



Project: Technical assistance to improve implementation of food safety standards and disease crisis preparedness

Training course: Prudent use of VMP and alternatives

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Date:

Place: Nicosia, Cyprus

*Project funded by the European Union within the scope of the Aid Programme for the Turkish Cypriot community,
implemented by the NSF Euro Consultants Consortium*



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- What is AMR
- Definition
- EU initiative
- Legislation
- Monitoring
- Prudent use of antimicrobials



- Prudent use of antimicrobials should lead to more **rational and targeted use**, thereby maximising the therapeutic effect and minimising the development of AMR.
- The final outcome of prudent use should be an **overall reduction in the use of antimicrobials**, predominantly by limiting their use only to situations where they are necessary.
- Antimicrobials should be used as targeted treatment and according to best practices, i.e. **based on clinical diagnosis** and, whenever possible, on the results of **microbiological susceptibility tests**, and using an antimicrobial agent of as **narrow-spectrum as possible**.
- Prudent use in short:

how to?	at the same time ...	synonyms
use of antimicrobials to benefits the patient	minimises the probability of adverse effects	judicious, rational, adequate, correct and optimal

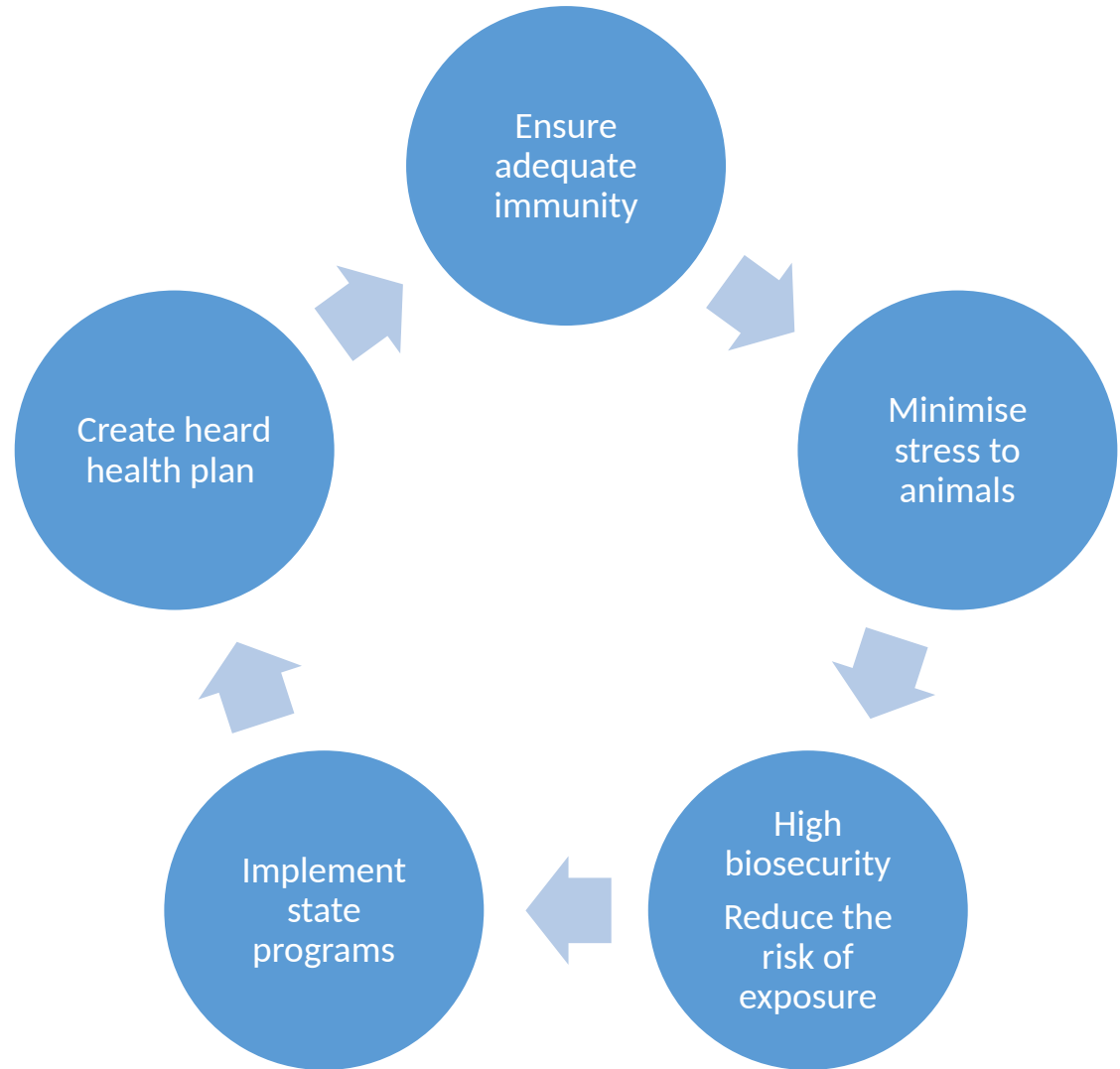
Issues to be considered before using antimicrobials



The ultimate objective is to reduce the need for antimicrobials by preventing disease

Animal diseases and infections should primarily be prevented by ensuring biosecurity, good production and good management practices,

implementing integrated disease control programs to minimise the occurrence of diseases and eradicate endemic disease





- ‘metaphylaxis’ means the administration of a medicinal product to a group of animals after a diagnosis of clinical disease in part of the group has been established, with the aim of treating the clinically sick animals and controlling the spread of the disease to animals in close contact and at risk and which may already be subclinically infected;
- ‘prophylaxis’ means the administration of a medicinal product to an animal or group of animals before clinical signs of a disease, in order to prevent the occurrence of disease or infection;
- ‘withdrawal period’ means the minimum period between the last administration of a veterinary medicinal product to an animal and the production of foodstuffs from that animal which under normal conditions of use is necessary to ensure that such foodstuffs do not contain residues in quantities harmful to public health;
- ‘medicated feed’ means a feed, which is ready to be directly fed to animals without further processing, consisting of a homogenous mixture of one or more veterinary medicinal products or intermediate products with feed materials or compound feed;

Guidelines for the prudent use of antimicrobials



- guidelines relate to the prudent use of antimicrobials in animals, and, in particular, how prudent usage can contribute to containing the development of AMR
- practical guidance for Member States on the development and implementation of strategies to promote the prudent use of antimicrobials, especially antibiotics, in veterinary medicine
- guidelines are addressed to Member States, however, some chapters or specific measures are addressed to other relevant parties, including industry, farmers, veterinarians, associations and academia

Guidelines for the prudent use of antimicrobials



- A legal frame for the use of antimicrobials should be in place to support these activities
- General principles of the prudent use of antimicrobials need to be applied as a matter of routine on farms and in veterinary practices



Principles for prudent use - 1



- The **prescription** and dispensation of antimicrobials must be **justified by a veterinary diagnosis** in accordance with the current status of scientific knowledge.
- Where it is necessary to **prescribe** an antimicrobial, the prescription should be based on a diagnosis made **following clinical examination** of the animal by the prescribing veterinarian. Where possible, **antimicrobial susceptibility testing** should be carried out to determine the choice of antimicrobial.
- **Antimicrobial metaphylaxis** should be prescribed only when there is a **real need for treatment**. In such cases, the veterinarian should justify and document the treatment on the basis of clinical findings on the development of a disease in a herd or flock. Antimicrobial metaphylaxis should **never be used in place of good management practices**.
- **Routine prophylaxis must be avoided**. Prophylaxis should be reserved for exceptional case-specific indications.



- Administering medication to an **entire herd or flock should be avoided** whenever possible. **Sick animals should be isolated** and treated individually (e.g., by administering injectables).
- **All information** relating to the animals, the cause and the nature of the infection and the range of available antimicrobial products must be taken into account when making a decision regarding antimicrobial treatment.
- A **narrow-spectrum antimicrobial** should always be the first choice unless prior susceptibility testing - where appropriate supported by relevant epidemiological data - shows that this would be ineffective. The **use of broad-spectrum antimicrobials** and antimicrobial combinations should be avoided (with the **exception** of fixed combinations contained in **authorised veterinary medicinal products**).



- If an animal or group of animals suffer from recurrent infection(s) requiring antimicrobial treatment, efforts should be made to eradicate the strains of the microorganisms by **determining why the disease is recurring**, and altering the production conditions, animal husbandry and/or management.
- Use of antimicrobial agents prone to propagate transmissible resistance should be minimised.
- A number of compounds on the World Health Organisation's **list of critically important** antimicrobials are only authorised in medicinal products for human use. As laid down in EU legislation, those that do **not have marketing authorisations** as veterinary medicinal products for use in **food-producing** animals may only be used **off-label** (following the cascade) in these animals if the substance in question is listed in Table 1 of the Annex to Commission Regulation (EU) No 37/2010.



- The **off-label use** (cascade) of the compounds referred to above for **non-food-producing animals** (e.g. pets and animals used for sports) should be avoided and strictly limited to very exceptional cases, e.g. where there are ethical reasons for doing so, and only when laboratory antimicrobial susceptibility tests have confirmed that no other antimicrobial would be effective.
- Antimicrobial treatment must be administered to animals **according to the instructions** given in the veterinarian's prescription.
- The need for antimicrobial therapy should be **reassessed** on a regular basis to avoid unnecessary medication.
- The **perioperative use** of antimicrobials should be minimised by using aseptic techniques.



- When possible, **alternative strategies** for controlling disease that have been proven to be equally efficient and safe (e.g. vaccines) should be preferred over antimicrobial treatment.
- The **pharmacovigilance system** should be used to obtain information and feedback on therapeutic failures, so as to identify potential resistance issues in the case of use of existing, new or alternative treatment options.
- A **network of laboratories** with the capacity for performing antimicrobial susceptibility tests in zoonotic and commensal microorganisms and target pathogens should be established in each Member State to ensure the availability of susceptibility testing.

Critically important antimicrobials



- These antimicrobials should only be used in situations where a veterinarian has assessed, on the basis of antimicrobial susceptibility testing and relevant epidemiological data, that there is no non-critically important effective antimicrobial available.
- In exceptional cases where the use of these antimicrobials under off-label use (cascade) is unavoidable and legally permissible, prescription and final use should be sufficiently justified and recorded. Such use should be based on clinical grounds, i.e. the prescribing veterinarian considers the use of a particular critically important antimicrobial necessary in order to avoid the suffering of diseased animals, and should also take into consideration ethical and public health concerns.



- Whenever possible, individual treatment of the affected animal(s) (e.g. injectable treatments) should be preferred to group or mass treatment
- When using group treatment, the following points should be taken into account:
 - Medicated feed contains a premix of veterinary medicines and requires, according to **EU legislation**, veterinary prescription.
 - Oral antimicrobial treatment given via medicated feed or drinking water must only be administered where **prescribed by a veterinarian**.
 - Antimicrobials should only be administered to groups of animals via feed or drinking water where there is evidence of microbial disease or infection; such treatment should **not be given as a prophylactic** treatment. The administration of antimicrobials via feed or water should be **limited to the animals requiring treatment**, and the drug delivery systems should be appropriate for the intended treatment.



- The quantities of antimicrobials administered in feed or water should be monitored and **documented** on a continuous basis, especially in intensive food production systems.
- The **instruction** given in the product information (SPC, leaflet, labelling) and by the veterinarian must be complied with, both in terms of **dosage and duration** of treatment.
- Where an antimicrobial is administered through **feed**, it is important to ensure the **homogeneity** of distribution of the drug, in order that each animal obtains the required therapeutic dose for treating the disease in accordance with the veterinary prescription.
- **Off-label** (cascade) use should be limited to the necessary minimum and to **exceptional occasions** where no other authorised treatment options are available.
- Adequate, **clean storage facilities** should be available on the farm to ensure proper storage of the medicated feed. Access to these facilities should be restricted.

Exercise - do you agree?



- Using antibiotics can prevent disease in future
 - Yes
 - No
- Antibiotics in milk or meat are as well antimicrobial resistance
 - Yes
 - No
- If antibiotics are given too often they might stop working
 - Yes
 - No



- should be a veterinarian familiar with the history of the herd, flock or animal being treated
- The prescriber should make the treatment decision in an independent way, so as to avoid a conflict of interest
- contracts or arrangements between the farmer and a veterinarian for a specific herd or flock, such that the veterinarian can develop a better understanding of the overall health status of the herd or flock, and thereby reduce the prevalence of disease and the use of antimicrobials
- prescribing veterinarian should ascertain himself by means of an on-site clinical examination
- Whenever possible, the prescriber should take appropriate samples for susceptibility testing
- should always consider using single substances instead of combinations of antimicrobials



- should closely follow the prescriber's instructions on administering antimicrobials and alternatives
- play a critical role in observing and monitoring sick animals and animals that do not need antimicrobials
- should always follow the prescriber's instructions, the product information
- should ensure that the correct group of animals is treated, at the required dosage, and for the specified duration of the treatment
- must obtain the antimicrobials from authorised sources, based on a veterinary prescription;
- must ensure the safety of the food production chain, by ensuring that withdrawal periods are observed
- be aware of the general aspects of prudent use of antimicrobials and AMR, including the need to take samples and perform antimicrobial susceptibility testing on target pathogens.



- implement best practices in the production of safe and nutritionally balanced feed,
- ensure that all ingredients meet the required standards
- does not allow the feed to be contaminated with deleterious agents, which could compromise the safety of the feed
- to be approved if producing medicated feed
- only produce medicated feed from authorised veterinary medicinal products and in accordance with a veterinarian's prescription
- ensure appropriate mixing to guarantee the homogeneity
- medicated feed must be appropriately labelled and only be supplied to the end-user on presentation of a valid veterinary prescription
- detailed records should be kept of the antimicrobials used



- The focus should be given to:
 - developing alternative, preferably preventive, tools for infection control;
 - evaluating the impact of the use of antimicrobials in animals on public health and the environment
 - further investigating pharmacokinetic and pharmacodynamic data and using models to simulate the effects of different dosing schedules (based on different combinations of: disease, pathogen, target tissue and animal species).
 - further investigating co-resistance and cross-resistance, including the co-resistance of disinfectants and antimicrobials and the co-resistance and development of resistance of antimicrobials to certain metals;
 - developing new classes of antimicrobials

Competent authorities



- ensure that national strategies are developed between the veterinary authorities, the human health authorities and other relevant authorities (e.g. environmental authorities)
- monitor the implementation of the national strategy and enforcement
- carry out, targeted checks on veterinarians and farms
- introduction of mandatory herd health programs promoting best practices, and ensuring that hygiene standards are improved
- fund and support the development, dissemination and implementation of guidelines for both the prudent use of antimicrobials and hygiene measures;
- fund and support awareness and training campaigns on AMR and the prudent use of antimicrobials
- develop control measures to limit the spread of resistant bacteria when a type of AMR is low or emerging
- Awareness raising

Other stakeholders



- Laboratories
- The pharmaceutical industry, pharmacists, retailers and wholesalers
- Food business operators
- Veterinary professional associations
- Industry stakeholder associations

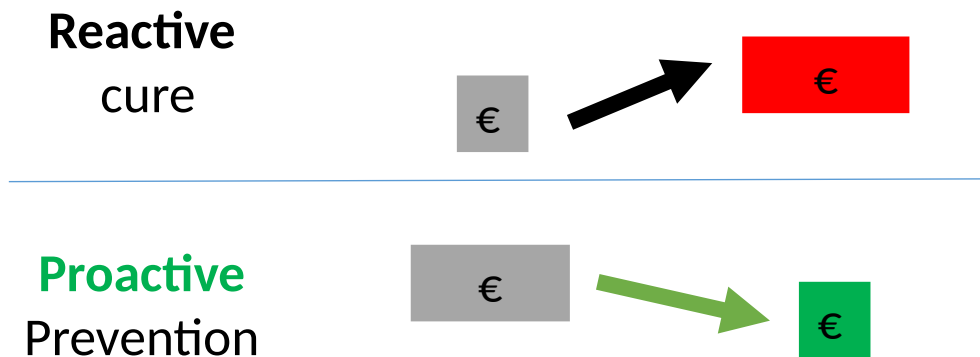


Reducing the need of use of antimicrobials



- General:

- Preventing infections in the first instance is the best way to achieve this reduction and minimise the need to use antimicrobials
- The objective of reducing the use of antimicrobials is also in line with animal welfare, reducing the density of the farm animal population is a major factor for a spared infection that require the use of antimicrobials
- Prevention is better than cure!!!



Reducing the need of use of antimicrobials



- General:

- implementing hygiene and biosecurity measures (including measures designed to prevent the introduction of infections),
- producing clear protocols for the prevention of infectious diseases and infection control and hygiene; making these available on farms;
- improving husbandry systems by providing appropriate housing, ventilation and environmental conditions for animals and appropriate and clean facilities during transport (e.g. the lairage area and vehicles);
- establishing integrated production systems which avoid the need to buy and mix animal populations and to transport animals with unknown disease status;
- avoiding stressful situations which can weaken animals' immune systems and make them more susceptible to infections, e.g. limiting the transport of animals, minimising transport time and ensuring that the recommended animal population density is adhered to (i.e. avoiding overcrowding);

Reducing the need of use of antimicrobials



- General:
- implementing other zootechnical treatments to minimise disease and decrease use of antimicrobials
- introducing herd-specific health plans designed to achieve a consistent stepwise improvement in herd health and avoiding and discouraging health programs in which animals are systematically treated with antimicrobials prophylactically
- implementing programs to control specific animal diseases (both viral and bacterial) by means of vaccination
- using scientifically proven, effective and safe alternatives to antimicrobials
- using only safe, high-quality feed and water

Reducing the need of use of antimicrobials



- Bovine and small ruminants:
- avoiding the prophylactic use of antimicrobials in new-born calves (e.g. antimicrobials added to milk replacers) by instead implementing good farming practices (e.g., to ensure high standards of hygiene)
- developing preventive strategies (e.g., vaccinations and feeding colostrum to calves), especially for the allotment of veal calves and beef cattle
- avoiding the systematic treatment of cows at drying-off, and considering and implementing alternative measures on a case-by-case basis
- establishing thorough hygiene measures and good farm practice and management strategies to minimise the development and spread of mastitis in dairy cows
- promoting the use of rapid diagnostic tests for identifying mastitis-causing pathogens, in order to minimise the use of both intramammary and injectable antimicrobials in milking cows
- avoiding feeding calves with waste milk from cows that have been treated with antimicrobials

Reducing the need of use of antimicrobials



- Poultry:

- to avoid the prophylactic and often recurrent group medication of poultry, which is frequently carried out immediately before or after the transport of day-old chicks
- hatcheries should keep records of any use of antimicrobials in eggs
- antimicrobials should not be used routinely on the arrival of day-old chicks at the farm, at this stage can be avoided by ensuring good hatchery hygiene and through good management
- vaccination management should include measures to avoid a stress reaction
- use of antimicrobials for non-infectious diseases with limited secondary infections should be avoided
- specific animal welfare programs should be introduced, potentially including footpad scores
- Antimicrobials shall not be used as a specific method to control Salmonella in poultry

Reducing the need of use of antimicrobials



- Pigs:
- avoiding the prophylactic use of antimicrobials in new-born piglets (and after weaning), as a part of a herd health strategy
- implementing an 'all-in all-out' system of production, thoroughly cleaning and disinfecting production units when animals move
- isolating the pathogen and considering a vaccination strategy where available (e.g. atrophic rhinitis);
- checking and ensuring that the ventilation system and general housing environment are functioning correctly and making sure it is possible to change the conditions if there is a high frequency of recurring respiratory diseases or environmental conditions are poor
- establishing appropriate feeding strategies based on the pigs' age, especially at weaning
- avoiding mixing within the herd, or quarantining stock for an appropriate period prior to mixing

Reducing the need of use of antimicrobials



- Pigs:
- reassessing weaning management in cases of recurrent weaning diarrhea (considering in particular hygiene, the age of the pigs, the use of 'all-in all-out' systems, ways of reducing the stress suffered by the animals and alternatives to the prophylactic use of antimicrobials)
- eliminating recurrent cases of post-partum dysgalactiae syndrome by ensuring appropriate selection of sows, good hygiene at parturition and adapted feeding
- limiting the trading and movement of pigs to mitigate the spread of infections and organisms such as methicillin-resistant *Staphylococcus aureus* (MRSA)

Reducing the need of use of antimicrobials



- Other animal:
- Aquaculture
- Rabbits
- Petts
- Fur producing animals
- Other non-food producing animals

WE NEED YOU TO HANDLE **ANTIMICROBIALS** WITH CARE

Fight
#AntiMicrobialResistance

- Misuse and overuse of antimicrobials increase resistance risk, endangering both animal and human health and welfare.
- But you can help. By acting prudently when using antimicrobials, you can preserve their efficacy for our future.

WE NEED YOU



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THANK YOU FOR YOUR ATTENTION



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