PUBLIC NOTICE Date: 05 January, 2018

INVITATION FOR COMMENTS

1. Tanzania Food and Drugs Authority (TFDA) is an Executive Agency under the Ministry of Health, Community Development, Gender, Elderly and Children established under the Tanzania Food, Drugs and Cosmetics Act, Cap.219. TFDA is responsible for controlling quality, safety and effectiveness of food, medicines, cosmetics, medical devices and diagnostics.

2. We would to inform all stakeholders involved in the manufacture, registration, importation, distribution and sale of human medicinal products that TFDA has recently reviewed guidelines for registration of biological, 2004 and developed draft guidelines for registration of human vaccines, draft guidelines for registration of biotherapeutics and draft guidelines for registration of similar biotherapeutics.

3. TFDA has also reviewed Application guidelines for variation of registered human medicinal product, 2008 and developed draft guidelines for variation of registered medicinal products, November, 2017.

4. All draft guidelines will be tabled in the stakeholder's meeting that has been scheduled to be held on Thursday, 25 January, 2018 at TFDA Headquarters, Dar es salaam starting from 9:00 a.m.

5. These guidelines will provide guidance to applicant for submission of documentation for market authorization of medicinal products in Tanzania.

6. In view of this, we wish to request all stakeholders to confirm attendance, submit their comments and suggestions regarding these draft guidelines by 19 January, 2018, 12:00 noon EAT.

7. The draft guidelines can be accessed here.

8. We would be grateful to receive your valuable comments not later than 19 January 2018 through (maoni@tfda.go.tz), as per below format:-

Comments and suggestions from stake holders/reviewers

Please tick in the appropriate box (separate form should be used for each guideline).

- EAC guidelines on submission for documentation for registration of biotherapeutic products.
- EAC guidelines for registration of similar biotherapeutic products.
- EAC guidelines on variations of registered medicinal products.
- EAC guidelines on submission of documentation for registration of human vaccines.

Reviewer name and position:..... Name of organisation and physical address:.....			
Indicate section, page, paragraph and line….	**Original Text**	**Comment**	**Suggested Amendment**

Other comments

For further information and confirmation of attendance please contact the Authority through the following address;

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