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## **Independent Review of Dispensing by Veterinary Surgeons**

The National Office of Animal Health represents those companies who research, manufacture and hold Marketing Authorisations for animal medicines in the UK. In 1999 our 34 Corporate members provided approximately 95% of all licensed animal medicines in the UK, for both farm and companion animals, and every category of marketing classification: POM, P, PML and GSL (see annex 1).

### **OVERALL SUMMARY**

We welcome the fact of this review and believe that, following analysis and consultation with our members, as well as bodies representing all stages in the supply chain, that the current arrangements are fundamentally sound and not in need of radical reform, although there may be benefit in some fine-tuning.

In reviewing dispensing we believe full consideration should be given to the potential negative effects of any changes on costs, medicines access, animal welfare and the ability of the Authorities to remain fully informed of the use and effects of animal medicines in the UK. There is scope for improving transparency of veterinary charges to clients, highlighting the professional fee, dispensing fee, and cost of the medicine.

Animal owners have always had the option to request a prescription and take it to a pharmacist to dispense. However, few clients are aware of this. We believe there is a case for strengthening this, making it a requirement for veterinary surgeons to offer a prescription.

The system whereby products are classified, and classification is reviewed, needs revision to ensure that each individual product is classified scientifically according to its own merits and within the UK system of distribution. The process of initiating review merits re-examination.

Above all, and consistent with the overall thrust of the Government's paper "A Strategy for Agriculture", a thorough review of current controls at all stages in the supply chain should be undertaken to minimise any bureaucratic constraints on medicines reaching the animals for which they are intended.

### **GENERAL OBSERVATIONS**

1. Animal medicines are a force for good, contributing to the welfare of both farm and companion animals, the control of disease and the relief of suffering. In short: 'Animals need Medicines too'. Moreover, for farm animals, animal medicines assist in the maintenance of farm profitability and control disease which might otherwise be spread to the consumer: 'Healthy food from Healthy Animals'. Thus the logic must be that those whose duty it is to care for animals should have the fullest access to suitable products, with the minimisation of unnecessary cost or bureaucratic restraint.

2. The animals medicines supply chain in the UK is probably more highly controlled and burdened by regulation than any other industry in Europe. This burden of regulation adds costs at every stage in the chain.
3. It is important to distinguished between true clinical/safety concerns and the commercial concerns of any particular sector – both are legitimate but should be kept separate.
4. If the key objective of this review is that announced by Mr Blair on 30 March 2000 – to reduce costs to farmers – then this will require thorough questioning of regulations and controls throughout the chain.

(It should be noted that, according to the British Cattle Veterinary Association, the average livestock farmer's veterinary bill is only 5% of turnover, so even a major reduction in medicines costs is unlikely to have significant effect on farm businesses. Alternatively, according to MAFF, UK farm gate value of livestock and livestock produce in 1999 was £8.25 bn. Compared to farm medicines sales of £165m (see below) this indicates a ratio of 50:1.)

Although the principal focus has been on sales of POM medicines to farmers, statistics show that these are in a minority and have fallen recently, while all the growth in POM sales has been in companion animals:-

	Year to 30/6/2000		Year to 30/6/1999
	£m		£m
<b><i>Food Animals</i></b>			
POM	74.1	}	74.5
(in feed) MSF (=POM)	10.2		10.6
PML	64.2	}	74.8
(in feed) MSFX/ZFA (=PML)	11.6		16.5
GSL	5.6		6.0
	165.7		182.4
 <b><i>Companion Animal (including horse)</i></b>	 £m		 £m
POM	147.6	83.1%	130.0
PML	22.1		21.5
GSL	7.9		8.4
	177.6		159.9

('P' excluded as insignificant)

(Source – NOAH Sales Survey – values at ex-manufacturer level)

5. In comparing costs with other countries it is very important to assess the total cost of providing a veterinary medicine service:

$$\text{Total cost} = \text{professional fee} + \text{medicine price} + \text{tax}$$

And to look at contributory local factors – legislative compliance cost, transport, product classification and distribution (see annex II). It has been suggested that the reluctance of the veterinary profession, over the years, to charge proper levels of fees, and instead rely on medicine mark-up to maintain practice income has been a contributor to the current concerns over medicine costs. It would, in our view, be helpful for the veterinary profession to re-assess the way in which it calculates its charges for goods and services.

6. If veterinary practices no longer receive the profit on sales of medicines then they will have to increase professional fees to maintain their businesses and level of service.

Alternative arrangements are unlikely to reduce the overall cost to users, and could increase it.

7. With the exception of some “outer-isles”, there is overlap of the territories served by veterinary practices. Thus, while the vet is restricted to “animals under his care”, there is no such limitations on clients who can and do shift between practices for a variety of reasons i.e. individual vets do not have a monopoly. Furthermore there is already wide variation in medicine prices and charging systems between practices.
8. Any review of the UK animal medicine supply system must take account of the other reviews taking place concurrently:
  - OFT review of animal medicines pricing
  - MAFF’s Quinquennial Review of VMD
  - EU ‘Regulation 2000’ review of EMEA and the EU licensing process

EU’s Regulation 2000 project could be particularly significant in the medium term if industry proposals to simplify the ‘POM’ criteria and allow centrally licensed products to be classified other than POM are accepted.

#### REVIEW OF DISPENSING

9. Animal owners have always had the option to request a prescription and take it to a pharmacist to dispense. However, few clients are aware of this. We believe there is a case for strengthening this, making it a requirement for veterinary surgeons to offer prescription.
10. One of the options raised in VMD’s memorandum of April 2000 was the ‘Danish Model’ whereby vets prescribed and pharmacists dispense. VMD suggest that this might (a) reduce the cost of medicines to farmers and (b) reduce the (alleged) tendency of vets to over-prescribe medicines to increase their income – this in turn would, they suggest, reduce consumption of antibiotics (see below).
11. In conducting such a review it is equally important to examine all the consequences of proposed change, not just the anticipated benefits. In particular, as outlined in our introduction, the consequences for access to medicines and to the supply of advice and services for animal welfare must be carefully considered:-

- (i) As stated in 3 (above) it is important to separate out the true clinical/safety aspects from commercial factors; however, the inter-relationship cannot always be avoided. For example, there are growing concerns about the viability of farm animal veterinary practice, particularly in remote areas. If Veterinary Surgeons were denied the profit from medicines sales to support their businesses, then it is questionable whether many large animal practices would survive, or how many ‘mixed’ practices would continue to serve farm clients.

The consequences for farm animal welfare and the availability of vets to participate in livestock Farm Assurance schemes designed to protect the consumer, could be very serious (see 12v below).

- (ii) The separation of prescribing and dispensing could increase costs:
  - Veterinary surgeons would need to increase fees to remain viable; will this deter animal owners from seeking advice?
  - Pharmacies would need to make a profit.
  - Manufacturers would need to consider the re-organisation of their sales and supply organisations to cover pharmacies while remaining in contact with vets (as already happens for human medicines).
  - Veterinary wholesalers, who currently provide a very cost effective service supply the complete range of veterinary requirements direct to practices, could have to make duplicate

calls – delivering medicines to pharmacies and ‘sundries’ to practices. Alternatively, if the ‘human’ wholesalers took over the major business of supplying veterinary medicines to pharmacies, would veterinary wholesalers survive?

- There are approximately 2500 veterinary practices, but 13,000 pharmacies, so the extra effort in servicing pharmacies could be very great, with business being spread too thinly to be viable.
- Currently vets may use a pack or multi-dose vial to treat a number of clients’ animals. If each client required a separate prescription dispensed by a pharmacy, would manufacturers have to supply smaller packs, single-dose vials, at greater unit cost? Experience from human medicines supply suggests that this will be the case.

(iii) As well as cost, the inherent inconvenience of the two-stage process: seeing a vet to obtain a prescription, then going to a pharmacy to obtain the medicine (and perhaps returning to the vet for administration), seems in danger of deterring animal owners, or delaying treatment and thus affecting animal health and welfare. Particular points for consideration are:-

- Farmers in remote areas could be many miles from a pharmacy.
- Veterinary practices increasingly hold surgeries at evenings and weekends when community pharmacies (‘High Street chemists’) are closed.
- Many community pharmacies are in precincts or supermarkets where pets are forbidden, while few chemists shops welcome animals – thus the opportunity for a pharmacist to give first hand advice on administering a medicine to a pet are limited.
- All pet vaccines are for ‘vet administration only’ – would practices be allowed to hold stocks, or would the client have to collect from the pharmacy and return to the vet? (Approximately 25% of all POM sales for companion animals are vaccines). It would seem to the detriment of animal welfare to introduce any system which deters pet owners from their annual vaccination visit to the vet, which also provides the opportunity for a general health check. Would temperature controls on vaccines suffer?
- How many community pharmacies would choose to stock the full range of POM veterinary medicines?
- How far would an owner have to travel to find a stockist, or to wait while a prescribed medicine is ordered?
- Currently vets supply medicines and services on credit, with customers, particularly farmers, paying in monthly instalments – would pharmacies provide this facility?
- Would vets be allowed to hold ‘emergency’ stocks – how would this be defined and controlled – how would they obtain them?

12. Please note all the above points are related to pharmacies and the practicalities of supplying POM animal medicines via community pharmacies or ‘High Street chemists’. We acknowledge that there are a small number of existing ‘agricultural pharmacies’ which provide excellent coverage in their areas, but any change in the law should investigate the likelihood of such service becoming available throughout the UK.

In this context, it should be noted that although pharmacies are already permitted to supply the wide range of PML and GSL medicines available on the UK market, very few have taken up this business opportunity. This must call into question the likelihood of a sufficient number taking on the additional work of dispensing veterinary POMs.

The question of pharmacists as professional individuals becoming more involved, for example as employees of vet practices, is quite different. However this would be unlikely to have the desired effects on the price charged for medicines by those practices.

13. Finally, serious consideration should be given to the damaging effect the introduction of an extra link in the supply chain could have on the Authorities’ ability to conduct post-marketing surveillance and monitor the supply of medicines via:

- Less precise information on the actual medicines used – particularly if pharmacies replicated their current tendency under the NHS to substitute the cheapest alternative for prescribed brand.
- This, in turn, encouraging a shift to use of the Cascade and human ‘Generics’ instead of fully licensed veterinary medicines.

- Less coherent record keeping reducing the efficiency of batch traceability and product recall.

### Antibiotics

14. It has been suggested that vets are tempted to over-prescribe antibiotics in order to make a profit, and that separation of prescribing from dispensing would prevent this.
- (i) This goal, of reducing antibiotics usage, seems inconsistent with the overall aim of reducing medicines prices to farmers, as high prices deter unnecessary consumption.
  - (ii) In the current farming climate, farmers are unlikely to accept veterinary advice to use more antibiotics – indeed the evidence from the PML sectors is of farmers consciously cutting back on medicine usage to reduce expenditure.
  - (iii) The increasing range of preventive treatments, especially vaccines, is reducing the need for antibiotic therapy.
  - (iv) There is already good experience of the separation of ‘prescribing’ and ‘dispensing’ with medicated feeds where the vet, taking only a fee, writes an MFS ‘prescription’ which is then ‘dispensed’ by the feed compounder. In fact this is the largest single use of antibiotics for farm animals, valued at £10.2m compared to approximately £32m for all other types of antibiotics for farm use, and in weight of antibiotics used it is the majority. We therefore do not believe that dispensing of antibiotics by pharmacists would lead to any reduction in the necessary use of antibiotics by farmers.
  - (v) Finally, assuming the intention is to increase the care with which antibiotics are used on farm, we commend to you the RUMA (Responsible Use of Medicines in Agriculture) project whose guidelines are designed to reduce the need to use antibiotics by improving animal and medicines ‘husbandry’. Such an approach is, however, dependent on the availability of expert veterinary advice (see 11(i) above).
15. There is a perception amongst some animal owners, both companion animal owners and farmers, that they are being overcharged for animal medicines. We believe there would be merit in veterinary surgeons introducing greater transparency of the veterinary charges to clients, highlighting the professional fee, dispensing fee, and cost of the medicine.
- 16 To summarise ‘Dispensing’
- The separation of prescribing and dispensing would add to overall costs and not reduce the price of medicines to farmers and companion animal owners.
  - Increased inconvenience in obtaining medicines for animals use could become a deterrent to treatment, putting animal health and welfare at risk.
  - There is no evidence that ending veterinary dispensing would reduce usage of antibiotics.
  - The authorities’ ability to carry out Pharmacovigilance and monitor medicine supply could be undermined.
  - For farm animals the added cost and complexity of the ‘Danish’ model could actually drive more farmers into the Black Market, as we understand has already occurred across the open boundary between Germany and Denmark – something you may wish to investigate. (A member of the EU’s Strategic Scientific Committee has reported Belgian wholesalers supplying faxed orders from Denmark by mail within 24 hours).
  - The option for pharmacists to dispense exists already: veterinary surgeons should promote this choice more widely.
  - More transparency in veterinary charges should be introduced.

## REVIEW OF CLASSIFICATION

17. The current system of classifying a product 'POM' is based on a set of criteria contained in Directive 81/851 (which closely resemble those used for many years under the UK Medicines Act (see annex III).

Inevitably these criteria require interpretation and this has led to some striking anomalies between Member States, often as result of their local cultures and distribution systems (for example some flea product which are POM in UK are GSL in the Netherlands, PML in Denmark).

18. In examining these criteria as part of its response to the European Commission's "Regulation 2000" Review, FEDESA, our European Federation, concluded that the only criteria directly related to the training requirements of a veterinary surgeon is the need for a diagnosis – indeed some criteria, such as user safety of ecotoxicology, are not normally covered at Vet School (see Annex IV).
19. FEDESA is equally emphatic that, as with all other parts of the animal medicines authorisation process, the classification decision should be based solely on the attributes of the product under consideration.
20. One particular problem of the present system is the automatic requirement that any product containing an active ingredient new to animal medicine must be POM (thus even a substance available in GSL form for humans must be POM when first introduced).

For products registered under the EU's centralised procedure this problem is compounded by the absence of any mechanism to review the POM classification of a product – something on which FEDESA has also proposed change.

21. Thus the opportunity to reclassify animal medicines currently classed as 'POM' in the UK will be constrained by current EU law. However, assuming FEDESA is successful with the above proposals, there may be greater scope in the future.
22. Nevertheless, there are undoubtedly examples of products which merit review. Bearing in mind that all licensed products have been through a system of exhaustive scrutiny, and bear labels containing detailed instructions for use, as well as contra-indications and warnings, it would seem sensible to consider whether some products really require the full expertise and 5 years of training of a veterinary surgeon for them to be safely and correctly used.
23. It should be noted that veterinary surgeons are already permitted to sell P, PML and GSL products to their own clients, thus changing the status of a product from POM would not deny vets access to such products. However, they may have to be more ready to compete on price and service with other suppliers.

### Who should initiate a review?

24. Currently review of a product's classification can only be initiated by the Authorities themselves following safety concerns, or at the request of the Marketing Authorisation Holder. Last year, before this present Review was proposed, VMD had floated the idea that other interested parties should be allowed to make a case for a product's classification to be reviewed, during public consultation on revisions to the POM and GSL Orders. Providing that those making the case were confined to scientific and clinical arguments (rather than commercial or political) and that the Authorisation holder has the opportunity to respond, we believe this idea merits further consideration. However we also recognise that some requesting a Review may wish for a product to be put in a higher classification i.e. change could be in either direction.
25. While the UK system of Classification is undergoing scrutiny, the Panel may also wish to consider whether the current distinction between 'P' and 'PML' offers any practical benefits to society. Both classes of products must be sold from premises registered with and inspected by RPSGB. Both types of premises must be under the control of a 'Suitably Qualified Person' – listed on the relevant Register.

PML, of course, stands for 'Pharmacy & Merchants List', so it could be that the continuing existence of a separate 'P' category is anachronistic.

To summarise 'classification'

26. We believe that, even under current EU law, there may be some products eligible for reclassification. The process of initiating review of classification merits examination. The value of continuing separate 'P' and 'PML' classification should be questioned.

OVERALL CONCLUSION

While welcoming this review, we believe full consideration should be given to the potential negative effects on costs, medicine access, animal welfare and the ability of the Authorities to remain fully informed of the use and effects of animal medicines in the UK.

The system whereby products are classified, and classification is reviewed, needs revision to ensure that each individual product is classified scientifically according to its own merits and within the UK system of distribution. The process of initiating review merits re-examination.

Above all, and consistent with the overall thrust of the Government's paper "A Strategy for Agriculture", a thorough review of current controls at all stages in the supply chain should be undertaken to minimise any bureaucratic constraints on medicines reaching the animals for which they are intended.

NOAH  
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