COMMISSION OF THE EUROPEAN COMMUNITIES

COM(92) 372 final - SYN 251 - 252

Brussels, 26 August 1992

Re-examined proposal for a

SYN 251

COUNCIL DIRECTIVE

widening the scope of Directives 65/65/EEC and 75/319/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products and establishing complementary provisions for homoeopathic medicines

---

Re-examined proposal for a

SYN 252

COUNCIL DIRECTIVE

widening the scope of Directive 81/851/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to veterinary medicinal products and establishing complementary provisions for homeopathic veterinary medicines

---

(presented by the Commission pursuant to Article 149.2(d) of the EEC treaty)

SYN 251

Re-examined proposal for a Council Directive widening the scope of Directives 65/65/EEC and 75/319/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products and establishing complementary provisions for homoeopathic medicines

On 8 July 1992, the European Parliament examined the Common Position reached by the Council on 25 February 1992 in the light of the proposal mentioned hereunder. The Parliament adopted nine amendments.

In accordance with Article 149(2)(d) of the Treaty, the Commission has re-examined its proposal and decided to take all the amendments adopted by the Parliament on Second Reading with the exception of amendments 3, 5 and 10, which it rejected for the reasons explained below. The amendments accepted by the Commission are set out in Annex 1. The amendments rejected by the Commission are at Annex 2. The purpose of Amendment 3 was to clarify the concept of homoeopathic medicine. In the opinion of the Commission however, this modification would have the effect of including, within the framework of the simplified registration procedure, preparations with a higher concentration of active principle; the potential risks of toxicity from these preparations must be assessed in accordance with the procedure set out at Article 9 of the Directive.

Amendment 5 was aimed at permitting, by derogation from Article 7 paragraph 2 first indent of the Common Position, the use of a brand name for homoeopathic medicines containing several active components. The Commission has not taken this amendment on board since it considers that the presentation of several active components simply under a brand name gives the impression of a therapeutic effect, whereas the procedure in Article 7 applies only to homoeopathic medicines which are marketed without a therapeutic indication.

Amendment 10 would have required the Commission to develop a complete policy covering medicines described as "alternative". Such an arrangement would clearly go beyond the scope of this proposal, which is concerned with the free circulation of medicinal products, and not the methods of training for and exercise of the associated therapies, a field in which Community competence would be difficult to justify.

ANNEX 1 : AMENDEMENTS ACCEPTED BY THE COMMISSION

Common position of the Council	Text as amended by Parliament
Article 1(2)a (new)	
	2a. A homeopathic preparation may contain, with the exception of catalysts, only homeopathic basic substances in a minimum dilution of 1:10.
Article 7(2), introductory clause	
2. In addition to the clear mention of the words "homeopathic medicinal product registered under a special, simplified procedure", the labelling and, where appropriate, package insert for the medicinal products referred to in paragraph 1 shall bear the following, and no other, information:	2. In addition to the clear mention of the words "homeopathic medicinal product", the labelling and, where appropriate, package insert for the medicinal products referred to in paragraph 1 shall bear the following, and no other, information:
Article 7(2), eleventh indent	
- "homeopathic medicinal product without approved therapeutic indications"	Deleted
Article 7(2), eleventh recital a (new)	
	- a sentence advising the user to consult a competent homeopathic therapist whilst using the medicinal product if the symptoms persist.
Article 8, second indent	
- dossier describing how the homeopathic stock or stocks is/are obtained and controlled, and justifying its/their homeopathic nature, on the basis of an adequate homeopathic bibliography;	- dossier describing how the homeopathic stock or stocks is/are obtained and controlled, and justifying its/their homeopathic nature, on the basis of an adequate homeopathic or anthroposophical bibliography;
Article 9(2)	
2. A Member State may introduce or retain in its territory specific rules for the pharmacological and toxicological tests and clinical trials of homeopathic medicinal products other than those referred to in Article 7(1) in accordance with the principles and characteristics of homeopathy as practised in that Member State.	2. A Member State may introduce or retain in its territory specific rules for the pharmacological and toxicological tests and clinical trials of homeopathic medicinal products other than those referred to in Article 7(1) in accordance with the principles and characteristics of homeopathy or anthroposophic medicine as practised in that Member State.

ANNEX 2 : AMENDEMENTS REJECTED BY THE COMMISSION

Common position of the Council	Text as amended by Parliament
(Amendment No. 3) Article 7(1), third indent	
- there is a sufficient degree of dilution to guarantee the safety of the preparation; in particular, the medicinal product may not contain either more than one part per 10 000 of the mother tincture or more than 1/100th of the smallest dose used in allopathy with regard to active principles whose presence in an allopathic medicinal product results in the obligation to submit a doctor's prescription.	- there is a sufficient degree of dilution to guarantee the safety of the preparation; in particular, the medicinal product may not contain either more than one part per 10 000 of the raw material or more than 1/100th of the conventional dose in allopathy with regard to active principles whose presence in an allopathic medicinal product results in the obligation to submit a doctor's prescription.
(Amendment No. 5) Article 7(2), first indent	
- the scientific name of the stock or stocks followed by the degree of dilution, making use of the symbols of the pharmacopoeia used in accordance with Article 1(1):	- the scientific name of the stock or stocks followed by the strength or strengths, making use of the symbols of the pharmacopoeia used in accordance with Article 1(1); for preparations containing several active components, another name may also be used, though without indication of the therapeutic effect;
(Amendment No. 10) Article 10(2a) (new)	
	2a. The Commission shall, within five years of the entry into force of this Directive, take or promote all measures necessary to ensure that the status of alternative medicine is harmonized, particularly in the following respects: - adoption of a European Pharmacopoeia, - adoption of a Directive on the legitimate practice of alternative medicines, - arrangements for social security organizations to refund the cost of services and medicinal products, - organization of officially recognized teaching.

SYN 252

Re-examined proposal for a Council Directive widening the scope of Directive 81/851/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to veterinary medicinal products and establishing complementary provisions for homeopathic veterinary products

---

On 8 July 1992, the European Parliament examined the Common Position reached by the Council on 25 February 1992 in the light of the proposal mentioned hereunder. The Parliament adopted 4 amendments.

In accordance with Article 149(2)(d) of the Treaty, the Commission has re-examined its proposal and decided to accept amendments 1 and 3; consequently it rejected amendments 2 and 4, for the reasons explained below. The amendments accepted by the Commission are set out in Annex 1. The amendments rejected by the Commission are at Annex 2.

The purpose of Amendment 2 was to clarify the concept of a homeopathic veterinary medicine. In the opinion of the Commission however, this modification would have the effect of including, within the framework of the simplified registration procedure, preparations with a higher concentration of active principle; the potential risks of toxicity from these preparations must be assessed in accordance with the procedure set out at Article 9 of the Directive.

Amendment 4 was aimed at permitting, by derogation from Article 7 paragraph 2 first indent of the Common Position, the use of a brand name for homeopathic veterinary medicines containing several active components. The Comission has not taken this amendment on board since it considers that the presentation of several active components simply under a brand name gives the impression of a therapeutic effect, whereas the procedure in Article 7 applies only to homeopathic veterinary medicines which are marketed without a therapeutic indication.

ANNEX 1 : AMENDEMENTS ACCEPTED BY THE COMMISSION

Common position of the Council	Text as amended by Parliament
Article 1(2)a (new)	
	2(a). Homeopathic preparation may contain, with the exception of catalysts, only homeopathic basic substances in a minimum dilution of 1:10.
Article 7(2), first paragraph	
2. In addition to the clear mention of the words 'homeopathic veterinary medicinal product registered without approved therapeutic indications under a special, simplified procedure', the labelling and, where appropriate, package insert for the medicinal products referred to in paragraph 1 shall bear the following information and no other information:	2. In addition to the clear mention of the words 'homeopathic veterinary medicinal product', the labelling and, where appropriate, package insert for the medicinal products referred to in paragraph 1 shall bear the following information and no other information:

ANNEX 2 : AMENDEMENTS REJECTED BY THE COMMISSION

(Amendment No. 2) Article 7(1), fourth indent	
- there is a sufficient degree of dilution to guarantee the safety of the medicinal product; in particular, the medicinal product may not contain either more than one part per 10 000 of the mother tincture or more than 1/100th of the smallest dose used in allopathy with regard to active principles whose presence in an allopathic medicinal product results in the obligation to submit a veterinary prescription.	- there is a sufficient degree of dilution to guarantee the safety of the medicinal product; in particular, the medicinal product may not contain either more than one part per 10 000 of the homeopathic stock or more than 1/100th of the dose customarily used in allopathy with regard to active principles whose presence in an allopathic medicinal product results in the obligation to submit a veterinary prescription.
(Amendment No. 4) Article 7(2), first indent	
- the scientific name of the stock or stocks followed by the degree of dilution, using the symbols of the pharmacopoeia used in accordance with Article 1(1):	- the scientific name of the stock or stocks followed by the potency or potencies, using the symbols of the pharmacopeia used in accordance with Article 1(1). In the case of medicinal products containing more than one active principle, another name may also be used, but without stating the therapeutic effect:

ISSN 0254-1475

COM(92) 372 final

DOCUMENTS

EN **06 05 03**

Catalogue number : CB-CO-92-385-EN-C

ISBN 92-77-47209-X

Office for Official Publications of the European Communities
L-2985 Luxembourg