Regulation of Blood and Blood Products in Tanzania: The Current Progress, Challenges and Way Forward

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Outline

• Background
• Blood Supply in Tanzania
• Regulation of Blood and Blood Products in Tanzania
• Challenges
• Current Progress
• Way Forward
• Conclusion
• Acknowledgment
Introduction

The Current Regulatory Framework

- TMDA formerly TFDA established by Cap 219
- Agency under MoH for regulating safety, quality and effectiveness of medicines, medical devices and diagnostics in Tanzania mainland
  - ISO 9001: 2015 in regulation of products;
  - ISO/IEC 17025: 2017 for laboratory testing (microbiology);
- WHO Maturity Level 3
Blood Supply in Tanzania

National Blood Transfusion Services (NBTS)

- Established in 2004
- Under the MoH
- Main provider of all blood services in Tanzania (Estimated Population of 54.2 million - 2018)
- Eight Blood Transfusion Zonal Centers - 14 blood collection and distribution sites and 30 regional blood collection centers
- Collects about 300,000 units per year
- Implementing QMS and Certified by AfSBT

Roles and Responsibilities

- Blood Donor Mobilization and Recruitment
- Blood donor selection
- Blood collection from Voluntary Non Remunerated Blood Donors (VNRBDs)
- Testing of TTI (HIV Ag/Ab, HBsAg, HCV, Syphilis - Full Automation for all markers)
- Processing of blood, storage and distribution of safe blood to all hospitals
Regulation of Blood and Blood Products

• Blood and Blood Products are included in a broad definition of medicine or drug Cap 219

• With the exception to PDMPs which are regulated as biological products, blood and blood components (including blood establishments and blood banks) were not regulated WHA 63.12

• “to take all the necessary steps to update their national regulations on donor assessment and deferral, .......”
Challenges

• No clear Legislative framework for provision of regulatory oversight
  • No clear definition to include blood and blood products and sections for regulation of product category
  • Standards for blood transfusion not defined
  • Roles and responsibility of stakeholders not stated and no defined coordination
  • No specified procedures to authorize, license or monitor compliance of blood establishments with cGMP
  • No procedures for registration of blood components or Hemovigilance system
• A new concept among blood operators as well as regulators
• Lack of adequate competencies and expertise
Steps Made

• Consultative meeting between NBTS and TMDA to discuss the importance, the roles and responsibilities of each institute in implementing regulatory framework
• Signing of memorandum of understanding and defining roles of each institute
• Drafting Regulations for Control of Blood and Blood products (2018) including all core functions of NRA as per the WHO Assessment criteria for national blood regulatory systems
• Partner Country in Global Health Protection Programme – Blood Train
• Benchmarking of systems for regulating blood and blood products using GBT (PEI, WHO, NEPAD) and develop IDP
• Developing guidelines - Ongoing

• Involved in Development of ToRs for formation of ABRF
Capacity Building

- Regional Workshop on blood regulatory systems Douala, Cameroon, 2018
  NBTS and TMDA
- Placement at PEI, Langen, Germany
  - Red Cross, CSL Plasma Frankfurt
  - Batch Testing, PDMP Licensing, Transfusion Medicine,
  - Inspection, mol. Virology, IVD,
  - Haemovigilance, Quality Management
- Inspection of Blood Facilities in Harare, 2019, attended by NBTS and TMDA
  - Mock-inspection of a blood establishment
- WHO/PEI/AfSBT workshop on regulatory systems, 2019 attended by NBTS and TMDA
Looking Forward 2019 - 2020

• Reviewing Main Law (Cap 219)
• Finalizing Regulations for Control of Blood and Blood Products
• Capacity building – Ongoing process
• Stakeholders meeting
• Mapping of Blood establishments activities conducted
• Inspection of blood establishments
• Licensing of blood establishments including components and processes
• Setting Hemovigilance systems as well strengthening existing ones IVDs
• Continuing with partnerships – ABRF
Conclusion

• Reviewing Legislative framework for provision of blood regulatory oversight
• Collaboration between stakeholders (NRA and NBTS)
• Capacity building
• ABRF a partnership to assist countries to close existing gaps
ACKNOWLEDGEMENT

- MoH
- TMDA
- NBTS
- WHO
- NEPAD
- ABRF
- PEI
- AfSBT

A Decade of regulatory harmonization in Africa: Where are we? Where do we go from here?