



The Consumer Voice in Europe

# European Commission's proposals to tackle antibiotic resistance in veterinary medicines and medicated feed laws

BEUC position paper

Contact: **Pauline Castres** – [food@beuc.eu](mailto:food@beuc.eu)

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## Summary

BEUC welcomes the European Commission's aim to address the issue of antibiotic resistance by reviewing of the veterinary medicines and medicated feed legislations.

Antibiotic resistance is a serious public health issue which needs to be addressed in both the human and veterinary medicine spheres. Without antibiotics which work infections become more difficult to cure and stronger drugs, with serious side-effects, must be used. In addition longer hospital stays and increased hospitals costs are usually associated. In certain cases it leads to therapeutic impasse meaning infections become life-threatening. Eventually without these precious drugs common interventions such as surgery or chemotherapy will become highly hazardous and a simple finger cut could escalate into difficult-to-treat infections.

Even though it is difficult to quantify the magnitude of the threat emerging from agriculture it is now clearly demonstrated that inappropriate use of antibiotics in both humans and in animals contribute to its spread. The joint ECDC/EFSA/EMA report shows a positive association between antimicrobial consumption in animals and in humans, especially for *E.coli* bacteria and the two antibiotics cephalosporins and fluoroquinolones which are used as last resort drugs in human medicine<sup>1</sup>.

If consumers and doctors were to take all the steps necessary to limit antibiotics use to cases where truly required for human health, this should also apply to food-producing animals. As more antibiotics are given to animals than humans in most EU countries, putting strict rules in place is all the more important. In addition those rules should apply not only to food-producing animals, but also to pets, as they are in close contact with humans and could be a source of resistant bacteria.

However antibiotics are still used today for prevention when simple hygiene and management measures could tremendously reduce the need to administer antibiotics. The benefits of giving healthy animals antibiotics are clearly outweighed by the risks linked to antimicrobial resistance while some antibiotics used as a last resort to treat complex infections in humans are used in livestock. At the same time off-label use, where veterinarians can prescribe antibiotics allowed only for humans to sick animals, is not sufficiently regulated and is not mandatorily reported to authorities while this practice has the potential to spur antibiotic resistance.

In human medicine doctors can only prescribe, not sell, antibiotics. This virtually eliminates any economic incentive to overprescribe. Yet in many countries veterinarians' revenue still depends on the sale of medicines, including antibiotics.

Eventually antibiotics are often given via feed. Because sick animals barely eat and because it is difficult to control which animals eat and which ones do not the option of banning antibiotics in feed altogether should be thoroughly considered.

All these issues need to be addressed in the two legislative proposals currently under discussion. Given the risks linked to antibiotic resistance and the many ways it can spread from the farm to the community, by food but also via air, environment and people, it is urgent to have strict EU rules regulating antibiotics use in livestock.

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<sup>1</sup> ECDC/EFSA/EMA first joint report on the integrated analysis of the consumption of antimicrobial agents and occurrence of antimicrobial resistance in bacteria from humans and food-producing animals, January 2015.

- **Phase out prophylactic use of antibiotics in livestock**

All too often antibiotics are given to healthy animals (i.e. animals not showing any clinical signs of disease) just for prevention purposes. Yet the benefits and risks of this practice, also known as 'prophylaxis', is unfavourable due to the risk of emergence and spread of resistant microorganisms<sup>2</sup>. With the exception of surgery, antibiotics should only be given to sick animals (therapeutic use) or to the whole herd, and preferably to restricted groups of animals, if some animals are clinically ill and a very high risk of transmission has been identified (metaphylactic use).

BEUC welcomes the European Commission's proposal to prohibit the preventive use of antibiotics in medicated feed.

However the same prerogative should be included in the veterinary medicines proposal. As of now the veterinary medicines proposal only indicates that '*the misuse of antimicrobials should not be allowed*' which is too vague and does not reflect on the need to phase out prophylaxis. It is critical to ban the prophylactic use of antibiotics in the medicated feed and the veterinary medicines legislations to make sure all routes of oral administration are covered by the prohibition. Indeed antibiotics given via drinking water or as top-dressing (i.e. antibiotics sprinkled over the feed) are not regulated under the medicated feed regulation but under the veterinary medicines regulation. If the veterinary medicines proposal still allows antibiotics to be used prophylactically they could still be given to healthy animals in the water or in the feed. This is all the more important knowing that the European Commission's impact assessment reported that medicated feed loses importance compared to other routes such as water medication and top dressing/mixing of ready-to-use veterinary medicine into feed for which prophylaxis would not be forbidden<sup>3</sup>. In addition it is critical to limit the use of antibiotics in drinking water to cases where most animals or the whole herd need antibiotics as it is difficult to ensure homogeneity.

As such the medicated feed and the veterinary medicines legislations should be aligned and clearly prohibit prophylactic use of antimicrobials without exception. Antibiotics use for healthy animals that undergo surgery should still be authorized but this exception should be directly mentioned in the text. Indeed as a general principle prophylaxis should be banned and if there are any specific and clearly defined circumstances where healthy animals need antibiotics, such as surgery, it should be explicitly mentioned in the text. On the contrary still authorizing this practice under exceptional circumstances without specifying the cases leaves the door open to the misuse of antibiotics.

To do so we need clear and unambiguous definitions of prophylaxis, metaphylaxis and therapeutic use in the two texts. Currently, the European Commission's proposals refer to "preventive use" - in the medicated feed proposal - and to "misuse" - in the veterinary medicines proposal. Both lack specificity. A clear distinction between prophylaxis and metaphylaxis is particularly relevant as the interpretation of 'preventive use' can differ among professionals.

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<sup>2</sup> Critically Important Antimicrobials for Human Medicine: Categorization for the Development of Risk Management Strategies to contain Antimicrobial Resistance due to Non-Human Antimicrobial Use, World Health Organization, 2007.

<sup>3</sup> Commission staff working document Impact Assessment accompanying the document Regulation on the manufacture, placing on the market and use of medicated feed, 2014.

The definition of prophylaxis should focus on the absence of clinical signs of disease. Metaphylaxis should be defined as a practice to administer antibiotics to clinically ill animals, and not to animals which are 'healthy carriers'<sup>4</sup>, and to other animals which are clinically healthy but at high risk of being contaminated.

The veterinary medicines proposal should also reflect the need to improve metaphylaxis by identifying groups of healthy animals to treat therefore limiting the treatment to sick animals and a few ones identified at high risk of being infected. Better targeted treatments will ensure sick animals recover fully while healthy animals would not be given antibiotics. This is particularly relevant as the European Food Safety Authority (EFSA) latest report on antimicrobial resistance showed that group treatment accounts for 91 % of consumption of antimicrobials while individual treatment only represents 9% of consumption.

Eventually if reducing the use of antibiotics is key it is critical that the full prescribed dose by the veterinarian is administered to animals. A lower dose would not kill the bacteria, leaving the animal sick, while increasing the ability for bacteria to become resistant to the molecule.

- **Restrictions of use of certain antibiotics in veterinary medicine**

Restricting the use of certain antibiotics in veterinary medicine to preserve their efficacy in treating infections in humans is critical. This is why we welcome the European Commission's ambition to set a list of principles to be used to determine which antibiotics should be restricted in veterinary medicine.

BEUC calls for strict principles to be used to determine whether an antimicrobial should be restricted or not. It should take into account both the World Health Organisation (WHO) and the World Organization for Animal Health (OIE) lists of critically important antimicrobials as well as national and international publications on the levels of resistance in animals and humans.

EU agencies including the European Medicines Agency (EMA), EFSA and the European Center for Disease Control (ECDC) should be consulted and provide advice to the European Commission. The EU list should not merely contain antimicrobials which are already prohibited in EU Member States such as Carbapenems.

In addition the restrictions should not only take the form of warnings and guidance on labels but, where necessary, should be translated into clear prohibitions of use. Therefore it should be better reflected in the veterinary medicine proposal that the list will be used to restrict but also prohibit the use of certain antibiotics. The veterinary medicines proposal should also clearly indicate that such principles will not interfere with Member States' right to go further and prohibit the use of certain antibiotics in some species if they deem it appropriate.

BEUC is firmly in favour of the prohibition of modern cephalosporins in all species. Indeed equivalent and better treatments exist for the therapeutic indications while they are used as a last option to treat antibiotic resistant infections in humans.

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<sup>4</sup> Evaluation des risques d'émergence d'antibiorésistances liées aux modes d'utilisation des antibiotiques dans le domaine de la santé animale, ANSES, 2014.

We also believe that the use of fluoroquinolones, in particular ciprofloxacin, in poultry should be forbidden. As highlighted by EFSA in its recently published report on antimicrobial resistance,<sup>5</sup> levels of resistance to fluoroquinolones in poultry are very high while we need to preserve the efficacy of fluoroquinolones in human medicine.

Eventually the European Commission states that “any measure restricting the use of certain antimicrobials may affect the trade of products of animal origins or the competitiveness of certain animal production sectors in the Union”. This should be counterbalanced by the argument that without strong rules to restrict the use of antibiotics in livestock, antibiotic resistance will negatively impact public health and global trade.

- **Forbid off-label use of certain antibiotics in livestock**

Off-label use (i.e. the practice to give antibiotics not authorized for the indication or species or antibiotics only authorised in human medicine to animals) must be strictly regulated as it has the potential to increase antibiotic resistance. As such BEUC welcomes the European Commission’s plan to establish a list of antibiotics which cannot be used off-label.

BEUC believes the list should contain critically important antibiotics such as modern cephalosporins and fluoroquinolones, as well as newly developed antibiotics. The off-label use of these antibiotics should not only be restricted, but clearly prohibited. BEUC also favours the mandatory registration of all off-label uses of antibiotics. More transparency will not impact veterinarians prescribing behaviour, but make sure off-label use is reserved to certain defined cases and used appropriately and in line with EMA recommendations.

BEUC is also worried that antibiotics that will not be included in the list will benefit from the new flexible system which abolishes the ranking system. As such the prescriber will not have to prioritise the use of certain antibiotics and to respect the ranking system but could decide to directly choose any antibiotic, including those only authorized for humans. On the contrary antibiotics only authorized in humans should remain a last resort solution to treat sick animals if no other authorised veterinary medicinal product is available.

- **Record system for consumption data**

In the veterinary medicines proposal the European Commission proposes to set a system to record and report the use of antibiotics. Right now the European Commission only collects sales data which do not represent the true situation on the ground. In addition Member States do not have the obligation to collect sales data which means EU sales data are based on sketchy information. BEUC welcomes the Commission’s proposal to mandatorily collect sales data and to develop a framework to assemble data on consumption of antibiotics in livestock.

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<sup>5</sup> EU Summary Report on antimicrobial resistance in zoonotic and indicator bacteria from humans, animals and food in 2013, EFSA, ECDC, 2015.

A record system for use data will greatly improve transparency and help determine where most efforts must be devoted. To do so it is important to collect relevant information and combine different kind of data to get a full picture of antibiotic use in livestock. BEUC believes collecting information at farm level, as this is already the case in several EU countries, is critical. Yet it should be combined with data collected at veterinarians' level, as suggested by some national food safety authorities<sup>6</sup>. Such data will not be used to stigmatise veterinarians who prescribe more but to make sure their prescription behaviour is only influenced by animal health status and disease occurrence.

However, to adequately inform policy makers and other stakeholders, consumption data should contain information related to the duration and type of treatment (e.g. metaphylaxis or cure) and indicate the type of administration (individual animals, groups of animals or the whole flock). Such criteria are missing from the scope of the European Medicines Agency's mandate, which is a missed opportunity to better understand and tackle antibiotic resistance. It is particularly important to monitor and record any metaphylactic use as this practice is not substantiated by any scientific studies but rather validated because of organisational matters<sup>7</sup>. In addition any off-label use should also be reported to national authorities.

- **Economic incentives to over-prescribe antibiotics**

The veterinary medicines proposal states that people who prescribe antibiotics should not be influenced '*directly or indirectly, by economic incentives*'. To address this issue they propose that the supply of veterinary antimicrobials should be restricted to the amount required for treatment of the animals under their care.

Yet to prevent any conflicts of interests decoupling the sale and prescription of antibiotics is necessary. Indeed the simple fact that veterinarians revenue depend on the sales of medicines, including antibiotics, can be an incentive to overprescribe. That does not preclude veterinarians being able to prescribe and sell antibiotics under exceptional circumstances, for instance in cases where animal health or welfare are at risk, as this is currently the case in Denmark. In contrast, veterinarians' income should be based on regular visits to the farms and on the quality of advice they provide to animal keepers.

Given that antibiotic resistance is a major public health threat decoupling sale and prescription at least for antimicrobials should be carefully considered by policy makers.

- **Antibiotics used in feed**

BEUC welcomes the European Commission's proposal to improve the legislative framework for antibiotics use in medicated feed by setting a new carry-over limit (i.e. limit of 1% of the active substance in the last batch of medicated feed before the production of non-target feed) and banning the preventive use of antibiotics.

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<sup>6</sup> Ibid. ANSES.

<sup>7</sup> Ibid. ANSES.

However BEUC believes that the option to ban the use of antibiotics in feed altogether should be thoroughly considered by EU policy makers. Indeed sick animals rarely eat which limits the efficacy of administering antibiotics via feed, whether this is by medicated feed or as top-dressing. This is particularly relevant as the impact assessment commissioned by the European Commission stressed that medicated feed survives mainly in those Member States with poorer manufacturing standards, thereby limiting its efficacy and increasing the risk of antibiotic resistance.

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