COMPETITION COMMISSION

VETERINARY MEDICINES INQUIRY

PUBLIC HEARING

held at

Queen Elizabeth Conference Centre

London

on

Friday, 26th April, 2002

FOR THE COMMISSION

Mrs D Kingsmill CBE

(Chairman)
Mr G Hadley
Mr C Henderson
Mr T Richmond

Transcript of the Shorthand Notes of Harry Counsell & Co.
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Companies and organisations represented at the hearing

Companies

Veterinary manufacturers

Bayer PLC
Boehringer Ingelheim Ltd
Dechra Pharmaceuticals PLC
Eli Lilly and Co
Fort Dodge
Intervet
Janssen-Cilag Ltd
Leo Laboratories
Merial
Norbrook Laboratories
Novartis
Pfizer ltd
Schering-Plough
Vétoquinol (UK) Ltd
Virbac Ltd

Wholesalers

Centaur
Genus Distribution
National Veterinary Services Ltd
W&J Dunlop

Other companies and organisations

Association of British Pharmaceutical Industry (ABPI)
British Equestrian Traders Association (BETA)
British Equine Veterinary Association (BEVA)
British Small Animal Veterinary Association (BSAVA)
British Veterinary Association BVA
Jobsons Farm Health
National Farmers Union (NFU)
National Farmers Union of Scotland (NFUS)
National Office of Animal Health (NOAH)
National Pet Insurance Association
National Pharmaceutical Association (NPA)
People's Dispensary for Sick Animals (PDSA)
Pet Plan Ltd
Phyllis Croft Foundation for Canine Epilepsy
Royal Association of British Dairy Farmers (RABDF)
Royal College of Veterinary Surgeons (RCVS)
Royal Pharmaceutical Society of Great Britain
Sheep Veterinary Society
Society of Practising Veterinary Surgeons (SPVS)

Government Bodies

Department of Trade and Industry
Veterinary Medicines Directorate

The following members of the public also attended

Mr G Malynicz
Ms M Moran
Mr NJ Meeker
Mr M Nelson

I N D E X

THE CHAIRMAN: It is a couple of minutes early, but I think we shall start. Welcome to this public hearing being held by the Competition Commission this morning. Let me make some introductions. I am Denise Kingsmill and I am chairing this inquiry. Sitting with me is Graham Hadley, Tim Richmond, and next to him is Charles Henderson. Also sitting with me is David Smith, the team leader helping us with this inquiry. The four of us, i.e. Graham, Tim, Charles and myself make up the group that are investigating this matter. We would normally have with us Professor Alan Hamlin. Unfortunately he cannot be with us today but he will get a transcript of the proceedings.

This inquiry was triggered by a reference to the Commission from the Director General of Fair Trading on 9th October, under the monopoly provisions of the Fair Trading Act. We have 15 months to carry out this investigation and we are due to deliver our report on 8th January, 2003. We are well on track and it will go to the Secretary of State and will be published later on.

At the Commission we collect information in a variety of different ways to assist us with our inquiries. We have hearings with third parties, we have written submissions from people, and we have also received quite a lot of electronic e-mails and other communications on our website.

The hearing today is part of our investigations. We are hoping to have a lively debate with contributions from all the different people who have an interest in this inquiry, and we think it is a very good idea that a greater transparency in our proceedings will also assist.

On 16th April, 2002 we published an Issues' Letter. This sets out those matters which have been drawn to our attention as being of the most significance in this inquiry. They are numerous, but we have selected for debate today those which seem to be the most important and the ones which, perhaps are best able to be dealt with in a public way.

We have not formed any conclusions about any of the issues which have been put forward to us. We are still at the stage of having completely open minds. We are in the process at the moment of coming to conclusions and the contribution that those of you who are here today can make will be very significant to us in helping us to formulate robust and clear conclusions, we hope.

As I said, the purpose of this morning is to collect as

many views as we can and to hear them expressed in a debating forum. Everybody is here on a voluntary basis, and nobody will be pressed to disclose any confidential information. I will rule out of order any attempt to try and interrogate people to elicit any confidential information. I might also say that we are not here as a group to answer questions. We are in listening mode, we are here to receive answers and we are looking forward to hearing the contributions that everybody has to make.

I think you will probably have had a provisional agenda and you will see the topics that we have. What I want to do is to invite speakers up to give short presentations. Some of the speakers have, I think, provided notes and you should have those. After the presentations I will throw the debate open to the floor to make contributions.

Speakers from the floor should try and be brief, and hopefully keep their contributions to about five minutes, so that we can get through the whole of the timetable. Just raise your hand if you wish to speak, and we have roving microphones which will be brought to you if you need them.

It is helpful for the record, because we are making a transcript of the proceedings today, if you give your name and your organisation before you make your contribution.

We are having the proceedings put on to the webcast, so that it is being broadcast on the internet, so that we can open up the debate to a wider audience than those we can accommodate here today. Members of the public have the facility to send in their comments electronically during the course of the morning, and we will be able to read some of these out to feed into the debate.

There are also some representatives of the media present I believe and they are seated at the back of the hall and are here to listen and observe.

As I said, there will be a transcript of the proceedings available. After we have checked it it will be available on the website and anybody who makes a request can get a paper copy from the Commission.

I am told to make to formal points, namely, could you please turn off your mobile phones and also there are some fire and evacuation procedures which are in your packs, so please take note of those.

May I now invite Steve Dean, who is the Chief Executive of the Veterinary Medicines Directorate, to introduce the first

topic, which is the regulatory system.
[Mr Dean not present, Mr Bennett called on to make presentation]]

Topic 1: The regulatory system

MR BENNETT (Veterinary Medicines Directorate): First, let me apologise on behalf of Steve - I am sure there is a reasonable excuse why he has not made it this morning! I do apologise for this presentation because it is based on a rough outline of what he was going to say. So please, I would be grateful if you would bear with me.

The issue is the regulatory system in the UK. The aim of the system is the protection of human health, animal health and welfare and the environment, and to harmonise the rules within the European Market. More recently attempts have been made to address the issue of availability of veterinary medicines, especially for minor species.

The regulatory system is founded upon the satisfactory assessment of three principles of which I am sure you are all aware. First, safety, i.e. the safety of the animal being treated, and other animals with which it comes into contact. The safety of people handling, and administering the treatment and the treated animal. Safety in the case of food producing animals, of consumers of produce from the treated animal, so they are not exposed to potentially harmful residues of veterinary medicines, and safety of the environment.

Secondly, quality - quality in the consistency and quality of the ingredients and of the manufactured formulations of veterinary medicines assuring the relevance of the safety and efficacy assessment.

Thirdly, efficacy - that the claims for the veterinary medicine can be proven. The assessment includes the aspects of target animal tolerance, and so the welfare of the treated animal is assured.

THE CHAIRMAN: I have just been told that Mr Dean has arrived.

MR BENNETT: I am very grateful! [Laughter] I shall have words with him at the end of the session!

THE CHAIRMAN: Thank you very much for stepping into the breach. Now, as I was saying, Steve Dean, Chief Executive of the Veterinary Medicines Directorate.

MR DEAN: May I apologise for being late, and I notice you are little early [laughter] I am a veterinary surgeon and so we are used to being there just on time!

I heard Colin giving you the introduction to the three principles of safety, quality and efficacy. In addition to that of course applicants need to establish an MRL for food producing animals, and they have to prove under the system of authorisation that the MRL has been approved for the active ingredient.

So the MRL actually underpins the assessment of consumer safety and it allows a suitable withdrawal period to be set for each product. The regulatory structure is essentially a risk assessment and risk management process, and its intent is to minimise any risk associated with the use of veterinary medicines. The overall intention is to provide a high degree of public confidence in the use of authorised veterinary medicines in both companion and food producing animals.

Let me now turn to Routes to authorisation. This could take all day but it is going to take just about a minute and a half! In order to be marketed in a member state Community law requires the veterinary medicinal product be subject to a marketing authorisation granted in accordance with a number of directives and regulations but the principal ones being 2001/82 EC and 2309/93.

The whole process recognises the fact that circumstances may differ between member states in respect, for example, of species and number of animals, animal husbandry methods, environmental conditions and disease patterns, and all of these may have an influence on the safety and efficacy of individual products.

The authorisation provisions of the Directive are implemented in the United Kingdom by the Marketing Authorisation for Veterinary Medicinal Products regulations 1994 (as Amended).

The marketing authorisations may be granted only where the applicant is able to demonstrate that the product meets the statutory requirements in respect of safety, quality and efficacy. There are in fact three procedures by which companies may apply for an authorisation.

The first is the centralised procedure which is essentially where a company makes an application to the European Medicines Evaluation Agency (EMEA) who co-ordinate the evaluation. If an authorisation is granted by the EMEA on behalf of the European Commission it is valid throughout the Community.

The centralised procedure is obligatory for products produced by biotechnology, and it is optional for innovative

products. Centralised products as a point of note are available on prescription only.

There is a national procedure which takes into account the fact that companies may have a niche market in a single country and wish to market a product in that niche market. In the UK, of course, the VMD is the competent authority dealing with national applications.

If the authorisation is granted it is valid only in the Member State concerned. In fact, since January, '98, member states have not been permitted to authorise products that have an authorisation in another member state.

National authorised products are, of course, subject to national distribution classifications, which I shall come to in a moment.

The decentralised procedure exists, which is also known as mutual recognition. Here the marketing authorisation holder may, if they have a national authorisation already, apply to other member states for mutual recognition of that authorisation. But the authorisation in the second Member State (or third or fourth) is granted by that Member State and again is subject to national distribution classification.

Each of those three procedures contributes to the creation of a harmonised market in the Community, a centralised procedure allowing companies to have a single authorisation throughout the Community; a national procedure permitting small niche markets to be developed, and it is also the procedure that starts the mutual recognition procedure where the company has an opportunity to have the authorisation developed across Europe at its request.

For a number of years the European Commission has introduced legislation with the aim of progressively harmonising controls on veterinary medicines throughout the EU and the introduction of the centralised and decentralised authorisation procedures are examples of such measures.

The European Commission have recently undertaken a review of the current procedures and this is, as we stand, under some considerable discussion at this time, and amendments have been proposed to legislation.

One point I should make is that there has been little harmonisation for long established national products. These are products that were authorised prior to the European procedures coming into force and there has been no incentive for the

holders of such marketing authorisations to act any differently. Therefore, a large number of veterinary medicinal products remain as nationally authorised products and this perhaps represents a major area where price differentials may exist.

The availability of veterinary medicines is the next part that I would like to turn your attention to and for food producing animals there is certainly a case where availability is a problem, where the market return is poor, and minor food producing species are a major focus of this attention. It is certain that the establishment of MRLs adversely affected the availability of medicines for minor species, minor food producing species.

However the European Commission has recently agreed an initiative to extrapolate the data to extrapolate MRLs from major food producing species to relevant minor species. In addition, where no veterinary medicine exists to treat a particular condition in the species, then under Community legislation member states are allowed to permit veterinary surgeons, to avoid unacceptable suffering, to administer a product under what is known as a "Cascade". This should be to a particular animal or a small number of animals on a specific holding, and there is a descending order of preference, and I will just run through it very quickly.

The first is that the veterinary medicine used should be authorised in the Member State in the UK for example, for a different condition or a different species. Alternatively, if there is no veterinary medicine available then human medicine may be used and if neither of those is available then a medicine made up on a one-off basis by the veterinary surgeon, or a properly authorised person in accordance with the veterinary surgeon's specification. That is generally known as the "Cascade".

When using the Cascade for food producing animals, veterinarians may use only products that already have active ingredients in existence in medicines authorised for food producing species. In other words, there needs to be an MRL in place otherwise the veterinary surgeon will not be able to set a withdrawal period and there are minimum withdrawal periods set down in the Cascade.

All food producing animals are included and the definition of "food producing animals" includes bees and horses, and it is probably the latter that has caused most controversy.

Another measure that deals with availability is the ability to parallel import veterinary medicines that are authorised in two or more member states, and this relies on the fact that the product being parallel imported is identical to the product on the Member State market, and of course we need to be assured that such products that are parallel imported are suitably labelled for use in the Member State where the use is intended.

Before I conclude, I should like to touch on one or two other issues. I think we should talk about the classification system. The current UK system allows for a veterinary medicine to be classified as follows:

* the general sales' list category which may be sold through any outlet.
* the prescription only medicine which may be sold only by pharmacists or prescribing veterinarians.
* the pharmacy category [the P category] which may be dispensed by pharmacists without a prescription.
* the Pharmacy and Merchants' List [PML] which may be sold by pharmacists or suitably qualified persons through agricultural merchants, businesses, and in certain circumstances through registered saddlers.

All newly authorised products are required to be classified, at least initially, as POM. This is in the Directive. But this may be reviewed at a later stage - somewhere in the first five years is the norm - resulting in a lower classification but only if it can be demonstrated that safety will not be compromised.

The definition of a prescription only product is contained in Council Directive 2001/82 and the classification of products other than POM is a matter for national authorities to determine, and as a result controls on supply differ widely throughout the Community.

There have been attempts by the Commission to harmonise the classification of veterinary medicines, but it has so far proved unsuccessful because of these widely different distribution systems across the Community.

A final word, if I may, on the international harmonisation. The Veterinary International Committee on Harmonisation [VICH] is producing, and has produced, a series of guidelines intended to harmonise data requirements internationally, but it is too early really for those to have

had a significant effect on EU authorisations, although many of those guidelines are now in force.

There are regional differences worldwide, even more so than across Europe in terms of animal husbandry, and it is recognised also that species, numbers of animals to be treated, environmental conditions and disease patterns may affect the safety and efficacy of these individual products, and VICH tries to take that into account.

I think that completes all I wish to say, and thank you for giving me the opportunity.

THE CHAIRMAN: Thank you, Steve. Before you sit down I wonder if I might just ask you to address two points. First, we are after all an economic inquiry here and I wondered if you would like to comment on the extent to which you think the current regulatory system means that prices of veterinary medicines are higher in the UK than they otherwise should be? What is it about the regulatory system perhaps that leads to this?

MR DEAN: The first comment is that if you have a regulatory system intended to deal with safety it obviously acts as a barrier and clearly when that is put into the hands of professionals you have the opportunity for there being some higher price than it would be if it was a commodity in the market place.

I have to say that the Veterinary Medicines Directorate does not involve itself in pricing and therefore I do not really think it is our remit to say why prices may or may not be higher, but I think we accept - and I think everyone does accept - that a regulatory system by its character raises prices. But the regulatory system should be equal across Europe. Of course, therefore, in terms of regulatory pressure it should be the same across the European Union.

THE CHAIRMAN: The second point that I wanted to ask, because it has been raised with us, is the regulatory system a bit indiscriminate in that it does not distinguish between pets and food producing animals?

MR DEAN: I do not think that is true because indeed there is a strong differentiation in the Directive. For example, we apply a different set of rules to food producing animal products because of the issue of MRLs and withdrawal periods and food safety. But the data requirements, for example, in terms of efficacy, in terms of target animal tolerance, are exactly the same. But then the argument has always been why should the pet animal suffer any less quality of medicine than the food animal, in fact, I

think some of the public may argue it should be quite the reverse. But as far as we are concerned, apart from the differences in terms of food safety the critical appraisal of pet and food animal medicines is exactly the same.

THE CHAIRMAN: Could I ask Philip Sketchley now come up and make his contribution? Philip is the Chief Executive of the National Office of Animal Health.

MR SKETCHLEY (National Office of Animal Health): Thank you. In the pack I have given the background to the request for our presentation so in the interests of brevity I will kick straight off with our comments.

Effectively, we have been asked to comment on the possible effects on competitiveness of UK medicines, and medicines availability brought about by the regulatory process. It is probably appropriate to refer at this juncture to statements from Sir John Marsh's Report:

"The difficulties of moving to a single system of veterinary medicines authority within the European Community must not be allowed to disguise the importance of making progress in this direction. An effective community wide system would make a major contribution to the removal of illegal imports and the unauthorised use of medicines. This would also promote a more competitive medicines market but it would also increase consumer confidence."

Obviously we need to make progress in this direction and it would require compromise and a willingness to adapt by all the member states.

"Whilst the underlying principles of Community law are applied in all member states, national governments are responsible for their implementation."

Obviously as Steve has mentioned in the UK this is the responsibility of the VMD.

"In this country the Veterinary Medicines Directorate has this responsibility. Regulations, which determine what products can be sold and how they can reach the final user, have an important influence on price and availability.

"The development of new medicines involves costly processes of research, development, market authorisation and market launch."

Therefore for NOAH members the discovery and development

of new products is not a certain process. Regulatory standards are obviously set high, and as data is generated many potential new products for the market place fall by the wayside, and due to the cost of getting the products to the market.

Obviously, the costs of these failed products must also be recovered by the industry on those products which are eventually brought to the market place. In fact, Sir John Marsh reinforced this by stating:

> *"These costs are so high that manufacturers need a large market to justify the investment, with consequent problems for minor species and for uncommon ailments. They [the industry] also have to recoup the initial costs through the selling price of their product before generic equivalents, which have not had to face the full costs of research and development or authorisation to reach the market. Without a price sufficient to cover these costs the supply of new animal medicines would cease resulting in avoidable economic losses to farmers and a less satisfactory range of treatments to ensure welfare for all animals. Patent law and the medicine authorisation process are designed to allow an innovator to recoup his costs and, during this period the price at which the medicine is available is necessarily higher than the direct costs of its manufacture. The regulations, which protect new products affect both the price and availability of competitive products. The task force [Sir John Marsh's] had to consider whether existing rules struck the right balance between the longer-term public interest in the development of improved medicines and access by animal owners to suitable, older generic medicines at much lower prices."*

Therefore, for the industry we have to evaluate the time for all of these necessary regulation processes, the size of the potential market for the said product, and the time to recover the costs of research and registration.

Therefore, maintenance on the product on the market is not just about the known cost of annual licence renewal but also subsequent to launch manufacturers are quite rightly faced with the task of completing further studies, either those brought in by new EU directives, or in fact, as is often the case, studies requested by local national regulatory authorities. For example, there is presently a review of avermectins and milbemycins in

the antiparasiticide market. These additional costs have to be recouped either by increasing prices or avoiding them by deciding whether it is commercially viable to continue with a product on the market.

There are also ongoing major costs of generating new data for safe and effective old products already licensed on the market within the five yearly renewals. Consequently, it is the cost of creating this new data and the possibility of it not being able to meet the latest standards at the end of it, which represent the main cost of maintenance in addition to the routine annual renewal fees.

Within the UK the regulatory authorities are keen in requesting new data for renewals, for example, Eco-tox data, in-use shelf life, new residue depletion data, etc. and obviously all these have a cost to the manufacturer.

Therefore, these regulatory costs will represent quite a significant burden and whilst registration fees in themselves are not particularly expensive, the cost of excessive and perhaps on occasions unnecessary data generation, for registering new and maintaining authorised products have a bearing. Therefore, we can and have seen an attrition of products on the market because it has not been commercially effective for them to remain on the market.

The requirement to update dossiers for old products with proven safety and efficacy in the market for some time is obviously an additional cost. We are, of course, going through five yearly renewals in most EU countries, and in many states these appear to be a simple administrative exercise. Examples that Steve has referred to and for example- MRLs for excipients - have been requested and it questions whether that is really necessary.

Despite the recommendation of the EU to remove the requirement for five year renewals, within the UK we have seen a continuation of current standards to old products that have already got a proven track record both in terms of safety and efficacy.

So for low turnover, niche products the investment needed to meet these requirements is often commercially not justified and is an example perhaps of the 'gold plating' of regulations.

Obviously it has to be said that NOAH members and the whole of the industry respect regulations, they are needed there for the safety of the consumer, but obviously we accept them

reluctantly when they may be excessive or unnecessary when compared to other member states. These will obviously have a bearing on comparable prices across Europe.

We accept that a lot of the regulatory burden is set within the EU, and obviously outside the remit of this particular UK hearing. Nevertheless, there are factors that have to be considered. A classic example, and one that Steve referred to, is MRLs in the equine market sector. Many manufacturers have been requested to produce data to this effect and are faced with the inevitable task of saying would it be really commercially viable to maintain those equine products on the market? Sadly, we have seen quite a number of products removed from the market for those reasons.

So really regulation has to be balanced with the commercial reality that manufacturers are not in the business for altruistic reasons. In fact, Sir John Marsh went on to recommend that the regulatory authorities examine their own procedures for dealing with applications for products whether they be through decentralised procedures or whatever, to ensure that there are no unnecessary obstacles put in the place of registering products through mutual recognition.

The Cascade has also been referred to and there was a recommendation by Sir John Marsh that:

> *"...the Minister encourages the European Commission to amend existing legislation to allow veterinarians to prescribe generic treatments after consultation, of course, with the owner."* It has to be said that the industry does not support this view. In the short term it may be beneficial for prices but, of course, in terms of long term medicine's availability there could be consequences, because it would not encourage the research and development based companies to develop new products and treatments that will be required for the market.

The other point that has to be mentioned is very often the veterinary manufacturers will take novel products from the human pharmaceutical market and do the necessary research to introduce them into the veterinary sector. There have been occasions with products already manufactured where additional quality data has been required, obviously we always expect safety and efficacy to be requested in new species, but obviously if additional quality data of manufacturing is required, of products already being manufactured in the human pharma sector, and already been used

for several years, that will obviously add additional cost.

In the short term that may be a solution to reducing costs, but we believe that it will not give innovative products for the future, and address the needs of medicine's availability which is also one of the main areas for this Commission and Sir John Marsh's enquiry to look at.

Another example of where the standards for veterinary licence have proven too onerous is the point I mentioned before in relation to the attempted launch of human pharmaceuticals into the veterinary sector. In other words, it appears that we are trying to apply higher standards for veterinary products to the ones already available in the human sector.

I am conscious of time, and obviously as Steve mentioned the regulatory process is a very difficult and very detailed area, and in the short time available we probably cannot do justice to all the points, but I hope that some of the comments that I have made will give everybody a better understanding and appreciation of the costs and implications to the veterinary medicine manufacturing industry on both medicines' availability and their competitiveness in the market.

Thank you.

THE CHAIRMAN: Thank you, Mr Sketchley. Before you step down, may I just ask you, do you think that this is an industry which has been characterised by considerable innovation?

MR SKETCHLEY: It depends over what period of time. I think in more recent years obviously because of the costs of research innovation has, perhaps slowed, but traditionally, yes it has.

THE CHAIRMAN: Do you think that the regulatory system is working against innovation at the moment?

MR SKETCHLEY: In some aspects it is.

THE CHAIRMAN: It is also working in your view to raise prices?

MR SKETCHLEY: Not directly in terms of the registration process, but in terms of the necessary research and data that is required in order to get that registration.

THE CHAIRMAN: Thank you very much indeed. I am about to throw this topic open for discussion by the floor, but before I do so I am going to ask one of my colleagues to read out some of the e-mails that we have received from members of the public on this topic.

E-Mails received

MR RICHMOND: Linking the e-mails to the Issues Letter we have published, both of them relate first of all to are there aspects

of the regulatory system in the UK that deter veterinary

manufacturers from applying for authorisation of medicines, and in particular because of the process does this result in fewer competing products. Also, does the classification procedure potentially give the veterinary manufacturers too much control over the classification and should the solution be to allow third parties to request reclassification?

One e-mail is from a dog owner who says:

"I can buy Frontline over the counter from a pharmacy in France and much more cheaply than in the UK. Furthermore, in the UK I would have to pay the additional price of a consultation with the vet before I could buy it. I have been told that this has nothing to do with the safety of the drug, but more to do with the fact that the manufacturer would have to pay for a different category of licence in order to supply the public direct."

The second e-mail is from a cat and dog breeder in Wales who writes:

"More prescription only medicines should be available on the free market in the UK. This would give animal owners the opportunity to deal with some medicines themselves without having to pay vets' consultation fees. Why shouldn't breeders and others working professionally with animals be able to vaccinate their own animals and have some type of antibiotic available in the same way as farmers? Further, all flea treatments and wormers should be available over the counter instead of needing a prescription.

There is an e-mail is from a dog owner in Buckinghamshire, this is quite a comprehensive one:

"My experience is that the restricted market for prescription only medicines operates against the public interest by enabling veterinary practitioners to overcharge for the prescribed products that they also dispense. If greater competition existed for the supply of these products veterinary practitioners would be obliged to reduce their charges for them. The mechanisms which I favour for introducing greater competition are:

1. Requiring veterinary practitioners to furnish a client with a written prescription for any medicine prescribed.

2. Making POMs more widely available through a variety

of retail outlets, all of whom should be empowered subject to appropriate evidence of staff training to dispense veterinary prescriptions.

3. *Undertaking a thorough review of all veterinary POMs, if necessary revising the applicable legislation with a view to removing the POM restrictions from as many veterinary medicines as possible.*

4. *Authorising the supply of veterinary medicines direct to recognised animal welfare organisations and licensed breeders under appropriate veterinary supervision."*

THE CHAIRMAN: Thank you. Some of those comments went a little bit further and wider than the discussion of the topic at hand, but nevertheless that does represent some interesting comments.

I would like to throw it open to the floor now and as I say please concentrate on the issues raised by the speakers and by the issues relating to the regulatory framework in which this industry operates. I will take comments from anyone from the floor although I have one or two people that I might ask to speak if there is a general desire to make comments.

Has anybody any comments about the regulatory framework on the prices of veterinary medicines, or any other comments they want to make about the regulatory framework?

I wonder if anybody from the Royal Pharmaceutical Society would like to speak? Mr Jobson, would you like to have something to say?

General Discussion

MR JOBSON (Jobsons Farm Health): Thank you. I think that the e-mails we have received are very pertinent and I trust that we will address those issues later in the morning, particularly relating to the regulatory issues. There are some issues that have been put into the Competition Commission statement, particularly suggesting that there be the issue of prescription only medicines by veterinary surgeons without need for a prior diagnosis. This is quite pertinent in terms of the role of the pharmacist in the supply of medicines in that the case for pharmacy is that there are certain products that require advice input in terms of the appropriate use, methods of administration and so on, or other factors relating to interactions with other medication where the pharmacist could provide that advice, but there is no need for a prior diagnosis. Perhaps this alludes to

the fact that there is a need to make the available choice wider for consumers without the need for a prior diagnosis.

I would suggest in that situation that the product not be classified as prescription only, but be classified as a pharmacy only, or indeed as a pharmacy only exempt classification which has been suggested to follow the Irish example, with particular safeguards. These particular products would be handled by the pharmacist.

THE CHAIRMAN: Can you give some examples of the kind of products that you are thinking of, or the kind of treatments that you are thinking of?

MR JOBSON: These products, as I say, would not require a prior diagnosis, they are prophylactic medicines. For example, on the farm animal side one could be looking a certain live vaccines, viral vaccines that could be used in the prevention of Orf, where there is already Orf present on the farm, where it is a routine procedure, the farmer has been using for many years, and there are probably situations for breeders and for prophylactic treatments of small animals also.

THE CHAIRMAN: Such as worms and fleas?

MR JOBSON: Flea preparations and the like.

THE CHAIRMAN: I might say that it is in relation to worming and flea treatments that we have had the most number of letters.

MR JOBSON: Recently, I was speaking someone who ran a cattery who was constantly having cats coming in to the cattery infested with fleas, had been used to using a particular flea preparation but went to their local veterinary surgeon to request a prescription to have it dispensed by a pharmacy and was quoted a prescription fee of £50 and the comment was made that the reason that it was so high was simply to compensate for the lost profit on the sale of the medication.

THE CHAIRMAN: Thank you very much, Mr Jobson. The past President of the British Veterinary Association I understand wanted to speak?

MR TYSON (Past President BVA): Going back to the cost of regulation, which is what I think this section is about, as a consumer of restaurant food I expect those premises to be regulated and inspected, and duly made safe - or as safe as they can be - for me when I go for my lunch after this meeting. Somebody has to bear that cost. If it is the local authority I am paying it through my Council Tax. If the restaurant owner has to pay the Council for that then I am paying for it in my food.

In terms of veterinary regulation it must be right that

there is regulation because we cannot just be giving anything to anything, and the cost therefore has to be borne by somebody. I think it is the case in this country that it is self-financing, in other words the manufacturer is paying therefore the consumers are paying in the end through the charges that have to be made.

Steve, in answer to your question, very carefully said that this "shouldn't" make a difference over Europe. Now I am not sure whether "shouldn't" means "doesn't" or not. My understanding is that Governments may pick up the bill in other parts of Europe rather than the industry itself, and that obviously does make a difference, and I think that is an issue across Europe, the cost of regulation and who bears it. We have argued for a long time that there really should be just one hurdle. We have heard all sorts of reasons why there should not be, but if there were it would reduce the cost of regulation across Europe and therefore on the other side of the coin - also very important - reduce the effect on the availability of new product, and that is a really serious issue both for pet vets and food producing vets particularly.

THE CHAIRMAN: Thank you. The issue seems, however, to make certain that the balance is struck between appropriate regulation designed to protect both human and animal health but at the same time not excessive regulation which then does nothing to make medicines more available, and more cheaply available to the people. It seems that there needs to be an appropriate balance struck. Is that what you would say?

MR TYSON: Yes, I think that is the case, but also if we go back to the comparative cost, you have a bar chart in here comparing our costs with France and the Netherlands. I do not know who bears the cost of regulation in those countries, whether it is the pharmaceutical companies and therefore the consumer, or whether in individual countries there is a sort of back door subsidy, if you like, because Government bears the cost.

MR CUTLER (NFU): To continue David Tyson's point of passing the cost of regulation through to the consumer. In the case of the food producing sector of course farmers are then unable to pass on that regulatory cost because of the structure within agriculture as it stands at the moment. It is the common misconception that we can pass on increased regulatory costs, but we cannot.

MR RICHMOND: There does not seem to be any response as to why third

parties should not be able to request re-classification. It does come up a lot.

THE CHAIRMAN: Does anybody have any comments on that part of the regulatory system, why third parties should not be able to request that drugs be re-classified?

MR MILLER (BVA): A very brief point which is that we should all realise that the Body that determines the appropriate distribution route is colleagues in the Veterinary Medicines Directorate advised by the Veterinary Products Committee. That is a fundamental fact that we should all remember when we are talking about this.

THE CHAIRMAN: Yes, what we as a Commission may want to get to the bottom of is the extent to which the regulatory system impacts on the prices paid by the consumer. There may be offsetting benefits for that increased price, but we need to understand exactly how the regulatory system impacts on prices to the consumer, and what effect that has overall.

MR MARSDEN (Royal Pharmaceutical Society of GB): I would like to question Steve Dean as to whether the interpretation of EU Rules actually increases the cost of production of medicines through the regulatory system. Is the interpretation of, say, the word "prescription" the same throughout the EC and is the interpretation followed through, does the VMD develop interpretations of rules effectively to reduce the costs? Is that clear enough?

THE CHAIRMAN: By all means, would you like to respond to that?

MR DEAN (VMD): Yes, of course interpretation does have an effect, but we certainly do not interpret the rules to reduce cost. We interpret the rules to maintain safety. When the European system started clearly there were 15 interpretations of the rules in terms of veterinary medicines.

One of the reasons that the veterinary mutual recognition facilitation group was put together, which has a role to play in mutual recognition, is to try and bring the thinking of those 15 member states together, and I would say since 1998 it has done so. So interpretation is a problem across Europe.

You asked about categories as well. The answer is and I tried to allude to it in my presentation, that the categorisation of products is regarded very differently across Europe and, therefore, for example in Germany nearly all veterinary products are prescription only unless they are on

free sale - there is no PML category.

Indeed, the PML category really only exists in the UK but France and Ireland have similar schemes but not quite the same. So categorisation is regarded differently across Europe and that does raise some problems. But you should be aware that the Commission are pressing very hard for the prescription only category to be more broadly applied rather than relaxed because the Commission are interested very much in terms of safety, predominantly human safety, and they regard the correct category for the vast majority of veterinary medicines would be prescription only. I hope that answers your question.

THE CHAIRMAN: Thank you. Any more comments on that issue? Are there any animal owners present who would like to comment upon the way in which this impacts upon them at all - the prescription only classification? [*No comments*] There will be an opportunity later on, when we have heard all of the topics, to be able to bring up general points that have been raised.

I am going to move on to the next topic, which is related, but it is the dispensing of prescription only medicines by pharmacists and I am going to as Trefor Williams of the National Pharmaceutical Society to make the opening points.

Topic 2 - Dispensing of prescription only medicines by pharmacists

MR WILLIAMS (National Pharmaceutical Association): I apologise for the absence of my colleague, John D'Arcy who is unable to attend. He and I have worked very closely on organising this presentation, although I have not quite the problem that the earlier speaker had.

I would like to take the first half of this slot dealing with prescription only medicines as an over view. I have some colleagues, fellow pharmacists from the Royal Pharmaceutical Society who will delve more into specific areas, particularly commenting on the statement of issues that you put out earlier.

I want to set the background which hopefully will more widely inform the people here of how pharmacy can help work with veterinary surgeons, work with consumers, work with manufacturers and suppliers to improve access to medicines whilst retaining all the requirements of safety and efficacy.

There are about 5,000 of community pharmacies in the UK. They own some 12,500/13,000 shops. They are in villages, suburban parades, high streets and shopping centres. Almost all of those are in voluntary membership of our association, so we look after Lloyds, Moss who have some 1,000 or more branches. We

look after the regional multiples and we look after the 4,000 pharmacies who own perhaps one shop each. What I am giving you is a picture of convenience, accessibility both in terms of locality and opening hours.

Those pharmacies are principally, to the extent of probably 90 per cent. of their business involved in healthcare.

The pharmacists themselves are both academically and professionally qualified in pharmacy and that, of course, includes physiology and pharmacology. They are registered by law, just the way veterinary surgeons are, and they are regulated by a professional body under a Royal Charter, just the way veterinary surgeons are. Their premises are regulated, and inspected by law officers. So in all that they do, safety underpins their activities. They have a duty under the Code of Ethics of Pharmacy to act only in areas where they are competent. So it is not a question of if pharmacies were to start looking at broadening the care they are able to provide to either humans, or animals, they can do it willy-nilly. They must be competent in the area in which they intend to work.

Their basic training ensures that they have the scientific knowledge to deal with a variety of veterinary situations. Just as importantly they have the ability and understanding to know when to refer. They are doing that in their every day lives in terms of human medicines. They are dealing with patients, they are dealing with consumers, and they know when to stop. I think that is something often misunderstood.

The community pharmacy is well able to deal with animal issues, particularly the dispensing of prescriptions for prescription only drugs and handling requests for medications that are classified less severely, and they thrive in a competitive retail environment - that ensures the consumer gets value for money and it also ensures that consumers can access that sort of care for animals in their own neighbourhood on any day of the week and at almost any time.

We see that there are three key barriers to pharmacies meeting the needs of consumers:

* Few prescriptions leave the veterinary surgery and are expensive when they do.
* Pharmacies find it very difficult to get supplies of prescription only medicines, and pretty hard to find efficacious non-prescription only medicines as well.
* Decisions on how widely available a drug is is solely in

the hands of manufacturers. The incidence of re-classification from POM down to P or PML seems, perhaps I can say, inexplicably rare.

If I can go through these issues - they are all very much tied together. On the prescription issue, we are not talking about any campaign to stop veterinary surgeons properly administering drugs to their animal patients in consultations, in visits to farms, or stables, then obviously anaesthetics, injected pain relief, other drugs for oral and topical treatment, nobody would consider it would be reasonable for a veterinary surgeon to always resort to issuing a prescription instead of treating on the spot.

But for repeat medication for chronic conditions, perhaps arthritis, diabetes, heart conditions, and for treatments particularly as you said, Chairman, for worms, topical parasites, we believe there is plenty of scope for client care by the issue of prescriptions.

Our perception is that in these circumstances it is common practice in veterinary surgeries for medications like these (particularly on the parasitic and worm issues) to be supplied on request on turning up at a surgery. It might not be the first visit because of course there needs to be examination of the animal and due consideration. But if I want to get some more anti-parasitic external treatment for my animal I can get it over the counter from the receptionist.

Let us just look at what is involved in writing a repeat prescription. Somebody at the surgery must take a message - in human medicine typically it is a phone call and "I will come and collect it next Tuesday", or maybe the patient sends in a stamped addressed envelope.

The client record obviously needs to be consulted and a prescription form filled out and then signed by a vet. An administration fee is a reasonable thing to provide on that occasion. It is also perfectly legitimate for the instruction to be "repeat monthly for three months", so that the animal owner does not have to spend too much money on the drugs in one go but does not have to visit the surgery unnecessarily. You get the situation where there is very little hassle, very little time involved, good client care, and good value for the consumer.

It is worth nothing that the numerical reality is that the location of community pharmacy is likely that it is far more convenient to visit a pharmacy than to go and traipse to the

veterinary surgery. When it comes to convenience the owner will find it easier to leave a prescription at a local pharmacy, and pick it up later than go to the vet, ask for the medication and either have to wait until a vet is available, or hang around while the receptionist can deal with it.

We have, in fact, submitted a dossier of evidence, and I would like point out two issues raised in that - one was mentioned earlier this morning. It does seem that on the rare occasion that a prescription is issued the charge for writing the prescription is often designed to ensure that when it is added to the cheaper price that a drug may be available through a pharmacy it would have been cheaper for the patient in the first place to have got the medication from the veterinary surgeon, and that does seem a little unfair to us.

It is also a fact that I have seen misleading statements written by veterinary surgeries suggesting that not only must they write prescriptions - one prescription per drug and therefore make multiple charges for writing those prescriptions - but also that it is actually illegal to write repeat prescriptions. That is quite clearly not the case.

If I move on to obtaining supplies, which is my second key point. As well as supplying vets and pharmacies and merchants, manufacturers can supply traders and dealers who hold the required authorisations under both the Medicines Act and the Misuse of Drugs Act. The same Acts of Parliament actually endow both veterinary wholesalers, and human pharmaceutical wholesalers. Yet, when an authorised wholesaler is in the business of supplying pharmacies, getting his hands on an account with a manufacturer seems fraught with difficulties. We are aware of one such wholesaler who happens to be a pharmaceutical company who does hold a wholesaler Dealers' Licence, but when he was trading as "Acme Pharmacy" shall we say, he could not get the supplies. He changed his name to "Acme Veterinary Supplies" and he was able to get supplies. I would hate to suggest why.

Similar situations exist for a pharmacy obtaining trading terms with a veterinary medicines' wholesaler. We have evidence that requests are constantly made of manufacturers and I have been unable to unearth a single occasion on which there has been a written refusal and any reasons given as to why that pharmacy wholesaler has been unable to get an account.

It is fair to say there are limited sources are a pharmacy can obtain supplies. There are particularly specialist veterinary pharmacies who do hold a wholesaler Dealers' Licence and have managed through the force of their business in farm supplies to get supplies through. But even a consumer giant like Safeway, the supermarket chain, which does operate some 100 in-store pharmacies, finds it only practical to get veterinary medicines from one wholesaler, and that wholesaler is a veterinary medicine wholesaler that is a pharmacy.

It has to be said that the specialist pharmacies still find themselves with difficulties in opening those wholesale accounts. We even have a rather incongruous example where a veterinary vet wholesaler will buy a particular poison from a veterinary pharmacy wholesaler, but he will not open an account with that pharmacy wholesaler.

Let us take the opportunity to move along to the reclassification or the de-classification of veterinary medicines and compare the situation with human medicines. The Medicines Control Agency is the direct equivalent in this respect of the VMD.

On the MCA website it says that reclassification is normally requested by the licence holder and that any interested party can do so as well. An "interested party" would certainly include a trade association or other major interested parties and it might include an organisation such as ourselves. If we are to apply a similar regimen in veterinary medicines, an animal welfare charity might be an interested party because it would be keen to control costs.

We then start to look at why human pharma companies look to reclassify their products downwards. Once all relevant safety issues have been resolved it is a straight forward commercial decision - wider availability of a former POM drug leads to greater exposure to the consumer, and hence increases sales. That situation can certainly apply in veterinary medicines because pharmacies are available to provide the safety back up.

So we then need to ask why animal health divisions of the same manufacturers are not interested in declassification? The same commercial environment certainly exists, and as somebody has already said one could argue that consumers are sometimes prepared to spend more on pet care than they are on human healthcare. We thus have to consider that there must be imperatives operating within the animal healthcare market that

do not exist in the human healthcare market.

Our contention is that there is unjustifiable and over-protective legislation that maintains a restrictive relationship between the current stakeholders in the provision of drug-related healthcare for animals, and this does not benefit the consumer.

To conclude I would like to visit the market as though it were a new market, not an existing market - let us assume we have an unfettered market place, and the players in that would be the consumers or the clients, the end suppliers to those consumers, the distributors and the manufacturers. The clients need confidence in their supply, the brands, they need value, they need freedom of choice, and that can be best met through a level playing field in which marketing authorisations are less restrictive and supplies available from differently, but appropriately qualified people: veterinary surgeons, pharmacies, merchants and perhaps even pet shops.

The end supplier needs to prosper by giving good service. Veterinary surgeons achieve it through quality of consultation advice, surgery and administration of medication. Pharmacies achieve it through their ready access, their "open door/no appointment" approach, their background as scientists and professionals, and by the supplying of appropriate products at competitive prices with referral back to the veterinary surgeon where necessary. At more basic levels, other end suppliers could similarly benefit the consumer.

The distributors will prosper by the efficient supply of the greatest number of products to the end suppliers in their locality. Delivery of extra products at extra points on van routes certainly increases income, but I suggest the costs are only marginally increased. Clearly manufacturers prosper by exposing as many of their products as possible to the widest possible consumer audience.

I believe that this market could be the market for veterinary medicines by insisting that veterinary surgeons be prepared to issue prescriptions for drugs which do not have to be administered during consultation, and that they make their clients aware that this is the standard procedure, not the exception. Likewise, for client convenience, and to limit the time spent on administrative tasks, veterinary surgeons should consider carefully the use of repeat prescriptions.

Veterinary surgeons should certainly be permitted to

charge administration fees for those prescriptions, but they must be realistic and an inconsequential part of the overall charges.

We believe that each of these steps can be dealt with by firm and clear instruction given to the profession by their Royal College.

Our other two points are that this Commission has the opportunity to forbid manufacturers from refusing to supply holders of the Wholesaler Dealers' Licence subject only to credit referencing and compliance with fair and open trading terms. It also has the opportunity to open up the regulatory procedures applied by the VMD so that consideration of de-classification can be initiated by interested parties, not just the licence holders.

Thank you.

THE CHAIRMAN: Thank you, Mr Williams, that is very helpful. I am now going to call upon Mr Green, from the Royal College of Veterinary Surgeons, to respond to some of the points there, and then following that I will call upon one of the representatives from the manufacturers. We will certainly be calling up on the Pharmaceutical Society as well to speak, but I think it is appropriate now to let these other Bodies respond, initially.

MR GREEN (President, Royal College of Veterinary Surgeons): First of all I think I should outline the role of the College and how we impinge upon the present proceedings today.

We are responsible under the Veterinary Surgeons Act, 1966 for supervising veterinary undergraduate education, maintaining the register of qualified veterinary surgeons and overseeing their conduct. No veterinary surgeon can practise in the UK without being a member of the RCVS. Of the 19,500 approximately who are on the register, approximately 10,000 are in general practice.

We have quite a narrow role in relation to the conduct of our members. The Disciplinary Committee of the College has power to remove members from the Register, or suspend their registration for a period if they are convicted of an offence which renders them unfit to practise veterinary surgery (including medicine), or they have been guilty of disgraceful conduct in a professional respect. There is actually no statutory role for issuing advice or laying down rules for the guidance of the profession. Nevertheless we do that. We do offer guidance - The Guide To Professional Conduct, which is also on

our website goes well beyond what members need to observe in order to avoid any charge of disgraceful professional conduct, and it covers the whole area of relations with clients, responsibilities towards their patients, towards the general public, and under the law.

Turning specifically to veterinary medicines, the Guide draws attention to the law on the use of veterinary medicines. Guidance is given on the interpretation of the requirement of the Medicines Act, namely, that medicines dispensed by veterinary surgeons should be for animals under their care. This care, of course, includes the welfare of these animals. It also includes attention to possible resistance to products that might be used, so that particular attention is drawn to the choice of medicines, including the requirement to select a product authorised for use in the target species for the condition being treated, and it really must work - that is the object of the exercise. Where there is no product, as Steve Dean has already said, we can have the alternative of working within the "cascade", and he has told you of the AMELIA 8 guidance, which we also incorporate as an annex to our Guide.

We do give the following guidance on the dispensing of veterinary prescription only medicines.

> *"Veterinary surgeons are encouraged to make their clients aware that veterinary medicines may be obtained on prescription from other suppliers, for example pharmacies, and should not unreasonably refuse to supply prescriptions if clients wish to provide veterinary medicines from other suppliers. A reasonable charge may be made for the prescriptions, which may only be issued for animals under the care of the prescribing veterinary surgeon."*

One of the problems that we have found, and this is only as anecdotal as the rest of the stuff that we have heard this morning, we have three instances reported to us where pharmacists have dispensed generic products in response to a veterinary prescription. This is not permitted under present law. Nevertheless on the human side it is permitted. So they have tended to adhere to this sort of advice. I think this results from a real problem that the pharmacists have at the moment. It is being discussed as we speak at the Royal Pharmaceutical Society between their representatives, and our Assistant Registrar, who appeared before you before (and who is also himself a pharmacist) about the competence of pharmacists

to handle veterinary medicines. There are very few who have taken the necessary qualification or continuing professional development to do this. Therefore, this is one of the matters that the pharmacists should address if they wish to dispense veterinary medicines and give the advice that we have just been told is available. I think that is a rather "gold plated" idea, actually I do not think pharmacists can cope with this particular problem at the moment. Nevertheless it is available, I know, and therefore they should, perhaps, pursue this. That is one thing I would like to say in response to what has been said this morning.

We also offer guidance on the fees that a veterinary surgeon should charge, because this appears later in your document concerning the relationship between goods and services and the charges, and the balance between the two. We said:

"All invoices should be itemised showing the amounts relating to goods and services provided by the practice. Fees for any outside services, any charge for additional administration and other costs to the practice in arranging such services should be shown separately".

That is our advice. At the moment we are in the process of investigating one particular case where this has not been done and we are taking it very seriously indeed.

I do not think I have any further comments to make about our particular role in this instance.

THE CHAIRMAN: Thank you very much. I am going to call on Simon Evans from Dechra Pharmaceuticals PLC to make a contribution in this area, and then I will go to the Royal Pharmaceutical Society, to Nigel Graham to make some comments before I throw it open to the floor.

MR EVANS (Dechra Pharmaceuticals PLC): Thank you. If I can make it clear that I am looking at the supply of veterinary medicines purely from a wholesaler's point of view, not from a manufacturer's point of view or clearly the ultimate supply to the end user. I am not going to touch on various clinical issues that have been raised by the two previous speakers.

If I start by reminding everyone the role of wholesalers, because wholesalers exist only if they supply value to the supply chain. What actually wholesalers provide is an efficient distribution system for veterinary medicines between manufacturers and veterinary practices. What they offer, firstly to veterinary practices, is a convenient one stop shop ordering

system which clearly saves administration costs, particularly in terms of having to order 1000 different products from 300 different suppliers. Veterinary wholesalers also offer high service levels and next working day delivery in most cases, which will minimise the stock level required to be held by the veterinary practice.

In terms of what they offer manufacturers, clearly the removal, duplication and distribution costs in that the manufacturers themselves are not distributing to 3,500 veterinary surgeries. Also, wholesalers offer buffer stocks so that if there are any short problems in production, i.e. a batch fails or whatever there is a stock in the chain so that supply is not impeded.

Full line wholesalers carry up to 12,000 product lines, and being a full line wholesaler we must stock the slow moving but necessary products as well as the faster moving lines.

There are six veterinary wholesalers in the UK, one of which supplies exclusively into Northern Ireland, the rest service England, Scotland and Wales. Of the five that do that, at least four of them would all say they are national wholesalers. Approximately 70 per cent. in sales' value terms of the wholesalers turnover is for prescription only medicines, which is the subject of the inquiry.

In terms of the economic factors affecting veterinary wholesalers one point, which may be obvious but should be borne in mind, is that the total wholesaler value of veterinary medicines, prescription only medicines is less than 5 per cent. of the human ethical market. Also, wholesalers retain a very low gross margin on prescription only medicines. A typical gross margin (not net margin) is 4 per cent. Also the cost base is relatively fixed within given ranges, so that you get to a certain point and if you go over that there is a step up in the cost so it is very much a stepped structure.

Given those low gross margins, really the wholesaling in prescription only medicines is viable only if: first, sufficient volumes are achieved; and secondly, if higher margin other products are sold alongside the prescription only veterinary medicines.

In terms of the potential effects of pharmacists dispensing more prescription only medicines - I do not want to touch on clinical matters, purely from a wholesaling point of view - it is not rocket science. Currently wholesalers in total

deliver to 3,500 veterinary practices and how things pan out from there depends on how many pharmacists actually get involved. If we take an example where all pharmacists are involved in the supply of veterinary medicines then clearly veterinary wholesalers would be delivering up from 3,500 delivery points in total up to an additional 13,500. Clearly, on the gross margins that are being achieved that huge step up in the distribution capability would require significant investment.

The other potential route for distribution is through human wholesalers. The first thing I would say is that to date they have actually shown little interest in supplying veterinary medicines. I do not know how many know but we were very briefly part of the largest human wholesaler, AH, when Geher took over Lloyds Chemist and basically as veterinary wholesaler they certainly had the opportunity to bring us in on the human side, but they basically could not wait to divest us because we were seen as "non-core" to their activities. I certainly do not think they would stock another 12,000 product lines and accept the low gross margins that we achieve.

In conclusion, from the point of view of Dechra we certainly support free and fair competition at all levels, and pharmacists who want to be involved, and more involved in the supply of veterinary medicines certainly should be allowed to do so and Dechra would certainly supply pharmacies on the same terms as veterinary surgeons. However, clearly delivering to a significant number of extra pharmacies would increase the cost base for veterinary wholesalers.

MR GRAHAM (Royal Pharmaceutical Society): I would like to go through the Issues Statement that was sent out previously and make comment individually, and then perhaps at the end just make specific comments against some of the statements that we have just heard in the two previous presentations.

Taking the first comment under "Regulations":

"Veterinary medicines may only be supplied in the UK if they have an MA, usually held by the manufacturer of the veterinary medicine..."

The Society wish to make a point of the fact that the MA holder can either manufacture the product themselves, or alternatively contract this out to a licensed manufacturer.

"Veterinary medicines classified as PML may only be dispensed by a veterinary surgeon, pharmacist or by a

registered agricultural merchant or saddler."

A correction to this in pharmacies PMLs must be sold by the pharmacist, or a person acting under his supervision. In registered merchants and saddlers' premises PML sales must be authorised by an SQP.

Under "Regulatory Issues":

"1(i) Whether the current MRL requirements restrict competition in, and availability of veterinary medicines, particularly for minor species..."

The Society does not support this view. Even minor species could end up in the food chain and so it is extremely important to retain the current MRL requirements.

"1(ii) Whether the inclusion of an efficacy test in the marketing authorisation procedure unnecessarily increases the barriers to introducing a veterinary medicine to the market".

The Society does not support this view. Gt. Britain and other member states have an enviable licensing system. All licensed medicines have been shown to be safe and produced to an acceptable quality efficacy in their use. Pharmacists would not wish to engage in the sale of medicines that had not been proven to work.

"I(iii) Whether the absence of provision for a third party to request reclassification of a veterinary medicine, or for regular review of classification, leads to an over classification of veterinary medicines."

The Society supports an agreed common, harmonised, POM list for the EU member states. However, it feels that individual member states should be at liberty to decide the classification of all other veterinary medicine products.

The Society supports the idea of a third party being granted permission to apply for reclassification of veterinary medical products without the need for substantial amounts of evidence, provided the product already exists safely in a similarly less restricted category in one of the other member states, and its safety in the less restricted category had been proven.

"1(iv) Whether the lack of a prescription only subclassification for medicines that could be prescribed by a veterinary surgeon (for animals under his/her care) without prior clinical examination restricts competition."

The Society supports the view that not all veterinary

medicines currently classified as POMs need this level of restriction. There is a genuine need for a subcategory of POM on which the Society is currently working. Such a classification would be similar in criteria to that of the Irish POM E, which requires the veterinarian or pharmacist to supply the product in person but without the need for a prior diagnosis.

Examples of products would include, amongst others, prophylactic treatments for flocks and herds. The Society will be submitting a proposal to the VMD later this year.

"1(v) whether the length of time allowed to regulators to reach a decision on marketing authorisations is a barrier to introducing a new medicine."

It is the Society's view that the registration authorities considering applications for marketing authorisations must be given sufficient time to complete all the necessary work required on a product before granting an MA.

However, regulatory authorities must agree a target completion date, and such schedules should not be exceeded.

"1(vi) Whether the requirement that medicines on the Pharmacy and Merchants List (PMLs) may only be dispensed by veterinary surgeons, pharmacists and Suitably Qualified Persons...."

The Society strongly disagrees with this. All premises are registerable. The barrier is the availability of SQPs when informed advice is essential. The only products that should be sold without advice, professional or informed, are GSLs.

"1(vii) Whether the current arrangements which preclude SQPs from breaking bulk in supplying veterinary medicines places them at a competitive disadvantage to veterinary surgeons".

In accordance with the Medicines Act medicines removed from the container in which they are licensed become unlicensed products. The company applying for a product licence must first prove, as part of an approval process, that the product is stable and that it is adequately labelled and accompanied by an information leaflet. Breaking bulk is a potentially dangerous procedure, and can only be safely undertaken by a professional who possess sufficient knowledge and understanding of the pharmaceutics of the product or products, i.e. the pharmacist and the veterinary.

"1(ix) Whether the potential for competition from extra EU markets is prevented by the lack of mutual arrangements

between the EU and other regulatory regimes."

Notwithstanding earlier references to the Irish POM E and the Society proposal for something similar in general terms the current regulatory controls are effective and safe. However, if there is a political will to develop mutual arrangements with the countries outside the EU in the future this could be possible in carefully controlled cases.

THE CHAIRMAN: Mr Graham, I do not want to interrupt you in this, except to say that I do not think it is really necessary at this hearing to go through it on a point by point basis. I think it would be extremely useful and helpful to the Commission to receive these points in writing, but for the purposes of the debate it makes for rather dull listening, if I may say so.

What I really would like you to do is to address the issues that have been raised by some of the speakers, and in particular what I want to know is do you feel that the pharmacists could practically, safely, and efficiently take over some of the dispensing role of veterinary medicines? Do you see any issues and problems, and would you like to respond to some of the points that have been made both by Dechra and by the vets as to why this is not a possibility?

MR GRAHAM: To put it succinctly, pharmacists are highly trained healthcare professionals. As part of the Code of Ethics they must not undertake any activities for which they do not feel competent. If pharmacists were to undertake a wider range of activities such as dispensing veterinary medicines they would be professionally, ethically obliged to make sure they were competent through training and continued education and experience to undertake those roles. In that sense, professionally speaking, there is no reason at all why a pharmacist suitably trained and competent to do so could not undertake any of the supply and dispensing function of veterinary medicines.

THE CHAIRMAN: Do you think that would make a contribution to reducing the cost of these medicines?

MR GRAHAM: From a professional perspective it is difficult to actually make comment on commercial issues other than to say that it is probably in the public interest to have as wide a range of access as possible to all services and routes of supply. These can vary in the public interest and there may be additional benefits relating to supply costs.

THE CHAIRMAN: So you are saying that there may be some pharmacists

who would like to compete with the vets in the provision of these medicines, and you think that they would competent to do so?

MR GRAHAM: I would say once some of the other issues had been addressed, such as the supply issues, then pharmacists I think would welcome the opportunity, if they wished to do so, to offer this as an additional service to their core activities.

THE CHAIRMAN: Having cut you short on your point by point critique of the Issue Letter, I apologise for that except for the context, and we would be very grateful to receive those comments, but to have them in writing, if we may.

MR GRAHAM: Certainly. Can I just make one other comment? A previous speaker mentioned generic substitution in human medicines. This is not permissible in human medicines. I would not like the impression to be given that pharmacists routinely generically substitute medicines on presentation of prescription. Thank you.

THE CHAIRMAN: Thank you very much indeed. Before I throw the discussion open to the floor there are a number of issues that have been raised there that I am sure people would like to comment on. What I would like to have - as I am trying to do throughout this hearing - is to get a sense of how some of these issues actually impact upon members of the general public, pet owners, and farmers alike. So I am going to ask my colleague, Mr Hadley, to comment on some of the e-mails that we have received from members of the public on whom this has impacted.

E-mails received

MR HADLEY: These are messages from animal owners who are in one way or another expressing frustration at steps which they allege their vet has taken to restrict availability of medicines and make it more difficult for them to go to other outlets. I will just read a few of the representations we have had.

A letter from a dog owner in Cheshire:

"My dog needs to take four Rimadil tablets a day at a cost of £23 for 30. I discovered that these tablets can be obtained by mail order at half the price. When I asked my vet for a prescription I was told it was not their veterinary group's policy to do that and I could purchase medicines only through them."

An e-mail from a horse owner:

"We have a horse that will have to be on analgesics for

the rest of his life. We have established that a pharmacy we use for non-prescription items can supply the drug in question at a considerably lower price but we will need a prescription. Our vet had never heard of prescriptions but after discussing the request with colleagues he advised the following:

* *that a fee of £10 will be charged for the prescription;*
* *that the horse will have to be re-examined before a prescription can be provided and after that the horse will have to be examined every three months."*

Then we have an e-mail from a cat owner.

"My cat will be on a prescription-only medicine for the rest of his life. I have found a cheaper source of supply but my vet was reluctant to write a prescription although he eventually did."

This vet goes on to offer an explanation:

"He told me that if more people do this, i.e. if more prescriptions were written, consultation costs will rise and consumers will pay more in the long run. He said that vets need the revenue from medicine sales to subsidise the practice costs."

The writer to us says:

"I disagree."

It will be quite interesting to get any reactions to that line of explanation from the floor, I think.

Lastly, we have an e-mail from a dog owner in Leicestershire:

"I asked my vet for a prescription for Soloxene tablets so that I could obtain them from a cheaper source. He said it was not his policy to give prescriptions. When I insisted he charged £9.40 for a non-repeatable prescription and also stipulated that if the animal was to remain under active veterinary treatment by the practice it must be presented for examination every three months."

So those are the kind of representations we have received. We have had a pretty large number of that kind. So this is perhaps a picture of how some animal owners at any rate perceive the restriction in outlet for POMs at the moment.

THE CHAIRMAN: Would anybody from the floor like to comment on those points?

General Discussion

MR TROWER (Sheep Veterinary Society): I take some encouragement from the fact that we have not yet had an e-mail read out from a complaining farmer. There are 40 million sheep in the UK but I believe we are classified as a minor species which goes into the human food chain.

Both of the two previous speakers from the NPA and the RPS have referred to the re-classification of POMs to be PMLs or P's. A previous speaker to my left here, from the floor, referred to the possible reclassification of routine prophylactic medicines such as vaccines.

I just had time to sit down and work out there are somewhere around about eight sheep vaccines on the market at the moment only three of which are classified as POMs. The other five are PMLs, they can be purchased from pharmacies or from agricultural merchants, and those include the two commonest which are clostridial and pasteurella vaccines which are routinely used by 85 per cent. of all the farmers in this country, so they are not classified as POMs.

The three that are classified as POMs are all modified live vaccines. They all contain zoonotic infectious organisms. They are two that cause abortions - abortions in sheep and abortions in humans - and the one to which the speaker on my left referred is Orf. Orf causes a skin disease and in the last foot and mouth outbreak it became very evident that lots of farmers were unable to distinguish between Orf and foot and mouth.

I think there is every justification - someone up there in the regulatory system has looked at these three live vaccines that can cause disease in humans as well as in animals and has decided that they should be regulated as a prescription only medicine. I would concur with that and I think the suggestion that they should not exposes a certain lack of understanding, shall we say, on the people who are suggesting that.

MR JOBSON (Jobsons Farm Health): As has been explained by my veterinary colleague, sheep is a minority species - that is surprising to me from Cumbria but after last year it perhaps is a minor species.

Certainly, the statistics regarding the number of products on the market is accurate of course. I would like to point out that pharmacists do have an understanding of human health and in particular they have an understanding of Zoonosis, and Zoonoses are an area of undergraduate education with all pharmacists.

They do understand the significance of Zoonoses and particularly in sheep areas it is very common for pharmacies to be consulted in instances of Orf and ringworm and so on and Zoonotic diseases that come from livestock animals. So it is an area that is understood.

I did make it very clear in my initial comments that the suggestion was that these products would be supplied in circumstances where they had been used routinely for a considerable length of time. I am grateful to my veterinary colleague for pointing out the importance of the aspects of careful administration so that the Orf virus is not introduced into flocks that hitherto had not been infected, and also the safety aspects of administration to avoid contamination.

THE CHAIRMAN: Thank you, Mr Jobson. I do not think the previous speaker was suggesting that pharmacists should not be allowed to dispense these medicines. I think what he was saying was that those particular medicines should not be declassified down from their current classification of POMs, and I might say that we would not, and I do not think anybody in the room would favour the declassification of medicines in that sense that have been properly classified in that way.

We have received complaints, however, that there are a number of other medicines - perhaps those affecting pet owners rather more than farmers - that are inappropriately classified, but I do not think the previous speaker was suggesting for one minute that pharmacists were not capable of recognising Zoonosis issues and dispensing such appropriately prescribed medicines.

Are there any other speakers who want to comment on this?

MR SALISBURY (Royal Association of British Dairy Farmers): I am a practising dairy farmer. Obviously we have to separate ourselves from the pet owners. Dairy farmers are professional operators nowadays. We have a wonderful working relationship with our veterinary surgeon.

The problem that we have is that the cost of medicines - this has already been alluded to - is not even over the EU. Please can we have some level playing field. The EU is there to support our industry. It is there to control and license medicines to be used. We have so many organisations who seem to want to make empires. What the farmer needs is to be competitive with his product at the end of the production line.

It has been mentioned that we are not allowed to pass on the costs due to the situation of food processing, but we do not

really have control of the final cost. We need to get the EU, along with the help of this Commission, to get an level playing field with respect to licences throughout the EU and preferably throughout the world. Animal husbandry is not that very different throughout the world.

THE CHAIRMAN: I would like to make the point that our jurisdiction is UK. Nevertheless, if we feel that European regulation is having an adverse impact on British consumers we are at liberty to make that quite clear, as we have done in the past in, for example, the car inquiry and our comments in those respects have been taken on board by the Commission. If we feel that this situation is adversely impacting on the competitiveness of the supply of veterinary medicines in the UK we can make appropriate recommendations.

As I said earlier on, we have a live webcast at the moment, and we would just like to take one particular comment from somebody who has just participated in the debate through the webcast.

MR SMITH: This is an e-mail we received two minutes ago which has come from a Mr Jonathan Head. It is very short and it responds to something he has just heard. He says:

> *"I hear the view that there may be an impact on prices adversely if Suitably Qualified Persons [SQPs] cannot break bulk packs. However, veterinary surgeons can only supply their own clients. Others may be able to supply anyone, and therefore have economies of scale not available to vets. Furthermore, pharmacies have an NHS subsidy, again not available to the veterinary practitioner".*

It is a comment rather than a question.

THE CHAIRMAN: Thank you.

MR WARE: (President Elect, RCVS. Immediate past President Preliminary Investigation Committee): I would just like to respond to a couple of points from the e-mails read out at the start of this open part of the session.

I am disturbed, but not entirely surprised at the alleged ignorance of some of my colleagues and their alleged attempts to inhibit competition. I say "not surprised" because I am sure exactly the same antics will go on in any other profession and in probably any other occupation. But it is the function, as we have already heard, of the Royal College, to investigate complaints and if those complaints are laid formally in front of

us then we will most certainly investigate them as we would any other complaint.

It is worth noting that in the last full year for which we have figures, which was only the last calendar year, there were 720 complaints to the Professional Conduct Department about the activities of veterinary surgeons. 60 (in round figures) of those involved fees in all its guises, and only one that I am aware of - and that was not even in the last full year, that is one we are investigating at the moment - involves the issue of the supply of prescriptions.

So the complaints' procedure exists, it is accessible, but the number of complaints which we receive from the public are very, very small in any form, but certainly considerably smaller in the relationship with fees.

Again from the regulatory point of view the College would entirely support those veterinary surgeons who wished to make re-examinations of animals who are suffering from chronic illnesses and on long term medication. Both the illnesses themselves evolve and the medication which they may be on may have internal implications for the health and welfare of those animals and we would be extremely critical if veterinary surgeons did not make regular examinations of animals under their care - just as we would be equally critical of any medical doctor who did not make regular examinations of patients under his care.

The timescale is not prescribed, it is open to judgment according to circumstances, and the important issue from the College point of view is that the veterinary surgeon should not institute procedures as a debarment to the provision of prescriptions which were not there when they were not providing prescriptions, when they were providing the medication themselves. So we would certainly take issue if such a procedure were followed, purely and simply as a disincentive to the supply of prescriptions and veterinary surgeons in the generality are well aware of the need to provide prescriptions.

THE CHAIRMAN: Thank you very much.

A SPEAKER: I am a general public person - a cat and a dog owner. Several of my neighbours realised I was coming today and did want me to stand up and try and speak, so I shall do my best.

One of the first things concerned complaints, so it is quite nice that I have just heard the gentleman speak. When we do have a complaint we do not actually know where to go. It

would be nice in the waiting room if perhaps the Royal College could have a sign saying "If you do have a complaint" - it may be next year he does not have 720 but 1,020, but at least that way we do know where to go.

Secondly, regarding the guidelines on prescription fees and things like that. I personally would love to go to a pharmacy and collect whatever I needed. Yes, I appreciate that vets are not earning as much as they would like to and that is why they want to charge us £10, £15 that I have been charged for re-doing prescription charges. I know that Mr Green said that everything has to be reasonably charged. I would like to define "reasonable", and perhaps again have something shown in the waiting room to say how much you are going to charge us. Whether this can be a range from £2 to £10, at least it would be advising us. Whenever I go the charge rate does seem to change from month to month. I understand that inflation does occur, but not from, say, £5 to £10 for the same product.

THE CHAIRMAN: Thank you very much for that contribution. I think it is worthwhile the room recognising that it is, after all, the public that we are all serving, and it is extremely useful to hear the voice direct. Thank you.

MR WILLIAMS: Just to come back on a few points made earlier. The point that education and training is essential - clearly it is. Pharmacists who have undergone continuing education particularly in veterinary areas are, as was stated, small but then you would expect that if they are not given the opportunity to get at the materials to apply that training in a practical way.

The second point concerns the remarks made by the representative from Dechra who mentioned that human wholesalers always had the opportunity to supply and to buy in veterinary medicines. I think we have to accept that it is the same reason why it remains that human pharmaceutical wholesalers do not stock veterinary medicines. Why would they when the pharmacist cannot do anything with them in the first place because of the lack of prescriptions?

MR A EVANS (Director, veterinary pharmacy): I am a director of a veterinary pharmacy that mainly deals mail order. We are also wholesale to other pharmacies as well, one of the niche wholesalers that Trefor was talking about.

I would like to make a few points. A year ago we dispensed probably one veterinary prescription a day, if that. I

have never come across anybody who has been offered a prescription by a vet in the five years that I have been involved in the business. It is only through, "aggressive" is probably the wrong word, but an aggressive press campaign by ourselves, that we have actually started to receive prescriptions from the general public.

We have found, and I would not wish to tar the whole profession with the same brush, but certainly a large number of vets, who have been charging and going through the type of practice we have heard via the e-mails, whether it be charging an excessive amount, the record so far is £70 for one prescription which basically made up the difference that we could save the lady on some epilepsy drugs for her dog.

I would also like to comment on the fact that the vet should see the animal within a certain length of time. That is obviously quite correct, and we would never tell any of our customers any different, and the likelihood is a three month regular consultation to make sure that the symptoms had not changed, or that the drug had become less effective, or whatever.

However, another ploy that is used unfortunately is that members of the public are asked to come in on a more regular basis than they were when the vet was prescribing themselves, and therefore incurring more consultation fees than they would have done when the supplier was originally there.

There are many, many hurdles. We now do about 170 prescriptions per month, but that is only after a full year of very extensive advertising.

MR ROACH (Dechra Pharmaceuticals Ltd): As a wholesaler my concern is only about the cost effective distribution and the availability of prescription only medicines on the veterinary side. I know nothing about the human side, so my comment really comes as a question. As my colleague said what concerns us is the mix of products as well, because when you are working on a 4 per cent. gross margin it is the mix of products that is important, actually to a certain extent other products can subsidise prescription only medicines. So on the human pharmacy side I suppose my question is is there a regulatory professional or ethical requirement that pharmacies stock, or make available a full range of products on presentation of a prescription, so they cannot just choose to supply let us call it the most popular products, and would they envisage that this approach

would continue in the future for their business if veterinary products were included in their business?

MR WILLIAMS: We can certainly give you some information if that helps.

THE CHAIRMAN: Just very briefly if you could answer that point, but then possibly it is something that can be done in writing in more detail.

MR WILLIAMS: Because of the NHS nature of most pharmacies, within the NHS all pharmacies are required to supply what is prescribed with reasonable promptness, therefore the wholesalers are obliged to stock widely, just the way vet wholesalers will. There are also short line wholesalers in the pharmacy area who do cherry pick. One would imagine that might start to occur within the vet world as well. But I do not think the vet wholesalers ought to be worried about 13,000 pharmacies coming on board as potential customers. I have presented you some data suggesting what just 10 per cent. of them might do to change things.

THE CHAIRMAN: Thank you. I think we should now move on to topic 3, and I am going to call upon Mr Andrew Scott, the President of the BVA to address us on this point.

Topic 3

Veterinary surgeons' charges for prescription only medicines

MR SCOTT (British Veterinary Association): In the paper work that we have received from the Competition Commission the BVA was asked to speak on veterinary surgeons' charges for prescription only medicines.

The BVA is the representative body for the whole profession and that includes academics, regulators, industrial vets as well as practitioners. We have, as the Competition Commission already knows, been involved in the development and implementation of veterinary medicines' policy for many years.

In the next few minutes we are asked to contribute to this morning's programme, and to restrict ourselves to charges for POM medicines. Reading section 4 of the Competition Commission's paper setting out 14 Jeremy Paxman-type statements we could be forgiven for thinking we should all be locked up and the key thrown away.

THE CHAIRMAN: I think they were put hypothetically and raised as issues for discussion rather than Paxman-style accusations----

MR SCOTT: It is nice to have a response! [**Laughter**] May I just

quote three of these fourteen statements:

"IV(iv) Whether veterinary surgeons refuse to write prescriptions, or by some action or omission, discourage requests from animal owners for prescriptions.

"IV(v) Whether veterinary surgeons by some action or omission may have indicated to veterinary manufacturers and/or veterinary wholesalers that they should refuse to supply pharmacists, or supply them on less favourable terms.

"IV(xi) Whether veterinary surgeons charge higher than necessary prices on prescription only medicines."

Of course the Competition Commission do not really mean to sound hawkish, and of course we do not behave in such a fashion. It is just that having started on this exercise the whole issue has been put under the microscope.

I would like to make three substantive points and I start with a twofold objective. We are veterinary surgeons providing a service in the private sector and we are business men earning a livelihood and doing both in a cost-effective way to survive in this market place.

We should be able to achieve both without creating a monopoly of whatever kind and without being greedy in spite of our privileged position as professionals.

Let us work backwards, not least because the practitioner is at the end of a long chain, the medicines' chain. The client has his animal treated, and is presented with a bill. The components of that bill are the same anywhere. They are labour, equipment, materials, overheads and profit.

A practice in Cumbria does not attract the same overheads as one in Mayfair. A Portakabin is not as expensive as a brand new, state of the art veterinary hospital. But the components of cost are the same.

The ratio of these cost components are not the same for different treatments for different animals. So all the numbers vary and the extent to which each component is listed and sub-divided can be short, or very long indeed and an itemised bill can read just like the checkout at Tescos.

Within these four categories we are talking about materials. Within that veterinary medicines, within that POMs, and within that POMs for different treatments. Incidentally it should be remembered sometimes with a zero POM cost since they might not be required.

Small volumes of POM will not be as expensive as large volumes. Companion animal treatment does not require the bulk purchase of a POM whereas farm animals can be very different.

By the time you have put all these variables together a picture emerges of a cost component being only part of a bill. Indeed, salaries, wages and overheads can both well exceed the percentage cost of POMs purchased. My first point is perspective and we should not lose sight of it.

My second point is profit and size - our operating surplus. For the last fourteen years the BVA has carried out inter-practice comparisons on veterinary surgeries involving round about 1200 veterinary surgeons. We work out income per vet, net profit per partner, percentage return on investment and so on. In real terms these indicate a show over the last few years, no growth at all. In fact, in many cases we have not kept pace with inflation.

There are integral parts of practice that will not provide a return. Greed is not self-evident to us, it is evidently absent but if there is it should be dealt with as we have heard from the Royal College. When the last investigation of veterinary prices and fees took place, 18 months ago, we commissioned a survey to try and show the distribution of POM costs and fees for a range of medicines. The distribution curve, of course, was normal, as seen by our independent analyst. Incidentally, the same analyst that did the work for the Competition Commission. There was no significant evidence of excess pricing. The figures were all published in the veterinary record at the time.

My third and final point is understanding the cumulative cost of the medicine chain. By the time that you have gone from the research budget of a manufacturer, the development of a measurable unit of product, through its development, through its regulation, through its distribution and eventually removed it from the pharmacy shelf to dispense to a client, one unit of product has gone from cost to cost plus, to cost plus plus. No business can survive on the basis of cost minus - well not for long anyway.

If there is a scope to increase competition dismantling the veterinary medicine chain may be required. Probably there is greater scope for price reduction further back up the chain than at the point of sale to the client.

So before I hand over to my colleague, David Miller, allow

me to be Jeremy Paxman. We shall take the role of the Competition Commission as monopolistic, nothing else matters. All you have to do is to eliminate all veterinary medicines legislation, go on general sales for everything. Do not bother with veterinary diagnosis. Forget all aspects of food safety and residues, and side effects, buy generics, which is Government policy for the NHS, and then wait for the supply of molecules for disease control to be run down.

David Miller, I hope, will put these policy issues in a slightly more constructive light.

THE CHAIRMAN: I feel I would like to emphasise to everyone that the Competition Commission is concerned with the public interest and we would make those recommendations, that may well follow those that have been suggested to us, but we would make those recommendations that we think will be most beneficial to the public interest.

MR MILLER: In respect of issues identified in the area of regulation may I, on behalf of BVA, make four points:

1. Efficacy. When the UK Medicines Act, 1968 was enacted as a component of consumer protection legislation introduced by the then Labour Government the three regulatory pillars of safety, quality and the efficacy were introduced into UK law.

Earlier than 1968 I remember, when I first joined the veterinary pharmaceutical industry, there was a scheme in operation called the Veterinary Products Safety Precautions Scheme. This was a voluntary scheme under which veterinary medicine manufacturers were required to produce evidence only of safety issues. There was no requirement under that scheme to have anything about efficacy or quality - safety only.

When the legislation came on we had the three pillars - safety, quality and efficacy - and they have subsequently become the norm worldwide and are presently fundamental to European Union, Japanese, and US legislation in this area on veterinary medicines.

These three bodies - the EU, the US and Japan - are of course the key members of the VICH initiative which is currently to establish some common standards in areas of regulatory information required from manufacturers.

Let me emphasise that data from manufacturers on efficacy are today considered essential to protect the consumer from spurious or misleading information, and it seems that a retro approach, going back to 1964 might not be the way forward.

EU influence: as a member of the EU the majority of UK veterinary medicines legislation law reflects EU directives and regulations developed and agreed in Brussels. The Veterinary Medicines Directive, as was said earlier, were in November, 2001, consolidated into one document, but currently a two to three year process is ongoing to modify that consolidated directive with a professed aim of increasing the number of approved therapeutic products for animals in the EU.

This brings me to the point on distribution thinking with in the EU. There is no EU agreement on distribution policy for veterinary medicines, however, an important proposal from the Commission is currently on the table, and it would require in the name of traceability and enhanced food safety, that all veterinary medicines for food animals should be available only under veterinary prescription.

To suggest distribution systems that may not enhance consumer protection appears therefore to be swimming against the tide, the tide of current community thinking on consumer protection and safe food.

Lastly, may I comment briefly on global influences. We live in an age of globalisation - animal health is no different. The rules on animal health adopted by the World Trade Organisation [WTO] have been compiled by the OIE - sometimes known in English as the World Animal Health Organisation. This represents member governments. The UK member is a fully paid up member of both WTO and OIE.

The OIE in December last year produced a draft document on the responsible and prudent use of antimicrobial agents, antibiotics in veterinary medicine. This document is expected to be ratified by the OIE next month, May, 2002, and it calls for member governments of the OIE to ensure that all food animal veterinary antibiotics are available only on veterinary prescription and furthermore supplied only to animals under the care, the terminology used in the document is very similar to that adopted by the RCVS here in the UK. It also says that not only food animal antibiotics should be on veterinary prescription only, supplied to animals under the care of the veterinarian, but also importantly after appropriate diagnostic procedures have been carried out.

THE CHAIRMAN: Mr Miller, I have indulged you---

MR MILLER: I have one second more if I may.

THE CHAIRMAN: Well, you may have one more second more but it would

be helpful if it was actually on the topic under discussion and that is veterinary surgeons' charges for prescription only medicines. That is the point. We have already had one speaker from the vets, there are others who want to speak. Let us hear it on charges.

MR MILLER: Very well. If I may just finish this comment I have---

THE CHAIRMAN: You promise to speak on charges?

MR MILLER: My general comment, and it is a sentence, says: the room for national manoeuvres and initiatives, particularly in the area of food animal veterinary medicines is substantially constrained by international obligations.

THE CHAIRMAN: Nothing on charges. Perhaps the speaker from the National Farmers Union will be able to enlighten us on what he thinks about veterinary surgeons' charges for prescription only medicines.

MR CUTLER: (Chairman, Animal Health and Welfare Committee, NFU): Our concerns with veterinary medicines are in three areas, and I will very briefly say what the other two are, the third one being charges. I am getting quite nervous. [**laughter**]

The first concern has to be safe and responsible use and food safety. We have been involved in Responsible Use in Medicines in Agriculture Alliance (RUMA), and a major part in it, which is a food chain initiative looking at responsible use.

Our second concern is availability from the animal health and welfare point of view, we need to have the medicines available, and therefore we welcome things like the extension of the extrapolation of MRLs for minor species.

Our third concern obviously has to be costs. I brought up the point earlier that in the agricultural industry it is very difficult for us to pass on costs and given the state of the industry at the moment the NFU has been very active at looking at input costs generally.

Our members have, for several years now, commented on drug prices simply because Irish prices are perceived to be lower, people travel to New Zealand and see different prices. We are competing on the world market and it is very important that input costs there are as similar as possible. When we have tried to look at this issue over the years the lack of transparency through the system has been very apparent. It is interesting how it has become a lot more transparent since the Competition Commission have been investigating - I seem to be able to get

more information from people than I used to be able to.

The Marsh review so far as we were concerned dealt with a lot of the concerns. We feel quite strongly that the encouragement for the use of prescription, the separation of prescribing and dispensing, even within veterinary practices, as long as there is a fixed charge on the prescription side, or a limit on the cost of the prescription, would encourage competition within the system.

The argument often put to us from the veterinary profession has been that it is necessary to cross-subsidise fees with the margin made on medicines. We believe that the time has come for the veterinary profession to take the opportunity, given the circumstances, especially within agriculture at the moment, to levy proper fees, and learn to sell their services differently, rather than providing an emergency call-out service and all availability - to start looking at service contracts with farmers, to start looking at herd health plans. The Curry Commission has pushed very firmly in the direction of farmers needing to be registered with vets, needing to develop herd health plans, and the use of a proper selling of services approach within the veterinary profession I think is the way forward. We can develop a far better approach to animal health.

That opportunity will be quite difficult to grasp because it requires a culture change within the veterinary profession, but it also requires a major culture change within the farming profession, and we hope to be able to work with the veterinary profession to be able to develop that approach. To put things on a fairly simple basis we feel that cross-subsidy of fees with a large margin on the medicine prices is untenable in the long run, that encouragement of the use of prescriptions would improve the situation, improve competitiveness within the system.

THE CHAIRMAN: So what you are saying is that, in a sense, to use some of the analysis that we would use in the Competition Commission, that there are in fact two markets - a market for veterinary services, that is to seeing animals, diagnosing them, indicating what is wrong with them, and prescribing, and there may be a second market place which is for the dispensing of the medicines and both vets and pharmacists could do that?

MR CUTLER: That is the analysis we have of it, and unfortunately the service side of it has not been developed well enough and this tends to be subsidised.

THE CHAIRMAN: We have heard from a lot of vets to say that they are not interested in the business side often, they are there to look after animals and perhaps they do no want to spend as much time as some of the other professions have had to in recent times, in learning to become businessmen.

MR CUTLER: I think there would be a lot of farmers who would say their interest is to produce food and not be businessmen, but in fact that is an untenable position we recognise, and I think the same is true in the veterinary profession.

THE CHAIRMAN: Thank you very much.

MR STEWART (National Farmers Union of Scotland): You may be dreading an identical presentation but I think you will see that there is a fundamental point of difference between the NFU and the NFUS. We are widely held to have been responsible for starting this whole procedure, and I make no apologies for that.

Obviously, coming as a farmer we deal almost exclusively with large animal practices, though if you have seen the size of Shetland sheep and some of the Ronaldsay Ewes I am sure that vets in inner city housing estates may be dealing with far larger alsatians.

This whole procedure is not an attack on vets' practices. We accept that the mark up is a vital part of their margins. In Scotland obviously we have a large percentage of remote areas and it is an absolutely vital service that the vet provides. We have often no access to pharmacies. We need the product immediately. We are not convinced that opening this up to pharmacies would lead to lower costs.

I have discussed this fully with my vet. It would be stupid to go into this argument unless I know the vet's position and had discussed it with him. I get an itemised, fully transparent bill from him as a matter of course. I have asked him, and he has told me his mark up and I have to say that his margin is reasonable. I have no complaints on that at all. Bearing in mind that he used to stock it, hold it, and eventually in some cases throw away stuff that was past its sell by date.

He buys through a buying group. That maximises the efficiency in transport, storage and all the rest of it, so he gets the benefits of bulk buying.

If we extend this principle of fully itemised bills it may actually make the problem worse in that it will highlight higher prices. You just go on to the internet and get prices instantly.

I was doing it last night just to see what the prices are around the world. These prices are open to everybody. They will find out the prices.

There is, in Scotland, a large black market. There is no point in running away from that. I believe that this is a serious threat to animal welfare, and it is obviously a serious threat to human health. That is obviously something that will exist where you can get products up to 70 per cent. cheaper. We are not talking about 10 per cent. here. Nobody is going to bother about 10 maybe even 15 per cent. It is when you start getting products about 70 per cent. cheaper there is a clear temptation.

You will perhaps hear later carefully chosen examples to deny the extent of the problem. It is possible to pick up prices in other countries that are fairly similar to ours, but be aware that there is a huge disparity

I think we have already heard at a previous conference that the mark up by the manufacturers is what the market will bear. They are quite right, if they can get away with it, to do that.

Yes, we need new products, and these new products must be paid for, but I would point out that Australia, America, Spain and Ireland - the countries where we can draw these products - they are a very cheap price. They are no different from us. They mostly have an exporting status, they are sensitive to all the concerns that we are sensitive to, and they will not take risks.

I think, madam Chairman, I hesitate to advise you, but I think we need a determined effort to figure out accurately the extra costs of our regulatory system. That has to be capable of being pinned down. If you think it is 40 per cent. it is adding to the costs, I for one do not think so. I think that we have to be careful that you, as a Competition Commission, are not side tracked by the share of the market that any wholesalers have. If you are not competitive as a wholesaler then you do not get the business.

To go back to a point that I made at the NOAH conference, there is a huge potential for vets and farmers to draw up a health plan. I was on this kick long before Don Curry started on it. If you look at the genetic potential that there is in the modern animal the best way to get that is for the vets and the farmer to sit down, knowing what that herd, and the management system and past problems are like, sit down and draw up a proper

health plan. I think it will result in less fire brigade treatment, and it will lead to a proper use of modern products. That, in short, requires confidence on the part of both the vets and the farmers that they are not being ripped off by the manufacturers; that they are getting a product at the same price as their competitors. It comes down to that.

THE CHAIRMAN: One point I would like to raise, and we will be discussing it a little further in the next topic, this business about prices, we have heard that vets do not know what they are paying for some of the drugs because of the system of retrospective rebates and so on, and when they are actually charging their farmer customers and the pet owner customers, they are charging their mark up based on the list price, and that that can sometimes lead to an excessive or, if you like, double profits.

MR STEWART: This would mirror exactly what happens in the crop chemicals market where, for example, product packs are marked with invisible markers so if you happen to get a cheaper offer elsewhere and your supplier sees the carton lying he can take it away and analyse it to find out what supplier stepped out of line, has traded outwith his area. If I thought for a second---

THE CHAIRMAN: Sounds like another investigation! [**laughter**]

MR STEWART: Well, there are similar issues here where we can buy these crop chemicals cheaper abroad. It may well be that this is something that we recommend. But, back to your stance that if there is a system of retrospective rebates based on how well they do and how much of that manufacturer's product they sell during the year and so on, and how well they hold their price, then I think that is something that should be looked at and done away with if possible.

THE CHAIRMAN: Thank you very much for that. I am going to ask my colleague, Mr Henderson, to comment and to reflect some of the e-mails that we have received during the course of this hearing and prior to it.

E-mails received during the hearing

MR HENDERSON: The striking thing is that in this general topic are we have not had anything from other than pet owners. I think we have had some very cogent interventions from the farming world, but they do not seem to have time to get to the e-mail and let us know individually how they feel about it. I hope that is the correct interpretation rather than that actually there are no

concerns. The e-mails that we get do tend to cover topics that we have also discussed. There is one specific topic which has not come up in the discussion so far at any point and this is to do with competition between vets. One e-mail from a cat owner in Essex said:

"The most frustrating element is that it is impossible to find a competitive price for annual vaccinations. I have failed to find any price variation between vets in my area. The price is extremely high and extremely consistent."

Another e-mail from a dog owner:

"Our vet seems keen on prescribing expensive drugs when cheaper alternatives are available. As a GP I am encouraged to prescribe the cheapest effective drug, why can't vets do the same?

I have two others which are to do with repeat prescriptions which I think we have already had.

THE CHAIRMAN: It is still useful I think for the floor to hear what is said.

MR HENDERSON: Yes, it states:

"My vet stated he will only issue one repeat prescription without seeing the dog again, hence charging another consultation fee".

The tone of that is now well familiar to us.

"The Competition Commission needs to look at the possibility of allowing repeat medication to be sold at other outlets such as pharmacies and pet shops."

So it is a theme which keeps recurring.

THE CHAIRMAN: A consistent picture. Any comments from the floor?

General Discussion

A SPEAKER: Madam Chairman, I am a farmer from the Wiltshire/Someset border. I am not used to public speaking so you will have to forgive me if I hesitate a bit. 4 per cent margin - I will give you one instance which I quoted to you in a letter many months ago, buying antibiotics for pigs a vet was charging £108, I found another source, legal source, I stress, for £42.50. I now get a prescription from my vet and get it from that source.

You are talking about a 4 per cent. margin and greed. I will leave it up to people here present to decide who is having what.

Every time I mention these prices to the vet I get a

little lecture about consultation fees would have to go up. Well I would sooner have it that way, at least I know what I am paying for.

I see the vet appears only has one wholesaler so I cannot see how he can get competitive prices from one wholesaler. When I order fuel I ring round three or four firms and get various prices it is amazing. So I do not see how the vet gets competitive prices from one wholesaler.

I have never been offered a prescription, well I have only recently been asking for a prescription but I have never been offered one. I do take up the point, we keep hearing about these cheap drugs in Ireland. The vets say "Oh they are not up to standard", but I would like to know if they are up to standard, and it is just the vet telling us the tale. Thank you.

THE CHAIRMAN: Thank you for that. I think Dechra wants to respond.

MR EVANS: Just to clarify, when I said 4 per cent. margin, that is the average wholesaler margin. Clearly the manufacturers have a margin and the veterinary practices themselves have a margin. So clearly the end price to the customer, the consumer, the farmer, is a combination of all three. So when I said "4 per cent", I was purely relating to the wholesaler margin.

The second point in terms of wholesalers, there are six wholesalers who operate, one of them is in Northern Ireland only, but the other five - all are Dechra's competitors - I think are in the room, and will all be pleased to offer their services to your veterinary surgeon. So at wholesaler level all the five wholesalers that operate in England, Scotland and Wales will be happy to offer a competitive price.

MR Dean (Society of Practising Veterinary Surgeons): I am a mixed practitioner from Cornwall. I would like to jump slightly to the defence of the veterinary practices who are being accused of perhaps being poor business people. As I understand it if you are bad in business your business usually fails. Practising veterinary surgeons have had many changes over the last 50/60 years. They have changed from the horse to the tractor and the lorry, losing vast amounts of their work. We are now struggling with the demise of the farm practice in many areas with shrinking numbers of farms available for us to treat.

We are changing from fire brigade work to advisory work - we are doing that. Even in the small animal sector now we are changing much more towards preventive medicine, much as is happening in the human market.

I have to stress that there is competition out there. I am in an area where there are several veterinary practices. If I charge £70 for a prescription my clients would go elsewhere, and if clients are feeling that they are being over charged, then they must go elsewhere, or at least communicate with their vet their disgust. Ask for a prescription, shop around for medicines, there is nothing to stop them doing that already, and at the end of the day if they are still unhappy go to the Royal College of Veterinary Surgeons and complain. We are man enough to cope with this. We are man enough to adapt and change. We are business people, but we are also in this for animal welfare, and don't forget that issue also.

Thank you.

THE CHAIRMAN: Just on that point of shopping around, we have had some complaints from people who suggest that they find it difficult to move vets because they have to get permission from the previous vet to move. Would you like to comment on that?

MS PAULL: I think sometimes it is a little bit misunderstood that permission is required. If a client comes in to me wishing to move to our practice, we would contact the previous veterinary surgeon, not to get permission, they can just walk out, there is no problem. What we would need to do is to get previous histories, because for instance, there may be evidence of disease situations and we do not need to repeat and go over the same investigative procedures and it is for the welfare of either the farm itself or for the pet that we get all the previous history. That is why we would contact the other veterinary surgeon, and for no other reason.

MR EVANS: May I clear up this word "generic"?

THE CHAIRMAN: Please, I am sure that would be very helpful.

MR EVANS: This word "generic" is used a lot and we hear about generic products being cheaper. I think it is probably worth just saying that on the human side generic products are authorised products. They are products that have been manufactured as copies, if you wish to use that term, of a branded product, but they have been through the authorisation process, and proved to be of equivalent quality, safety and efficacy.

We have the same situation on the veterinary side, and there are a number of products on the veterinary side where other companies have produced branded generic copies of other people's products. But the other term that is used for generic

is this generic substitution where there is the potential to use the human product in the veterinary sector, but that human product, whilst being a generic of a human product, has not been through the authorisation process.

So I think we need to be a little careful when we are talking about generics. There are authorised generic products, but there is the issue of generic substitution where it means using unauthorised products. I think that goes to the importation side as well. The question was asked about the Irish products. All of the Irish products that are authorised have been through the Irish Medicines Board process, which is virtually identical to ours, so they are authorised products. The problem that anyone has is just because the brand name is the same does not necessarily mean that the formulation is exactly the same. Therefore, importation of a product authorised in Ireland can only be legal if the same product has been authorised in the UK as well, and you can tell that because we actually have a mutual recognition process and we are in the process of producing a list with the Irish Medicines Board so customers can identify products that are available in Ireland that are also available here, that have been mutually recognised.

Thank you.

THE CHAIRMAN: Thank you for that, that is helpful. Before we leave this topic I would like to throw out a couple of questions that we have not actually covered, and that is what the role of the insurance industry is in this at all? Do veterinary surgeons discriminate between clients in their charges for POMs according to whether or not the animal is insured? I do not know whether anybody has any insight in to this? This is one of the issues that has been raised with us.

MR EVEREST (Pet Plan Insurance): I have to say we have heard these allegations in the past about veterinary surgeons and insurance, but we have never seen any evidence to back that up.

Just talking generally from what I have heard today about insurance, I am not sure whether having a mix between veterinary surgeons dispensing medication and pharmacists would actually benefit our customers at the end of the day by reducing the premiums. Currently we have the information coming through the vet with the claim. If we then involve the pharmacist as well we are getting information from two different areas. We are getting perhaps invoices that come through with a claim and we will have

more pieces of paper to deal with, and another area to gain information from, to speak to pharmacists to gather information as to what is on that invoice. At the end of the day with the volume of claims that we have it may potentially create more admin costs which would have to relate in premium to our customers at the end of the day.

THE CHAIRMAN: How do the human health insurers cope with this?

MR EVEREST: There is no real equivalent between pet insurance and human health, because obviously what we are talking about here with a vet is like a GP, whereas the human health is talking about referring to consultants, and surgery. So it does not really apply in the same way.

THE CHAIRMAN: I am not sure I have entirely understood this, but I am sure it is something I can investigate at a certain point.

MR EVEREST: Well, I can give you as much information as you want on that.

THE CHAIRMAN: All right. Are there any other comments? I did want to hear a little bit more from the floor about the way in which veterinary surgeons are influenced in their buying decisions by the rebates and discounts that are offered by the veterinary manufacturers - the point that I raised with one of the speakers. Is there anyone on the floor who would like to make any comments on that, because there is some suggestion that the rebates and discounts reduce the choice of medicine supplies and the value for money obtained by animal owners. Has anybody any comments on that one? It is obviously a sensitive subject I am sure, but nevertheless--- [**no comments**]

All right, I will move on to the next item, and that is prices effectively, Manufacturers' list prices for prescription only medicines - perhaps this issue of rebates will come into that. I am going to call upon Mr Mike Nelson to speak to us about this.

Topic 4

Manufacturers' list prices for prescription only medicines in the UK

MR NELSON: Madam Chairman, ladies and gentlemen - I am not sure that that is politically correct, but I do not believe that political correctness should have a monopoly.

I believe I should justify my presence here today. You are wondering how this old gentleman should be coming in on the act - not representing any organisation but listed as "an

investigative veterinary journalist". I hope my appearance may offer at least the view of experience if not wisdom. I can claim experience, but my innate modesty prevents me referring to the wisdom.

Until I retired from practice nearly six years ago I had a fairly varied professional life - four years of mixed practice, 18 years in the pharmaceutical industry, and then I gave up the rat race and started a small animal practice in South London, and in 1976 retired after 20 years at that.

On October 20th I read that the Competition Commission invited submission of evidence by November 9th in that day's Veterinary Record. I believed that my experience and contacts might help because there was one thing that the Marsh Report did not cover and that was the price paid by vets for their medicines that they supplied, and it seemed important to me to at least look at it because I knew very well that there were differences.

It so happened that I sat next to Roger Green, the President of the Royal College at a meeting on October 25th. The following day he e-mailed me the addresses of two of his contacts, one in Holland and one in Belgium.

We were expected to make submissions by November 9th, although that was subsequently changed to November 23rd. I only mention this because it is really due to these contacts that we managed to get information. Although I received no response from Belgium with my e-mail I did from Holland, along with a price list that arrived on November 12th (from October 26th).

Following a fax to my own contact in France on October 26th I received a telephone call the following day and a price list arrived the following week. There was no comparable list in Spain. Three weeks ago at the Small Animal Congress I was told by a Spanish vet that I met that in Spain manufacturers will appoint a distributor and there is no one real veterinary wholesaler which covers everything to supply the vets, so the vets have to go to various sources, so there were no price lists.

In order to compare apples and apples I restricted the comparison and prices to the identical branded products between the UK, France and Holland, and I went through all this piece by piece. There happened to be 179 French products, and 181 Dutch products that were in the UK price list. Why did I choose these? Because you must rule out any other variables like the use of

generics and we have had a very useful definition which saves me time to cover.

So by comparing like with like there were one or two differences. There were five products marketed in France. They were a different pack size, or a different concentration. So the price comparison could only be calculated on an equivalent active ingredient involvement. The list price to French vets with 181 products averaged 67.05 per cent. of the UK price list, and the average for Holland was 67.9 per cent.

In your folders on the back of my sheet there is a chart which actually shows the spread of all those products France and Holland, as percentages of the UK list price. In fact, 42 per cent. of the products in France cost the vet (all list prices were to the vet) between 60 and 80 per cent. of the UK list price. It was 50 per cent. of the Dutch products that came within that category in Holland. On this basis it is hardly surprising that clients are charged more for POMs in the UK than on the Continent.

Now, there will be people who would argue that the list price is not necessarily what the vet pays. But what I wanted to do was compare like with like. In fact, if you go around veterinary practices you will find that different practices maybe pay a different price for the same product, depending on a number of variables, and it is not my concern to go into that. Maybe the discounts on the Continent are of a completely different structure to that here. Again, that is not something I feel that I should go into. All that remains is that there is a very clear difference between the UK and France and Holland, and if I had had more time and maybe managed to get a few more price lists within the time limits, maybe we could have established a bit more. Then, on the other hand, I think the Competition Commission could very well be working on that.

Finally, I feel rather flattered that you should invite me to come along and make this presentation. I think it adds another layer into the complexities of the Competition Commission inquiry. My length of hair is not because of any shortage of money, I have not made that much money in veterinary practice but having attended every BVA Congress except three since 1959 and every BSAVA Congress without exception since 1962 I have met an awful lot of vets and I can assure you that the only fat cats I saw were on my surgery table.

Thank you, madam Chairman.

THE CHAIRMAN: Thank you very much indeed, Mr Nelson. We are grateful to you for your contribution. We were advised that you might be provocative and I hope your contribution this morning has succeeded in provoking some responses.

I have to say that there is one sector that we have heard very little from today, and that is from the representatives of the manufacturers, and I wondered if any of them would like to come back and comment on some of the points that Mr Nelson has made or any of the other points that have been heard today. [**no comments**]

Is there any convincing evidence other than what we have heard from Mr Nelson that list prices in the UK are higher compared to other European countries?

General Discussion

MR EDDY (Royal College of Veterinary Surgeons): Speaking as a farm animal practitioner in Somerset of 35 years' experience, I did a similar exercise to Mike Nelson two years ago, comparing products in Ireland, Northern Ireland and Gt. Britain, looking like for like at list prices from wholesalers and the amazing thing was there were even differences - big differences - for some products for some companies between Gt. Britain and Northern Ireland, let alone differences, much bigger differences between Gt. Britain and the Republic of Ireland.

There is a lot of anecdotal evidence but there are a lot of veterinary surgeons in Northern Ireland who get their supplies from Southern Ireland - it is just across the border, not far to go.

Now, the gentleman from the Scottish NFU mentioned the black market which is quite strong in Scotland. We understand it is very strong in South Wales, and other parts of Gt. Britain. We have heard mention, and there is an insinuation in your documentation that perhaps veterinary surgeons are not very good businessmen. We have also heard that to succeed you have to be a reasonable practitioner at business as well as veterinary medicine. I would suggest that in those areas where the black market exists, and it exists because farmers - we are talking about farm products - can get products very much cheaper on the black market as we have heard, that exists because the vets cannot compete. If they could compete I am sure they would compete.

So the evidence that Mike Nelson has presented, and the evidence I accumulated myself two years ago add to the support

and suggestion that like motor cars, like washing machines, like beer everything costs more in the United Kingdom than it seems to cost in most of the other European countries.

THE CHAIRMAN: Again, I would call upon perhaps the manufacturers to give us some explanations of this. I would not expect manufacturers to discuss prices in detail in the presence of their competitors, but it would be helpful to hear from them as to what factors might account for price differences between the UK and other countries. [**no comments**]

I have to say it is of concern to me that there is a deafening silence from those who perhaps might be best able to give us some help in this area. [**no comment**]

Well, we will draw our conclusions in those circumstances.

Is there anybody else who would like to comment in this area? [**no comment**]

Is there any representative from the veterinary side who would like to say anything about comparative prices between the UK and the rest of Europe? [**no comment**]

We have an e-mail here which I think I would ask my colleague to read out.

E-mail received

MR SMITH: This has just come in. It is from an Ann Thomson. She has a question and a couple of comments. The first question is addressed at Mr Dean of the VMD.

"Could it be that Her Majesty's Government's view that the VMD be a total cost recovery agency be a factor in the high cost of veterinary medicines. Comparisons of prices from other EC countries, while useful in itself as an indicator, does not necessarily indicate a comparison of cost of placing a veterinary medicine or product on the market. Furthermore, as far as pricing rebates and discounts are concerned, it would appear to me that within all business sectors some form of volume related benefit exists. It would surely be crass stupidity to deny the existence of economies of scale derived from normal business practices."

THE CHAIRMAN: Quite a helpful intervention. Is there anything else that anybody wishes to say?

MR SMITH: There is the question about the cost of the UK regulatory system being part of the explanation of the high cost of the marketing and supplying in the United Kingdom?

A SPEAKER: The issue of manufacturers' prices is an immensely complex issue. I think you can appreciate that there are many reasons why list prices will differ between countries. I understand that you are going to implement a market research programme yourselves, and we have offered to comment on the methodology, but I think that it is very difficult to comment generally, particularly on list prices and prices between markets.

THE CHAIRMAN: I accept that totally. What we are interested in is some of the broad factors, some of the broad indicators that we perhaps ought to be directing our attention towards. As I say, it is inappropriate in a forum like this to discuss price comparisons in detail, but there does seem to be from many sources that prices are higher in the UK than they are elsewhere. There may be very good reasons for that. There may be quite appropriate reasons for that associated with the regulatory regime, with health, with all sorts of things. What we need to do, and what we wish to hear is simply some of those factors that might take that into account.

MR DEAN (Veterinary Medicines Directive): I think I did try to make the point to answer that question when I spoke and that is the cost of the regulatory system is equivalent across Europe in terms of the development of data because we have common data requirements, and that is the lion's share of the cost of a veterinary medicine authorisation. It is the development of data.

THE CHAIRMAN: But that should be the same throughout the EU.

MR DEAN: Yes, it should, correct. In terms of what we charge to actually do the assessment work. It is true that we go for 100 per cent. cost recovery. It is true that it ranges throughout Europe from 100 per cent. down to zero per cent. But the other factor, which I have to put in if for nothing else to defend the VMD, is that there is the issue of time taken. From the industry perspective if it costs you nothing but it takes you five years to get an authorisation, or it costs you let us say £10,000 but you get the authorisation in 18 months, there is a huge benefit to the industry in that type of efficiency. I think there is a valid question about the cost of the actual authorisation process, but I do not think it is a significant factor in terms of the cost of a veterinary medicine. It is really the data generation that would be the significant cost.

MR THEMANS (Chairman, Inputs Group, NFU): When we look at legislation it is not the immediate cost that we ought to be concerned with, it is the disincentive, in fact the impossibility through approval systems, but in encouraging trade any disincentive can have a huge effect on the market.

I was a member of the Inputs Task Force which was another one of Professor Marsh's, and in asking why do farmers not import the other inputs legally it actually took about a 10 per cent. premium to actually make that import necessary. It is a disincentive. You must not dismiss this one, it is a very important factor.

MR WILLIAMS (NPA): On the subject of manufacturer prices, we tried to make some comparisons by asking pharmacies throughout Europe from our list of contacts about relative manufacturer prices. We did get some which we submitted to you, but we also got an interesting letter from the British office of a European manufacturer, who we did not contact, so presumably in all innocence one of the pharmacies in Europe contacted him, who said:

> *"Your request for veterinary prices in Europe has been passed to me by our European office. We have sent all European prices directly to the Competition Commission and this information should cover their needs."*

So they continue, perhaps, to find it difficult to discuss this matter.

THE CHAIRMAN: We at the Competition Commission do not take the stance that we are pointing the finger at anyone. We are investigating the whole of the supply chain here, and we want to know, because this is what we are concerned with, whether or not the market is operating competitively, and the point of competition is to benefit those who are the recipients of the goods or services which are being investigated, and at the present moment we have had more complaints in this area than we have in any other subject that we have investigated. There certainly seems to be a ground swell, certainly of those who write to us anyway, that prices are too high, and we are trying to get to the bottom of why.

MR BLACK: (Chairman, NOAH): One of the things that would perhaps cause a difference in prices across Europe is that many of the drugs, the POMs that you are using are derived from their human equivalents. Most of the drugs that are used in our industry come from that source because as an industry there is no money,

the markets are not big enough and therefore you derive your source from the human.

Now, as somebody who has spent 20 years on the human side before moving into the animal health side, most of the cost of drugs on human medicine are negotiated with national governments and therefore it comes as no surprise that the poorer countries in Europe, such as the countries that have been mentioned, are supplied these drugs at cheaper than the United Kingdom and the more wealthier countries of Northern Europe.

There is just another comment I would like to make. As somebody who has moved from the one side to the other, in the ten years that I have been involved I have watched this side of the business being reduced from about 30 major companies down to 15. Now, if people are in the business to make profit as our gentleman from the pharmacy infers, maybe he could tell me why the number has halved in ten years. There is not one British company left in animal research in medicine - not one. The only two or three that are available, and that are doing research are doing it into vaccines and anthelminthics which are the products that these people seem to be interested in.

As somebody who has made this industry my life I would like to say to everyone if we are not careful there will not be an industry, and the very animals that we are here to try and look after and protect will be the ones that will suffer at the end.

MR BOWER (Veterinary Advisory Group to Pet Insurance Industry): Practising veterinary surgeon, small animal practice, also an adviser to one of the pet insurance companies, and here representing the Veterinary Advisory Group to the pet insurance industry.

Surprisingly nobody has said what I think will happen if there is an extra link in the chain of the supply of veterinary medicines. I have been trying to think of any other industry, any other profession, where you add an extra link in the supply that does not actually increase costs, and I cannot help thinking that this will be so.

In fact, this was brought home at a recent meeting between the Royal College and the pet insurance industry where a director of major pet insurance company which, let us face it, are a consumer as much as the pet owner - they pay the fees - said "Surely, surely you are not going to add another link in the chain, it can only put up prices". That is the first point I

would like to make.

The second point is veterinary fees, and I think Sir John Marsh pointed this out, and I believe the Competition Commission has already expressed surprise at how low the veterinary surgeons fees for their time are. Let us just analyse what is involved in writing a prescription. One of the first speakers today said that to write a prescription you have first of all to take a telephone call, and it cannot be a message passed on. Only a veterinary surgeon can write a prescription, not a nurse, not a receptionist. So they have to take the telephone call, then they have to very carefully check the history and the previous treatment of that particular pet which takes time, calling it up on a computer or looking at the record cards. They have to check the history and the dates. They have then to decide on the appropriate medication. When you realise that our patients can weigh anything from a budgerigar up to a great Dane, and there are different licences for different products, we have to work out which product to use, what the dose rate is and this is not a two minute job. Then having decided all that we have to decide on the safety aspects of the number of repeats we can write on that prescription. Having decided all that we then write the prescription.

Now, it does not take out very long to work out that that is not a two minute job. That is a job that will take some little time and if we charge appropriately dare I say it, at the same rate as lawyers, solicitors, accountants, indeed private doctors would charge, then it is not a matter of just an administrative charge. This is a veterinary surgeon's time spent in performing a very important function.

THE CHAIRMAN: Thank you. Before I start winding-up, are there any more comments? I do not want anybody to leave this room feeling they have not had their chance.

MR WILLIAMS: May I respond to the point about putting extra links in the chain. In human medicine pharmacy might be described as an extra link in the chain, but in fact dispensing doctors who do it all themselves cost the NHS more than pharmacies do. When opticians were forced to give prescriptions for glasses costs fell. Finally, remarks about the administration of repeat prescriptions, GPs manage to do it very well with technicians, and the highly qualified technicians who assist veterinary surgeons ought to be able to do the same.

MR SKETCHLEY (NOAH): As I have mentioned before to the Commission

it is not our role within NOAH to comment on costings and pricings etc., because as we explained we are mainly involved in regulatory issues.

However, I think it has to be said that Mr Nelson made some interesting comparisons, and I acknowledge his points about comparing apples with apples. I think it is now important through certainly the questions that I know the Commission has already asked our individual members, that comparisons are made of the true net buying price after discounts have been applied either by wholesalers and or manufacturers, and then compare those to other European equivalents. Then we will perhaps be able to see if there are any true differences.

Closing remarks

THE CHAIRMAN: Thank you, and I think on that note I am going to draw the proceedings to a close. We have had a very useful discussion and I would like to thank everybody who has taken part. We will be reflecting on much of what we have heard this morning in the rest of our inquiries.

Some of those present will be asked to attend private hearings to explore the matters outlined in the Issues Statement. There is obviously a difference between those issues that it is sensible to discuss in public, and those which it is better to explore in more depth in private. We will, however, still be interested to receive any comments on any of the issues that we have had today or indeed any other matter which is relevant to our inquiry. We are interested to receive that from any of the organisations present or indeed anybody who is participating in this inquiry via the webcast.

We are particularly grateful to the veterinary practitioners and the pharmacists who have contributed to our lively discussion today. I do not want anybody to go away, however, with the sense that this is a "them" and "us" situation at all. As I said in my comments, we are looking to see how the whole of the supply chain works, how it interacts with each other, and what impact that has on the end consumer. But that will be the subject of our deliberations over the next few months and I am grateful for your help and your contributions this morning.

Thank you very much indeed.

(**The hearing concluded at 1 pm**)
