

Q12 What University will deliver such a module?

A12 University College Dublin has indicated their interest and willingness to deliver such a module. They have all the necessary expertise and discussions have been held between the industry and the University. It is anticipated that other Universities around the country may offer such a module.

Q13 Would veterinary surgeons have to do the animal health module?

A13 No. Veterinary surgeons already have a detailed knowledge of the information relevant to the use of POM C products.

Q14 How will the people who can write prescriptions for POM C products be regulated?

A14 It is anticipated that the Department of Agriculture and Food will maintain a register of people, other than veterinary surgeons, who have the relevant qualifications to write prescriptions for POM C medicines. The Department already manage registers in relation to the training of licensed merchants and this would be an additional register with the names being made publicly available.

Q15 Is the advertising of veterinary medicines controlled?

A15 Yes. The Directive requires that medicines available on a prescription only basis are not advertised to the general public.

Q16 Are farmers the general public?

A16 No. Farmers are defined in various regulations dealing with the Common Agricultural Policy and they are an appropriate group of people to be in receipt of advertising relating to veterinary medicines. The same could be said of those individuals who are allowed to write prescriptions and also the retailers of animal health products.

Q17 How can advertising be directed at the relevant groups?

A17 It is to be anticipated that advertising will be confined to media that is directed at prescribers, retailers and farmers.

Q18 Pet medicines are not for use in food producing animals. Are they affected by the new legislation?

A18 Pet medicines that are classified as POM are impacted by the ban on advertising.

Q19 Will it be impossible to advertise pet medicines to the general public?

Q19 If the medicines are POM, they cannot be advertised to the general public. Given the fact that it is highly desirable to ensure that the general public are aware of the measures that they should take to protect the health and welfare of their pets, it is considered desirable that such products should be advertised to the general public. As a means of providing a solution to this issue, the industry proposes that pet medicines that are currently POM should be reclassified as Pet Medicine Veterinary (PMV) if the product is to be confined to availability from veterinary surgeons. Other pet medicines should be reclassified as Pet Medicine General (PMG) and should be available through a range of outlets. With this approach, the advertising ban would not impact on pet medicines. This proposal recognises the value of providing information, in the form of advertising, to the general public as a means of encouraging pet owners to protect the health and welfare of their animals.

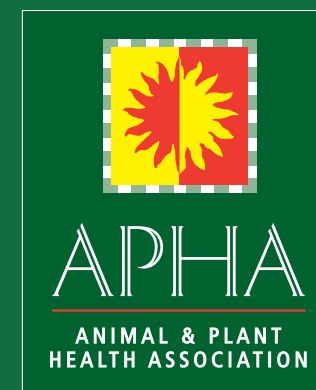
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**Future Distribution Routes
for Veterinary Medicines**

March 2005

Introduction

In December 2003, a piece of legislation (Directive 2004/28/EC) was agreed by the Member States of the European Union. The legislation updates the legal framework concerning the control of veterinary medicines in a variety of ways. For the purposes of this brochure, we are focussing on the issues of distribution and advertising.

The Directive requires that all medicines destined for use in food producing animals should be the subject of a prescription only medicine (POM) regime.

The Directive also introduces a ban on the advertising of POM medicines to the general public.

The POM A, B, C Proposal

The APHA proposes that certain products should only be available from a veterinary surgeon and only be used under his or her direct supervision. These medicines are referred to as POM A medicines. Potent anaesthetics would be an example.

POM B medicines would be available on foot of a prescription written by a veterinary surgeon from a veterinary surgery or from a pharmacy. These would be products such as injectable antibiotics. It is anticipated that some of these medicines, such as intramammaries, would also be available via co-ops and merchants.

POM C medicines consist of materials such as wormers, ectoparasiticides, fluid replacement, certain vaccines, minerals and vitamins. Such materials should be available from the veterinary surgery, the pharmacy, co-op or the merchant. The veterinary prescription should be written by a veterinary surgeon or a person with a life sciences degree who has also completed a University module in animal health.

Frequently Asked Questions (FAQ) on the POM A, B, C Proposal

Q1 What is the definition of a veterinary prescription?

A1 Any prescription for a veterinary medicinal product issued by a professional person qualified to do so in accordance with applicable national law.

Q2 Does a veterinary prescription have to be written by a veterinary surgeon?

A2 No. A veterinary prescription may be written by a professional person qualified to do so. This will include veterinary surgeons but may include other professional persons.

Q3 Who decides who can write a veterinary prescription?

A3 It is up to the individual country to make this decision.

Q4 Can Ireland decide that people other than veterinary surgeons can write prescriptions?

A4 Yes. It is up to the Department of Agriculture and Food to decide if a veterinary surgeon and other professional persons may write a prescription.

Q5 Does every medicine have to be a prescription only medicine (POM)?

A5 No. However, all medicines destined for use in food producing animals must be POM.

Q6 Do teat dips have to be POM?

A6 It is recognised that teat dips should not be subject to a POM regime. As such, the idea of exempting certain medicines from the POM regime has been introduced. It is anticipated that simple medicines, such as teat dips, will be exempted.

Q7 Will a wide range of medicines be exempted?

A7 It is anticipated that a very limited range of medicines will be exempted. It is expected that teat dips, oral vitamins and minerals and relatively few other products will be exempted.

Q8 Who decides what can be exempted?

A8 It is up to an individual Member State to request that a specific product be exempted. This request will be considered by a Committee made up of the 25 Member States and the Commission. This Committee will decide which products will or will not be exempted.

Q9 Will a veterinary surgeon have to write a prescription for intramammaries?

A9 Yes. This is a significant change. It is anticipated that a veterinary surgeon will write a prescription that will be valid for a period of time.

Q10 What is a life sciences graduate?

A10 Typical examples would be a person who has completed a degree programme in agricultural science, dairy science and pharmacy.

Q11 What is a University module in animal health?

A11 If the relevant graduate has not completed a module in animal health as part of their degree programme, it is considered appropriate that they complete such a module. This will ensure that they have specific information concerning the appropriate use of the products that they will be allowed to write prescriptions for, ie, the POM C medicines.