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English Speaking Africa Training Seminar for National Veterinary Products

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WHO Guidelines and Regional AMR Activities

Prof Aaron O. Aboderin
Antimicrobial Stewardship Consultant
AMR Unit_ ARD Cluster
WHO/AFRO

Presentation outline

- Introduction /Background
- AFRO's AMR priority areas & support to member countries
- Mainstreaming of Antimicrobial Stewardship into Regulatory Inspections and Manufacturing of Medical Products

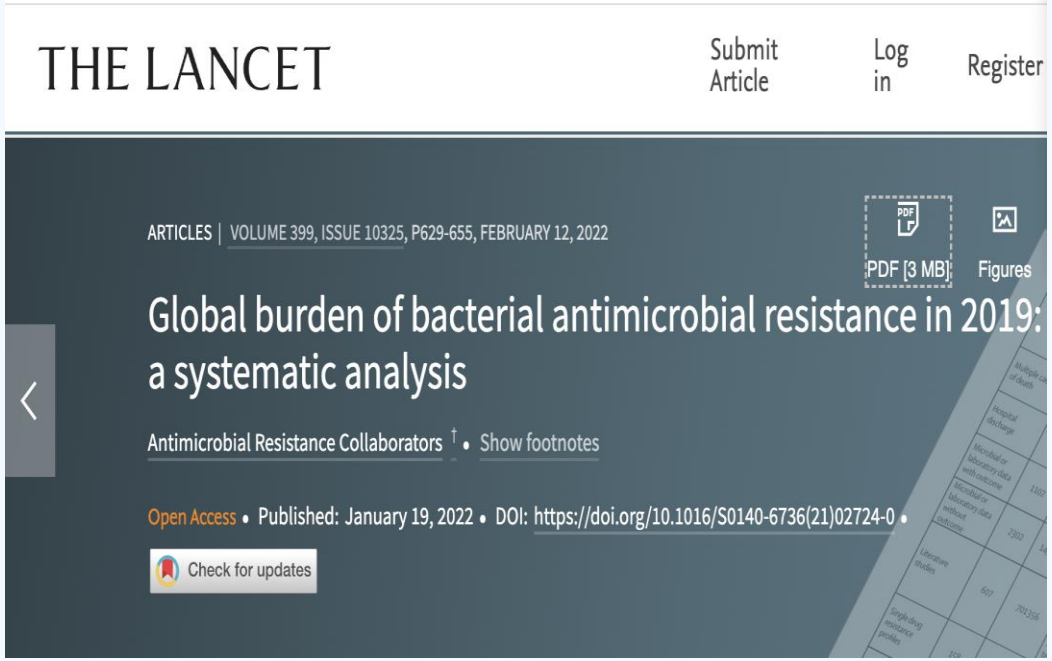
AMR, a global crisis

- AMR is one of the leading causes of deaths globally
- Lancet report – in 2019, 4.95 million people who died suffered from drug-resistant bacterial infections.
- Globally, more people died due to reasons related to AMR than HIV/AIDS or malaria.

The largest burden occurred in the sub-Saharan Africa region

- Number of deaths attributable to AMR - 255,194 deaths
- Deaths associated - 1.07M

'It will be DEATH OF MAN' Sir Alexander Fleming WARNING over antibiotic resistance (Image: GETTY)



WHO's 13th General Program of Work (GPW)

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Focused on the SDGs, UHC & WHO Impact Framework; By 2023

- UHC coverage – **1 billion more** people with health coverage
- Health emergencies – **1 billion more** people made safer
- iorities – **1 billion**
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AMR Unit

Supports Member States to address AMR across key technical areas:

- Strengthening Governance, Multisectoral partnership and Coordination
- Raising awareness and understanding on AMR
- Strengthening surveillance systems and laboratory capacity
- Promoting optimal use of antimicrobials

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AFRO's AMR priority areas & support to member countries

NAP Development & Implementation Progress

01

One Health - AMR plans

❖ AMR NAP development -46 countries with AMR NAPs of which 34 approved by national authorities

❖81% of NAPs linked to other National plans(NHSP, NAPHS etc)

❖ 6 countries trained on the AMR WHO Costing and budgeting tool & 4 have used the tool to cost NAP operational plans

01

One Health - AMR plans

❖ Multisectoral Leadership and coordination tools for capacity building

❖ 42 countries (89%) responded to the 6th round TrACSS 2022

❖Documentation of 2021 and 2022 TrACSS findings to inform country progress

46 countries had developed AMR National Action Plans: Angola; Benin; Botswana; Burkina Faso; Burundi; Cabo Verde; Cameroon; Chad; Comoros; Congo; Cote d'Ivoire; DRC; Equatorial Guinea; Eswatini; Eritrea; Ethiopia; Gabon; Ghana; Guinea; Kenya; Liberia; Madagascar; Mali; Malawi; Mauritania; Mauritius; Mozambique; Namibia; Niger; Nigeria; Rwanda; Senegal; Seychelles; Sierra Leone; South Africa; United Republic of Tanzania; Togo; Uganda; Zambia and, Zimbabwe

34 of which are approved by national authorities: Burundi, Cameroon; Chad; Comoros; Congo, DRC; Equatorial Guinea; Eritrea; Eswatini; Ethiopia; Gabon; Ghana; Guinea; Kenya; Liberia; Madagascar; Malawi; Mali; Mauritius; Mozambique; Namibia; Nigeria; Sierra Leone; Rwanda; Senegal; South Africa; United Republic of Tanzania; Togo Uganda ; Zambia and, Zimbabwe

Awareness & Education

02

❖DRASA Pilot Project producing AMR ambassadors who will be positive change agents in their families, among their peers and communities at large.

❖AMR Education and Awareness Regional Webinar series-Over 19 countries capacitated in packaging and effective communication

❖170 regulators trained to mainstream AMR into regulatory & manufacturing product inspections

02

❖Regional Education and Awareness Status Report for the WHO Afro Region completed – Targeted for release during WAAW

❖ Quadripartite, ACDC & AU-IBAR Joint commemoration of World Antimicrobial Awareness Week at the continental (2019, 2020,2021 and 2022)

WAAW Commemoration

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DRASA AMR Awareness Pilot Project

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Surveillance

03

- ❖ 79% (36) of countries enrolled in GLASS for standard AMR surveillance
- ❖28 enrolled into EQA for AMR Surveillance
- ❖ 13 countries reported AMC data in 2022

03

- ❖8 countries implementing intergrated surveillance (ESBL Tricycle)
- ❖Countries supported in development of policy briefs for use of AMR data for decision making

Infection Prevention & Control

04

- ❖Capacity building-Training of trainers in IPC (7,000 +)
- ❖Establish sub national IPC taskforces & committees in health facilities
- ❖Guidance on linkage between IPC and AMR
- ❖Implementation of standard precaution-Hand hygiene ,respiratory hygiene, waste reprocessing of reusable materials

Optimal use of antimicrobials

05

❖ 15 countries supported in point-prevalence surveys on antimicrobial use in hospitals & 13 countries capacities strengthened in monitoring antibiotic

❖Mainstreaming AMR into Medical Products Manufacturing & regulatory Inspections

❖Regional Antimicrobial Stewardship Webinar Series to build capacity for AMS implementation in the region

05

❖Capacity strengthening of experts from 33 member states: more than 270 national experts trained AWaRe Categorization

❖ 27 (57.4%) countries have integrated Aware Categorization into the national essential medicines list/ formulary

❖8 (17%) countries have developed national antimicrobial stewardship implementation policy

Mainstreaming of Antimicrobial Stewardship into Regulatory Inspections and Manufacturing of Medical Products

Rationale

- The need to address AMR in line with the One Health approach necessitates the co-opting of NMRAs, regulators and manufacturers into strategies to mitigate the threat posed by AMR

- The NMRAs regulatory inspectors conduct Good Manufacturing Practice (GMP) inspections for medical products to verify that the producers adhere to global best standards for manufacturing of medical products.

- NEMAs enforce regulations for the protection of the environment from industrial waste, which in the case of pharmaceuticals may contain antimicrobial product residues that can result in AMR.

Rationale

- As a result, NMRAs and EWPAs are well-positioned to spot any problems with the production procedures that might eventually lead to the development of AMR.

- Manufacturers have to address these AMR concerns under the guidance of national drug regulatory agencies and environmental protection agencies.

Part 1: Training of regulatory inspectors & development of Technical Guidance & Aide-Mémoire

Training

In 2020, **Training** of inspectors for medical products conducted &

an **Aide-Mémoire** was developed

In 2021, a **technical guidance** that provides the framework for the use of the Aide-Mémoire was developed

Piloting done to determine the **suitability** & **applicability** of the technical guidance & aide-mémoire during regulatory inspections

Piloting the Technical Guidance & Aide-Mémoire (Inspection Tool)

Piloting done by a team that consisted of:

- GMP inspectors
- Environment Management Authority inspectors
- AMR experts

at two pharmaceutical manufacturing facilities:

Cipla Quality Chemical Industries Ltd., Uganda;

Yash Life Sciences Ltd., Zambia.

Pilot inspection of Effluent Treatment Plants

ETP in Uganda

WHO Team & Environmental inspectors during the pilot inspection in Uganda

ETP in Zambia

WHO Team & Environmental inspectors during the pilot inspection in Zambia

Inspecting residue air discharged at the exhaust unit of an air handling unit

Air Handling Units, (point of dust/ antimicrobial product residue discharge at factories)

Environment inspector checking discharge residues in Uganda

Discharge limits and results – ***currently not aligned to AMR limits***

Part 2: Recommendations from Pilot Inspections of the Inspection Tool

Recommendations From Pilot Inspections

NMRAs and national environment management authorities

01

should receive specialised training and awareness on antimicrobial waste management (including specialised training in AMR site risk assessments) as part of their stewardship towards the fight against AMR.

Governments and the United Nations procurement agencies

02

should provide incentives geared towards encouragement of pharmaceutical manufacturers to voluntarily comply with the AMR reduction requirements.

03

04

Recommendations From Pilot Inspections

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AMS recommendations

Central/accredited analytical laboratories

01 should be supported to build capacity to sample and test antimicrobial residues in the effluent discharge waters, including water bodies nearest to the pharmaceutical factories, to levels as small as those required for the PNEC-ENV or PNEC-MIC of the antimicrobial APIs..

03

National environment management authorities

02 should be supported to amend their respective National Environment Standards for Discharge of Effluent into Water or Land Regulations so as to provide maximum permissible limits that are within the PNEC-ENV or PNEC-MIC for all antimicrobial active ingredient.

04

Recommendations From Pilot Inspections

AMS recommendations

API Manufacturers

05 provide information on waste and waste water treatment methods for each antimicrobial API as part of Material Safety Data Sheets (MSDS.

WHO and coordinating UN agencies on AMR (FAO, WOAH, UNEP)

06 should consider publishing guidance on test methods that are able to quantify antimicrobial residues in solid, semi-solid and liquid waste at the level of the PNEC values (**in µg/L**) as these are currently not available to the pharmaceutical industry). Also provide references for the discharge targets, PNEC values for all antimicrobial APIs.

Recommendations From Pilot Inspections

Laundry companies and Waste disposal companies

should be required to apply decontamination methods that deactivate the antimicrobial residues in the effluent and waste water generated during the laundering of the protective clothing.

This should be made one of the licensing requirements

07

04

AMS recommendations

Objective of the Inspection Tool

To provide key areas that regulatory / self-inspection inspectors need to consider in embedding the AMR perspective into their routine inspection practices.

- *Particularly issues relating to:*
  - *waste management and protection of the environment from antimicrobial waste; &*
  - *cross-contamination of antimicrobial products*

Scope of the Inspection Tool

The tool applies to all areas where the handling of antimicrobial substances, ingredients (APIs) or products could lead to cross-contamination, or discharge to the

- Include manufacturing sites for antimicrobial ingredients (APIs) &
- finished pharmaceutical products (FPPs) for human and veterinary use.

Developed Training Prospectus and Training Materials

Intended to raise awareness of:

- AMR as a global health challenge
- what NMRAs, NEMAs & manufacturers of antimicrobial products can do in spearheading AMR awareness & implementation of appropriate controls for curbing AMR, in the spirit of One Health approach

Capacity Building for heads of NMRAs & NEMAs

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AMR Unit
WHO/AFRO
Brazzaville, Congo