

Resolutions towards Endorsement

19th AHWP Meeting
18-21 Nov 2014, Seoul, Korea

Mr. Bryan So
Executive Deputy Secretary General, AHWP



Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

Resolution towards Endorsement

AHWP new member economy application

- 1) United Republic of Tanzania

WG documents

- 2) White Paper on Medical Device Software
- 3) Comparison between CSDT & STED for IVDDs
- 4) Adverse Event Reporting Timelines
- 5) Quality Management System – Distributors
- 6) Roles of Standards

Amendment to the AHWP House Rules

- 7) Amendment 3 to the AHWP House Rules

AHWP New Member Economy Application

United Republic of Tanzania

Tanzania FDA submitted the application to AHWP Secretariat with:

- Official letter for application
- Nominated Representatives

AHWP Representatives

Primary (Regulatory Authority) – Hiiti B. Sillo

Secondary (Regulatory Authority) – Adam Mitangu Fimbo

AHWPTC Representatives

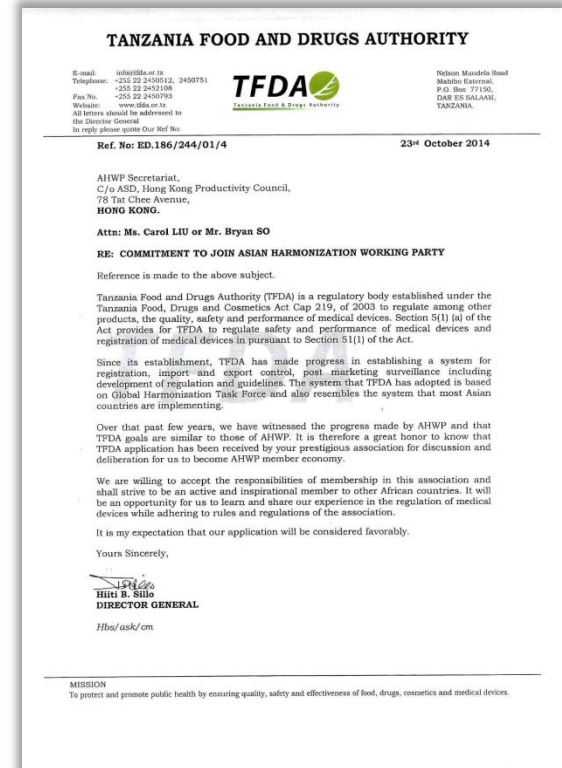
Primary (Regulatory Authority) – Agnes Sitta Kijo

Secondary (Regulatory Authority) – Engerasia Mtui

Endorsement

Yes / No?

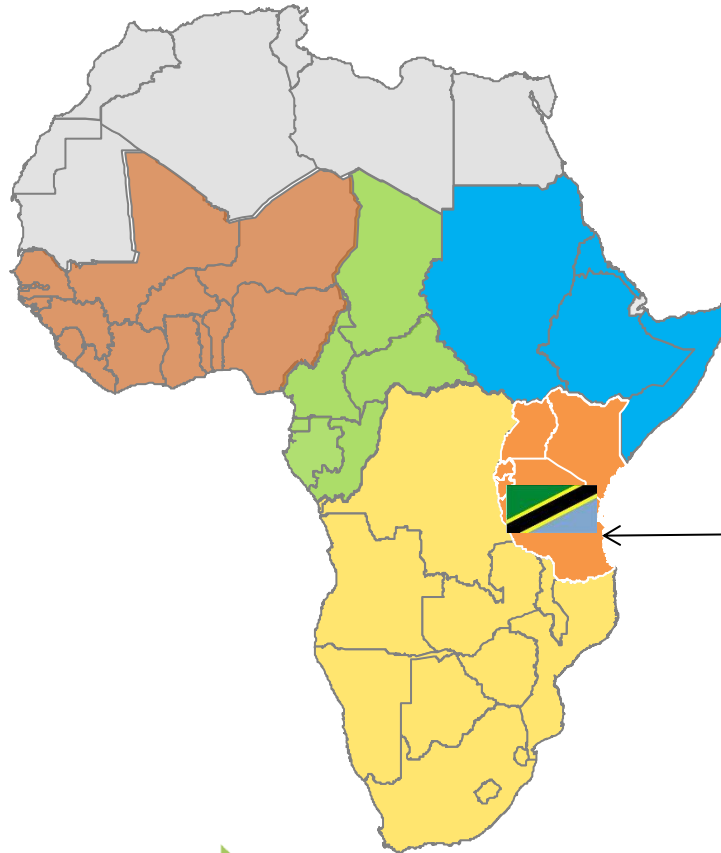
(Short speech by Dr. Sillo, Director General, Tan-FDA)



UNITED REPUBLIC OF TANZANIA



AFRICA



TANZANIA

55 countries



6 regions



1 continent



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White Paper on Medical Device Software Regulation – Software Qualification and Classification

FINAL DOCUMENT – REFERENCE DOCUMENT

- Prepared by WG 1 – Pre-market: General MD
- Discussed at AHWP TC Leaders Meeting, May 2014
- Post on AHWP Website and Calls for Comments

Endorsement

Yes / No?

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Comparison between the Common Submission Dossier Template (CSDT) format for In Vitro Diagnostic Medical Devices and the GHTF Summary Technical Documentation (STED) formats for In Vitro Diagnostic Medical Devices

FINAL DOCUMENT – REFERENCE DOCUMENT

- Prepared by WG 2 – Pre-market: IVDD
- Discussed at AHWP TC Leaders Meeting, May 2014
- Post on AHWP Website and Calls for Comments

Endorsement

Yes / No?

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Adverse Event Reporting Timelines Guidance for Medical Device Manufacturer and its Authorized Representative

FINAL DOCUMENT – GUIDANCE DOCUMENT

- Prepared by WG 4 – Post-market
- Discussed at AHWP TC Leaders Meeting, May 2014
- Post on AHWP Website and Calls for Comments

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Yes / No?

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Guidance on Medical Device Quality Management System – Requirements for Distributors

FINAL DOCUMENT – GUIDANCE DOCUMENT

- Prepared by WG 7 – Quality Management System: Operation & Implementation
- Discussed at 18th AHWP Annual Meeting & AHWP TC Leader Meeting, May 2014
- Post on AHWP Website and Calls for Comments

Endorsement

Yes / No?

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Roles of Standards in the Assessment of Medical Devices

FINAL DOCUMENT – REFERENCE DOCUMENT

- Prepared by WG 8 – Standards and WG 2 – Pre-market: IVDD
- Discussed at AHWP TC Leaders Meeting, May 2014
- Post on AHWP Website and Calls for Comments

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Yes / No?

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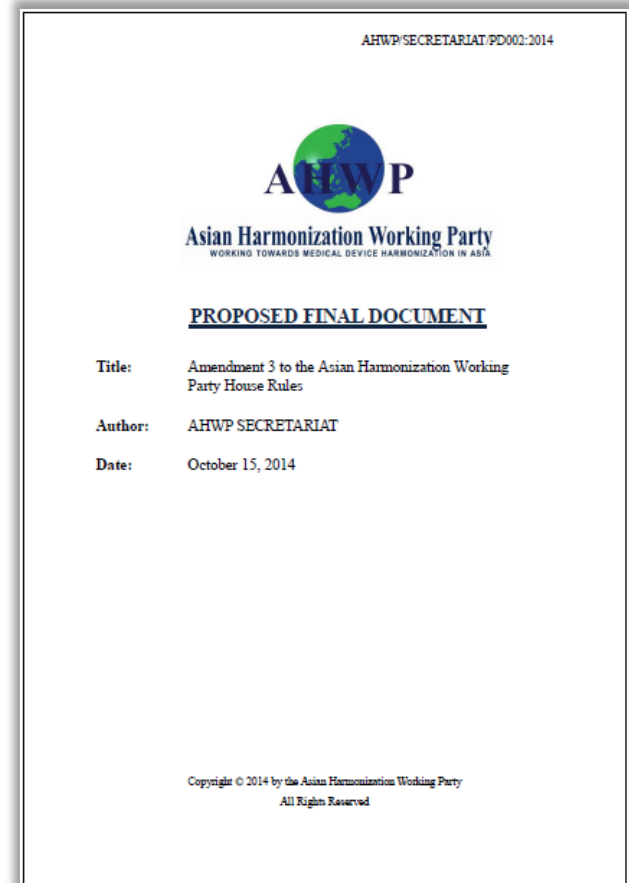
Amendment to the AHWP House Rules

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Amendment 3 to the Asian Harmonization Working Party House Rules

Overview

- Prepared by AHWP Secretariat
- Discussed at AHWP TC Leaders Meeting, May 2014
- Post on AHWP Website and Calls for Comments



Amendment 3 to the Asian Harmonization Working Party House Rules

Background

- The current AHWP House Rules is specified under the Final Document *AHWP/SECRETARIAT/F002:2013* resolved in the 18th AHWP Meeting and announced on 6 December 2013
- To *clarify* the roles of AHWP Technical Committee (TC) Advisors as the *responsibilities of AHWP TC Leaders and TC Advisors should be distinguished*
- AHWP & AHWPTC Terms of Reference can override AHWP House Rules when there is any discrepancy

Amendment 3 to the Asian Harmonization Working Party House Rules

Newly Proposed Text*

Clause 17 Advisor to AHWPTC **

B. The roles of TC Advisors is to bring their knowledge and experience to support the activities of the AHWP. This is accomplished via such activities as

- **providing objective advice,**
 - **gauging future trends for new strategic positioning,**
 - **advocating for the AHWP's harmonization work with the increase in its visibility globally, as well as**
 - **providing input on the scope of work through comments and recommendations,**
 - **providing support to TC's activities covering guidelines development,**
- for the decision making by AHWP TC and WG leaders on WG work items. TC advisors operate and provide input under the direction of the TC Chair.

* *The proposed clause is **changed into bullet point format for this presentation.***

** *The above **new clause 17.B** Advisor to AHWPTC is proposed to be added in AHWP House Rules between the **current** clause 17.A and 17.B with numbering of clauses under Clause 17. Advisor to AHWPTC to be updated accordingly.*

Endorsement

Yes / No?



THANK YOU

Amendment 3 to the Asian Harmonization Working Party House Rules

Newly Proposed Text

Clause 17 Advisor to AHWPTC *

B. The roles of TC Advisors is to bring their knowledge and experience to support the activities of the AHWP. This is accomplished via such activities as *providing objective advice, gauging future trends for new strategic positioning, advocating for the AHWP's harmonization work with the increase in its visibility globally,* as well as *providing input on the scope of work through comments and recommendations, providing support to TC's activities covering guidelines development,* for the decision making by AHWP TC and WG leaders on WG work items. TC advisors operate and provide input under the direction of the TC Chair.

** The above **new clause 17.B** Advisor to AHWPTC is proposed to be added in AHWP House Rules between the current clause 17.A and 17.B with numbering of clauses under Clause 17. Advisor to AHWPTC to be updated accordingly.*

Endorsement

Yes / No?