
DRUG USE IN FARM ANIMALS

Regulatory review



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Briefing paper

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Summary

UK regulators are currently consulting stakeholders on the design of new rules on veterinary drugs. This is an opportunity to address problems with the current regulatory system and to put forward a more progressive vision of drug use in farming and food production. The Food Ethics Council will be engaging in this consultation process by producing a short policy paper and by meeting with regulators. We encourage others to take part in the consultation independently or to contribute to our response. This paper contains details of how to take part in the consultation process.

Context

Drugs are given to farm animals for three main reasons: to treat them if they are sick, to prevent disease and to increase productivity. A single substance might be able to achieve all three of these objectives, depending on the species to which it was being given, the dose and the way it was being applied.

UK law distinguishes between three main types of veterinary drug, taking account not only of the substance, but also the dose, the reason for using it and the method of application:

- *Medicines* – These drugs come under the terms of the Medicines Act of 1968. They are assessed by regulators for safety, manufacturing quality and efficacy. Those which are approved for sale are categorised according to how they can be distributed. Some are available only by prescription whereas others can be sold directly by pharmacists.
- *Feed additives* – The use of feed additives is regulated under the Feedingstuffs (Zootechnical Products) Regulations 1999. Medicated feedingstuffs are animal feeds with prescription medicines added to treat or prevent disease. Zootechnical feed additives (ZFAs) are substances such as antibiotics, trace elements and enzymes, added to animal feeds to increase productivity. Feed additives are generally used at a lower dose than equivalent medicines though, in some cases, the line between prophylaxis and production-boosting is blurred.
- *Homeopathic preparations* – Homeopathic preparations are assessed for safety and quality, but not for efficacy.

Regulating the use of these veterinary drugs in the UK is primarily the responsibility of the Veterinary Medicines Directorate (VMD). The VMD is an Executive Agency of the Department for the Environment, Food and Rural Affairs (DEFRA). Its structure mimics that of a business and it aims meet its costs through the fees that it charges to its various 'customers'. The VMD's activities fall into two main categories:

- *Licensing* – Authorising new drugs for sale in the UK.
- *Residues* – Surveillance of drug residues in domestic and imported animal products.

It is advised in these tasks by two scientific committees, respectively the Veterinary Products Committee and the Veterinary Residues Committee.

Since the early 1980s, drug regulation has become increasingly co-ordinated across the European Communities. Although there is a central agency concerned with drug licensing in the EU, it has overseen the exchange of information and drug approvals between countries, rather than replacing the national authorities.

The European rules are intended to reduce costs and bureaucracy for companies planning to market drugs in multiple countries, or to trade in animals and animal products between member states. In effect, the rules

mean that drugs approved by the VMD or its equivalents in other member states do not have to be re-assessed before being sold elsewhere. There is also a centralised licensing procedure that applies to certain classes of product, such as those produced using genetic techniques. In 2001, various different laws concerning veterinary drugs were grouped together under a new Directive, 2001/82/EC.¹

The government's approach to European negotiations, as represented by the VMD, has generally been to minimise changes to existing UK regulation. The existing rules have been considered by the VMD to serve the needs of the its 'customers' adequately, ensuring a cheap supply of safe and useful drugs whilst minimising obstacles to drug manufacturers and suppliers.

Concerns

Since the late 1990s, however, the assumption of economic benefits has come under increasing scrutiny. In 2001, the Ministry of Agriculture published the Marsh Report, which questioned whether animal owners were getting value for money and speculated that there might be a large illegal market for veterinary drugs.² In 2003, the Competition Commission reported that three complex monopolies existed in the animal drugs market, favouring veterinarians, drug manufacturers and wholesalers.³ The concerns of the Marsh Report and the Competition Commission related to the ways that drugs were categorised for sale.

There have also been safety concerns. The use of antimicrobial drugs (antibiotics) in farming has come under increasing scrutiny, because of fears that their overuse in animals speeds the development drug resistant human and animal diseases. Since the late 1990s, this has been the focus of more than ten reports by government advisory committees to the UK and the EU. The response to this concern has been a series of bans on the use of specific antibiotics as growth promoters.

According to the Soil Association, the most sustained critic of antibiotic use in farming, banning individual drugs is not the solution.⁴ It argues that overall antibiotic use has risen despite these bans: the nominally non-therapeutic use of antibiotics as growth promoters had been masking systematically poor animal health, meaning that reductions in the use of growth promoters have led to increased prescriptions for therapeutic and prophylactic drugs.

Therefore, the Soil Association insists that a rational approach to combating antimicrobial resistance must aim to promote animal health and welfare by changing farming practices. Simply banning these drugs can exacerbate the problem and is likely to compromise animal welfare. A similar concern was expressed by the Policy Commission on the Future of Farming and Food.⁵

In addition to concerns about the economic implications of veterinary drug licensing and about antimicrobial resistance, the Food Ethics Council has questioned the high level of secrecy in drug regulation and the implications of scientific uncertainty for licensing.⁶ A previous report by the Food Ethics Council concluded that the assessment process should be changed:

- It should incorporate a precautionary approach, because scientific data on the safety of drugs for animals and for the people who eat their products are uncertain.
- Only narrow notions of safety, manufacturing quality and efficacy are considered in regulation, yet broader principles of welfare, autonomy and justice are as important in evaluating veterinary drugs in the public interest.
- The regulators frequently had close relationships with drug manufacturing firms, and the assessment process was insufficiently transparent to ensure that they acted independently and in the public interest.

¹ **Council of the European Communities** 2001. *Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products* (2001/82/EC), Brussels, November 6. http://europa.eu.int/eur-lex/pri/en/oj/dat/2001/l_311/l_31120011128en00010066.pdf

² **Ministry of Agriculture, Fisheries and Food** 2001. *Report of the independent review of dispensing by veterinary surgeons of prescription medicines*. Ministry of Agriculture, Fisheries and Food, London. <http://www.vmd.gov.uk/ird/irdfinal.pdf>

³ **Competition Commission** 2003. *Veterinary medicines: a report on the supply within the United Kingdom of prescription-only veterinary medicines*. Competition Commission, London. http://www.competition-commission.org.uk/rep_pub/reports/2003/478vetmeds.htm

⁴ **Harvey, J. and Mason, L.** 1998. *The use and misuse of antibiotics in UK agriculture - part 1: current usage*. Soil Association, Bristol, December.

[http://www.soilassociation.org/web/sa/saweb.nsf/0/80256ad800554549802567e100808993/\\$FILE/Antibiotics%20Part%201.pdf](http://www.soilassociation.org/web/sa/saweb.nsf/0/80256ad800554549802567e100808993/$FILE/Antibiotics%20Part%201.pdf)
Young, R., Cowe, A., Nunan, C., Harvey, J. and Mason, L. 1999. *The use and misuse of antibiotics in UK agriculture - part 2: antibiotic resistance and human health*. Soil Association, Bristol, August.

[http://www.soilassociation.org/web/sa/saweb.nsf/0/80256ad800554549802567d1003eb4e5/\\$FILE/Antiboitics%20Part%202.pdf](http://www.soilassociation.org/web/sa/saweb.nsf/0/80256ad800554549802567d1003eb4e5/$FILE/Antiboitics%20Part%202.pdf)

⁵ **Policy Commission on the Future of Farming and Food** 2002. *Farming and food: a sustainable future*. DEFRA, London.

<http://www.cabinet-office.gov.uk/farming/pdf/PC%20Report2.pdf>

⁶ **Food Ethics Council** 1999. *Drug use in farm animals*. Food Ethics Council, Southwell, Notts. <http://www.foodethicscouncil.org/library/reportspdf/drugusefarmanimals.pdf>

A window for change

Over the next few months, there will be an opportunity to address some of these concerns, albeit in a fairly modest way. The VMD is consulting stakeholders on the design of new rules on veterinary drugs, which will enter force in the UK in October 2005, replacing the Medicines Act of 1968.

The main prompt for this change is an overhaul of the EU drug rules, which was timetabled to take place five years after new procedures were introduced in the 1990s. This process, known as 'Review 2001', will result in amendments to Directive 2001/82/EC, expected to be passed in May. The new UK rules will implement these amendments.

However, the EU rules will not determine what happens in the UK. They leave some flexibility for member states to set rules that suit their own circumstances. The VMD is responsible for drawing up and advising ministers on rules that will not only meet the EU requirements, but will also be best for the UK. The new legislation proposed by the VMD will also take into account the recommendations of the Marsh Report and the Competition Commission.

In drawing up the new UK rules, the VMD will consult with stakeholders. It is currently holding an informal consultation process. It will then draft the rules and present them to ministers. After that, there will be a formal consultation on the draft rules, by which time the scope for modifying them will be considerably diminished. The approximate timetable for this process is:

<i>March – May 2004</i>	Informal consultation (Round 1) – VMD listens to ideas
<i>May 2004</i>	EU Directive amending Directive 2001/82/EC expected to be passed
<i>June – September 2004</i>	Informal consultation (Round 2) – VMD makes suggestions
<i>September – February 2005</i>	Draft rules to ministers
<i>Spring – Summer 2005</i>	Formal consultation
<i>October 2005</i>	New UK rules expected to come into force

The VMD has already consulted with a number of industry bodies and professional organisation. At a Consumer Liaison meeting on 2nd March, the VMD told delegates that they were also keen to hear the views of consumers and other people do not have a professional interest in veterinary drugs. They stated that they would meet with any groups who wished to discuss the proposed new rules during the current informal consultation.

The VMD have also stated that this informal consultation will be as transparent as they are allowed to make it. They will describe the different options presented to them and explain how they reached their conclusions.

What you can do

We would encourage you to contact the VMD directly (see 'Contacts' below) to obtain relevant documents, such as the draft text of the amended Directive 2001/82/EC, to contribute your views and to meet with policy makers. Additionally, or instead, you may wish to take part in the Food Ethics Council's working group on this topic. We are planning to contribute our views to the VMD and to meet with them, and you are welcome to join us in this. You may wish to take part in our working group because you think we might otherwise miss an important point, or because you do not have the resources to liaise with the VMD independently.

Membership of our working group on 'Drug use in farm animals' will be completely open. To take part, all you need to do is let us know that you are interested in this issue, preferably by 15th April 2004. We shall then send you a policy paper drafted by Food Ethics Council staff and members. Anyone who wishes to may take part in the working group by then adding their comments to ours, by phone, fax, post or email. By 20th May, we will redraft the policy paper to incorporate some of these comments, and submit it to the VMD. The Food Ethics Council will retain editorial control of the policy paper but all comments, even those which are not incorporated in the main text, will be appended in full to the paper that we send in. Once the VMD has had a chance to digest the paper, we shall meet with them to discuss it. Anyone working group member – that is, anyone who has contributed to our policy paper – will be welcome to take part in this meeting.

The deadlines for the working group process are as follows:

<i>By 15th April</i>	We circulate draft policy paper to all who have expressed an interest (and copy to the VMD)
<i>By 10th May</i>	If you wish to take part, you submit a contribution to us by phone, fax, post or email

- By 20th May* We submit the full briefing paper and all comments received to the VMD
- By 31st May* The Food Ethics Council and all contributors to the briefing paper meet with the VMD
- Subsequently* Follow up as appropriate

The draft policy paper shall begin with our vision for veterinary drug regulation and then outline how to get there. It will include the following elements:

- *Drug use in farm animals: a vision* – This section will look at the place of drugs in farming and food production. It will emphasise the need for a joined up approach to drug regulation, which complements and is consistent with other areas of food and farm policy. It will also critically examine the ethical assumptions underpinning the current rules. It will identify the crucial features of a drug regulation system that is fair, humane, secure and sustainable.
- *Risk management* – This section will examine opportunities within the new EU rules to move towards such a vision when it comes to risk management. It will focus on new references to the ‘risk-benefit balance’. The reference to ‘benefit’ – a concept which is not as intimately associated with quantification as ‘risk’ – appears to concede that licensing decisions are not purely technical. This section will also consider the implications of uncertainty for risk management. Both these avenues of inquiry could potentially open up opportunities for greater public involvement in risk management.
- *Distribution* – The new EU rules look set to change the system by which veterinary medicines are classified for distribution. In particular, all medicines for food-producing animals will be classified as prescription only medicines (POMs). This raises the questions of whether non-veterinarians should be allowed to prescribe certain sub-categories of POMs (within the UK), or certain classes of product should be exempted (at the EU level). The new EU rules also prohibit the advertising of POMs to the ‘general public’. However, it remains to be decided whether farmers count as the general public in relation to all drugs, only sometimes, or never. Our paper shall examine the ethical arguments around these issues.

The briefing paper may well include other elements. The ‘vision’ section will go beyond the scope of the VMD’s informal consultation. For instance, it will also relate to forthcoming rules on the public availability of information about animal drugs, to DEFRA’s Animal Health and Welfare Strategy,⁷ and to the review of the advisory committee system for human and animal medicines being conducted by the Medicines and Healthcare products Regulatory Agency.⁸ The sections on risk management and distribution will look at the leeway for implementing this broader vision within the amended Directive 2001/82/EC.

Contacts

If you wish to get in touch with the VMD directly, please contact John Fitzgerald, who is leading the consultation process:

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Further information about the VMD is available at <http://www.vmd.gov.uk>.

If you wish to receive the Food Ethics Council’s draft briefing paper in April and perhaps take part in our open ‘working group’ by contributing your views to us, please contact:

Tom MacMillan, Executive Director, Food Ethics Council, 39-41 Surrey Street, Brighton BN1 3PB

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All papers associated with the working group will be published on the ‘Farming animals for food’ project pages of our web site: <http://www.foodethicscouncil.org>.

⁷ DEFRA is deciding how to implement its new ‘Animal Health and Welfare Strategy’. Formally, the consultation process is already over. However, they are still accepting comments.

⁸ The Medicines and Healthcare products Regulatory Agency (MHRA) is reviewing the system of advisory committees (human and animal) that was set up under the Medicines Act of 1968. Their proposal is to leave the VPC unchanged.