
**The use of Critically Important Antimicrobials in food producing animals in India**

CSE Webinar – on the 'CONSERVATION AGENDA'

Nov 22, 2021

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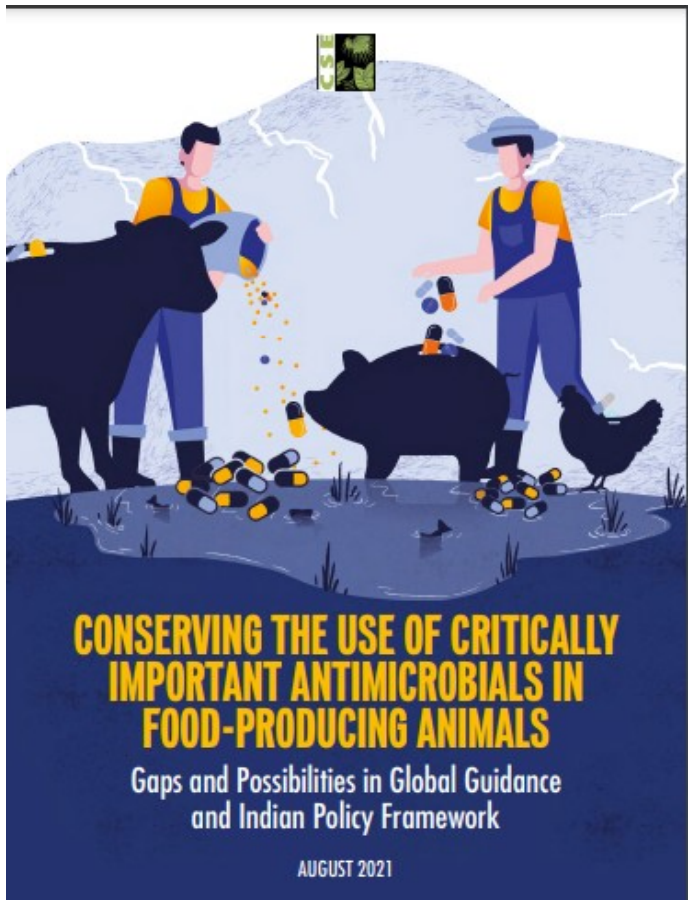
# CSE's latest report on conserving the use of critically important antimicrobials in food-producing animals

- **India**
  - Presents the **on-the-ground situation** in India wrt use of critically important antimicrobials in food-animal sector
  - Provides **a series of policy measures** including a roadmap to contain the misuse of critically important antimicrobials in food-animal production
- **Global**
  - Analyses the **global guidance of the Tripartite organizations** with regard to critically important antimicrobials
  - **Calls for coherence and uniformity in global guidance** on use of critically important antimicrobials in food-animals



# What are critically important antimicrobials?

- The **WHO has ranked all medically important antimicrobials** for risk management of AMR due to non-human use of antimicrobials
- Based on a criteria, antimicrobials are categorized into **critically important**, **highly important** and **important antimicrobials**
- Critically Important Antimicrobials are the **sole or one of the limited available therapies to treat serious bacterial infections in humans and are used to treat bacterial infections transmitted from non-human sources or infections from bacteria that may acquire resistance genes from non-human sources**
- Further categorized into **highest priority critically important antimicrobials (HPCIAs)** and high priority critically important antimicrobials based on 3 additional prioritization factors. HPCIAs meet all three.
- WHO 2018 list—Total 178 antimicrobials; **17 classes of CIAs; five out of which are HPCIAs**

| **Highest priority critically important antimicrobials** |
|---|
| **Cephalosporins (third-, fourth- and fifth-generation)** |
| **Glycopeptides (Also includes lipoglycopeptides)** |
| **Macrolides and ketolides** |
| **Polymyxins** |
| **Quinolones (also includes fluoroquinolones)** |
| **Critically important antimicrobials (other than HPCIAs)** |
| **Aminoglycosides** |
| **Ansamycins** |
| **Carbapenems and other penems** |
| **Glycylcyclines** |
| **Lipopeptides** |
| **Monobactams** |
| **Oxazolidinones** |
| **Penicillins (antipseudomonal)** |
| **Penicillins (aminopenicillins)** |
| **Penicillins (aminopenicillins with beta-lactamase inhibitors)** |
| **Phosphonic acid derivatives** |
| **Drugs used solely to treat tuberculosis/ mycobacterial diseases** |

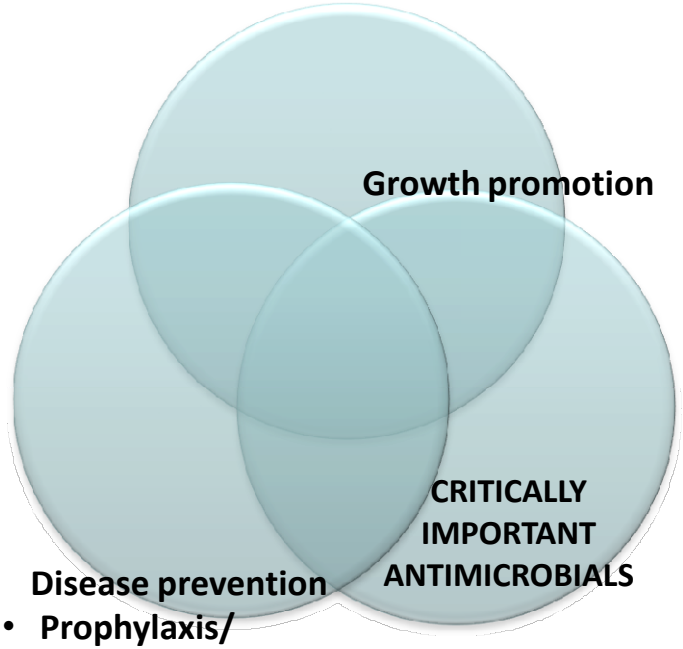
# Use of critically important antimicrobials in food-producing animals for different purposes

**PROPHYLAXIS/PREVENTION**

- Antimicrobials administered to an individual or group of animals with no clinical sign of a disease
- Often done routinely/intermittently

**METAPHYLAXIS/CONTROL**

- Antimicrobials administered in therapeutic doses to a group of animals wherein one or more animals are infected but others do not show clinical signs.
- Acts as a treatment for those who are ill but preventive for others




**GROWTH PROMOTION**

- Use of antimicrobials to increase the rate of weight gain or efficiency of feed utilization
- Routinely used at a mass scale through feed at sub-therapeutic doses

**TREATMENT**
Use of antimicrobials at therapeutic dose to treat an infectious disease having clinical signs and/or symptoms

# Key findings of the CSE report

- Critically important antibiotics are **misused and overused** in Indian food-animal production sector
- Used for **treatment, prevention and control of diseases, growth promotion** and also in case of **non-bacterial diseases/infections**
- Overall, **twenty seven** critically important antimicrobials from **seven classes** were found to be used in **dairy, poultry and aquaculture** for both therapeutic and non-therapeutic purposes
- **Eighteen** were from **three highest priority critically important antimicrobial classes**, i.e. macrolides and ketolides; third-, fourth- and fifth-generation cephalosporins; and quinolones and fluoroquinolones
- Several **gaps and possibilities identified in the policy framework** related to antimicrobial use in food-producing animals: most do not target **critically important antimicrobials** except one against colistin in 2019 by the Ministry of Health and Family Welfare

# Dairy sector

**21 CIAs from six classes** are used

| Critically important antimicrobials used in the Indian dairy sector to prevent, control or treat diseases | | |
|---|---|---|
| Antimicrobial | Antimicrobial class | Disease |
| **Highest priority critically important antimicrobials considered veterinary critically important antimicrobials** | | |
| Cefoperazone | Third-, fourth- and fifth-generation cephalosporins | Mastitis |
| Ceftiofur | | Mastitis, haemorrhagic septicaemia, anthrax |
| Ceftriaxone | | Mastitis, haemorrhagic septicaemia; viral disease: footand mouth disease |
| Cefquinome | | Mastitis |
| Ciprofloxacin | Quinolones and fluoroquinolones | Anthrax, diarrhoea; viral disease: foot and mouthdisease |
| Enrofloxacin | | Mastitis, haemorrhagic septicaemia, diarrhoea; viraldisease: foot and mouth disease, infectious bovine rhinotracheitis |
| Norfloxacin | | Diarrhoea |
| Ofloxacin | | Diarrhoea |
| **Critically important antimicrobials considered veterinary critically important antimicrobials** | | |
| Amoxicillin | Penicillins | Mastitis; viral disease: foot and mouth disease |
| Ampicillin | | Mastitis, black quarter, brucellosis; viral disease: footand mouth disease, infectious bovine rhinotracheitis |
| Amikacin | Aminoglycosides | Mastitis, brucellosis |
| Gentamicin | | Mastitis, diarrhoea; viral disease: foot and mouthdisease |
| Streptomycin | | Mastitis, black quarter, brucellosis, tuberculosis; viraldisease: foot and mouth disease |
| **Critically important antimicrobials considered veterinary highly important antimicrobials** | | |
| Rifampicin | Ansamycins | Brucellosis, tuberculosis |
| **Highest priority critically important antimicrobials not mentioned in OIE list** | | |
| Cefotaxime | Third-, fourth- and fifth-generation cephalosporins | Mastitis, haemorrhagic septicaemia |
| Ceftazidime | | Mastitis |
| Ceftizoxime | | Mastitis |
| Levofloxacin | Quinolones and fluoroquinolones | Mastitis |
| Moxifloxacin | | Mastitis |
| **Critically important antimicrobials not mentioned in OIE list** | | |
| Ethambutol | Drugs used solely to treat tuberculosis or other mycobacterial disease | Tuberculosis |
| Isoniazid | | Tuberculosis |

Note: In addition to the above, antimicrobials which are not critically important and used in Indian dairy sector include tetracycline, oxytetracycline, doxycycline, trimethoprim, sulfamethoxazole, sulfadimidine, cloxacillin, benzylpenicillin, nitrofural, cefalexin, ornidazole and metronidazole.

# Poultry sector

**14 CIAs from four classes** are used

| Critically important antimicrobials used in the Indian poultry sector to prevent, control or treat diseases | | |
|---|---|---|
| Antimicrobial | Antimicrobial class | Disease |
| **Highest priority critically important antimicrobials considered veterinary critically important antimicrobials** | | |
| Ciprofloxacin | Quinolones and fluoroquinolones | Pullorum disease, fowl typhoid, colibacillosis,salmonellosis |
| Enrofloxacin | | Fowl cholera, infectious coryza, pullorum disease, fowltyphoid, colibacillosis, necrotic enteritis, salmonellosis,chronic respiratory disease; viral diseases: Ranikhet disease, infectious bronchitis, avian influenza, Marek'sdisease, infectious bursal disease |
| Norfloxacin | | Colibacillosis |
| Erythromycin | Macrolides and ketolides | Infectious coryza |
| Tylosin | | Chronic respiratory disease; fungal disease:mycotoxicosis |
| Tylvalosin | | Chronic respiratory disease |
| **Critically important antimicrobials considered veterinary critically important antimicrobials** | | |
| Amoxicillin | Penicillin | Necrotic enteritis; viral disease: Ranikhet disease |
| Ampicillin | | Necrotic enteritis |
| Amikacin | Aminoglycosides | Infectious coryza, pullorum disease, fowl typhoid,colibacillosis, salmonellosis |
| Gentamicin | | Pullorum disease, fowl typhoid, salmonellosis |
| Neomycin | | Pullorum disease, colibacillosis, necrotic enteritis; fungaldisease: aspergillosis, mycotoxicosis |
| Streptomycin | | Fowl cholera |
| **Highest priority critically important antimicrobials not mentioned in OIE list** | | |
| Azithromycin | Macrolides and ketolides | Fowl cholera |
| Levofloxacin | Quinolones and fluoroquinolones | Fowl cholera, Infectious coryza, pullorum disease, fowl typhoid, colibacillosis, necrotic enteritis, salmonellosis; viral disease: Ranikhet disease |

Note: In addition to the above, antimicrobials that are not critically important and are used in the Indian poultry sector include tetracycline, oxytetracycline, doxycycline, trimethoprim, sulfamethoxazole, tiamulin, cefalexin, furazolidone and chloramphenicol.

# Aquaculture sector

**3 CIAs from class of quinolones and fluoroquinolones used**

| Critically important antimicrobials used in the Indian aquaculture sector to prevent, control or treat diseases | | |
|---|---|---|
| Antimicrobial | Antimicrobial class | Disease |
| **Highest priority critically important antimicrobials considered veterinary critically important antimicrobials** | | |
| Ciprofloxacin<br>Enrofloxacin<br>Oxolinic acid | Quinolones and fluoroquinolones | For one or more of the following:<br>Infections caused by *Aeromonas* spp.: e.g. motile aeromonadsepticaemia, hemorrhagic septicemia, red sore, tail rot and fin rot, furunculosis<br>Infections caused by *Vibrio* spp.: e.g. vibriosis, intestinalnecrosis, anaemia<br>Infections caused by *Pseudomonas* sp.: e.g. pseudomonassepticaemia, fin rot<br>Infections caused by *Flavobacterium* sp.: e.g. columnarisdisease, bacterial gill disease<br>Infections caused by *Edwardsiella* sp.: e.g. edwardsiellosis |

Note: In addition to the above, antimicrobials that are not critically important and are used in the Indian aquaculture sector include tetracycline, oxytetracycline, doxycycline, trimethoprim, sulfamethoxazole, cefalexin, furazolidone, chloramphenicol and nitrofurans.

# Resistance and susceptibility trends in bacteria against CIAs used in Indian food-animal production

| Antibiotic(class) | *S. aureus* | *Enterococcus* sp. | *E. coli* | *Klebsiella* sp. | *Pseudomonas* sp. | *Acinetobacter* sp. | *S. aureus* | *E. faecalis* | *E. faecium* | *E. coli* | *K. pneumoniae* | *P. aeruginosa* | *A. baumannii* |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Per cent resistance (NCDC, 2019) | | | | | | Per cent susceptibility (ICMR, 2019) | | | | | | |
| Cefotaxime (third-, fourth- andfifth-generation cephalosporins)* | – | – | 78.0 | 79.0 | – | – | – | – | – | 14.5 | 21.3 | – | – |
| Ceftazidime (third-, fourth- andfifth-generation cephalosporins)* | – | – | – | – | 53.0 | 78.0 | – | – | – | 20.0 | 25.3 | 63.1 | 12.2 |
| Ciprofloxacin (quinolones and fluoroquinolones)* | 66.0 | 77.0 | 79.0 | 71.0 | 54.0 | 65.0 | 17.8 | 16.4 | 8.0 | 20.8 | 36.0 | 57.7 | – |
| Levofloxacin (quinolones and fluoroquinolones)* | – | – | – | – | – | – | – | – | – | 19.0 | 35.0 | 56.5 | 19.1 |
| Erythromycin (macrolides and ketolides)* | 60.0 | 80.0 | – | – | – | – | 40.2 | – | – | – | – | – | – |
| Gentamicin (aminoglycosides) | 23.0 | 48.0 | – | – | 49.0 | 55.0 | – | 57.5 | 35.0 | – | – | 62.2 | – |
| Amikacin (aminoglycosides) | – | – | – | 47.0 | 45.0 | 60.0 | – | – | – | 79.2 | 50.1 | 67.9 | 20.4 |
| Ampicillin (penicillins) | – | 61.0 | 87.0 | – | – | – | – | 80.8 | 18.1 | – | – | – | – |

While almost all these antimicrobials are recommended for treating infections in humans, a **high degree of resistance was found** in several common and severe infection causing bacteria from humans against them (e.g., cefotaxime, ceftazidime, ciprofloxacin, levofloxacin, erythromycin, gentamicin, amikacin and ampicillin)

# India should consider developing a road map and necessary policy framework to conserve the use of CIAs for both human and non-human sector initiatives (1/3)

- **New/revised guidelines that recommend antimicrobials for all food-animal sectors such as dairy and poultry.**
  - The guidelines should aim to phase out use of critically important antimicrobials for all non-therapeutic purposes with immediate priority given to highest priority critically important antimicrobials.
  - Use of critically important antimicrobials for therapeutic purposes should not be resorted to when alternative effective antibiotics are available. All the necessary details on conditions of use should be mentioned. Their use for treatment should always be under professional supervision based on appropriate diagnosis and sensitivity testing.
- **Use of highest priority critically important antimicrobials for treatment should also be considered for phase-out.** They should only be allowed in exceptional situations as a last resort and through necessary policy instruments.
- **Prohibition of antibiotic growth promoters in food-producing animals such as in the case of the poultry sector.** The poultry feed standards are being modified but are voluntary. It is important that they are made mandatory and medically important antimicrobials—including critically important antimicrobials—are not allowed in feed.

## India should consider developing a road map and necessary policy framework to conserve the use of CIAs for both human and non-human sector initiatives (2/3)

- **Antimicrobial use for disease prevention (including control) should be recognized as non-therapeutic.** All measures should be adopted and/or promoted to discourage such use in farms.

- **Necessary focus should also be placed on promoting and incentivizing use of non-antimicrobial alternatives, biosecurity, hygiene and sanitation, and good animal-rearing practices.**

- **The definition of "drug" in the Drugs and Cosmetics Act, 1940 includes the word "prevention". It is important to revise and/or clarify the definition to ensure that it is not used to justify the use of antimicrobials in disease prevention in food-producing animals. The definition also needs to ensure that antimicrobials in feed are regulated, and include antimicrobial use in crops**.

- **A long-term research agenda should be developed and implemented for non-antimicrobial alternatives and their effectiveness understood in managing diseases in animal farms.** Programmatic interventions should be made for their greater promotion and adoption.

## India should consider developing a road map and necessary policy framework to conserve the use of CIAs for both human and non-human sector initiatives (3/3)

- **Setting up systems and mechanisms to gather data and enhance understanding on critically important antimicrobial use and resistance in food-producing animals.** This data on sector-wise use should be analysed with resistance in animals and humans and the reports should be made public annually.

- **Investment in creating awareness among farmers and building capacity for good animal-rearing practices to prevent occurrence and spread of disease at farms.**

- **Programmatic interventions to ensure that veterinarians prescribe antimicrobials responsibly only and when necessary.**

- **Routine monitoring by the central food regulator (FSSAI) and state food regulators on antimicrobial use and residues to ensure that withdrawal periods are followed and residue standards are met.** FSSAI should also modify its standards as soon as use of a specific critically important antimicrobial is restricted or banned as in the case of colistin.

# Indian practices reflect the collective impact of the global guidance and national policy-related actions

Analyses the **global guidance of the Tripartite organizations** with regard to critically important antimicrobials reflect three key issues

**Key Issue 1: Significant overlap in antimicrobials considered critical for humans and food-producing animals**

**Key Issue 2: Need for coherence in position on use of critically important antimicrobials in food-producing animals**

**Key Issue 3: Need for clarity and strong action on use of antimicrobials for disease prevention in food-producing animals**

## Key Issue 1: Significant overlap in antimicrobials considered critical for humans and food-producing animals

- **47 antimicrobials in OIE list overlap with WHO list**
  - **Overlap with nine WHO CIA classes; 28 antimicrobials from four HPCIA classes** (third-, fourth- generation cephalosporins, macrolides and ketolides, quinolones and fluroquinolones, polymyxins)
  - 38 veterinary critically important antimicrobials (VCIAs) and nine veterinary highly important antimicrobials (VHIAs);
  - 39 antimicrobials for >1 species; 28 for >3 species of food-producing animals

# Key Issue 2: Need for coherence in position on use of critically important antimicrobials in food-producing animals

**Interpretation of global guidance on use of critically important antimicrobials in food-producing animals**

| | WHO | OIE | FAO |
|---|---|---|---|
| **Highest priority critically important antimicrobials (Quinolones and fluoroquinolones, third- and fourth-generation cephalosporins and colistin)** | | | |
| Growth promotion | Should not be used | Should not be used | Should not be used |
| Prevention | Should not be used | Should not be used | Should not be used |
| Control | Should not be used | Could be used | Should not be used |
| Treatment | Should not be used | Could be used | Should not be used |
| **Highest priority critically important antimicrobials (Macrolides and ketolides, polymyxins other than colistin, glycopeptides and lipoglycopeptides, fifth-generation cephalosporins)** | | | |
| Growth promotion | Should not be used | Should not be used | Should not be used |
| Prevention | Should not be used | Could be used | Should not be used |
| Control | Should not be used | Could be used | Should not be used |
| Treatment | Should not be used | Could be used | Should not be used |
| **Critically important antimicrobials^** | | | |
| Growth promotion | Should not be used | Should not be used* | Should not be used |
| Prevention | Should not be used | Could be used | Should not be used |
| Control | Should not be used | Could be used | Could be used** |
| Treatment | Could be used | Could be used | Could be used |

Note: For easy reference words used to reflect position are “should not be used” and “could be used”. The exact wording is mentioned in text. The red text highlights incoherence.* Could be used if there are no specific restrictions are mentioned in the OIE list, or if risk is low upon formal risk analysis; ** Under exceptional circumstances ^ Critically important antimicrobials other than highest priority critically important antimicrobials

# Key Issue 3: Need for clarity and strong action on use of antimicrobials for disease prevention in food-producing animals

- **Difference in the way antimicrobial use is categorized:**

  - WHO: therapeutic, growth promotion and disease prevention.
  - FAO: therapeutic, metaphylactic and prophylactic, and growth promotion (sub-therapeutic)
  - OIE: "veterinary medical use" (includes treatment, control or prevention of infectious disease) and "veterinary non-medical use" (includes growth promotion).

- **Difference in the definition and the wording adopted,**

  - WHO: both prevention and control under disease prevention; OIE and FAO define each separately
  - WHO and FAO use the term "prophylaxis", FAO uses "metaphylaxis" and OIE uses "prevention and control"

**Difference in definition of disease prevention by Tripartite organizations**

| WHO | FAO | OIE |
|---|---|---|
| "Disease prevention use (or prophylactic use) refers to use of antimicrobials in healthy animals considered to be at risk of infection or prior to the onset of clinical infectious disease.<br>This includes use for control of the dissemination of a clinically diagnosed infectious disease identified within a group of animals, and prevention of an infectious disease that has not yet been diagnosed clinically." | Prophylaxis:<br>"The administration of an antimicrobial to susceptible but healthy animals to prevent the occurrence of infectious disease."<br><br>Metaphylaxis:<br>"The administration of an antimicrobial at therapeutic doses to all animals within a group in which some individuals have exhibited infection. Metaphylaxis acts both as a treatment for those animals currently infected and a preventive measure against infection in those animals who are healthy but risk becoming infected." | "To prevent: means to administer an antimicrobial agent to an individual or a group of animals at risk of acquiring a specific infection or in a specific situation where infectious disease is likely to occur if the drug is not administered."<br><br>"To control: means to administer an antimicrobial agent to a group of animals containing sick animals and healthy animals (presumed to be infected), to minimize or resolve clinical signs and to prevent further spread of the disease." |

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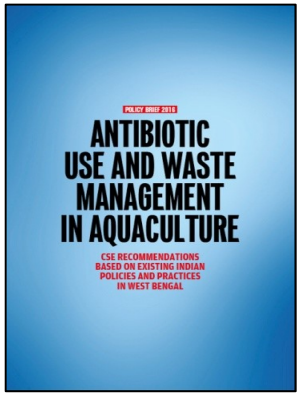
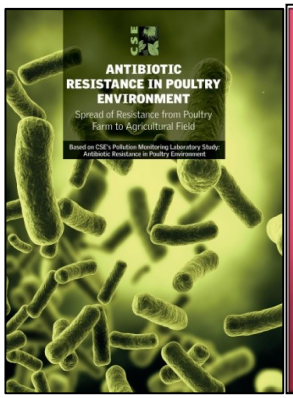
# CSE's work on food systems and environment in India


Antibiotics in honey, 2010


Antibiotic use in poultry, 2014




Antibiotic use in aquaculture, 2016



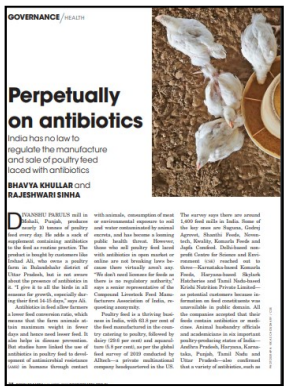

AMR in poultry environment, 2017


Antibiotic use in fast food supply chain, 2017


Disposal of pharma manufacturing waste, 2017


Antibiotic use in crops, 2019

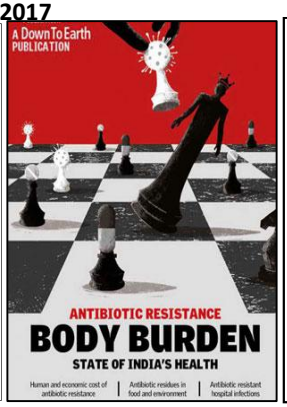

Disposal of unwanted drugs, 2019




Antibiotic use in feed, 2020


Antibiotic use in fast food supply chain, 2020

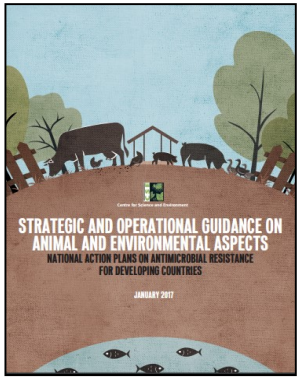

Antibiotic use in dairy, 2020



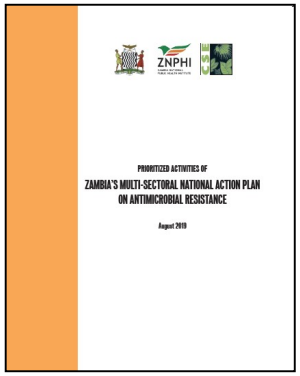

Body Burden, 2020


Use of ethnoveterinary medicines in dairy sector, 2021

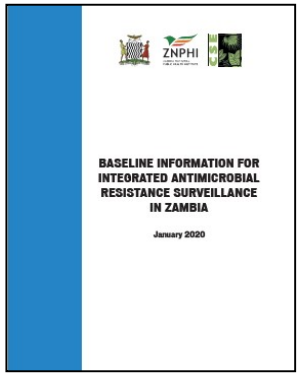
# CSE's global work on food systems and environment



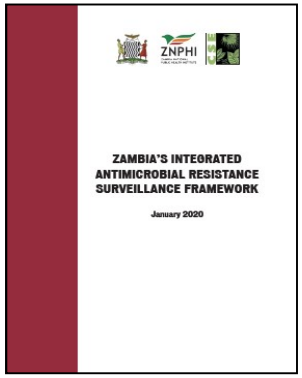

Strategic guidance for NAP for developing countries, 2016



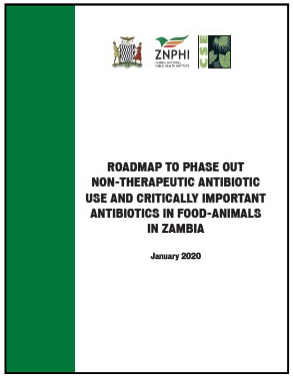

Prioritized NAP-AMR (Zambia, 2019)



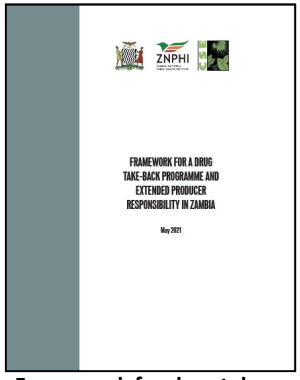

Baseline information for Integrated AMR surveillance (Zambia, 2020)



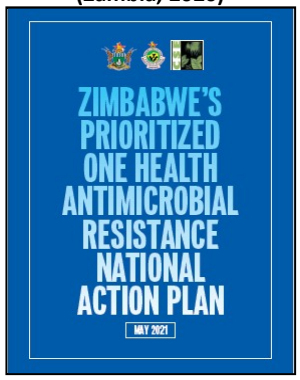

Framework for Integrated AMR surveillance (Zambia, 2020)



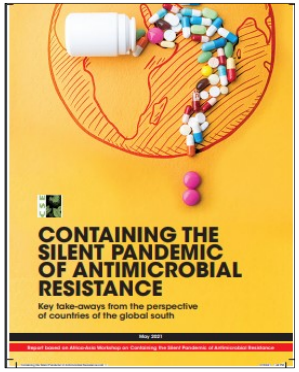

Roadmap to phase out antibiotic misuse in food-animals (Zambia, 2020)



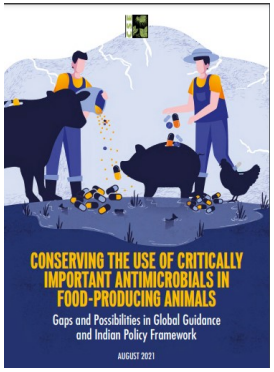

Framework for drug take-back and EPR (Zambia, 2021)




Prioritized NAP-AMR (Zimbabwe, 2021)




Containing the silent pandemic of AMR (2021)




Conserving the use of critically important antimicrobials (2021)

## The Tripartite should consider developing a uniform and strong guidance for countries on the use of critically important antimicrobials across all food-animal sectors

- **This should include a clear message for all categories of critically important antimicrobials w.r.t. their use as growth promoters and for disease prevention, control and treatment in sectors such as poultry, dairy and aquaculture**.
- **It should be specific about antibiotics that could be used in a particular sector along with explanations related to disease and conditions wherein antimicrobials can be used.**
- **It should specify which antibiotics must be immediately prohibited and those that need to be phased out over a limited period of time.**
- While such guidance should be a collectively agreed-upon message from human and non-human global stakeholder agencies, **it should be strong and ambitious enough to conserve the use of critically important antimicrobials** instead of the lowest possible consensus-based decision. For example, it should aim at immediate prohibition of all critically important antimicrobials instead of highest priority critically important antimicrobials for growth promotion**.**

## The Tripartite should consider developing a uniform and strong guidance for countries on the use of critically important antimicrobials across all food-animal sectors

- This guidance should consider stronger and specific action against critically important antimicrobial use for disease prevention and control. In particular, strong action is required against routine group preventive use of antibiotics, which often substitutes good rearing practices. The guidance should come up with an agreed-upon definition of disease prevention and control and consider recognizing such use as non-therapeutic.
- This uniform message which can be adopted and/or adapted by countries should help reduce chances of misinterpretation as well as generate greater consensus among national stakeholders. In addition, this should help civil society organizations to effectively push for necessary action.
- This clear information should also be able to help countries develop their sector-specific road maps to conserve the use of critically important antimicrobials, based on local realities of use and resistance across different sectors (human and non-human) and help develop sector-specific targets for critically important antimicrobial use and reductions.

## Concerted intervention is required to develop a good understanding of global and country-level use of critically important antimicrobials and resistance trends in food-animal sectors

- There is some action at the global and national level, but there still however is a big gap with respect to overall global understanding and related to developing countries of the global South.
- This gap can be filled by information focusing on critically important antimicrobials w.r.t. food-animal sectors and type of use (growth promotion, disease prevention, control and treatment).
- It is also important to develop greater understanding on the linkages between antimicrobial use in food-producing animals and resistance in animals and humans for an informed future action.

# Key Issue 3: Need for clarity and strong action on use of antimicrobials for disease prevention in food-producing animals

- **One possible reason could be the difference in the way antimicrobial use is categorized:**
  - WHO categorizes such use as therapeutic, growth promotion and disease prevention.
  - FAO recognizes such use as therapeutic, metaphylactic and prophylactic, and growth promotion (sub-therapeutic)
  - OIE categorizes as “veterinary medical use” (includes treating, controlling or preventing infectious disease) and “veterinary non-medical use” (indicates use other than “veterinary medical use” and includes growth promotion). This adds to the confusion:
    - First, it is a quite a different way of classification from that adopted by WHO and FAO;
    - Second, it implies that prevention, control and treatment are similar and therefore under one category, i.e. “veterinary medical use”;
    - Third, it also implies that use in prevention and control happens under veterinary supervision, which is not necessarily the case.
- **The second possible reason is the difference in the definition and the wording adopted:**
  - WHO includes both prevention and control as part of disease prevention whereas OIE and FAO define each separately.
  - Both WHO and FAO use the word “prophylaxis”, FAO uses “metaphylaxis” and OIE uses “prevention and control” while explaining
  - **But most importantly, the wording used to define and the emphasis put on certain words varies.**

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