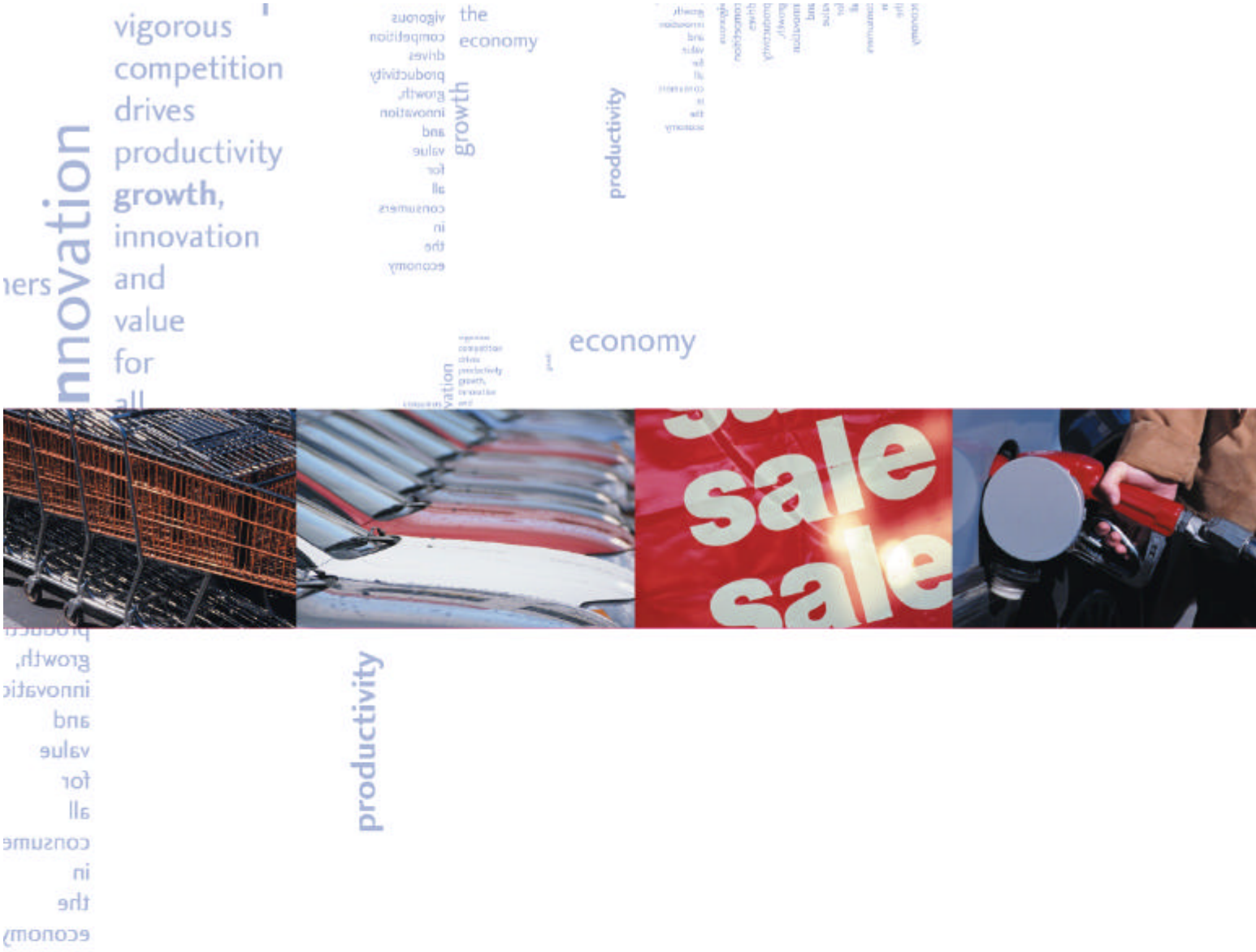

Comments of The Competition Authority on the Preliminary Draft of the Animal Remedies Regulations, 2005

Submission to the Department of Agriculture and Food

September 2005

The Competition Authority
An tÚdarás Iomaíochta

CONTENTS

INTRODUCTION

1.1 The regulation of animal remedies is necessary to ensure both public health and animal health. Consumers, generally in this case farmers, need to have confidence that animal remedies are fit for purpose and that they will be dispensed in accordance with appropriate levels of expertise. The Competition Authority recognises that the Department must balance the policy objectives of ensuring public and animal health, and also promoting efficiency and competition in this field.

1.2 A number of the draft Regulations can be expected to promote competition. In particular, the requirement that, where vets both prescribe and dispense an animal remedy, they issue separate invoices for each of these services; and the proposal to permit Licensed Merchants to supply certain prescribed animal remedies. These proposals are welcomed.

1.3 A number of the draft Regulations appear to have the potential to interfere with the supply of animal remedies beyond levels required to guarantee public and animal health:

- Requiring only vets to write prescriptions raises concerns that the Department may be concentrating monopoly power in the hands of vets
- Reliance on an unproven and untested EU exemption regime to provide for a liberalised prescribing regime
- Reducing the umber of animal remedy categories may have the effect of dampening competition in the supply of animal remedies
- Prohibiting all advertising of certain remedies hinders entry into the market by new manufacturers, and hinders the development and promotion of new and innovative products
- Requiring vets to prescribe branded drugs makes it difficult for new, relatively unknown, manufacturers to enter the market, and may also allow vets to create local monopolies in the supply of prescription drugs

1.4 The draft regulations will have two inter-related negative effects. First, competition will be restricted and second, the objective of assuring animal health will not be met. Lower standards of animal welfare will therefore ultimately prevail. Other, more proportionate, measures should be taken to accomplish the Department's objectives. The final draft of this legislation should be drafted in a way that avoids the creation of barriers to competition. These comments focus in particular on the proposed prescription regime.

1.5 The Competition Authority is available to discuss any of the matters contained herein in further detail, should the Department find this useful.

RESTRICTION ON PRESCRIBING TO VETS ONLY

2.1 The draft Regulations will require that veterinary practitioners must in all cases issue written prescriptions, including for day-to-day preventative medicines.[1,2] This requirement arises from EU Directive 2004/28, but EU legislation also allows for an exemption regime to be implemented, which would provide for certain categories of medicines to be excluded from this requirement. This proposal needs to be addressed, as it has potentially serious implications for competition.

2.2 It is to be expected that such a radical proposal, following from EU legislation, is intended to address a serious problem in the prescribing regime. However, no such problem has been identified by the Department in relation to the prescribing regime in Ireland. In the absence of compelling public and animal health justifications, the prescribing regime should be as liberal as possible. Since the Department has not identified any concern to justify restricting the prescription regime, it should not do so.

2.3 If it is determined that a problem does arise which requires traceability of animal health histories and accountability for these histories, the draft regulation can be seen as disproportionately restrictive. Draft Regulation 46 already provides for farmers to maintain a detailed and up to date "Animal Remedies Record", along with copies of prescriptions issued. Where such transparent records of animal health histories exist, the requirement for one individual (a veterinarian) to be the sole prescribing entity is diminished, as any potential prescribing entity will be able to examine the Animal Remedies Record in order to issue the most appropriate remedy. The maintenance of up-to-date Animal Remedies Records allows for professionals other than vets to be given prescribing rights, as in the UK.

2.4 If, however, the Department remains convinced that public and animal health is not best served by the provision of a detailed paper trail (the Animal Remedies Record), it should then ensure that farmers have the greatest possible choice of remedy, consistent with a veterinary prescription-only regime. This would require that:

- Prescription drugs be made available from the maximum number of supply routes (veterinarians, pharmacists and licensed merchants)
- Veterinarians prescribe generic drugs or active ingredients, rather than specific brand names (over which they themselves may have a local monopoly)
- Veterinarians be permitted to issue long-term prescriptions, as specified at draft Regulation 48(4)

A Disproportionate Means of Achieving Objectives

2.5 The Department should review the terms of Article 1(1)(h) of EU Directive 28/2004/EC, which defines a veterinary prescription in the following terms: *"Any prescription for a veterinary medicinal product issued by a professional person qualified to do so in accordance with applicable national law"*. This formulation specifically allows for

[1] "Department consults on draft regulations which change the current control regime for veterinary medicines" Available online at http://www.agriculture.gov.ie/index.jsp?file=pressrel/2005/152-2005.xml

[2] It is understood that this refers to medicaments for food-producing animals only.

suitably-trained persons, vets or otherwise, to write prescriptions. The Directive does not restrict prescribing rights to veterinary practitioners only. The draft Regulations are therefore more restrictive than required by the Directive, and should be redrafted to permit consumers to benefit from the expertise and competition which trained professionals, for instance, prescribing pharmacists, can provide.

2.6 The Department should also give consideration to licensing training schemes which would allow for suitably qualified persons of the type specified under draft Regulation 37 to prescribe certain categories of animal remedies.

Why this will negatively effect Competition

2.7 The effect of this Regulation would be to dampen competition in the supply of animal remedies. Current practice is that not all animal remedies require a prescription from a veterinary practitioner. The new regulation would require animal remedies for food-producing animals which historically did not require a vet's prescription now to be prescribed by a vet. Such a requirement restricts competition and raises transaction costs, but it does not achieve its stated goal of protecting public and animal health. Indeed it may have the opposite effect, as consumers may forego basic treatments, (e.g. Avermectin pour-on), which they would previously have bought during a trip to their local agricultural merchant, once they are confronted with the extra time and expense incurred in obtaining a prescription. This indicates that the Regulations need to be more proportionate, and need to be established on a more reliable foundation that the expectation of a successful exemption application at EU level.

Farmer-Veterinarian relationship

2.8 A good working relationship with a local vet is an important requirement for a farmer, due to the often onerous working conditions encountered by vets, particularly during the lambing and calving season. Therefore, it is likely that, once a farmer has been issued a prescription by a vet, he will proceed to purchase the prescribed medicines from the vet. Farmers will be reluctant to purchase animal remedies from alternative suppliers for fear of damaging the working relationship with their vet.

2.9 The effect of this Regulation on its own will be to reduce competition in the supply of animal remedies, as farmers will rely even more than they already do on vets both to prescribe and supply animal remedies. This will have the effect of unfairly advantaging vets over alternative supply channels, particularly pharmacies and licensed merchant outlets, who will no longer be able to offer for sale animal remedies without a vet's prescription.

Northern Ireland Licensing Regime

2.10 Given the land border with Northern Ireland, which will be operating a very different, more liberal, licensing regime to the one proposed for the Republic, there exists significant potential for an illicit cross-border trade in animal remedies to develop. This has the potential not only to harm public and animal health, but also to damage competition, as consumers may opt to purchase animal remedies from the illicit, but

cheaper, cross-border trade, rather than the legal, but more expensive, trade in the Republic of Ireland.

Exemption Procedure

2.11 Article 67 of Directive 2001/82/EC allows for an exemption regime. Member states can apply to an EU Standing Committee to have certain animal remedies exempted from the general requirement that they be dispensed only in accordance with a veterinary prescription. Where a member state intends to pursue this route, it is permitted to continue with its own national supply provisions either until the Standing Committee makes a decision, or January 1st 2007, whichever is sooner. The Department's stated aim to avail of this EU exemption regime to the fullest extent possible may well mitigate the worst effects of the draft Regulation; however, it is important to bear in mind that this is a second-best solution which is designed to lessen the negative effects of a restrictive regulation, rather than a first-best solution, which would be the promulgation of a liberalising regulation in the first place.

2.12 If the Department succeeds in having declared exempt all relevant categories of animal remedies, the negative effects on competition of the draft Regulation will be lessened. If, however, the exemption procedure fails to deliver this result, then Irish consumers will pay the price of restricted competition – higher costs and less innovative service. There may be an unjustified presumption that the exemption regime will indeed deliver real benefits. This is a very real concern, since exemption decisions are made collegially at Standing Committee level, and apply to all member states, not just the member state which requested the exemption. The Competition Authority understands that the criteria which the committee will use to adjudge on exemption requests have not been published. Given the high degree of uncertainty attaching to the exemption regime, it should not be depended on as a reliable means of avoiding the requirement to have all animal remedies prescribed by a vet. If the Department pursues this avenue and is unsuccessful, Irish farmers will suffer[3] and the Department will have to reconsider this issue all over again, in consultation with relevant parties.

2.13 As a first best approach, the Department should reconsider this proposal and consider the approach taken in other jurisdictions, most notably the UK. As a second best approach, the Authority fully supports the Department's intention to make maximum use of the EU exemption regime, and urges that as many animal remedies as possible, consistent with best practice in public and animal health, be exempted from the veterinary prescription requirement.

Extension of Prescription Lengths

2.14 The proposal at 48(4) that vets be permitted to prescribe animal remedies to a maximum quantity of six months supply is welcome. This will promote competition by loosening the tie between vets and farmers, as farmers will not need to return to vets frequently for repeat prescriptions, thereby affording them greater freedom to shop around for the animal remedy. However, this in no way compensates for the restriction on competition imposed by draft Regulation 48(1).

[3] The IFA estimates that the proposed regulations will cost farmers €60-€80 million per annum in terms of increased medicines costs. *The Irish Times*, August 30th, 2005.

ROUTES OF SALE OR SUPPLY OF ANIMAL REMEDIES

3.1 Draft Regulation 16 alter the classification established under the Animal Remedies Regulations, 1996. The principal effect of this is to abolish the *Prescription Only Medicine (Exempt)* (POM[E]) category. It appears that draft Regulation 16 potentially makes the supply of animal remedies more restricted than stipulated in the 1996 Regulations. Restrictions on supply frequently distort competition.[4]

3.2 The Competition Authority understands that the current POM(E) category allows pharmacists to prescribe animal remedies which by therapeutic classification should be "Prescription Only" medicines, but which do not require prior diagnosis. The POM(E) category is therefore clearly distinct from the "Pharmacy Only" category.

3.3 The POM(E) category consists mostly of vaccines. By preventing disease, the usage of vaccines helps avoid reliance on antibiotics. Given concerns in the animal health community relating to the dangers of pathogens developing resistance to antibiotics due to overuse, there are sound public health and animal health reasons for retaining this categorisation.

3.4 Of 1,308 veterinary products currently (August 31st, 2005) authorised by the Irish Medicines Board,[5]

- 7 are designated "Pharmacy Only"
- 51 are designated "Veterinary Surgeon Only"
- 54 are designated "Companion Animal Medicine"
- 70 are designated "POM(E)
- The remaining 1,126 are designated either "Prescription Only" or "Licensed Merchant"

The POM(E) supply route is therefore the most-frequently designated of the four minor supply routes. This suggests that the removal of this category will have detrimental effects on the supply of such medicines.

3.5 Concerns arise that animal remedies which were previously categorised as POM(E) will henceforth be categorised as "Prescription Only". This will have the effect of reducing competition, as the diversity of supply routes for such remedies will be reduced. Vets will therefore potentially have the ability to earn monopoly profits on the supply of these medicaments, as the price and service competition offered by pharmacists will have disappeared. This will especially be the case in rural areas which are not well-served by pharmacists.

3.6 Farmers benefit from a diversity of animal medicine supply routes as this promotes competition on price, service and innovation. Given an environment in which prescribing is restricted to vets,[6] these benefits will be lost if the POM(E) category is abolished and the remedies categorised thereunder are moved to the "Prescription Only" category. The Department should either retain the POM(E) category, or ensure that medicines previously covered by this category are moved to the less restrictive "Pharmacy Only" category.

---

[4] The discussion of Regulation 16 is only of relevance if the requirement that vets issue written prescriptions for all animal remedies for food-producing animals is lifted.

[5] Available online at http://www.imb.ie/veterinary_authorised_products.asp?nav=70&all=1&letter=-1&todo=show&print=1

[6] As stated in the Department's press release at http://www.agriculture.gov.ie/index.jsp?file=pressrel/2005/152-2005.xml

RETAIL SALE OF ANIMAL REMEDIES

4.1 Section 36(1) of Regulation 36 states that *"A person shall not sell or supply an animal remedy by retail except under and in accordance with a licence ("Animal Remedies Merchant's licence")."* No exceptions to this requirement are listed in the Regulation. This leads to the conclusion that any retailer of animal remedies will require an Animal Remedies Merchant's licence, including vets, pharmacists and other suppliers.

4.2 Following the tenets of *Regulating Better*, both the necessity for and effectiveness of requiring already suitably-qualified personnel, notably vets and pharmacists to hold such a licence are open to question. The requirement to hold an Animal Remedies Merchant's Licence should be extended only to individuals who do not already have proven prior expertise in this field, specifically, veterinary practitioners and pharmacists.

PROHIBITION ON ADVERTISING ANIMAL REMEDIES

5.1 The prohibition on advertisements in the general press of animal remedies of the categories specified under draft Regulation 43(1)(a) and (b) may well be justified, however, the prohibition under Regulation 43 is disproportionate to the goal which is sought. Advertising of such remedies should be allowed in the pages of industry publications, especially those directed towards veterinary practitioners and pharmacists. Non-qualified persons are unlikely to regularly consult such publications and therefore will not be influenced by the content therein.

5.2 A blanket ban on advertising is both disproportionate and harmful to competition because it makes it difficult for

- New manufacturers to promote the existence of animal remedies of this category which they have begun to manufacture
- Existing manufacturers to promote newly-developed animal remedies, or improvements and innovations to existing animal remedies

5.3 Regulation 43, as currently drafted, therefore acts as a barrier to innovation and to entry in the animal remedy manufacturing market, since manufacturers are prevented from informing their target audience in a comparatively cheap and transparent manner of new or improved medications. This Regulation should be redrafted to permit the advertisement of the animal remedies specified above in the specialised industry press.

PRESCRIBING OF BRANDED ANIMAL REMEDIES

6.1 Part 1 of the Second Schedule stipulates the information which must be included in a veterinary prescription, in particular, the *"precise name as it appears on the veterinary product authorisation".* As the Regulations appear to grant veterinarians a monopoly on issuing prescriptions, the Second Schedule has potentially severe consequences for competition. Veterinarians may act as "market makers" in the localities which they serve. This may restrict competition from alternative treatments which have similar characteristics, and also from other suppliers which may not stock the prescribed remedy because the veterinarian is the sole local agent for the manufacturer.

6.2 In particular, this may discourage new entry to the manufacturing market, as vets may be unaware of, or reluctant to, prescribe animal remedies from a firm which does not have widespread name recognition, or "generic" remedies. This requirement also hinders the emergence of price competition at the local level, since farmers will have no choice in the prescribed remedy which they are obliged to purchase.

6.3 The Competition Authority agrees that for certain potent medicaments, it may be appropriate to specify a particular brand name; however, for less potent remedies used to treat commonly-occurring animal ailments, particularly where side effects are minimal, it should suffice to specify the active ingredient, along with other relevant information, such as strength, dosage, contra-indications, incompatibilities, withdrawal period, method of administration and so on. The Department and other relevant bodies should give consideration to whether such a scheme should be statutory or voluntary.

6.4 The UK Competition Commission recommended in its 2002 Report, *Veterinary Medicines: A report on the supply within the United Kingdom of prescription-only veterinary medicines*, that a voluntary scheme for specifying a range of alternative remedies be investigated:

> *"… where an animal owner requests a prescription, veterinary surgeons should provide one in a form that will allow identification and dispensing of alternatives which, in their clinical judgement, would be equally acceptable so as to give the animal owner maximum opportunity to seek the most cost-effective solution. This is not only in the interests of consumer choice and competition, but, as it may lead to some animals being treated that would otherwise go untreated, because of cost, it may also yield benefits in terms of animal welfare. We urge the RCVS to encourage veterinary surgeons to do this and, in order to facilitate such behaviour, to consider the desirability of drawing up or endorsing lists of alternative veterinary medicines to be considered by veterinary surgeons in writing prescriptions for common conditions."*[7]

The usefulness of a similar scheme in Ireland should be investigated.

[7] "Veterinary Medicines: A report on the supply within the United Kingdom of prescription-only veterinary medicines", p.48. Available online at http://www.competition-commission.org.uk/rep_pub/reports/2003/fulltext/478c2.pdf

The Competition Authority, Parnell House, 14, Parnell Square, Dublin 1, Ireland
Tel: +353 (0)1 8045400 LoCall 1890 220224 e-mail: info@tca.ie

www.tca.ie