

Government Response to the Recommendations of the Veterinary Products Committee's Report on Antimicrobial Resistance in Relation to Veterinary Medicines

“Therapeutic and prophylactic use of antimicrobials in livestock should be restricted under veterinary control and should therefore be considered as prescription only medicines (POMs).”

1. The Government agrees with this recommendation. All veterinary medicines with antimicrobial properties are classed as prescription only medicines in the UK. One of the key planks to the Government's strategy to reduce the amount of antibiotics used on farm is to ensure the prudent use of all medicines. The Government actively supports the Responsible Use of Medicines in Agriculture (RUMA) alliance and its published advice on prudent use of veterinary medicines.

“Coccidiostats should be authorised under EU Legislation 2001/82/EEC and should be considered as licensable under the Marketing Authorisations Regulations 1994. The VMD should make representation to the EU authorities with regard to the necessity for some oral therapeutic products, which are only going to be administered in feedingstuffs, to be of pharmaceutical quality. Exemptions should be considered for these products, on the basis of fitness for purpose.”

2. The Government agrees with this recommendation. It has made representations to the European Commission for coccidiostats to be removed from the scope of the proposed new Council Regulation on Feed Additives and included within the scope of Council Directive 2001/82/EEC. Similar representations have been made by a number of other Member States and at the European Parliament. The EU Commission has proposed that these products should remain classified as feed additives for the time being but that the Commission should be charged with reviewing their status before 1 January 2008 with any change coming into effect by 2012. The UK has supported this proposal.

“Drugs essential for the treatment of a serious or life-threatening disease in humans for which there is no alternative, or where the drug is a member of a class of drugs that may cause cross-resistance to agents essential for human therapy, should be authorised with special consideration by the licensing authorities for use in animals.”

3. The Government agrees with this recommendation which is already applied in the assessment of a new antibiotic product for the treatment of animals.

“Data should be provided for the antimicrobial under test to demonstrate whether dose v time distribution results in a time-dependent activity, a concentration-dependent activity or a co-dependence for concentration and time.”

4. The Government agrees with this recommendation. Data that can provide this information are already required as part of the application for a Marketing Authorisation (MA).

“Where guidelines are changed, a review of generic chemical groups should be undertaken to include existing products as well as new products.”

5. The Government does not agree with this recommendation. The European Medicines Evaluation Agency’s (EMA) Committee on Veterinary Medicinal Products (CVMP) has recommended that such changes to guidelines should only be applied to new products, unless there is evidence that there is a problem with existing products, for example through pharmacovigilance. VMD agrees with this position. It would not be legal to impose requirements on UK MA holders above those required in other Member states.

“Alterations to the guidelines for the submission of data in support of a licensing claim should be phased in over a period of time as identification of appropriate dosage strategies could lead to alterations in withdrawal periods that would require acquisition of appropriate data.”

6. The Government agrees with this recommendation. Any changes in dosages could potentially lead to residues issues. Where dosage regimes are increased this may result in the original withdrawal period being insufficient to ensure that any veterinary medicinal product residues are at or below the Maximum Residue Limit (MRL) set in EU law. In such cases new data would be required in support of a new withdrawal period.

“A post marketing antimicrobial resistance-monitoring scheme should be established, which is independent and transparent. Surveillance should be undertaken on UK samples collected at abattoirs and be extended to imported meat and meat products.”

7. The Government agrees with this recommendation. Defra’s Veterinary Laboratories Agency (VLA) currently collects samples of healthy cattle, pigs and sheep destined for the food chain from abattoirs on an annual basis. This survey is designed to determine the prevalence of food borne pathogens and patterns of antimicrobial resistance in these animals. Results from these surveys provide a base line on the prevalence of *E.coli* O157, *E.coli* coliforms, *Enterococci*, *Campylobacter* spp. and *Salmonella* spp. Their findings are published annually in reports available from the VLA. The additional surveillance required under this recommendation will be included in Defra’s antimicrobial resistance surveillance strategy.

“Four sentinel bacteria should be used for surveillance purposes and these organisms should be utilised where it is practically possible during the pre-authorisation resistance assessment. These organisms should be agreed standards throughout the EU.”

8. The Government disagrees with this recommendation. Bacteria to be covered by a surveillance programme of this nature should include those bacteria that are pathogenic to animals, zoonotic organisms and commensal bacteria to produce data on risks to public health and linked with resistance as well as patterns of disease in animals. This kind of survey would also identify emerging problems of lack of efficacy in antimicrobials used to treat diseases in animals that may be used to resistance. Recent OIE Guidelines have recommended a list of bacteria that should be tested for in cattle, pigs, sheep and poultry samples. These Guidelines recommend that up to 13 bacteria should be used in surveillance in cattle and pigs, 11 in sheep and 10 in poultry.

“The VPC, VMD, DEFRA, FSA and DH should work together to determine the acceptable level of risk of development of antimicrobial resistance.”

9. The Government agrees with this recommendation and it already has several cross-departmental committees in place addressing the issue of antimicrobial resistance. The Specialist Advisory Committee on Antimicrobial Resistance (SACAR) and the Interdepartmental Steering Group on Antimicrobial Resistance (IDSG) include members from VPC, VMD, Defra, FSA and DH, as well as others. Further Committees such as the Defra Antimicrobial Resistance Coordination (DARC) Group and the Advisory Committee on Microbiological Safety of Food (ACMSF) also address antimicrobial resistance and closely corroborate with IDSG and SACAR. These groups discuss, and where necessary, investigate further issues related to AMR and put in place systems for assessing the risks associated with those issues.

“The potential for development in veterinary pathogens of cross-resistance to antimicrobials used therapeutically in humans and in veterinary species associated with the use of antimicrobial growth enhancers needs to be considered.”

10. The Government agrees with this recommendation. The antimicrobials chosen for the surveillance programme reflect their therapeutic importance in man and animals. Some may no longer be used or available, but given that resistance may persist long after use of a particular agent, continued surveillance may provide important longer-term information on trends and understanding epidemiology. The surveillance programme should also be flexible, changing in time to reflect changes in antimicrobial availability, developments in the medical field and prescribing practices. Antimicrobials to be monitored should be in line with those proposed in the recent OIE Guidelines.

“Because of lack of data further consideration should be given to the possibility of non-food animals transferring antimicrobial resistant bacteria to humans. Nevertheless, during the authorisation process, attention should be given to appropriate usage guidelines, including personal hygiene. The Working Group support and commend Government recommendations on prudent use guidelines and continued education of veterinary surgeons and the medical profession.”

11. The Government agrees with this recommendation. The DARC Group has identified that surveillance of antimicrobial resistance in companion animals, and its transfer to humans, as a potential risk. However, the Group also considered that surveillance of antimicrobial resistance in food producing animals, e.g. cattle, pigs, sheep, poultry, fish and game, was of a higher importance, as one food producing animal has the potential to affect many humans.

The Government agrees that it is good practice for anyone handling any animal for any purpose to take appropriate hygiene precautions. However, it does not consider that it would be appropriate to include advice on this on medicines labels, as this could reduce the impact of the primary information and safety warnings relating to the products themselves.

The Government welcomes the Working Group’s support for its promotion of the guidelines on prudent use and continued education of veterinary surgeons and the medical profession.