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| **Sponsors – AODC 2017** | **DECLARATION LETTER FOR THE SAMENESS** | ***TMDA/DMC/MRE/F/046***  ***Rev #: 00***  ***Page 1 of 1*** |

To be completed by the applicant:

|  |  |
| --- | --- |
| Reference Application details {Product name, strength, dosage form} |  |
| Name of recognised regulatory authority |  |
| Approval date/Registration date |  |
| Date(s) of approval of post-registration variation(s), if applicable |  |

I, {Full name}, {Job title} at {Company’s full legal name}, hereby confirm the following for application {Application number, Product name, strength, dosage form} submitted to the Tanzania Medicines and Medical Devices Authority (TMDA) on {Date of application submission} declares that: -

1. The information and documentation provided in support of this submission for marketing authorisation are true and correct;
2. The product submitted for marketing authorisation to TMDA is the same as the product registered/approved with the above-specified recognized regulatory authority/authorities; and
3. The technical information in the dossier submitted to TMDA for marketing authorisation is the same as the latest updated technical information approved by the above-specified recognized regulatory authority/authorities, taking into account all accepted variations.

Any differences in the technical documents related to the quality, safety, efficacy, product information and labelling are discussed, justified and annexed to this declaration letter.

Responsible Person authorised to communicate with the Authority: -

Full name:………………………………………………………………

Job title, company:……………………………….…………………….

Email address:…………………………………………..…………..….

Tel. No:…………………………………………………..………………

Signature:………………………………………………..………………

Date:…………………………………………………….………………

Place:…………………………………………………….………………