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The fight against substandard and falsified medical products in “Sub-Saharan” Africa : AUDA-NEPAD’s interventions

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Outlines

1.Introduction

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1-Introduction

AUDA-NEPAD is the the technical body of the African Union. The mandate of AUDA-NEPAD is to:

- **Coordinate and Execute** priority regional and continental projects to promote regional integration towards the accelerated realisation of Agenda 2063; and **Strengthen** capacity of African Union Member States and regional bodies, advance knowledge-based advisory support, undertake the full range of resource mobilisation and serve as the continent's technical interface with all Africa's development stakeholders and development partners.

- **African Medicines Regulatory Harmonization Initiative (AMRH).** The AMRH's inception in 2009, was the first step towards collective action to create an enabling policy and regulatory environment for medical products that are of good quality, safety and effective of health products in the continent.

- **The Regulatory framework** was found weak and affected by multiplication of fragmented initiatives across the continent adversely allowing SF to enter into African market (Vet and huaman)

2-Current situation and how to strengthen the control of SFVP

1. **Weak regulatory systems that may cause lack of oversight to the products and allowing the SF to enter the market.**
2. **Poor quality control which may render to inadequate quality control within the manufacturing and distribution process which may result into production and circulation of SF.**
3. **Lack enforcement in that even when regulation are present, weak enforcement might hinder detection and removal of SF**
4. **Presence of illicit trade networks and criminal organizations that are involved in production and distribution of SF.**
5. **Limited access to quality health care provision that can create demand for cheaper alternatives, making patients vulnerable to purchasing SFs.**
6. **Corruption in healthcare system that can facilitate entry of SFs through bribes, fraud or illicit means.**
7. **Lack of public awareness to consumers and health and livestock care workers about the risk of SFs can contribute to continued circulation of SFs.**
8. **Globalization of supply chain that makes it challenging to track and verify authenticity of products in African market**

3-Interventions for control of SFVPs to AU Member States [1]

Development of Policy and Standards:

1. Revised of the AU Model on medical products Regulation to respond to SFVP
2. Existence of a treaty for establishment of AMA that recognize medicines to include veterinary medicines (Art 2)
3. Development of the Reference Manual on legislation of SFVP
4. Development of the Continental Plan to fight SFVP providing a holistic approach to prevent, detect, respond and afford crosscutting actions to be taken against SFVP

Support to AU Member States:

1. **Somalia:** to improve legislation on medical products to include provisions on SFVP
2. **Namibia :** roadmap developed to improve legislation on medical products , including SFVP – Amendment of Medicines and related Substances control Act of 2003)
3. **Zambia** : to improve legislation on medical products, including provisions on SFVP – Amendment of Medicines and Allied Substances Act of 2013)
4. **DRC** : development of a National Action Plan on SFMP/SFVP

3.1 Interventions by support to AU RECS-SADC and EAC [2]

- SADC Veterinary Medicines Collaborative Initiative- Joint assessment of dossier. three (3) products (February 2025), cGMP inspection, training for Assessors workshop, process for biological and Vaccines and stakeholder engagement
- Funding TWG, leadership of HoA and coordination (ZAMRA, BoMRA and SAHPRA
- EAC: Harmonized Registration requirements, Joint assessment of dossier and Registration guidelines are in place

3.2 - Intervention-Declaration of African Ministers of Health against SF [3]

- **Fifth Ordinary Session** of the AU Specialised Technical Committee on Health, Population, Nutrition And Drug Control held in Addis Ababa, Ethiopia on 5-9 August 2024 (Expert Session &Ministerial session)
- **Deeply Concerned** that the proliferation of SF on the continent poses a real threat to public health and economy loss in Africa. The number of SF incidents from Africa reported through the WHO Global Surveillance Monitoring System have been increasing over the years. In October 2022, several deaths of children registered in the Gambia were linked to SF, number of Anti Microbial resistance(AMR) incidences in Africa ect
- **Need to change the approach**
- **Decision on NQCL, promote cooperation and reliance**

  - Led by AUDA-NEPAD to coordinate interventions on SF, the Ministers of health held in Addis Ababa, Ethiopia on 5-9 August 2024 called on AUDA-NEPAD, AUC and A-CDC to develop *a **continental Plan** for combating SF and "propose tangible actions at the continental, regional and national levels*"

  - RECs, Member States, and partners involved

3.3 Interventions- Finalize the SF Plan

Activities

Rationale

- Proliferation of SF
- Multiplication of fragmented initiatives across the continent
- Inexistence of a common Strategy
- Holistic Approach/strategy on the fight against SF

Objectives [4]

- Propose tangible actions to address (prevent, detect, respond and afford crosscutting activities) SF at the continental, regional and national in Africa.
- Promote a multi-sectoral approach to fight SF on the Continent
- Improve coordination and collaboration

Goals :

- Enhance legislative, enforcement and regulatory frameworks,
- Improve surveillance and monitoring systems,
- Foster regional and international cooperation, and strengthen the capacity of national stakeholders including, but not limited to, regulatory authorities, law enforcement, judiciary and civil society

3.4-Key actions by countries-2 [vet & human]-[5]

6.Having in place the supply chain management that enhance the traceability to track and prevent SF products from entering into the market -(vet inclusive).

7. Facilitating technological use of block chain, serialization, track and trace systems to enhance authentication of products.

8. Promoting public awareness about the risk posed by SFs and provide education including campaigns in the communication strategies.

9. Continental cooperation and partnership to address the size of the problem and facilitate sharing of information and Reliance.

10. Allocating important resources to interventions against SF, including intensifying research and situational analysis to assess the nature and extent of the problem

3.5-Priority interventions-Preventive [vet & human]-[6]

1. Finalize the Continental Plan against SF
2. Establish a Technical Committee on SF (Multispectral coordination mechanism): 2025
3. Expand advocacy : Nomination of AU Champion on the fight against SF(Head of State): **2025-2026**
4. Develop policy Framework on pre-shipment screening of products / engagement with producing countries which export to Africa (**2025-2026)**
5. Support the African Network of SF focal points (Common African position) from **2023**
6. Policy support (development of NAPs & strengthen national legislation, ratification of AMA) : **30 countries** in the next **3yr.**
7. Improve collaboration between Regulatory & procurement authorities :**2024-2028**
8. Support to Pooled Procurement Mechanisms : **2024-2028**

3.6-Key Actions- Detection & response [vet & human]-[7]

9. Implement AU STC Decision on NQCL: promote cooperation and reliance
10. Operationalize the NARL (2025)
11. Accreditation & ISO certification
12. Support NRAs to approach ML3 in market surveillance and control module including setting digital reporting systems and market sampling, and data system/analytics capabilities
13. Support the implementation of cross border surveillance (RECs)

4- Way forward-**Strengthening collaboration- WOAH and AUDA NEPAD**

- Strengthening collaboration- WOAH and AUDA NEPAD for tackling SFVP in Africa
- Exploring WHO existing framework for SF to address the context of WOAH
- Harmonizing the legal and institutional regulatory policy and framework for both veterinary and human medical products at national, continental and global paradigms
- Continental state of affairs calls for comprehensive and effective one health approach in the context of WOAH and WHO
- Review of legal texts, standards and current processes/governance initiatives relevant to the continent (soft law and hard law) to improve SFVPs
- Review of legal texts, standards and current processes/governance initiatives relevant to the continent (soft law and hard law) and evaluate their impact to the continent to address the SFVP on the same regime with human SFMPs