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February 1984 DOCUMENT 1-1409/83

Report

drawn up on behalf of the Committee on Agriculture

on the approximation of the laws of the Member States relating to the distribution of veterinary medicines

Rapporteur: Mr Brian HORD

PE 74.398/fin.

English Edition

By letter of 9 January 1980, the Committee on Agriculture requested authorization to draw up a report on the approximation of the laws of the Member States relating to the distribution of veterinary medicines.

At its sitting of 13 October 1980, the European Parliament authorized the Committee on Agriculture to report on this subject. The Legal Affairs Committee and the Committee on the Environment, Public Health and Consumer Protection were asked for opinions.

On 20 October 1980, the Committee on Agriculture appointed Mr Brian Hord rapporteur.

At its meetings of 1 December 1983 and 2 February 1984, the Committee on Agriculture considered the draft report. It adopted the motion for a resolution as a whole on 2 February 1984 by 23 votes to 1 with no abstentions.

The following took part in the vote: Mr Curry, chairman; Mr Früh, Mr Colleselli and Mr Delatte, vice-chairmen; Mr Hord, rapporteur; Mr Abens (deputizing for Mrs Castle), Mr Barbagli (deputizing for Mr Clinton), Mr Battersby, Mr Dalsass, Mrs Desouches (deputizing for Mr Gatto), Mr Eyraud, Mr Gautier, Mr Goerens (deputizing for Mr Maher), Mr Helms, Mr Kirk, Mr Maffre-Baugé, Mr Marck, Mr Mertens, Mr Provan, Mr Stella (deputizing for Mr Diana), Mr Sutra, Mr J. D. Taylor (deputizing for Mr Simmonds), Mr Tolman and Mr Woltjer.

The present report was tabled on 10 February 1984.

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The opinions of the Legal Affairs Committee and the Committee on the Environment, Public Health and Consumer Protection are attached.

C O N T E N T S

The Committee on Agriculture hereby submits to the European Parliament the following motion for a resolution together with explanatory statement:

A

MOTION FOR A RESOLUTION

on the approximation of the laws of the Member States relating to the distribution of veterinary medicines

The European Parliament,

- having regard to the report of the Committee on Agriculture and the opinions of the Legal Affairs Committee and the Committee on the Environment, Public Health and Consumer Protection (Doc.1-1409/83),

(a) having regard to two Directives on the approximation of the laws of Member States relating to veterinary medicinal products and to analytical pharmaco-toxicological and clinical standards and protocols,[1]

(b) having regard to the entry into force on 18 December 1981 of the Directive 78/1016 concerning the right of establishment, which will allow veterinary surgeons the right to establish themselves in EEC countries other than their country of origin,

(c) having regard to the setting up of an Advisory Committee on veterinary training and a Scientific Veterinary Committee,

(d) whereas veterinary and animal health products constitute one of the principal means by which the dramatic advance in agricultural productivity in the past decades has been possible,

1. Emphasises that veterinary medicines are of major importance to the economic performance and welfare of the Community's livestock population, and constitute one of the principal elements of prophylatic and eradication measures;

2. Stresses, furthermore, that veterinary medicines are of major importance to public health, in particular in view of the creation of unacceptable residue levels and transferable drug resistance in man;

3. Notes that differences in rules applied by Member States result in differing costs to producers, profit margin and prices for food and livestock;

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[1] OJ No L 317, 6.11.81, p.1 and 16

4. Points out that the directives adopted by the Council concerning veterinary medicinal products and analytical, pharmaco-toxicological and clinical standards and protocols will not be able to achieve their essential objectives in the absence of an adequate regulation of the distribution and use of veterinary medicinal products;

5. Considers that measures for the control of the distribution and use of veterinary medicines should begin with a classification of those products according to their degree of toxicity and the residue levels in foodstuffs of animal origin (milk and meat in particular) and thus to be distributed

   (a) by prescription only

   (b) by pharmacist, veterinary surgeon or licensed retailer only

   (c) by pharmacist or animal health products retailer

   (d) by general sale;

6. Considers that the conditions of sale of veterinary products should be determined on the basis of the classification provided for in paragraph 5;

7. Accepts that there exists a range of mass-use prophylactics, routine treatments and applications which are safe for general sale and supply to farmers; further, that the general sale of these is a determining factor in the competitiveness of livestock farming;

8. Considers that the sale of medicinal products other than those on general sale should be by prescription from a veterinarian only; the seller - pharmacist, veterinary assistant, technician employed by a cooperative or producer group - should be required to authenticate the signature of the veterinarian and the geographical area for which he is responsible;

9. Considers, however, that the supplementing of animal feedingstuffs with medicinal products should be avoided as far as possible;

10. Notes that a proper balance, based on scientific criteria, should be made between each list, in order to avoid encouraging the development of a black market in certain products, as well as a cumbersome bureaucratic structure;

11. Points out that any unnecessary restriction in supplies of veterinary products could lead to an increase in their costs which may, through a reduction in use, affect the health of the Community's livestock;

    Notes, at the same time, that costs of these products by outlet vary considerably from country to country;

12. Considers that the Member States should agree on common regulations and standards for determining and quantifying the residues of medicinal products in foodstuffs of animal origin;

13. Insists on the need to harmonize the recruitment and qualifications of abbatoir inspectors in the Member States by bringing Community legislation into line with that of the Member State with the most stringent requirements;

14. Stresses the importance of effective control measures and adequate sanctions in order to ensure respect for measures adopted;

15. Instructs its President to forward this resolution and the report of its Committee to the Council and Commission of the European Communities.

Proposal for a Council Directive on the approximation of the laws of Member States relating to the distribution of veterinary medicines

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament,

Having regard to the opinion of the Economic and Social Committee,

Having regard to the proposal for a directive,

Whereas the proposed directives on the standard of veterinary medicines will be ineffective in the absence of measures concerning the distribution of such medicines;

Whereas the primary purpose of any rules for the production and distribution of veterinary medicinal products must be the safeguarding of public health;

Whereas, however, this objective must be achieved by means which will not hinder the development of industry and trade in medicinal products within the Community;

Whereas distribution of veterinary medicinal products within the Community is hindered by disparities between certain national provisions, in particular between provisions relating to the controls on distribution and sale and such disparities directly affect the establishment and functioning of the Common Market.

HAS ADOPTED THIS DIRECTIVE:

CHAPTER I

Definitions and scope of application

Article 1

For the purpose of this Directive, the following definitions shall apply:

- veterinary medicinal product shall mean any medicinal product intended for animals;

- animal includes any mammal, bird or fish;

- animals under care of a veterinarian means those animals which he sees from time to time or those specially examined for the purpose of diagnosis and treatment;

- animal health products retailer means

  (i) a person duly qualified and licensed or registered to practice pharmacy; or

  (ii) persons experienced in the sale of veterinary medicinal products listed or recognized as such by a Member State. Experienced means a person with at least five years practical veterinary product sales experience, or one who has completed a course of tuition recognized by one or more Member State governments on veterinary medicinal products and their proper use;

- veterinarian means a person duly qualified and licensed or registered to practice veterinary surgery and medicine.

CHAPTER II

Classification and sale of veterinary medicinal products

Article 2

All veterinary medicinal products shall be placed in one of four lists according to method of retail supply being:

(a) prescription only

(b) by pharmacist, veterinary surgeon or licensed retailer only

(c) by a pharmacist or animal health products retailer

(d) for general sale

Article 3

Prescription only products may be supplied or sold only by a veterinarian to persons owning or responsible for animals under his care for such animals. Veterinarians should prescribe prescription only products and such prescriptions may be dispensed and supplied by pharmacists.

Article 4

Pharmacy products may only be sold or supplied by registered pharmacies or by veterinarians to persons owning or responsible for animals under their care. In addition products in category 2(d) may be sold by animal health retailers from listed premises.

Article 5

General sale list products may be sold by anyone provided the sale is made in unopened and original packages.

Article 6

A Veterinary Products Committee composed of representatives of all the Member States will keep the lists and classifications of veterinary medicinal products under review. Before making any alteration, addition or deletion to the lists, the Committee shall consult the Veterinary Associations, commercial organizations dealing with veterinary medicinal products and Pharmaceutical Societies of the Member States.

CHAPTER III

Inspection, labelling and packaging

Article 7

All premises of animal health products retailers must comply with accepted standards of hygiene and be inspected at regular intervals by the authorities of the Member States.

Article 8

Premises shall provide adequate and suitable storage facilities to permit the storage of veterinary medicinal products in accordance with accepted standards or the manufacturers' recommendations.

Article 9

The provisions of Chapter VII, Article 43, of Council Directive 81/851/EEC of 28 September 1981 shall apply.

Article 10

Packaging shall be adequate and suitable and sufficiently impervious to withstand accidental contamination. No general sale list trader may break or open bulk packages.

CHAPTER IV

Supervision and sanctions

Article 11

Adequate records of purchases and sales shall be kept in respect of trade in veterinary medicinal products.

Article 12

The competent authority of the Member State concerned shall ensure by means of inspection, that the legal requirements relating to the distribution of veterinary medicinal products are complied with.

Such inspections shall be carried out by officials representing the competent authority who shall be empowered to:

1. inspect commercial establishments;
2. take samples;
3. examine any documents relating to the object of the inspection.

Article 13

The competent authorities of the Member States shall suspend or withdraw authorization to distribute veterinary medicinal products when it is clear that:

1. the obligations referred to in the Directive have not been fulfilled;
2. the information given in the dossier pursuant to Article 11 is incorrect.

CHAPTER V

Implementing provisions

Article 14

Member States shall put into force the measures needed in order to comply with the Directive within eighteen months of its notification and shall inform the Commission. They will also inform the Commission of the main provisions of the National law which they adopt to conform with the Directive.

Article 15

This Directive is addressed to the Member States.

B

EXPLANATORY STATEMENT

The role of veterinary medicine in the CAP

The main aims of the Common Agricultural Policy are to improve the efficiency of farming, and freedom of movement of goods throughout the Community. Some of the more technical areas, such as veterinary medicine, may be overlooked but they make an extremely valuable contribution to these aims.

(a) Farmers' incomes

The health of livestock is important to farmers' incomes; the economics of modern livestock production are influenced through the elimination of certain types of animal diseases.

The importance of animal health and veterinary medicines has become of increasing importance both to the farmer and to the consumer in the process of the modernization of production technology. Veterinary and animal health products constitute one of the main arms by which the dramatic advances in productivity over the past few decades has been made possible. Veterinary medicines are important to the welfare of the individual animal, improving its performance as well as reducing suffering. They are also important to the welfare of the Community's herds and flocks as a whole, constituting the principal element of prophylatic and eradication measures.

(b) Public health and the consumer

Veterinary medicines also raise the equally important issue of public health. It is obvious that the elimination of diseases which can be transmitted to humans has a beneficial effect for the consumer. But this type of consumer protection must extend to the entire production chain to prevent many pathogenic micro organisms and toxic or otherwise harmful substances used in farming being passed on in foodstuffs. Significant dangers exist if medicines are used incorrectly, and in particular to the health of the consumer from unacceptable residue levels. It is also possible that transferable drug resistance can be created in man. For example, it is generally recognized that the widespread use of chloramphenicol in food producing animals may build up resistance to a drug vital for the treatment of salmonellosis (e.g. typhoid).

(c) Free competition

A further problem arises from differences in rules applied by Member States resulting in differing costs to producers, profit margins, and prices at which livestock and foodstuffs of animal origin can be offered for sale throughout the Community. To the extent that the costs of maintaining stock healthy vary from country to country, this brings about differences in costs of production, so undermining free competition.

The necessity for measures to regulate veterinary medicines

It is clear therefore that the Community must seek to ensure common standards of safety for veterinary medicines used throughout the Community. To this end, the Council adopted two directives in November 1981, one on the approximation of laws of the Member States relating to veterinary medicinal products[1], and the other on the approximation of laws relating to analytical, pharmo-toxicological and clinical standards and protocols for the testing of veterinary medicinal products[2]. The Commission has extended the scope of these measures by a directive on the manufacture, putting into circulation and supply of medicated feeding-stuffs in the Community.[3]

It it is true that it is unsafe in terms of the welfare of the public and livestock for the use of veterinary medicines to remain uncontrolled, it follows logically that the distribution of such medicines cannot remain unregulated. Without proper control of sales there can be no adequate guarantee for the final destination of these products.

Therefore, while taking note of the fact that the Council has adopted two draft directives on veterinary products and standards, a further directive on their distribution is required.

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1 Directive 81/851/EEC, OJ L317, 6 Nov, 1981, p.1

2 Directive 81/852/EEC, OJ L317, 6 Nov, 1981, p.16

3 The European Parliament approved this measure OJ C128 of 16.5.83, p.76

Deciding on the proper approach to regulating the sale of veterinary medicines

The arguments laid out above carry considerable weight but as in most areas a proper balance must be sought.

It is possible that increased legislation will lead to higher costs; and the cost of production for the sake of the producers and the consumers should not be increased unnecessarily as a matter of principal.

Moreover, it is probable that if costs were to be increased considerably any legislation would be self:defeating as use of essential medicines decreased creating even greater dnagers for the animals and public.

Any proposal for regulation of distribution of veterinary medicines therefore should examine conscientiously the arguments for sufficient flexibility, as well as for greater restrictions in distribution.

We should be aware, furthermore, that substantial financial issues are at stake. Veterinary medicines are high volume products, whose sales are of considerable value to the outlets in rural areas. In countries where more than one outlet is permitted, conflicts of interest exist between the pharmacies, the veterinarians and the merchants/cooperatives.

The merchants and cooperatives seek a degree of flexibility in the sale or supply of products.

The veterinarians, on the other hand, believe they should be more largely responsible, and that agricultural merchants are unsuitable outlets for veterinary medicines unless their medicine sales are carried out under the same conditions as a pharmacy.

Arguments for greater flexibility

(i) UK farm input costs of animal medicines is estimated by the traders at between £65-70 million per annum. Merchants argue that greater restriction in distribution could increase costs in some countries by up to 30%. Any reduction in use resulting from increased cost would affect the future health of livestock and the public. It is

probable that an increase in costs would create a black market of less strictly controlled products used increasingly by less knowledgeable people.

At the same time, less use might be made of veterinary medicines and veterinary products leading to deterioration in the health of the Community livestock population, and even the resurgence of diseases which are at present under control.

(ii) Apart from increasing costs, the traders argue that restrictions:

(a) retard the proper development of these medicines

(b) produce an undesirable professional bureaucracy

For these reasons the traders seek to make a clear distinction between:

- veterinary products designed for use by the veterinary surgeon (approx. 10% of production); and
- animal health products designed to be sold by retail to the farmer (90% of production).

Arguments for greater restrictions

The pharmacists have a number of reasons for imposing tight restrictions on sales:

(i) Hazards of incorrect use

As with many medicines, serious hazards may be created for the health of the animal, and for public health through transference of antibiotic residues, as a result of incorrect use of medicines used by unqualified persons;

(ii) Toxic properties

Toxic properties of medicines cannot be properly judged by unqualified persons and therefore these products should not be made freely available to the public;

(iii) Storage and shelf life

Storage and shelf life is vital to safe and effective use of medicines, and this may not be respected by traders, who are not trained to realize the particular dangers of these products;

(iv) Role of veterinary surgeon

Veterinary surgeons can give comprehensive advice which is not in the posession of the trader, and can ensure that the drugs are used properly and only where necessary. This may lead to savings for the farmer.

Legislation in the Member States

Clearly, we are dealing here with a multitude of products which can range from innocuous treatments for improving animal performance to complex medicines which in the unpracticed hand may produce dangerous toxic results for the animal and the consumer. These differences between products is reflected in the legislation of certain Member States.

In the United Kingdom and France, categories have been created according to whether the products may be sold by pharmacists, veterinarians or merchants and cooperatives. In other countries, the sales are in the hands of the pharmacists or the veterinarians. Only in Ireland a free for all situation exists.

The situation may be summarized as follows:

France: In the past, veterinarians sold a great majority of medicines, while cooperatives were allowed to sell certain innocuous medicines and animal health products they had sold traditionally. New legislation is intended to restrict cooperatives/merchants to a shorter list while the French pharmacy sector has campaigned to restrict all products not currently sold on prescription to the pharmacy only.

Germany: 90% of distribution under veterinary control and 10% by pharmacists.

Italy: Pharmacists have a monopoly of supply and veterinary surgeons may hold emergency stocks.

Belgium/Luxembourg: Sales are under the control of pharmacists from whom veterinary surgeons and farmers must purchase supplies.

Netherlands: All distribution whether by prescription or sale is in the hands of the veterinary profession.

Denmark: Veterinary surgeons must purchase from a pharmacy and farmers have to obtain their supplies on prescription.

United Kingdom: The situation is as in the list system proposed on page 18.

Ireland: Veterinarians, pharmacists and cooperatives all compete for sales of all types of products

It has been calculated that for the Community as a whole distribution outlets are as follows:

Veterinary surgeons	40%
Pharmacists	40%
Merchants and Cooperatives	20%

It has also been calculated that a black market has developed as follows in those countries with restricted outlets:

Germany	20% to 30%
Italy	90%
Belgium/Luxembourg	30% to 40%

Creation of a list system

Given the differences in the present distribution of animal health products throughout the Community, future legislation is likely to be the result of a compromise between those countries adopting a flexible position and those with a very strict regulation of sales. A compromise is likely to take the form of a list of categories under which products will be classified according to permitted types of outlet.

The categories are

Prescription Only Medicines (POM)

Medicines which must be administered or prescribed by doctors and veterinarians; they and pharmacies may carry stocks.

Pharmacy Only (P)

A relatively short list of products restricted to sale by pharmacies. May be stocked as above.

General Sales List (GSL)

Innocuous medicines that can be sold by any retailer.

Pharmacy, Merchants List (PML)

These are animal health products which ought to be classified as POM but, because agricultural merchants, cooperatives etc., have sold them traditionally, they can continue to be sold by merchants for a temporary period that has yet to be specified.

As PML products comprise the major market value and volume of all AHPs sold, there is conflict about which categories will be allocated to PML products once the 'temporary period' ends.

DENMARK - PRODUCERS' VETERINARY COSTS 1975/76 - 1979/80

	CATTLE	DAIRY COWS	SOWS AND BACONERS	SOWS AND WEANERS	HENS	KR PER HEAD
	Dairy cows & young stock					
1975/76	-	106	144	104		
1976/77	142	114	151	108	0.33	
1977/78	171	136	160	112	0.23	
1978/79	202	161	165	117	0.14	
1979/80	217	175	-	-	0.13	
				OTHER COSTS 1979/80		
TOTAL	14,241	10,206	10,594	4,631	99.01	
of which:						
- foodstuffs	4,815	3,250	6,608	2,553	76.55	
- energy	135	100	59	59	2.17	
- interest	866	583	857	336	3.62	

FRANCE - INTERMEDIATE CONSUMPTION OF THE AGRICULTURAL SECTOR (value in millions of francs)

	Value 1980	Volume Index	Value 1980 at 1979 prices	Price Index	Value 1981
Animal feed	28,151	104	29,277	114	33,376
Fertilizer	18,027	99	17,847	111	19,810
Oil products	5,005	99	4,955	128	6,342
Plant protection products	7,589	109	8,272	109	9,016
Maintenance of buildings	2,772	102	2,827	113	3,195
Equipment repairs	8,182	101	8,264	115	9,504
Veterinary expenses	3,930	104	4,087	113	4,618
Other goods	8,700	103	8,961	111	9,947
Other services	3,843	103	3,958	113	4,473
TOTAL	86,199	102.6	88,448	113.4	100,281

Opinion

of the

Legal Affairs Committee

Draftsman: Mr MEGAHY

At its meeting on 28 October 1980, the committee appointed Mr Megahy draftsman.

The committee considered the draft opinion at its meeting of 25 and 26 January 1984 and adopted it by 8 votes to 1.

The following were present at the vote ; Mr LUSTER, vice-chairman and acting chairman; Mr MEGAHY, draftsman; Mr DEL DUCA, Mr GEURTSEN, Mrs Tove NIELSEN, Mr PROUT, Mr SIEGLERSCHMIDT, Mr TYRRELL, Mrs VAYSSADE and Mr VETTER.

Introduction

1. By letter of 26 September 1980, the Enlarged Bureau requested the Legal Affairs Committee to draw up an opinion on the own-initiative report which the Committee on Agriculture had been authorized to draw up concerning veterinary medicinal products.

2. The subject of the present opinion is the draft report drawn up by Mr Hord (PE 74.398) which proposes certain measures for the control of the distribution and the use of veterinary medicinal products, on the basis of a tripartite classification of these products according to the retail outlets from which they should be obtained. Apart from the draft motion for a resolution, the draft report also contains a "proposal for a Council Directive on the approximation of the laws of the Member States relating to the distribution of veterinary medicines"[2] which is presumably intended to give effect to the committee's proposals, though, strangely, no mention is made of this "proposed directive" either in the draft motion for a resolution or in the explanatory statement attached thereto.

Legislative Background

3. The basic provisions of Community law on proprietary medicinal products were laid down in Council Directive 65/65/EEC of 26 January 1965[3]. "Medicinal product" is defined in Article 1(2) of this Directive to include "any substance or combination of substances presented for treating or preventing of disease in human beings or animals", though the substantive provisions of the Directive were expressly restricted to proprietary medicinal products for human use by Article 2. The Directive sets out a system of authorization by the competent authority of the Member States to place a proprietary medicinal product on the market, and lays down the particulars which must accompany an application for authorization.

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[1] At its meeting of 25 and 26 January 1984, the Committee was only able to examine the text of this proposal in the original language, English.

[2] The term "medicinal products" rather than "medicines" is employed in the relevant Community legislation and is used throughout this opinion.

[3] OJ No. 22, 9 February 1965, page 369/65.

4. Two Council Directives of 20 May 1975[1] extend Directive 65/65/EEC; Directive 75/319/EEC sets up a Committee for Proprietary Medicinal Products which can give the requisite authorization where the applicant already in possession of one marketing authorization wishes to market the same product in at least five other Member States, while Directive 75/318/EEC lays down in some detail the testing requirements for these products. A further Council Directive of 26 October 1983[2] extends the earlier provisions to facilitate the free movement of proprietary medicinal products for human use by allowing the Committee for Proprietary Medical Products to give an authorization for marketing in at least two MemberStates and by obliging the competent authorities of a Member State which is examining an application to give "due consideration" to any earlier authorization granted to the same applicant in respect of the same product.

5. For veterinary medicinal products, two Council Directives of 28 September 1981[3] set up a marketing authorization system similar to that then in force for medicinal products for human use adapted to the particularities of the veterinary sector, e.g., the broader range of medicaments[4], the problem of noxious residues in animals destined for human consumption and the increased costs in testing products for such residues, the limitation in the use of certain medicinal products such as antibiotics and hormones and the flourishing black market in veterinary medicinal products in Member States where the control of their distribution is strictest. As with the legislative provisions on proprietary medicinal products for human use, these directives attempt to balance the requirements of the protection of public health with those of the free movement of goods, the latter including not only pharmaceutical products but also animals and animal products within the territory of the Community.

The Proposed Directive

6. Your draftsman drew to the committee's attention that, without prejudice to the merits or demerits of the distribution scheme proposed by the Committee on Agriculture, there are a number of factors which could militate against the proposing of such a draft Council Directive in the report of a parliamentary committee. In its resolution of 9 July 1981 on the right of

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[1] OJ L 147, 9 June 1975, pages 1 and 13.

[2] OJ L 332, 28 November 1983, page 1: Directive 83/570/EEC.

[3] OJ L 317, 6 November 1981, pages 1 and 16: Directives Nos. 81/851/EEC and 81/852/EEC.

[4] See "L'harmonization des législations concernant les médicaments vétérinaires", 1982 R.M.C., page 156.

legislative initiative and on the role of the European Parliament in the legislative process of the Community[1], the European Parliament considered that it should "develop further its right to make proposals concerning Community policy through resolutions requesting the Commission to introduce legislative proposals"; the Parliament did not assert any right to propose legislation in its quasi-definitive form, for reasons which were outlined very clearly in the opinion[2] submitted to the Political Affairs Committee by the Legal Affairs Committee on the subject:

> "The exercise of legislative initiative necessitates a formidable amount of technical means and data. That is all the more true at European level, there account must be taken of existing laws in ten different Member States. The institution that, in the Community, disposes of the appropriate means is the Commission. Of course, the European Parliament can continue to give political guidelines to the Commission, over which it has control, for tabling such drafts as it thinks should be proposed; in exceptional cases, these guidelines can go as far as an articulated proposal (that has been done in the past: for example, the proposal - Doc. 340/73 - on the European Cooperation Grouping which the Commission tabled after Messrs. Armengaud and Jozeau-Marigné had presented - 9 August 1971 - a motion for a resolution embodying a draft regulation)".

7. A further, legal, difficulty could arise from the wording of Article 100 of the EEC Treaty, which is proposed as a legal basis for this Directive; this obliges the Council to issue directives "acting unanimously on a proposal from the Commission". Thus, for a proposal emanating from the Parliament to be adopted by the Council, it would need to be taken over in its entirety by the Commission and be forwarded as a Commission proposal; where the implementation of such a directive would involve the amendment of legislation in one or more Member States, as this directive certainly would, the European Parliament would then be consulted once again on its own proposal. However, the Council could argue that further consultation was unnecessary; this would deprive the European Parliament the opportunity to modify its earlier views in the light of a change in circumstances or a long delay by either of the other institutions involved or of any textual changes effected by the Commission. Be that as it may, the question arises as to whether

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[1] OJ C 234, 14 September 1981, page 64.

[2] Attached to Doc. 1-207/81: draftsman, Mr PROUT.

Parliamentary action of this type does not, save in very exceptional cases, give rise to more problems than it solves, and if it does not, rather than save time for the Commission, waste that of the Parliament.

8. The proposal for a directive may also be premature, in so far as the earlier veterinary medicinal products directives have only come into force in the Member States a matter of months ago (on 9 October 1983); the draft measure appears to ignore the obligations incumbent by virtue of Article 23(2) of Directive 81/851/EEC[1] on the Commission to propose "not later than 4 years after the entry into force of this Directive ... all the appropriate measures for the abolititon of any remaining barriers to the free movement of veterinary medical products" and on the Council to "take a decision on the Commission proposal not later than one year after its submission."

9. Apart from the obligations deriving from Article 23(2), the Commission could also be given the opportunity to benefit from its experience of Directive 83/570/EEC[2] which, as mentioned above (paragraph 4), extends and improves the market authorization system for proprietary medicinal products for human use. It might be that similar modifications could eventually be proposed to the procedures of the Committee on Veterinary Medical Products. In such a complex area of the approximation of the laws of the member States - it took the Council six years from the submission of the Commission's proposals to adopt the two existing directives - it might be neither realistic nor necessarily desirable for the Parliament to press for the Commission or Council to act with what could appear to be indecent haste.

10. The committee, however, took the view that, in the matter of legislative initiative, the European Parliament should keep its options open: it was observed that Parliament had adopted a "proposal for a Council resolution" as part of its resolution of 19 January 1984 on the Communication from the Commission of the European Communities to the Council on "Energy and energy research in the Community: a five-year programme of action and its financing" on the initiative of the Committee on Energy, Research and Technology.

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[1] OJ L 317, 6 November 1981, page 1.

[2] OJ L 332, 28 November 1983, page 1.

Conclusion

11. The Legal Affairs Committee considered that it would be possible for the Commission on Agriculture to produce a Council directive on the approximation of the laws of the Member States relating to the distribution of veterinary medicinal products.

The Committee would wish to reserve its position on the details of any such legislation until such time as it is proposed by the Commission.

OPINION OF THE COMMITTEE ON THE ENVIRONMENT, PUBLIC HEALTH AND CONSUMER PROTECTION

Letter from the Chairman of the Committee to Mr CURRY, Chairman of the Committee on Agriculture

Subject: Own-initiative report on the liability of producers and distributors of veterinary pharmaceuticals

Luxembourg, 7 February 1984

Dear Mr Chairman,

The Committee on the Environment, Public Health and Consumer Protection considered the above mentioned subject at its meeting of 3 February 1984.

The Committee on the Environment, Public Health and Consumer Protection has come to the following conclusions:

a) distribution of medicines with a withdrawal period for residues should be restricted to pharmacists and veterinary surgeons and the issue of a prescription should be compulsory. The prescription should indicate the withdrawal period when animals are treated;

b) if after analysis the product is found to contain residues, it will be impounded, at the manufacturer's expense, if he cannot produce a prescription or has not respected the prescribed withdrawal periods. This is a highly educative measure, it would curb the inoppertune, ill-considered and clandestine use of medicines;

c) the considerable pressure applied by those who manufacture, distribute or sell medicines through legal, semi-legal or illegal channels makes it very difficult to apply controls at source, i.e. upstream.

The important thing is to impose downstream controls, systematic analytical checks on products prior to sale with impounding of goods and fines for the manufacturer if the offence is repeated.

Please consider this letter as the opinion of the Committee on the Environment, Public Health and Consumer Protection.

Yours sincerely,

(sgd) Kenneth D. COLLINS
Chairman

The following took part in the vote: Dr SHERLOCK, chairman; Mr ESTGEN (replacing Mr ALBER); Mr GHERGO; Mrs LENTZ-CORNETTE; Mrs SCHLEICHER; Mrs SEIBEL-EMMERLING; Mrs SPAAK; Mrs SQUARCIALUPI.