Safety moves up the agenda

*Africa Health* is going to start taking a regular detailed look at aspects of medical technology. To kick the series off, herewith news from the African Union on an important new initiative it has taken in the pharmaceutical sector.

Africa has taken a major step in accelerating access to safe, efficacious and quality medicines 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.

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 the NEPAD Agency (New Partnership for African Development) revealed that while some countries have legislation 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 harmonisation 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 governments to undertake their obligation to protect the health of their people.

The African Union Model Law is expected to facilitate harmonisation of regulation of medical products by Member States through their Regional Economic Communities (RECs) with the support of the African Medicines Regulatory Harmonisation (AMRH) Programme. Through the programme, RECs are harmonising 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 harmonisation of medical products regulation in Africa.

The AMRH programme is a collaborative programme of the NEPAD Agency, African Union Commission, Pan African Parliament, RECs, WHO, World Bank, the Bill and Melinda Gates Foundation, the UK Department for International Development, United States Government, and Global Alliance for Vaccine and Immunisation. The Model Law development process also received support from the United Nations Development Programme.