# BLOG

## NEW LAW TO REGULATE MEDICAL SUPPLY IN THE AFRICAN UNION

By ADP | On 15 Feb 2016 | Read 320 | Comments 0

Africa has taken a major step in accelerating access to the needed safe, efficacious and quality medicines for the treatment of priority diseases by adopting the African Union Model Law on Medical Product Regulation. The Summit of Heads of State and Government of the African Union that convened in Addis Ababa, Ethiopia from 30 to 31 January 2016 adopted the Model Law in recognition of the need to promote and protect the public health of Africa's citizens.

By adopting the Model Law, the Heads of State and Government reaffirmed their commitment to upholding health as a human right as expressed in the Universal Declaration of Human Rights and International Covenant on Civil and Political Rights, as well as the African Charter. Through the African Union Agenda 2063, African States have committed to develop a healthy human capital for the attainment of the Union's human and socio-economic development goals.

One of the challenges in ensuring effective regulation of medical products in Africa is the existence of gaps in legal frameworks existing in most Member States. An analysis conducted by NEPAD Agency revealed that while some countries have legislations in line with the World Health Organization (WHO) recommended standards, others lacked comprehensiveness with some having no medicines regulatory laws in place. Aside from hampering effective regulation at the national level, the gaps and inconsistencies in legislation are a major hurdle in harmonization and mutual recognition at the regional level.

The Model Law thus avails a reference guide and systematic approach in the review and development of national legislation that will enable the Member States to undertake their obligation to protect the health of their people. Furthermore, the model law domestication in the Member States will contribute to building stronger regulatory systems that will support the fight against the proliferation of substandard medical products on the continent which poses a major public health threat.

The African Union Model Law is expected to facilitate harmonization of regulation of medical products by Member States through their Regional Economic Communities (RECs) with the support of the African Medicines Regulatory Harmonization (AMRH) Programme. Through the programme, RECs are harmonizing medicines regulations and facilitating work-sharing among countries for faster, quality, predictable and transparent approval of medical products in African countries. The ultimate goal is to facilitate faster access to life saving medical products.

The AMRH is implemented as part of the Pharmaceutical Manufacturing Plan for Africa (PMPA) and the AU Roadmap on Shared Responsibility and Global Solidarity for AIDS, TB and malaria Response in Africa. The Model Law adoption, which was developed through a consultative process, is therefore an important milestone in the harmonization of medical products regulation in Africa.

The AMRH programme is a collaborative programme of the NEPAD Agency, African Union Commission (AUC), Pan African Parliament (PAP), RECs, World Health Organisation (WHO), World Bank, the Bill and Melinda Gates Foundation, the UK Department for International Development (DFID), United States Government (PEPFAR) and Global Alliance for Vaccine and Immunization (GAVI). The Model Law development process also received support from the United Nations Development Programme (UNDP).

Source: NEPAD e-Alert 1 February 2016

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