COMMISSION OF THE EUROPEAN COMMUNITIES

COM(90) 135 final - SYN 189-190

Brussels, 26 April 1990

Amendment to the proposal for a

COUNCIL REGULATION (EEC)

laying down a Community procedure for the establishment of tolerances for residues of veterinary medicinal products

COM(90) 135 final

Amendment to the proposal for a

COUNCIL DIRECTIVE

amending Directive 81/851/EEC on the approximation of the laws of the Member States relating to veterinary medicinal products

COM(90) 135 final - SYN 189

Amendment to the proposal for a

COUNCIL DIRECTIVE

extending the scope of Directive 81/851/EEC on the approximation of the laws of the Member States relating to veterinary medicinal products and laying down additional provisions for immunological veterinary medicinal products

COM(90) 135 final - SYN 190

(presented by the Commission pursuant to Article 149(3) of the EEC Treaty)

Com 155 f.

EXPLANATORY MEMORANDUM

Following the opinions given by the European Parliament during its part session of March 1990, the Commission has decided, in accordance with Article 149, paragraph 3 of the EEC Treaty, to amend the following proposals:(1)

1. Proposal for a COUNCIL REGULATION (EEC) laying down a Community procedure for the establishment of tolerances for residues of veterinary medicinal products;

2. Proposal for a COUNCIL DIRECTIVE amending Directive 81/851/EEC on the approximation of the laws of the Member States relating to veterinary medicinal products

3. Proposal for a COUNCIL DIRECTIVE extending the scope of Directive 81/851/EEC on the approximation of the laws of the Member States relating to veterinary medicinal products and laying down additional provisions for immunological veterinary medicinal products

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1. O.J. N° C 61 of 10.3.89, pp 3-20; COM (88) 779 final)

1. Proposal for a COUNCIL REGULATION (EEC) laying down a Community procedure for the establishment of tolerances for residues of veterinary medicinal products;

Original Proposal	Amended Proposal
Visas and recitals 1-9 unchanged	
Tenth Recital	Tenth Recital
Whereas the tolerances should be adopted by a rapid procedure which ensures close cooperation between the Commission and the Member States through the Committee for Veterinary Medicinal Products established by Directive 81/851/EEC; whereas an urgent procedure is also required to ensure the swift review of any tolerance which may not be sufficient to protect public health;	Whereas the tolerances must be adopted by a rapid procedure which ensures close cooperation between the Commission and the Member States through the Committee for Veterinary Medicinal Products established by directive 81/851/EEC; whereas an urgent procedure is also required to ensure the swift review of any tolerance which may not be sufficient to protect public health;
Last recital and Articles 1-3 unchanged.	
Article 4	Article 4
A provisional tolerance may be adopted for a substance used as an active ingredient in veterinary medicinal products provided that there are no grounds for supposing that residues of substance concerned at the level proposed present a hazard for the health of the consumer. A provisional tolerance shall apply for a defined period of time, which shall not exceed three years, and shall not be renewed more than once.	A provisional tolerance may be adopted for a substance used as an active ingredient in veterinary medicinal products provided that there are no grounds for supposing that residues of substance concerned at the level proposed present a hazard for the health of the consumer. A provisional tolerance shall apply for a defined period of time, which shall not exceed three years, and shall not be renewed more than once and only under exceptional circumstances and for the same maximum period.

Original proposal	Amended proposal
The list of substances used as active ingredients in veterinary medicinal products in respect of which provisional tolerances have been established shall be contained in Annex III to this Regulation, which shall be adopted in accordance with the procedure laid down in Article 9. Except as provided for in Article 10, any amendments to Annex III shall be adopted in accordance with the same procedure.	unchanged
	At end of Article 4 add a new paragraph as follows:
	Medicinal products which contain active substances included in Annex III shall be authorized only for the period for which a provisional tolerance has been established; this authorization may be extended if the provisional tolerance is renewed.

Articles 5 and 6 unchanged.

Article 7(1) unchanged.

Article 7(2)	Article 7(2)
2. After verifying that the application is submitted in correct form, the Commission shall forthwith submit the application for examination by the Committee for Veterinary Medicinal Products established by Article 16 of Directive 81/851/EEc (hereinafter referred to as "the Committee"). The Committee may request one of its Members to act as rapporteur and to undertake an initial evaluation of the application.	2. After verifying that the application s submitted in correct form within thirty days, the Commission shall forthwith submit the application for examination by the Committee for Veterinary Medicinal Products established by Article 16 of Directive 81/851/EEC (hereinafter referred to as "the Committee"). The Committee may request one of its Members to act as rapporteur and to undertake an initial evaluation of the application.

Original proposal	Amended proposal
Rest of Article 7 and Article 8(1) unchanged.	
Article 8(2)	Article 8(2)
2. After verifying that the information is submitted in correct form, the Commission shall forthwith submit the information to the Committee for examination. The Committee may request one of its members to act as rapporteur and to undertake an initial evaluation of the application.	2. After verifying that the information is submitted in correct form within thirty days, the Commission shall forthwith submit the information for examination by the Committee, which shall deliver its opinion within a period - which may be extended of 120 days. The Committee may request one of its members to act as rapporteur and undertake an initial evaluation of the information.
Article 8(3)	Article 8(3)
3. Having regard to the observations formulated by the Members of the Committee, the Commission shall prepare a draft of the measures to be taken. However if, after consulting the Committee, the Commission considers that the information submitted by the person responsible for marketing is insufficient to enable such a draft to be prepared, the Commission may request that person to provide additional information, within a specified period.	3. Having regard to the observations formulated by the Members of the Committee, the Commission shall prepare a draft with the measures to be taken, within thirty days at the latest. However if, after consulting the Committee, the Commission considers that the information submitted by the person responsible for marketing is insufficient to enable such a draft to be prepared, the Commission may request that person to provide additional information, within a specified period.
Rest of Article 8 unchanged.	
Articles 9-18 unchanged.	
Annex V upto point 4.3 unchanged.	
Annex V, 4.4	Annex V, 4.4
4.4 National maximum residue limits.	4.4 Maximum residue limits.
Rest unchanged.	

II. Proposal for a COUNCIL DIRECTIVE amending Directive 81/851/EEC on the approximation of the laws of the Member States relating to veterinary medicinal products

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Original Proposal	Amended Proposal
Visas and recitals unchanged.	
Article 1 (1) unchanged.	
Article 1 (2); Directive 81/851/EEC, Article 1 (5), sub-paragraphs 1 and 2 unchanged.	
sub-paragraph 3	sub-paragraph 3
Before the date of implementation of this Directive, Member States shall communicate to the Commission a list of the veterinary medicinal products which are available without veterinary prescription.	Before the date of implementation of this Directive, Member States shall communicate to the Commission a list of the veterinary medicinal products which are available without veterinary prescription. When the Commission has received the communication from the Member States, it shall examine whether to propose appropriate measures for drawing up lists of medicinal products which may be administered without prescription within the Community.
Article 1 (3) unchanged.	
Article 1 (4), Directive 81/851/EEC, Article 4, paragraph 1 unchanged.	
Paragraph 2	Paragraph 2
2. No veterinary medicinal product may be administered to animals unless the authorization referred to above has been issued, except for the tests of veterinary medicinal products referred to in point 10 of Article 5 which have been notified to or approved by the competent national authorities in accordance with the national rules in force.	2. No veterinary medicinal product may be administered to animals unless the authorization referred to above has been issued, except for the tests of veterinary medicinal products referred to in point 10 of Article 5 which have been notified to or approved by the competent national authorities in accordance with the national rules in force.
	A written prescription shall be required for dispensing to the public the following veterinary medicinal products:

Original proposal	Amended proposal
	(a) those subject to official restrictions on use for reasons of public or animal health,
	(b) those which, because of their residual effects in foodstuffs of animal origin, require monitoring in their administration in order to ascertain the relevant withdrawal period;
	(c) those which may present risks for animals or for public health or may cause disorders in the persons who administer them;
	(d) those intended for treatments or pathological processes which require a precise prior diagnosis or the use of which may cause effects which impede or interfere with subsequent diagnostic or therapeutic measures;
	(e) magistral formulae intended for animals;
	(f) those which contain narcotic or psychotropic drugs or any other substance subject to international restrictions.

paragraphs 3-4 unchanged.

Article 1(5); Directive 81/851/EEC, Article 5
paragraphs 1-10 unchanged.

paragraph 11	paragraph 11
11. a summary in accordance with Article 5a of the product characteristics, one or more specimens or mock-ups of the sales presentation of the veterinary medicinal product together with a package insert where one is to be enclosed.	11. a summary in accordance with Article 5a of the product characteristics, one or more specimens or mock-ups of the sales presentation of the veterinary medicinal product together with a package insert (six words deleted).

Original Proposal	Amended Proposal
paragraphs 12 and 13 unchanged.	
a new paragraph 14 is inserted:	
	paragraph 14
	Medicinal products containing new active ingredients not included in Annexes I, II or III of the Regulation shall be accompanied by copies of the documents submitted to the Commission in accordance with Annex V of the Regulation.
Article 1(6) (Article 5a of Directive 81/851/EEC), paragraphs 1-4 unchanged.	
paragraph 5	paragraph 5
5. Clinical particulars	5. Clinical particulars
5.0 Target species 5.1 Therapeutic indications, specifying the target species	5.0 Target species 5.1 Therapeutic indications specifying the target species, diagnositic, preventative or other functions, in accordance with the product characteristics and, in general, any functional changes in the animal
rest of paragraph 5 and paragraph 6 unchanged.	
Articles 1 (7), (8), (9) and (10) unchanged.	
Article 1(11); Directive 81/851/EEC, Article 16, paragraphs 1-2 unchanged.	
paragraph 3	paragraph 3
3. The Committee shall draw up its own rules of procedure.	3. The Committee shall draw up its own rules of procedure.
	Membership of the Committee shall be made public. When each appointment is published, the professional qualifications of each member shall be specified, and his links, if any, with industrial or commercial undertakings.

Original Proposal	Amended proposal
	The Committee members may not hold financial or other interests in the pharmaceutical industry which could affect their impartiality. All indirect interests which could relate to this industry shall be entered in a register held at the Commission which the public may consult.

Article 1(11); Directive 81/851/EEC, Article 17, paragraphs 1 and 2 unchanged.

paragraph 3	paragraph 3
3. The holder of the marketing authorization shall notify the dates on which the dossiers were sent to the Member States concerned. As soon as the Committee has noted that all the Member States concerned are in possession of the dossier, it shall forthwith inform all the Member States and the applicant of the date on which the last Member States concerned received the dossier. The Member State(s) concerned shall either grant the authorization valid for their markets within a period of 120 days of the aforementioned date, taking into due consideration the authorization issued within the meaning of paragraph 1, or put forward a reasoned objection.	3. The holder of the marketing authorization shall notify to the Committee the dates on which the dossiers were sent to the Member States concerned. The Member States shall immediately inform the Committee and the person responsible for placing the product on the market that they have received the dossier. As soon as the Committee has noted that all the Member States concerned are in possession of the dossier, it shall forthwith inform all the Member States and the applicant of the date on which the last Member States concerned received the dossier. The Member State(s) concerned shall either grant the authorization valid for their markets within a period of 120 days of the aforementioned date, taking into due consideration the authorization issued within the meaning of paragraph 1, or put forward a reasoned objection.

Article 1(11); Directive 81/851/EEC, Article 18, paragraph 1 unchanged.

paragraph 2	paragraph 2
2. Upon the expiry of this period the matter shall be referred to the Committee and the procedure referred to in Article 21 shall be applied.	2. Upon the expiry of this period the matter shall be referred to the Committee and the procedure referred to in Articles 21 and 22 shall be applied.

paragraph 3 unchanged.

Original proposal	Amended Proposal
Article 1(11); Directive 81/851/EEC, Article 19	
paragraph 1	paragraph 1
If several applications submitted in accordance with Articles 5 and 5a have been made for a marketing authorization for a particular veterinary medicinal product, and one or more Member States have granted an authorization while one or more of the other Member States have refused it, one of the Member States concerned or the Commission may refer the matter to the Committee for application of the procedure referred to in Article 21.	If several applications submitted in accordance with Article 5 and 5a have been made for a marketing authorization for a particular veterinary medicinal product, and one or more Member States have granted an authorization while one or more of the other Member States have refused it, one of the Member States concerned the Commission or the person responsible for placing the product on the market may refer the matter to the Committee for application of the procedure referred to in Articles 21 and 22.
paragraphs 2 and 3 unchanged. Rest of Article 1(11) unchanged.	
Article 1 (12),(13),(14),(15),(16),(17),(18),(19) and (20) unchanged.	
Article 1(21)	Article 1(21)
In Article 48, the first paragraph is replaced by the following:	In Article 48, the first paragraph is replaced by the following:
"The inclusion of a package insert in the packaging of veterinary medicinal products shall be obligatory unless all the information required by this Article can be conveyed on the packaging itself. Member States shall take all appropriate measures to ensure that the information included on the package insert of a veterinary medicinal product relates solely to the veterinary medicinal product concerned."	"The inclusion of a package insert in the packaging of veterinary medicinal products shall be obligatory unless all the information required by this Article can be conveyed on the packaging itself. Member States shall take all appropriate measures to ensure that the information included on the package insert of a veterinary medicinal product relates solely to the veterinary medicinal product concerned. It shall be written in one of the languages of the Member State in which the medicinal product is marketed."

Original proposal	Amended proposal
Article 1 (22)-(23) unchanged.	
Article 1 (24); Directive 81/851/EEC, Article 51 unchanged. Article 52, paragraph 1 unchanged. Article 52, paragraph 2, subparagraphs (a)-(f) unchanged.	
Sub-paragraph (g)	Subparagraph (g)
(g) name and address of the prescribing veterinarian, if any, date of the prescription:	(g) name and address of the prescribing veterinarian, date of the prescription and the contents of the veterinary prescription;
Article 1 (24) rest unchanged.	
Article 1 (25) unchanged.	
Articles 2-3 unchanged.	

III. Proposal for a COUNCIL DIRECTIVE extending the scope of Directive 81/851/EEC on the approximation of the laws of the Member States relating to veterinary medicinal products and laying down additional provisions for immunological veterinary medicinal products

Original Proposal	Amended Proposal
Visas and recitals unchanged.	
Article 1, paragraphs 1 and 2, unchanged.	
Article 1(3)	Article 1(3)
This Directive and Directive 81/851/EEC shall not apply to autogenous vaccines which are manufactured from organisms found in discharges from the body of an animal and used for the treatment of the individual animal from which the organisms are derived.	This Directive and Directive 81/851/EEC shall not apply to inactivated immunological veterinary medicinal products which are manufactured from pathogens and antigens obtained from an animal or from a holding and used for the treatment of that animal or the animals of that holding in the same locality.
Rest unchanged.	