

CONSULTATION ON THE HUMAN AND VETERINARY MEDICINES REGULATORY AUTHORITIES SUMMIT AND FORUM TO PRESERVE ANTIMICROBIALS

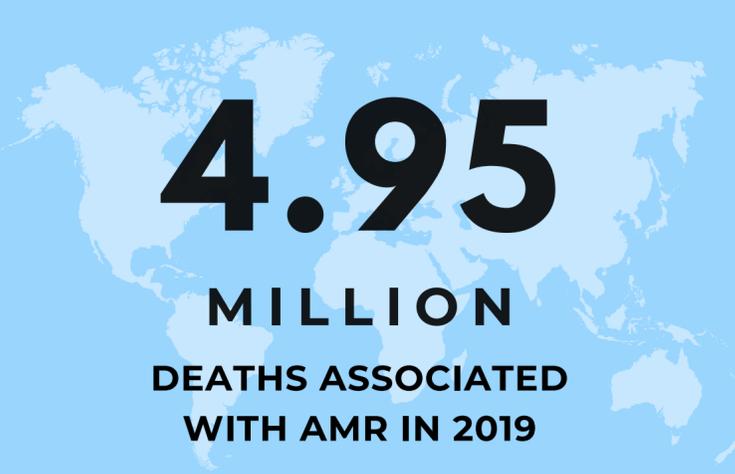


OBJECTIVE 2023:
PHASING OUT OVER-THE-COUNTER SALES OF ANTIBIOTICS

WHAT IS AMR?

Antimicrobial Resistance (AMR) poses an existential threat to human and animal health and modern medicine. In 2019, an estimated 1.27 million deaths were directly attributable to AMR, while 4.95 million deaths were associated with AMR. This makes it a leading cause of death around the world.

AMR occurs when bacteria, viruses, fungi and parasites no longer respond to antimicrobial agents. As a result of drug resistance, antibiotics and other antimicrobial agents become ineffective and infections become difficult or impossible to treat, increasing the risk of disease spread, severe illness and death.



4.95
MILLION
DEATHS ASSOCIATED
WITH AMR IN 2019

Modern medicine is dependent on the ability to prevent and treat infections using antibiotics, including during joint replacement surgery, organ transplantation, cancer chemotherapy and the treatment of chronic diseases like asthma and diabetes.

Antimicrobials are also important to treat, prevent and control infectious diseases in animals. Loss of efficacy of antimicrobials can seriously compromise animal health, welfare, and productivity. Furthermore, it can negatively impact food security, livelihoods, and national and global economies.

Although AMR occurs naturally over time, its emergence and spread is accelerated by the misuse and overuse of antimicrobials to treat or prevent infections in humans, animals, and plants.

WHAT PART DO MEDICINES REGULATORY AUTHORITIES PLAY?

Urgent action is needed to mitigate AMR. Human and Veterinary Medicines Regulatory authorities play an important role in curbing AMR by, for instance:



- Collaborating to preserve critically important antimicrobials used in both the human and animal sectors
- Facilitating access to effective, quality, and safe antimicrobials for appropriate and prudent use
- Classifying antibiotics to be accessed as Prescription Only Medicine (POM or POM-V)
- Reviewing and approving the accuracy and completeness of information provided by manufacturers (sponsors) on summary of product characteristics, package inserts and labels to support prudent use by healthcare providers, patients, animal health providers and animal owners, and farmers
- Regulating antimicrobial manufacturing, supply, use, and sales across all stages of their life cycle
- Restricting and monitoring the use of antimicrobials and other chemicals or pollutants that increase the risk of AMR
- Encouraging safe disposal of antimicrobials and limiting their release into the environment
- Facilitating compliance and enforcement of the regulations and implementation of smart solutions to mitigate inappropriate and imprudent use of antimicrobials.

YOUR ROLE

- Inform the consultation about existing regulatory provision for antibiotics in your countries and contexts
- Discuss existing practices and enforcement of legislation in your contexts
- Share ideas for smart solutions to phase out over-the-counter sales of antibiotics

