

TANZANIA FOOD AND DRUGS AUTHORITY



PRESS RELEASE

TFDA ADOPTS THE EAST AFRICAN COMMUNITY (EAC) HARMONIZED GUIDELINES ON EVALUATION AND REGISTRATION OF MEDICINES

On **Wednesday, 15th January 2015**, Tanzania Food and Drugs Authority (TFDA) adopted the East African Community (EAC) harmonized guidelines on Medicines Evaluation and Registration (MER). These guidelines contain the common technical document as well as the common criteria to be used for evaluation and registration of medicinal product dossiers in the region.

This adoption follows the Decision **EAC/CM29/Decision 36** to approve the EAC harmonized guidelines on medicines evaluation and registration by the 29th Ordinary Meeting of the Council of Ministers (*“the Council”*) on 20th September 2014. The Council also agreed 1st January 2015 as the effective date for domestication and implementation of the harmonized guidelines at EAC Partner States’ level. To effect Council’s Decision, the EAC Secretariat issued a Press Release on Tuesday, 14th January 2015.

In order to ensure smooth domestication and implementation of these guidelines in Tanzania, TFDA wishes to inform its esteemed marketing authorization holders and future applicants that:-

- a) With effect from 15th July 2015, all applications for registration of medicinal products must comply with the harmonized guidelines on medicines evaluation and registration.
- b) From now onwards, interested applicants may apply for marketing authorization of their medicinal products in Tanzania and the region by referring to the [Press Release](#) issued by the EAC Secretariat on 14th January 2015 available on www.tfda.or.tz and www.mrh.eac.int

Issued by

Director General
Tanzania Food and Drugs Authority
Off Mandela Road, Mabibo - External
P. O. Box 77150
Dar es Salaam
Tel: +255-22-2450512/2450751/ 2452108
Fax: +255-22-2450793
Website: www.tfda.or.tz
Email: info@tfda.or.tz