
African Medicines Regulatory Harmonisation Programme