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SUSTAINABLE DEVELOPMENT GOALS

FAOs project activities sensitive and specific to Substandard medical products and (or) counterfeit (falsified) medical products

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Food and Agriculture Organization of the United Nations

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SUSTAINABLE DEVELOPMENT GOALS

Introduction

- Circulation of substandard and (or) counterfeit (falsified) medical products poses serious threat to the health and welfare of the people and animals - *Undermine food security and economic development*
- **Solutions lie in – prevent, detect and minimize their circulation** (imports, national distribution, and exports)
- To do this, we need regulatory instruments, including rules for destruction of substandard and counterfeit medicines when they are detected
- Enforcement of the rules
- Need for compliance by all actors
- Monitoring for compliance and barriers by regulatory authorities
- Policy and Technical solutions to remove barriers to compliance

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Key Actions Taken by FAO at regional level

Capacity Building for Veterinary and Farm-Level Surveillance

- Training veterinarians, farmers, and animal health professionals to identify and report SF antimicrobials
- Strengthening farm-level surveillance systems to detect counterfeit and low-quality antimicrobial products used in poultry, dairy, and livestock farms

Enhancing Regulatory Frameworks and Governance

- Supporting national governments in developing and enforcing policies to regulate antimicrobial quality control.
- Collaborating with national regulatory authorities to strengthen laws preventing the sale and distribution of SF antimicrobials
- Collaborating with regulatory authorities to strengthen compliance and enforcement of laws on SFM – case in point Zimbabwe through the ACE program

Laboratory Strengthening and Quality Control

- Equipping laboratories with advanced diagnostic tools to analyse and confirm antimicrobial quality
- Introducing field-testing kits to detect substandard products at farm supply points

Promoting Good Practices Among Farmers

- Launching awareness campaigns through Farmer Field Schools (FFS) to educate farmers on recognising and avoiding SF antimicrobials
- Promoting best practices in antimicrobial use (e.g., correct dosing, storage, and disposal) to prevent resistance development

Regional and International Partnerships

- Working with WHO, WOAH and national food and drugs authorities to track and curb the spread of SF antimicrobials across borders
- Setting up cross-border monitoring programs to detect and report illegal antimicrobial trade at farm level

Regulatory instruments strengthening

- Regulatory assessments
- Focus on - entire Agriculture sector (env, crops, AH, etc) – e.g. of countries with reports available - Kenya, Malawi, Madagascar, Mozambique, Lesotho
- PMP - Tanzania, Uganda, Kenya, Burundi, Rwanda, Ethiopia, Benin, South Sudan, DRC, Guinea Conakry, Burkina Faso, Togo, Sudan, Ghana - Helps to:
  - PMP tool - identifies NAP formulation to gaps to address the SFs issues at all levels, including farms
  - Identifies NAP implementation gaps to address the issue at all levels, including farms
  - E.g. After PMP - FAO supported the Ethiopia government in integrating SFM antimicrobial surveillance into its NAP on AMR. The country has since improved reporting mechanisms and veterinary authorities have successfully intercepted shipments of counterfeit animal drugs
- Developed guidelines for the safe disposal of unfit-for-use veterinary medicines (Ethiopia)
- Working with WHO on One Health Legal Assessment Tool (OHLAT) – extends the tool into the PH sector - piloted in Zimbabwe in 2022/23

Strengthening Legislation and Building Capacity to Support Agrifood Systems Implementation, Compliance and Enforcement Programme

Outcome

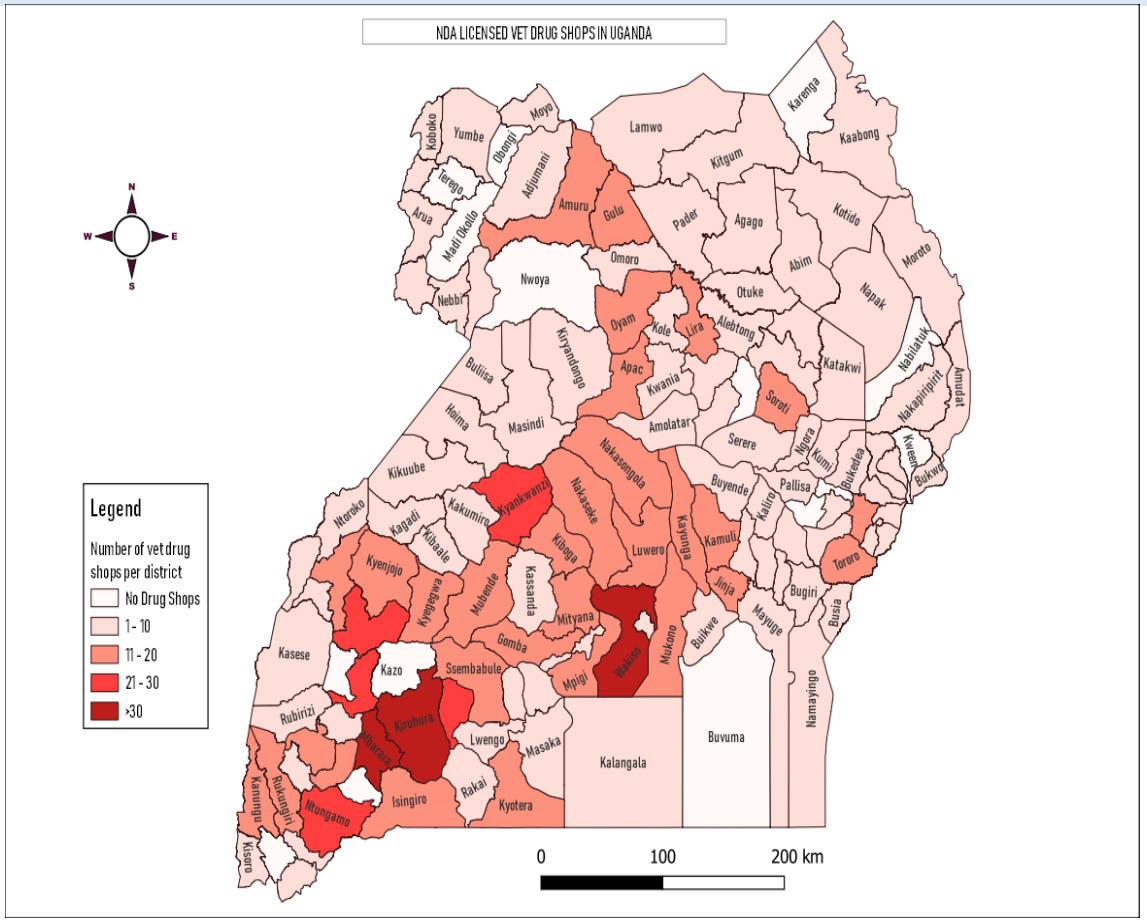
Strengthened regulatory frameworks and effective institutional capacity for implementation, compliance and enforcement of agrifood systems legislation.

Regional ACE Programme

- Started on 27 September 2024,
- Objective:
  - Strengthen legal frameworks for sustainable agrifood systems, with a focus on compliance and enforcement in Zimbabwe, Eswatini, and Lesotho
  - Field component focusing on strengthening the compliance and enforcement of national legislation under a One Health approach
  - training sessions for veterinary inspectors on handling SFMs and collaborative efforts with the Southern African Development Community (SADC) countries to harmonize regional legislation
  - In Zimbabwe, the ACE programme will focus on compliance and enforcement of laws on SFM
- Training of Trainers has been conducted for RA inspectors as well as for judiciary, Police, prosecutors and Revenue Authority to enhance capacity for compliance and enforcement trough Nelson Mandela University

Mapping of drug supply chains and barrier to compliance

- To understand the circulation system
- Key findings relevant for SFM - Kenya, Mozambique, Uganda, Tanzania
  - Inadequate information systems to capture imports, exports, and distribution and use
  - The supply chain is dominated by the private sector - Issues of compliance and self–regulation arise (Govt cannot be everywhere)
  - Public sector underfunded to monitor for SFMs
  - Circulation of unregistered drugs – need for testing
  - Perceived high cost of medicines – may push for cheaper substandard
  - Inadequate lab capacity to test the quality and effectiveness of drugs entering the country.
  - Mislabeling of medicines



The distribution of veterinary drug shops in the districts of Uganda

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DESCRIPTION:

[redacted] Egg Formula wsp is a highly effective combination of broad-spectrum antibiotics and vitamins. Oxytetracycline belongs to the group of tetracyclines and acts bacteriostatic against many Gram-positive and Gram-negative bacteria like Bordetella, Campylobacter, Chlamydia, E. coli, Haemophilus, Mycoplasma, Pasteurella, Rickettsia, Salmonella, Staphylo-coccus and Streptococcus spp. The action of oxytetracycline is based on inhibition of bacterial synthesis. Oxytetracycline is mainly excreted in urine and for a small part in bile. Neomycin is an amino-glycoside with bactericidal action against mainly Gram-negative bacteria like E. coli, Klebsiella, Pasteurella, Salmonella and Staphylococcus spp. Vitamins are essential for the proper operation of several physiological functions.

INDICATIONS:

[redacted] Egg Formula wsp is especially produced for layers and ensures:

- Higher peak egg production level.
- Maintenance of high production level throughout the laying period.
- Increased egg production when there is a drop in performance caused by stress situations.
- Reduced mortality throughout the laying period.
- Increased feed conversion efficiency.

SIDE EFFECTS:

None.

DOSAGE AND ADMINISTRATION:

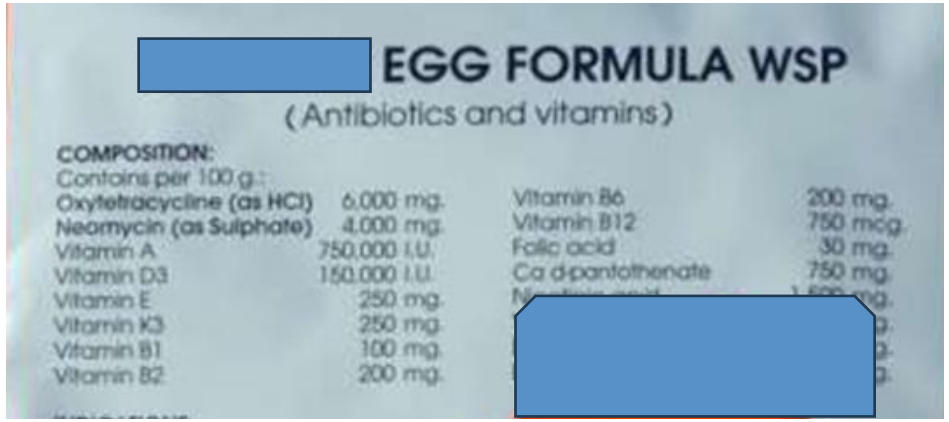
For oral administration via drinking water.

- Poultry: : 100 g per 100 litres of drinking water during 3 – 5 days.

Medicated drinking water should be used within 24 hours.

WITHDRAWAL PERIOD:

Edible tissues : 7 days
Eggs : 2 days



[redacted] EGG FORMULA WSP

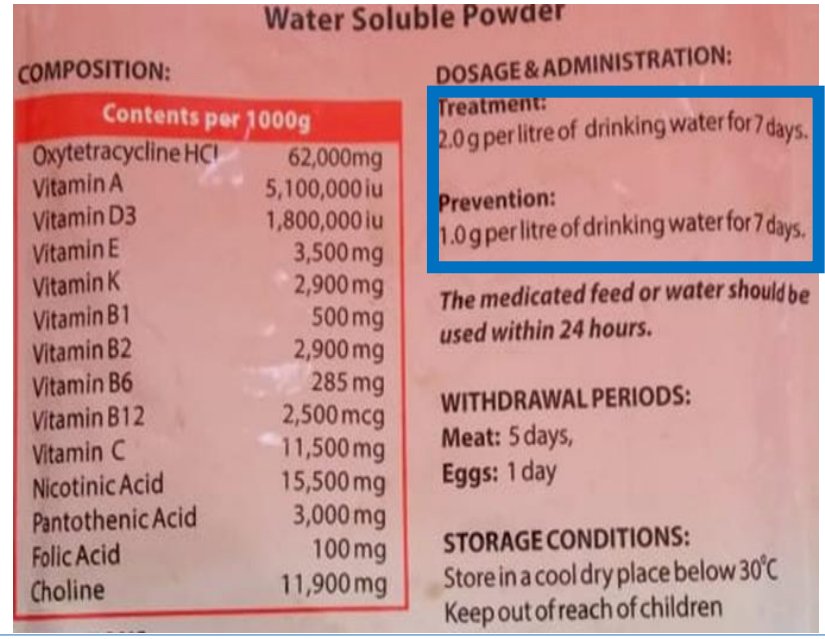
(Antibiotics and vitamins)

COMPOSITION:
Contains per 100 g.:

Oxytetracycline (as HCl)	6.000 mg.	Vitamin B6	200 mg.
Neomycin (as Sulphate)	4.000 mg.	Vitamin B12	750 mcg.
Vitamin A	750.000 I.U.	Folic acid	30 mg.
Vitamin D3	150.000 I.U.	Ca d-pantothenate	750 mg.
Vitamin E	250 mg.		
Vitamin K3	250 mg.		
Vitamin B1	100 mg.		
Vitamin B2	200 mg.		

[redacted]

Mislabelling



Water Soluble Powder

COMPOSITION:

Contents per 1000g	
Oxytetracycline HCl	62,000mg
Vitamin A	5,100,000 iu
Vitamin D3	1,800,000 iu
Vitamin E	3,500 mg
Vitamin K	2,900 mg
Vitamin B1	500 mg
Vitamin B2	2,900 mg
Vitamin B6	285 mg
Vitamin B12	2,500 mcg
Vitamin C	11,500 mg
Nicotinic Acid	15,500 mg
Pantothenic Acid	3,000 mg
Folic Acid	100 mg
Choline	11,900 mg

DOSAGE & ADMINISTRATION:

Treatment:
2.0 g per litre of drinking water for 7 days.

Prevention:
1.0 g per litre of drinking water for 7 days.

The medicated feed or water should be used within 24 hours.

WITHDRAWAL PERIODS:
Meat: 5 days,
Eggs: 1 day

STORAGE CONDITIONS:
Store in a cool dry place below 30°C
Keep out of reach of children

Is it correct to have antibiotics for prophylaxis?

antibiotics

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Understanding Antimicrobial Use Contexts in the Poultry Sector: Challenges for Small-Scale Layer Farms in Kenya

by Stella Kiambi [1,*], Rosemary Mwanza [2], Anima Sirma [3], Christine Czerniak [4], Tabitha Kimani [1], Emmanuel Kabali [4], Alejandro Dorado-Garcia [4], Suzanne Eckford [5], Cortney Price [4], Stephen Gikonyo [1], Denis K. Byarugaba [6] and Mark A. Caudell [1]

Antibiotic Symbol	Main Chemical Components	Manufacturer's Description on the Label	Manufacturer's Indications for Use on the Label	Withdrawal (Eggs)	No. of HHs Reporting Use (%)
AB1	- Oxytetracycline (as HCl) - Neomycin (as sulphate) - Multivitamins	- Oxytetracycline bacteriostatic (gram-positive and gram-negative bacteria) - Neomycin bactericidal (gram-negative bacteria) - Vitamins are essential for the proper operation of several physiological functions	- *Higher peak egg production level* - *Maintenance of high production level throughout the laying period* - *Increased egg production when there is a drop-in performance caused by stress situations* - *Reduced mortality throughout the laying period* - *Increased feed conversion efficiency*	2 days	69
AB2	- Erythromycin thiocyanate - Oxytetracycline hydrochloride - Streptomycin sulphate - Colistin sulphate - Multivitamins	- Colistin bactericidal action (Gram-negative bacteria) - Oxytetracycline bacteriostatic (gram-positive and gram-negative bacteria) - Erythromycin bacteriostatic (gram-positive bacteria) - Streptomycin bactericidal (gram-negative bacteria) - Vitamins are essential for the proper operation of several physiological functions	- *Stimulates egg production, increases growth, improves feed conversion and is used as vitamin supplement during periods of diseases and stress* - Effective against gastrointestinal, respiratory and urinary infections caused by colistin, oxytetracycline, erythromycin and streptomycin sensitive micro-organisms	1 day	44
AB3	- Oxytetracycline hydrochloride	- Oxytetracycline bacteriostatic (gram-positive and gram-negative bacteria)	- Treatment of bacterial infections where the causative agents are sensitive to oxytetracycline - *In chicks: it maintains appetite during stress periods like vaccination, temperatures changes or changes in feeds*	Not shown	21
AB4	- Oxytetracycline - Neomycin - Multivitamins	- Oxytetracycline bacteriostatic (gram-positive and gram-negative bacteria) - Neomycin bactericidal (gram-negative bacteria) - Vitamins are essential for the proper operation of numerous physiological functions	- *Stimulates egg production* - *Increases growth* - *Improves feed conversion* - **Used as a vitamin supplement during periods of diseases and stress** - Treatment of gastrointestinal, respiratory and urinary infections caused by oxytetracycline and neomycin sensitive micro-organisms	1 day	19

https://www.mdpi.com/207
9-6382/10/2/106

Methods of detection SF – provision of minilabs – Rwanda and Ethiopia

Rwanda's Minilab provided by FAO to field-test substandard and falsified (SF) veterinary products

10 samples (Sulfamethoxazole/Trimethoprim) out of 130 (7.7%) passed the visual inspections but later failed to comply with Thin-Layer Chromatography result specifications.

Ethiopia

KAP of farmers and AHCPs on SFMs

Visual/physical, screen and pharmacopeial quality testing of veterinary antimicrobials from the market

Provided capacity training development on the use of minilabs for veterinary antimicrobials

Screened substandard and falsified medicines from the market using minilabs

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Farmer Field Schools AMU/SFM data collection

- KAP surveys identify sources of drugs for producers
  - Unlicensed sources – risk for introduction of SFMs
- Detailed information on antimicrobials used in broiler production including price and photos of packaging
- Falsified and sub-standard medicines likely to be identified through packaging photos, including labelling information – visual inspection
- FAO has raised awareness among farmers on identifying SFM antimicrobials, proper drug use, and the dangers of using counterfeit or poor-quality veterinary drugs

Challenge: counterfeiters are smarter, and labels are almost becoming the same as the original product, and it is difficult to differentiate the two

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Some Indicators used in for monitoring SFM antimicrobials.....Ghana Case study

Variable	Number	Percentage (%)
Product contain vitamins	150	46.0%
Are active ingredient(s) name spelt correctly	302	92.6%
Are the manufacturer's name and logo legible, and correct?	303	92.9%
Manufacturer's full address legible, and correct?	301	92.3%
Amount of active ingredient per unit - clearly stated on the label	289	88.7%
Dosage clearly indicated on the label (e.g., grams per liter of drinking	306	93.9%
Number of treatment days clearly indicated on the label?	306	93.9%
Are directions for use (process of administration clearly stated? (easy for fa	306	93.9%
Are the indications of use clearly stated?	302	92.6%
Manufacture and expiry dates clearly indicated on the label	302	92.6%
Are the storage conditions clearly indicated on the label?	288	88.3%
Does the package indicate product can be used as prevention?	185	56.7%
Does the package contain any growth promotion language?	70	21.5%
Was antimicrobial prescribed?	190	58.3%

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Substandard and Falsified VMPs Control and Management – global initiative adopted at the UNGA 2024

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FAO's RENOFARM initiative

FAO's **RENOFARM** initiative, part of the UNGA-AMR 2024 declaration, is the **key approach** to achieve the global target of **significantly reducing global antimicrobial use in agrifood systems by 2030.**

3rd High-level Ministerial Conference, Oman

RENOFARM Launch 25/4/24

TARGETS

- **100 countries subscribed** to the initiative, with their NAPs for AMR fully implemented in Food and Agriculture
- **50% of animal/plant health workers** from participating countries are trained
- **80% of all participating countries** contributing data to InFARM (global surveillance platform for AMR in Agric and AMU in crops)

UNGA-AMR 2024 (26/9/24)

4th Global High-level Ministerial Conference, Saudi Arabia

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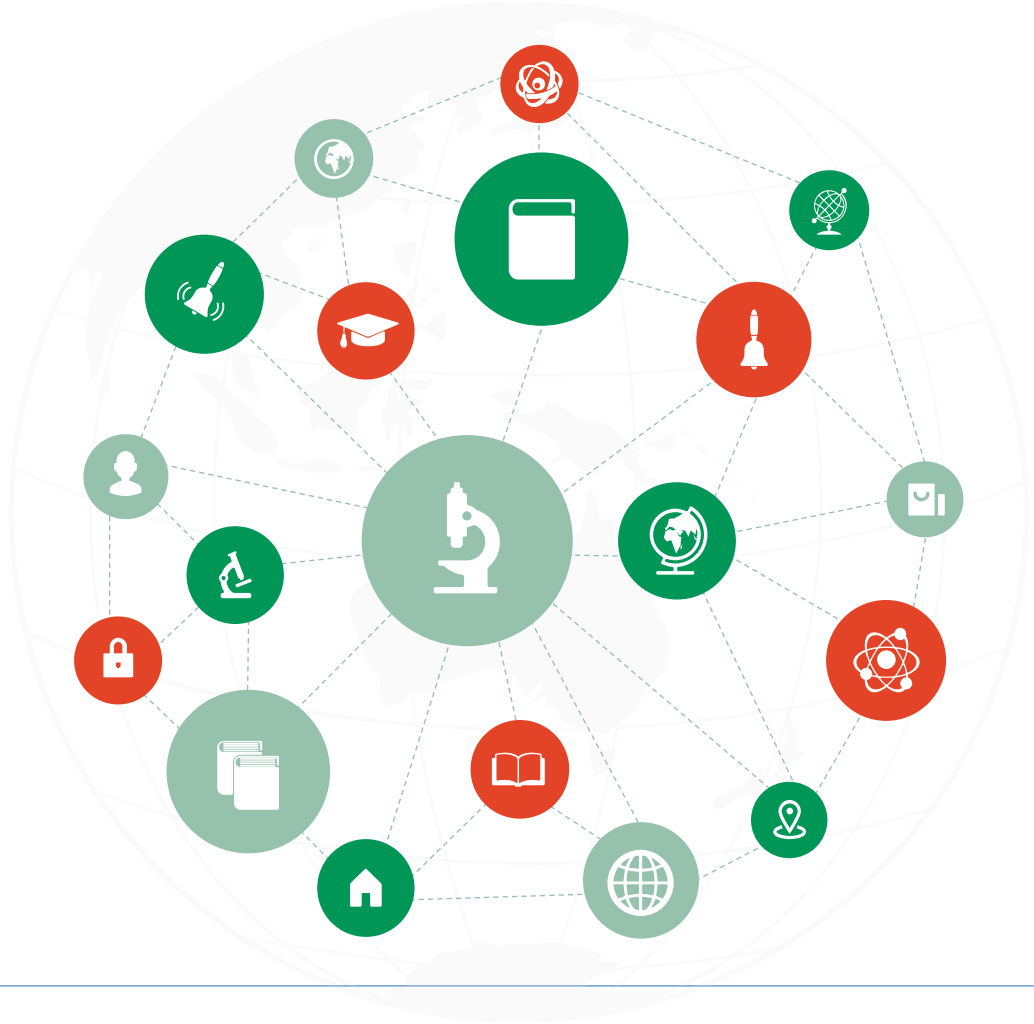
GOALS - SFMs Control and Management



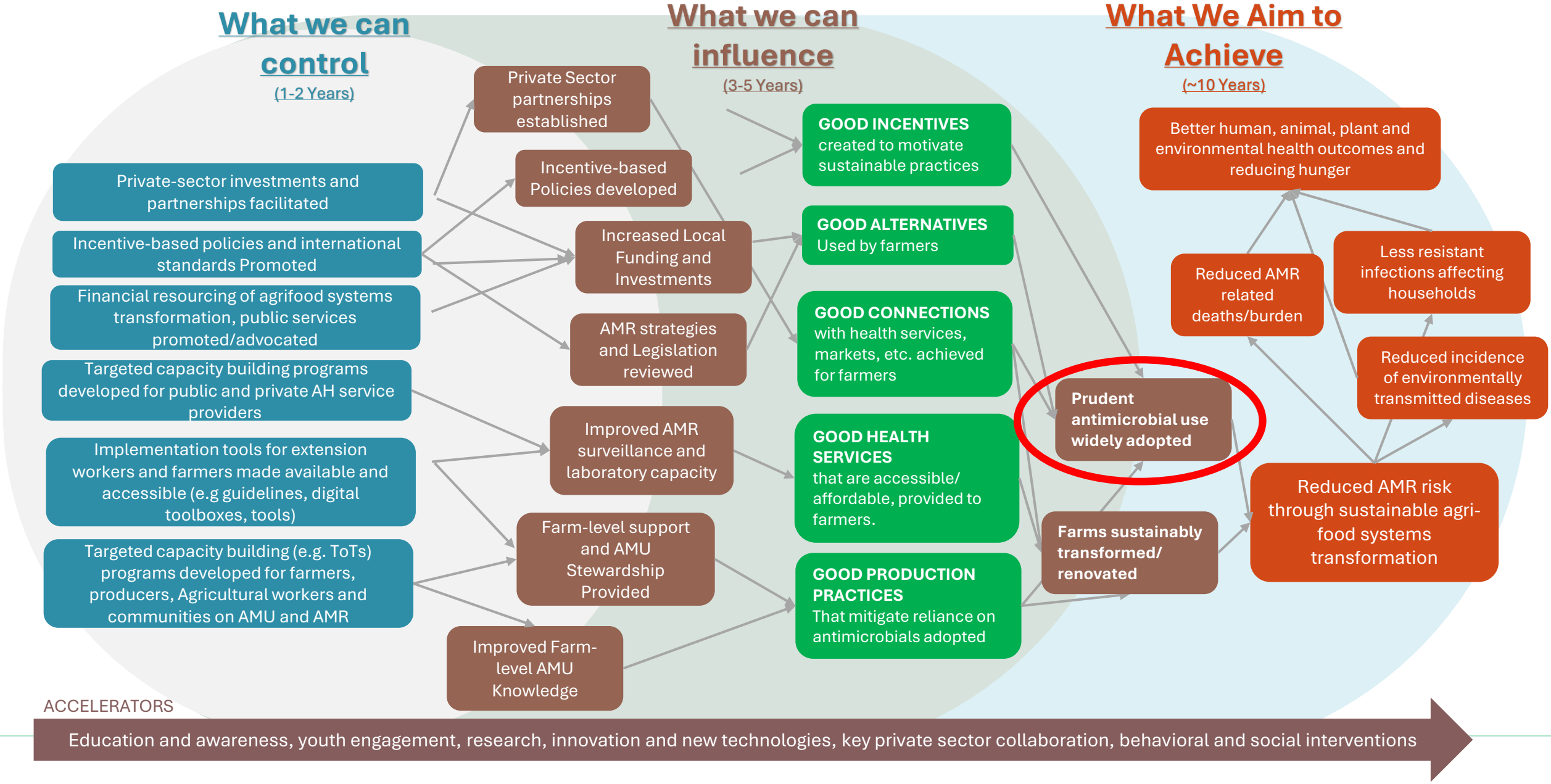
Provide guidance to member countries on SFMs control and management

Share good practices on SFM control

Support RENOFARM and One Health

Strengthen the network (FAO decentralized offices, FAO reference centres, WHO, WOAH, ICPO…)

Finalization of the RENOFARM Theory of Change



Thank you!

Merci!

Ahsante!