## CODEX ALIMENTARIUS COMMISSION





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### JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX ALIMENTARIUS COMMISSION

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# COMMENTS ON FAO/WHO SCIENTIFIC SUPPORT TO CODEX: REPORT ON ACTIVITIES AND FUTURE WORK

Comments of Health for Animals

#### **HEALTH FOR ANIMALS**

HealthforAnimals is the international non-profit organization that represents the animal health sector: manufacturers of veterinary pharmaceuticals, vaccines and other animal health products. The animal health industry provides value to society by protecting animals and as a consequence, humans, from diseases. Our products help keep pets and food-producing animals healthy. The public health benefits we bring include safer and more secure food supplies, more efficient production for increased food supply, improved sustainability, and prevention of the transmission of zoonotic diseases.

HealthforAnimals has considered the update and offers the following comments to complement it.

# Points 20-22: WHO guideline for use in food animals of critically important anti-microbial for human medicine

The categorization of antimicrobial agents based upon their importance in human and veterinary medicine is important to ensure that these agents are used responsibly. Over the past decade, the WHO has developed, and regularly updated a categorization scheme based upon the importance of specific agents to human medicine. While the WHO list is widely cited and used by academic researchers and non-regulatory government agencies, it has no regulatory force behind it. The WHO list is a hazard-based list, not a risk-based list, thus the degree to which the use of antibiotics on this list contribute to AMR in humans has not undergone a risk assessment. Various regulatory agencies around the world (e.g., FDA, EMA, Health Canada, etc.) have developed their own antimicrobial categorization schemes taking also into account WHO's categorization, and have added a risk management component to it, as is normal for regulatory agencies. Moreover, the OIE has developed a separate scheme that categorizes antimicrobial agents based on their importance in veterinary medicine, which also includes some responsible use recommendations.

It should be noted that the use of antibiotics in animals has a low likelihood of contributing to AMR in humans.

- A US Centers for Disease Control (CDC) report in 2013 listed 18 strains of antibiotic-resistant bacteria
  which pose a threat to human health, and in only two cases did they identify that livestock could be a
  potential source for resistant strains of Salmonella and Campylobacter. Both are omnipresent in the
  environment and can cause unpleasant gastrointestinal infections whether the strain is resistant or not.
- A team of interdisciplinary scientists the Medical University of South Carolina in 2016 studied the link between antibiotic use in farm animals and drug-resistant foodborne Campylobacter infections in humans. The study was published in Critical Reviews in Food Science and Nutrition (volume 56, issue 13) and considered chicken, turkeys, pigs, beef cattle, and dairy cows. The research team found no conclusive evidence of a definitive link between use of antibiotics in food animals and emergence of drug-resistant Campylobacter. However, their findings did lead the team to important concerns about Campylobacter. For example, recent cases of Campylobacter infections have been linked directly to drinking raw milk or eating food products made from raw milk.
- Europe's preeminent group of regulatory assessors at the European Medicines Agency Committee for Medicinal Products for Veterinary Use (CVMP), wrote in its draft strategy on antimicrobials that: "...it is recognized that the biggest driver of AMR in people is the use of antimicrobials in humans or human health."

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• The UK Department of Health 5 year strategy on AMR stated that whilst antibiotic use in animals is an important factor that: "Increasing scientific evidence suggests that the clinical issues with antimicrobial resistance that we face in human medicine are primarily the result of antibiotic use in people, rather than the use of antibiotics in animals."

HealthforAnimals believes that risk management recommendations for veterinary medicines should remain ultimately with the appropriate organizations which have veterinary medicines in their remit, like the OIE and veterinary regulatory agencies.

HealthforAnimals believes that harmonization of the various antimicrobial categorization schemes using the "One Health" principles is critically needed. This scheme would take into consideration the importance of various agents in both human and veterinary medicine and place equal burdens on both the human and veterinary medicine and environmental impact in regards to use of the most critically important agents. This would ensure that both human and veterinary medicine equally recognize the need for responsible use and would enhance the development of effective antimicrobial stewardship programs. This could be achieved through the tripartite collaboration between FAO, OIE and WHO.

### Points 20-22: Animal welfare is not sufficiently considered

FAO, OIE and national governments have animal welfare within their remit. WHO and Codex do not. As a result, WHO and Codex guidance does not take into account animal welfare considerations. Yet when governments make risk management recommendations they must include, rightly, animal welfare considerations and recommendations. This leads to incongruence between WHO and Codex recommendations, and national implementation.

To illustrate, if a producer has a disease level of 3% using conventional methods and then switches to an antibiotic free system, and disease levels increase, as they often do, this means animal welfare has declined.

Whatever measures are taken, they need to include animal welfare considerations and be balanced under the remit of OIE and national authorities.

#### Points 23-24: Alternatives to antimicrobials in food production systems

HealthforAnimals supports the continued need to develop alternative approaches to achieve the core goal: minimizing antimicrobial resistance in humans.

Vaccination play an important role in reducing the need to treat disease - the sector has been investing in vaccines for many years; but vaccines should not be described as alternatives because they do not treat disease, rather they prevent it.

There needs to be a greater clarity and differentiation when discussing non antibiotic applications. These can be split into three categories:

- Therapeutic alternatives for treatment after disease is diagnosed
- Preventive alternatives (e.g. vaccines) to prevent disease
- Alternatives products that assist an improved general health status

Many animal health companies - both large and small - are working to develop alternatives. This is not an easy task and many technologies which looked promising in the past only provided limited or partial solutions. The route to market for many alternatives is complex and costly because many product approval regulatory systems are not designed to deal with novel types of products.

The sector is increasing its R&D investments in alternatives such as immunostimulants, pro-biotics, etc., but it will be a long way before true alternatives – if any – can fully replace an antibiotic in cases of severe disease outbreaks caused by bacterial pathogens. There needs to be more realism regarding the perception that alternatives can largely replace antibiotics. The 2016 O'Neill report "Vaccines and alternative approaches" wrote that "it seems there are relatively few products (alternatives) coming to market to replace or compensate for weakening antibiotic effectiveness for at least another 10 to 15 years". <a href="https://amr-review.org/sites/default/files/Vaccines%20and%20alternatives\_v4\_LR.pdf">https://amr-review.org/sites/default/files/Vaccines%20and%20alternatives\_v4\_LR.pdf</a>

Even if significant alternatives to antibiotics are developed there will always be a need to treat animals, because just like people, sick animals deserve treatment, and there are no real alternatives to treating life-threatening bacterial infections. Any consideration on restrictions and/or even banning antibiotic classes from the already limited antibiotic veterinarians toolbox (in comparison to human medicine) should carefully take into account unintended health and welfare consequences for animals.

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### Points 25-27 and 36: Antibiotic Usage Monitoring

HealthforAnimals collaborates with various global organizations and national governments in order to ensure progress of antibiotic use monitoring. HealthforAnimals supports in particular the work of the World Animal Health Organization (OIE) who launched an annual collection of data on the use of antimicrobial agents in animals in the 180 OIE Member Countries in the last trimester of 2015. Two reports have now been completed.

HealthforAnimals wants to emphasize that such antibiotic use data should always been considered in context, as countries differ much in many respects, like climate, types of livestock raised, quantity of meat produced, distribution of veterinary medicines, prescription systems, veterinary infrastructure, etc. It is therefore important to consider such antibiotic use data within a broader framework.

HealthforAnimals does consider that the goals of building an antibiotic usage system must be carefully considered by governments, as the goals that each country may pursue will influence the setup of data collection systems to a great extent. Use data can be collected for scientific purposes, risk management purposes or simply for transparency reasons and there is value in giving due consideration to the rationale of such efforts.

#### Additional resources

- Understanding Group Treatment of Animals
- A One Health Approach to Antibacterial Efficacy in Animal Health
- What the veterinary world has done on AMR
- Antibiotics and antibiotic resistance in veterinary science