



All correspondence should be addressed to the Director General

In reply, please quote  
DMS/7/9/22/CT/102

# ZAMBIA MEDICINES REGULATORY AUTHORITY

2<sup>nd</sup> October, 2020

Dr Mwansa Ketty Lubeya  
The University Teaching Hospital  
Woman and Newborn Hospital  
P.O Box RW1X  
Lusaka

Email: mwansaketty@gmail.com  
Cell: + 260 977 308 465

Dear Sir/Madam,

**RE: APPLICATION FOR AUTHORISATION OF CLINICAL TRIAL: A RANDOMISED CONTROLLED TRIAL TO ASSESS THE PHARMACOKINETICS AND PHARMACODYNAMICS OF INTRAMUSCULAR, INTRAVENOUS AND ORAL ADMINISTRATION OF TRANEXAMIC ACID IN WOMEN GIVING BIRTH BY CAESAREAN SECTION**

Reference is made to your application to conduct the above stated clinical study.

We wish to advise that we have completed our review of the submissions and are pleased to inform you that the Zambia Medicines Regulatory Authority (ZAMRA) considered the additional information and the corresponding evaluation reports and based on the submitted information, **approved** the conduct of the study indicated below with clinical trial number and protocol version as indicated below:

No.	Name of Clinical Trial	ZAMRA Clinical Trial Application No.	Protocol version
1.	A Randomised Controlled Trial to assess the Pharmacokinetics and Pharmacodynamics of Intramuscular, Intravenous and Oral administration of Tranexamic Acid in Women Giving Birth by Caesarean Section	CT102	1.3

We wish to advise that you are required to provide periodic updates on the study and report any adverse events that may occur during the study. Furthermore, ZAMRA will carry out clinical site inspections as may be deemed necessary.

**Head Office**  
Plot No: 6903, Tuleteka Road/ Off Makishi Road  
P.O. Box 31890 Lusaka, ZAMBIA  
Tel: +260 211 220429, Telefax: +260 211 238458  
E-mail: pharmacy@zamra.co.zm

**Ndola Office**  
No: 41 Kafironda Drive, Itawa  
P.O. Box 70876  
Telefax: +260 212 610522  
Website: [www.zamra.co.zm](http://www.zamra.co.zm)

**Report Adverse Reactions to:**  
Pharmacovigilance Unit, Lusaka  
Tel: +260 211 220088 / 220098 / 220109  
E-mail: pharmacy@zamra.co.zm

Should you have any questions, please do not hesitate to contact the Secretariat.

Yours faithfully,  
for **Zambia Medicines Regulatory Authority**



B C Mwale (Mrs)  
**DIRECTOR-GENERAL**