

PUBLIC NOTICE

Date: 21st September, 2017

THE TANZANIA FOOD, DRUGS AND COSMETICS (ORPHAN MEDICINES) REGULATIONS, 2017 - 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 developed draft regulations of orphan medicines.
3. These regulations will enable the Authority to establish a formal system for designating an orphan status and subsequent procedure for handling such applications.
4. In view of this, we wish to request all stakeholders to submit their comments and suggestions regarding these draft regulations.
5. The draft regulations can be accessed by [Clicking here](#).
6. We would be grateful to receive your valuable comments not later than 10th October 2017, as per below format:-

TEMPLATE FOR COMMENTS

TITLE OF THE DOCUMENT	THE TANZANIA FOOD, DRUGS AND COSMETICS (ORPHAN MEDICINES) REGULATIONS, 2017	
Chapter	Page number, regulation no., sub-regulation no./line no.	Comment and rationale

7. For further information please contact the Authority through the following address;

Director General,

**Tanzania Food and Drugs Authority, Nelson Mandela Road,
P. O. Box 77150, Dar es Salaam. Email: info@tfda.go.tz**

Phone No.: +255: 658 445222, 685 701735, 777 700002

Fax No.: +255 22 2450793

Website: www.tfda.go.tz