EUROPEAN PARLIAMENT

1999 *2004*

Session document

FINAL
A5-0444/2003

2 December 2003

***II
RECOMMENDATION FOR SECOND READING

on the common position adopted by the Council with a view to adopting a European Parliament and Council directive amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products
(10951/3/2003 – C5-0465/2003 – 2001/0254(COD))

Committee on the Environment, Public Health and Consumer Policy

Rapporteur: Françoise Grossetête

Symbols for procedures

*	Consultation procedure *majority of the votes cast*
**I	Cooperation procedure (first reading) *majority of the votes cast*
**II	Cooperation procedure (second reading) *majority of the votes cast, to approve the common position* *majority of Parliament's component Members, to reject or amend the common position*
***	Assent procedure *majority of Parliament's component Members except in cases covered by Articles 105, 107, 161 and 300 of the EC Treaty and Article 7 of the EU Treaty*
***I	Codecision procedure (first reading) *majority of the votes cast*
***II	Codecision procedure (second reading) *majority of the votes cast, to approve the common position* *majority of Parliament's component Members, to reject or amend the common position*
***III	Codecision procedure (third reading) *majority of the votes cast, to approve the joint text*

(The type of procedure depends on the legal basis proposed by the Commission)

Amendments to a legislative text

In amendments by Parliament, amended text is highlighted in ***bold italics***. Highlighting in *normal italics* is an indication for the relevant departments showing parts of the legislative text for which a correction is proposed, to assist preparation of the final text (for instance, obvious errors or omissions in a given language version). These suggested corrections are subject to the agreement of the departments concerned.

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PROCEDURAL PAGE

At its sitting of 23 October 2002 Parliament adopted its position at first reading on the proposal for a European Parliament and Council directive amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products (COM(2001) 404 – 2001/0254(COD)).

At the sitting of 9 October 2003 the President of Parliament announced that the common position had been received and referred to the Committee on the Environment, Public Health and Consumer Policy (10951/3/2003 – C5-0465/2003).

The committee had appointed Françoise Grossetête rapporteur at its meeting of 13 September 2001.

It considered the common position and the draft recommendation for second reading at its meetings of 3 November 2003, 26 November 2003 and 27 November 2003.

At the last meeting it adopted the draft legislative resolution by 49 votes to 0, with 6 abstentions.

The following were present for the vote: Caroline F. Jackson, (chairman), Mauro Nobilia, Alexander de Roo and Guido Sacconi (vice-chairmen), Françoise Grossetête (rapporteur) and María del Pilar Ayuso González, Juan José Bayona De Perogordo (for Martin Kastler pursuant to Rule 153(2)), Hans Blokland, Armonia Bordes (for Mihail Papayannakis), David Robert Bowe, John Bowis, Dorette Corbey, Raffaele Costa, Chris Davies, Véronique De Keyser (for Torben Lund), Avril Doyle, Säid El Khadraoui, Harald Ettl (for Yvonne Sandberg-Fries pursuant to Rule 153(2)), Anne Ferreira, Christel Fiebiger (for María Luisa Bergaz Conesa), Karl-Heinz Florenz, Pernille Frahm, Cristina García-Orcoyen Tormo, Robert Goodwill, Cristina Gutiérrez Cortines, Jutta D. Haug (for Karin Scheele), Marie-Thérèse Hermange (for Martin Callanan), Marie Anne Isler Béguin, Bashir Khanbhai (for Raquel Cardoso pursuant to Rule 153(2)), Peter Liese, Minerva Melpomeni Malliori, Patricia McKenna, Rosemarie Müller, Riitta Myller, Giuseppe Nisticò, Ria G.H.C. Oomen-Ruijten, Béatrice Patrie, Marit Paulsen, Frédérique Ries, Didier Rod (for Hiltrud Breyer), Dagmar Roth-Behrendt, Francisca Sauquillo Pérez del Arco (for Bernd Lange pursuant to Rule 153(2)), Ursula Schleicher, Horst Schnellhardt, Inger Schörling, Jonas Sjöstedt, María Sornosa Martínez, Dirk Sterckx (for Jules Maaten), Catherine Stihler, Robert William Sturdy, Nicole Thomas-Mauro, Astrid Thors, Antonios Trakatellis, Peder Wachtmeister and Phillip Whitehead.

The recommendation for second reading was tabled on 2 December 2003.

DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

on the common position adopted by the Council with a view to adopting a European Parliament and Council directive amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products
(10951/3/2003 – C5-0465/2003 – 2001/0254(COD))

(Codecision procedure: second reading)

The European Parliament,

– having regard to the Council common position (10951/3/2003 – C5-0465/2003),

– having regard to its position at first reading[1] on the Commission proposal to Parliament and the Council (COM(2001) 404)[2],

– having regard to the amended proposal (COM(2003) 163)[3],

– having regard to Article 251(2) of the EC Treaty,

– having regard to Rule 80 of its Rules of Procedure,

– having regard to the recommendation for second reading of the Committee on the Environment, Public Health and Consumer Policy (A5-0444/2003),

1. Amends the common position as follows;

2. Instructs its President to forward its position to the Council and Commission.

Council common position	Amendments by Parliament
Amendment 1 RECITAL 8	
(8) The veterinary medicinal products sector has a number of very specific features. Veterinary medicinal products for food-producing animals may be authorised only on conditions that guarantee that the foodstuffs produced will be harmless to consumers as regards any residues of such medicinal products.	(8) The veterinary medicinal products sector has a number of very specific features. Veterinary medicinal products for food-producing animals may be authorised only ***for therapeutic purposes and*** on conditions that guarantee that the foodstuffs produced will be harmless to consumers as regards any residues of such medicinal products.

[1] Texts adopted, 23 October 2002, P5 TA (2002) 0506
[2] OJ C 75 E, 26.3.2002, p. 234.
[3] Not yet published in OJ.

Justification

This amendment reinstates Amendment 2 adopted at first reading.

Amendment 2
RECITAL 17 a (new)

(17a) Despite the significant differences in the legal status of alternative therapies in the Member States, the freedom to choose a therapy, with the necessary guarantees as regards product quality, should be ensured.

Justification

Exact reinstatement of Amendment 64 adopted at first reading on 23 October 2002. Freedom to choose allopathic and homeopathic therapies must be guaranteed. This provision already figured in the original Directive 92/74/EEC and should be reinserted in Directive 2001/82/EC.

Amendment 3
RECITAL 21 a (new)

(21a) The Commission should investigate whether it is possible to develop a standardised environmental classification system for veterinary medicinal products and, if it finds a suitable model, it should submit a proposal to that effect to the European Parliament before May 2004.

Justification

This amendment reinstates Amendment 3 adopted at first reading.

Amendment 4
ARTICLE 1, POINT 1 (B)
Article 1, point 2 (b) (Directive 2001/82/EC)

(b) any substance or combination of substances which may be used in***, or administered to,*** animals with a view to making a medicinal diagnosis***,*** or to restoring, correcting or modifying physiological functions;	(b) any substance or combination of substances which may be used in animals with a view ***either*** to making a medicinal diagnosis ***or*** to restoring, correcting or modifying physiological functions ***by exerting a pharmacological action;***

Justification

The aim of the amendment is to align the definition of veterinary medicinal products with that of medicinal products for human use.

Amendment 5
ARTICLE 1, POINT 1
Article 1, points 19 and 19 a (new) (Directive 2001/82/EC)

(g) point 19 shall be replaced by the following:	***Point (19) is*** replaced by the following:
*'19. Risks **relating** to **the** use of the product:*	*'19. Risks **related** to use of the product:*
Any risk relating to the quality, safety ***or*** efficacy of the veterinary medicinal product as regards animal or human health***.'***;	**-** any risk relating to the quality, safety ***and*** efficacy of the veterinary medicinal products as regards animal or human health;
	- any risk of undesirable effects on the environment.
	19 a. Risk/benefit balance:
	An evaluation of the positive therapeutic effects of the veterinary medicinal product in relation to the risks as defined above."

Justification

Reinstating Amendment 5 from first reading. Veterinary medicinal products or their residues may, after excretion to the environment, have adverse effects. These effects might be necessary to accept if the veterinary medicinal product has a definite therapeutic value. However, the authorisation of a new veterinary medicinal product that has no therapeutic value beyond that of existing alternatives, but serious adverse environmental effects, should be possible to question. The adverse environmental effects of a new veterinary medicinal product can only be properly evaluated and accepted when balanced against its favourable therapeutic effects. Such an evaluation should be made by the pharmaceutical drug authority. A proper risk/benefit evaluation can only be made within the framework of pharmaceutical legislation. Environmental effects of veterinary medicinal products are not, and should not be, evaluated in other types of Community legislation.

Amendment 6
ARTICLE 1, POINT 1 (H)
Article 1, paragraph 22 (Directive 2001/82/EC)

22. Veterinary prescription:	22. Veterinary prescription:
Any prescription for a veterinary medicinal product issued by ***a professional person qualified to do so in accordance with***	Any prescription for a veterinary medicinal product issued ***in writing*** by ***an authorised member of the veterinary profession after a***

applicable national law.	***clinical examination of the animal(s) or of a representative sample of the group of animals involved or in accordance with good veterinary practice.***

Justification

This amendment reinstates Amendment 67 adopted at first reading.

Amendment 7
ARTICLE 1, POINT 1 (H)
Article 1, paragraph 29 a (new) (Directive 2001/82/EC)

	29a. Food-producing animals ***For the purpose of this Directive, food-producing animals are:*** ***(a) animals bred, raised, kept or slaughtered specifically for the purpose of producing food for human consumption, or*** ***(b) those animals, bred, raised and kept for sport and leisure purposes, from the time when they become destined for the food chain.***

Justification

This amendment reinstates Amendment 60 adopted at first reading.

Amendment 8
ARTICLE 1, POINT 2
Article 2, paragraph 2 (Directive 2001/82/EC)

2. ***In cases of doubt, where a product falls within the definition of 'veterinary medicinal product' this Directive shall apply, even in cases where the product also falls within the scope of other Community legislation.***	2. ***If, taking account of all its characteristics, a product falls within the definition both of 'medicinal product' and of a product governed by other Community legislative provisions, the provisions of this Directive shall apply.***

Justification

In order to avoid any difficulties arising from borderline products, this amendment seeks to ensure that one and the same product cannot be simultaneously governed by different legislative provisions. This amendment also reinstates the principle established through the

case law of the Court of Justice that a product may be either a pharmaceutical product or another type of product but not both simultaneously. Thus for the purposes of classifying a product it is appropriate to take account not only of the definition of a medicinal product but also of all the characteristics of the product (its composition, pharmacological properties, conditions of use, extent of its marketing, what consumers know about it and the risks involved in its use).

Amendment 9
ARTICLE 1, POINT 6
Article 11, paragraph 1 (Directive 2001/82/EC)

1. Member States shall take the necessary measures to ensure that, if there is no authorised veterinary medicinal product in a Member State for a condition affecting a food-producing species, by way of exception, the veterinarian responsible may, under his direct personal responsibility and in particular to avoid causing unacceptable suffering, treat the animals concerned on a particular holding with:	1. Member States shall take the necessary measures to ensure that, if there is no ***effective*** authorised veterinary medicinal product in a Member State for a condition affecting a food-producing species, by way of exception, the veterinarian responsible may, under his*/her* direct personal responsibility and in particular to avoid causing unacceptable suffering, treat the animals concerned on a particular holding with:

Justification

There will inevitably be cases where an authorised product may be available but not effective for the treatment of a disease, and where the practitioner may have to have recourse to the cascade. A typical example could be that the only authorised antibiotic for a species would prove to be inefficient because of resistance problems and that the practitioner would then have to use an antibiotic licensed for another species.

Amendment 10
ARTICLE 1, POINT 6
Article 11, paragraph 2 (Directive 2001/82/EC)

2. Paragraph 1 shall apply provided that pharmacologically active substances included in the medicinal product are listed in Annex I, II or III to Regulation (EEC) No 2377/90, and that the veterinarian specifies an appropriate withdrawal period.	2. Paragraph 1 shall apply provided that pharmacologically active substances included in the medicinal product are listed in Annex I, II or III to Regulation (EEC) No 2377/90, and that the veterinarian specifies an appropriate withdrawal period. ***However, where no such substances exist but good veterinary practice recognises that treatment with substances not included in the Annexes of Regulation (EEC) No 2377/90 is indicated, the veterinarian***

	responsible may, in exceptional circumstances, such as to avoid animal suffering, treat an animal or a limited number of animals on a particular holding with such substances provided that he/she specifies an appropriate withdrawal period.
Unless the medicinal product used indicates a withdrawal period for the species concerned, the specified withdrawal period shall not be less than: – 7 days for eggs, – 7 days for milk, – 28 days for meat from poultry and mammals including fat and offal, – 500 degree-days for fish meat. However, these specific withdrawal periods may be modified in accordance with the procedure referred to in Article 89(2).	Unless the medicinal product used indicates a withdrawal period for the species concerned, the specified withdrawal period shall not be less than: – 7 days for eggs, – 7 days for milk, – 28 days for meat from poultry and mammals including fat and offal, – 500 degree-days for fish meat. However, these specific withdrawal periods may be modified in accordance with the procedure referred to in Article 89(2).

Justification

Amendment 59 to Article 11(2)(1)a (new) adopted at first reading on 23 October 2002 is reinstated.

Amendment 11
ARTICLE 1, POINT 6
Article 11, paragraph 2 a (new) (Directive 2001/82/EC)

	2a. With regard to homeopathic veterinary medicinal products in which the level of active principles figures in Annex II to Regulation (EEC) No 2377/90, the withdrawal period referred to in the second subparagraph of paragraph 2 shall be reduced to zero.

Justification

This amendment reinstates and reformulates (in accordance with the initial Commission proposal) Amendment 13 adopted at first reading.

Amendment 12
ARTICLE 1, POINT 6
Article 12, paragraph 3, point (j) (Directive 2001/82/EC)

Point (j) is replaced by the following:

- tests assessing the potential risks posed by the medicinal product for the environment,

Justification

Reinstating Amendment 68 from first reading. Since drugs are excreted by the user into public waste systems they reach the environment, often in biologically active form. To make a proper risk/benefit assessment, pharmaceutical drugs authorities need to have information on the results of risk assessment tests of the product they evaluate.

Amendment 13
ARTICLE 1, POINT 8
Article 10, paragraph 2, point (b) (Directive 2001/82/EC)

(b) ′generic medicinal product′ shall mean a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies. The different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance shall be considered to be the same active substance, unless they differ significantly in properties with regard to safety and/or efficacy. The various immediate-release oral pharmaceutical forms shall be considered to be one and the same pharmaceutical form. Bioavailability studies need not be required of the applicant if he can demonstrate that the generic medicinal product meets the relevant criteria as defined in the appropriate detailed guidelines.	(b) ′generic medicinal product′ shall mean a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies. The different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance shall be considered to be the same active substance, unless they differ significantly in properties with regard to safety and/or efficacy. ***In such cases, additional information providing proof of the safety and efficacy of the various salts, esters or derivatives of an authorised active substance must be supplied by the applicant.*** The various immediate-release oral pharmaceutical forms shall be considered to be one and the same pharmaceutical form. Bioavailability studies need not be required of the applicant if he can demonstrate that the generic medicinal product meets the relevant criteria as defined in the appropriate detailed guidelines.

Amendment 14
ARTICLE 1, POINT 8
Article 10, paragraph 4 (Directive 2001/82/EC)

4. Where a biological medicinal product which is similar to a reference biological product does not meet ***certain*** conditions in the definition of generic medicinal products, owing to, in particular, differences in manufacturing processes of the biological medicinal product and the reference biological medicinal product, the results of appropriate pre-clinical tests or clinical trials relating to these conditions must be provided. The results of other tests and trials from the reference medicinal product's dossier shall not be provided.	4. Where a biological medicinal product which is similar to a reference biological product does not meet ***the*** conditions in the definition of generic medicinal products, owing to, in particular, differences ***relating to raw materials or*** in manufacturing processes of the biological medicinal product and the reference biological medicinal product, the results of appropriate pre-clinical tests or clinical trials relating to these conditions must be provided. ***The type and quantity of supplementary data to be provided must comply with the relevant criteria stated in Annex I.*** The results of other tests and trials from the reference medicinal product's dossier shall not be provided.

Amendment 15
ARTICLE 1, POINT 6
Article 13, paragraph 5, subparagraph 1 (Directive 2001/82/EC)

5. In the case of veterinary medicinal products intended for one or more food-producing species and containing a new active substance that has not been authorised in the Community by … * the ten-year period provided for in the second subparagraph of paragraph 1 shall be extended by one year for each extension of the marketing authorisation to another food-producing species, if it is authorised within the five years following the granting of the initial marketing authorisation	5. In the case of veterinary medicinal products intended for one or more food-producing species and containing a new active substance that has not been authorised in the Community by … * the ten-year period provided for in the second subparagraph of paragraph 1 shall be extended by one year for each extension of the marketing authorisation to another food-producing species ***or to one or more significant new therapeutic indications***, if it is authorised within the five years following the granting of the initial marketing authorisation.

Justification

Reinstates part of Amendment 18 at first reading, adopted on 23 October 2002.

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* The date of the entry into force of this Directive.

* The date of the entry into force of this Directive.

Amendment 16
ARTICLE 1, POINT 6
Article 13, paragraph 5 (Directive 2001/82/EC)

5. In the case of veterinary medicinal products intended for one or more ***food-producing*** species and containing a new active substance that has not been authorised in the Community by ... the ten-year period provided for in the second subparagraph of paragraph 1 shall be extended by one year for each extension of the marketing authorisation to another ***food-producing*** species, if it is authorised within the five years following the granting of the initial marketing authorisation.	5. In the case of veterinary medicinal products intended for one or more species and containing a new active substance that has not been authorised in the Community by ... the ten-year period provided for in the second subparagraph of paragraph 1 shall be extended by one year for each extension of the marketing authorisation to another species, if it is authorised within the five years following the granting of the initial marketing authorisation.
This period shall not, however, exceed a total of 13 years, for a marketing authorisation for four or more ***food-producing*** species***.***	This period shall not, however, exceed a total of 13 years, for a marketing authorisation for four or more species.
The extension of the ten-year period to 11, 12, or 13 years for a veterinary medicinal product intended for food-producing species shall be granted only if the marketing authorisation holder also originally applied for determination of the maximum residue limits established for the species covered by the authorisation.	The extension of the ten-year period to 11, 12, or 13 years for a veterinary medicinal product intended for food-producing species shall be granted only if the marketing authorisation holder also originally applied for determination of the maximum residue limits established for the species covered by the authorisation.

Justification

New data is also needed for extending products to companion animals or to new diseases in the same food-producing animal and should also be protected. Developing this data and registration may take more than five years.

Amendment 17
ARTICLE 1, POINT 6
Article 13, paragraph 5, subparagraph 1 a (new) (Directive 2001/82/EC)

	'Significant new therapeutic indications are those which, during the scientific evaluation prior to their authorisation, are held to bring a significant clinical benefit in comparison with existing therapies.'

Justification

Reinstates part of Amendment 18 at first reading, adopted on 23 October 2002.

Amendment 18
ARTICLE 1, POINT 6
Article 13, paragraph 6 (Directive 2001/82/EC)

6. Conducting the necessary studies, tests and trials with a view to the application of paragraphs 1 ***to 5*** to a generic medicinal product and the consequential practical requirements shall not be regarded as contrary to patent-related rights or to supplementary-protection certificates for those medicinal products.***'***;	6. Conducting the necessary studies, tests and trials with a view to the application of paragraphs 1***, 2 and 3*** to a generic medicinal product ***and 4 to a biosimilar medicinal product*** and the consequential practical requirements ***relating to these provisions, as well as for export,*** shall not be regarded as contrary to patent-related rights or to supplementary-protection certificates for those medicinal products.***'***;

Justification

Amendment to ensure consistency with the amendment to Article 10(5) of the directive on medicinal products for human use.

Amendment 19
ARTICLE 1, POINT 8
Article 16, paragraph 1 (Directive 2001/82/EC)

1. Member States shall ensure that homeopathic veterinary medicinal products manufactured and placed on the market within the Community are registered or authorised in accordance with Articles 17, 18 and 19, except where such veterinary medicinal products are covered by a registration or authorisation granted in accordance with national legislation on or before 31 December 1993.	1. Member States shall ensure that homeopathic veterinary medicinal products manufactured and placed on the market within the Community are registered or authorised in accordance with Articles 17, 18 and 19, except where such veterinary medicinal products are covered by a registration or authorisation granted in accordance with national legislation on or before 31 December 1993. ***Each Member State shall take due account of the registrations effected and of the authorisations issued by other Member States.***

Justification

This amendment reinstates Amendment 21 adopted at first reading.

Amendment 20
ARTICLE 1, POINT 9
Article 17, paragraph 1, point (c) (Directive 2001/82/EC)

(c) there is a sufficient degree of dilution to guarantee the safety of the medicinal product. In particular, the medicinal product shall not contain more than one part per 10 000 of the mother tincture.	(c) there is a sufficient degree of dilution to guarantee the safety of the medicinal product. In particular, the medicinal product shall 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.***

Justification

This amendment reinstates Amendment 22 adopted at first reading.

Amendment 21
ARTICLE 1, POINT 12
Article 21, paragraph 1, subparagraph 1 (Directive 2001/82/EC)

1. Member States shall take all appropriate measures to ensure that the procedure for granting a marketing authorisation for a veterinary medicinal product is completed within ***210*** days after the submission of a valid application.	1. Member States shall take all appropriate measures to ensure that the procedure for granting a marketing authorisation for a veterinary medicinal product is completed within ***150*** days after the submission of a valid application, ***including 80 days for the analysis of the scientific data and the drawing up of the assessment report by the rapporteur.***

Justification

Reinstates the Commission's proposal to shorten the time limits.

Amendment 22
ARTICLE 1, POINT 17
Article 28, paragraph 2 (Directive 2001/82/EC)

2. The authorisation may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance.	2. The authorisation may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance.

To this end, the marketing authorisation holder shall submit a consolidated ***version of the file*** in respect of quality, safety and efficacy, including all variations introduced since the marketing authorisation was granted, at least six months before the marketing authorisation ceases to be valid in accordance with paragraph 1.	To this end, the marketing authorisation holder shall submit a consolidated ***list of all documents submitted*** in respect of quality, safety and efficacy, including all variations introduced since the marketing authorisation was granted, at least six months before the marketing authorisation ceases to be valid in accordance with paragraph 1.

Justification

Wherever possible, bureaucracy should be reduced. In the case of the authorisation procedure it does not seem desirable to expend energy on consolidating a file in a case where an overview of changes and of information already submitted will ensure clarity, safety and certainty.

Amendment 23
ARTICLE 1, POINT 20
Article 34, paragraph 1 (Directive 2001/82/EC)

1. If two or more applications submitted in accordance with Articles 12 to 14 have been made for marketing authorisation for a particular veterinary medicinal product and Member States have adopted divergent decisions concerning the authorisation of that veterinary medicinal product, or suspension or revocation of authorisation, a Member State, or the Commission, or the marketing-authorisation holder ***may*** refer the matter to the Committee for Medicinal Products for Veterinary Use, hereinafter referred to as ″the Committee″, for the application of the procedure laid down in Articles 36, 37 and 38.	1. If two or more applications submitted in accordance with Articles 12 to 14 have been made for marketing authorisation for a particular veterinary medicinal product and Member States have adopted divergent decisions concerning the authorisation of that veterinary medicinal product, or suspension or revocation of authorisation, a Member State, or the Commission, or the marketing-authorisation holder ***shall*** refer the matter to the Committee for Medicinal Products for Veterinary Use, hereinafter referred to as ″the Committee″, for the application of the procedure laid down in Articles 36, 37 and 38.

Justification

This amendment reinstates Amendment 30 adopted at first reading.

Amendment 24
ARTICLE 1, POINT 32 (a) (ii a) (new)
Article 58, paragraph 1, point (f) (Directive 2001/82 EC)

	(ii a) Point (f) shall be replaced by the

following text:

'(f) The species of animal for which the veterinary medicinal product is intended; the method and route of administration. Space must be provided for a pharmacist to indicate the prescribed dose for the animal concerned;'

Justification

Amendment 37 to the introductory sentence to Article 58(1), adopted at first reading on 23 October 2002.

Amendment 25
ARTICLE 1, POINT 32
Article 58, paragraph 1, point (j) (Directive 2001/82/EC)

Point (j) is replaced by the following:

'(j) specific precautions relating to the disposal of unused medicinal products or waste derived from medicinal products, where appropriate. Unused medicinal products must be returned to the point of purchase. Not to be disposed of with other waste."

Justification

Reinstating Amendment 38 from first reading. This provision seeks to avoid a situation where unused medicinal products are disposed of along with other waste and where their active substances are discharged, for example, into soil or water.

Amendment 26
ARTICLE 1, POINT 37 (a)
Article 64, paragraph 2 (Directive 2001/82/EC)

′2. In addition to the clear mention of the words ′homeopathic veterinary medicinal product without ***approved*** therapeutic indications′, the labelling and, where appropriate, package leaflet for the homeopathic veterinary medicinal products referred to in Article 17(1) shall bear the following information and no other information:′;	′2. In addition to the clear mention of the words ′homeopathic veterinary medicinal product without therapeutic indications′, the labelling and, where appropriate, package leaflet for the homeopathic veterinary medicinal products referred to in Article 17(1) shall bear the following information and no other information:′;

Justification

This amendment concerns a new formulation by the Council.

Amendment 27
ARTICLE 1, POINT 41
Article 67, paragraph 1, point (aa) (Directive 2001/82/EC)

(aa) veterinary medicinal products for food-producing animals,	(aa) veterinary medicinal products for food-producing animals, ***except in Member States which permit on their territory the dispensing of those products by, or under the supervision of, a person registered for the purpose in accordance with national legislation. The Member States shall notify this arrangement to the Agency.***

Justification

Reinstates Amendment 43 (Consolidated Amendment 3 in the name of EPP-ED and PSE) of First Reading, adopted on 23 October 2002 and accepted in principle by Commissioner Liikanen. Where Member States have existing legislation controlling the sale and supply of certain medicines for food-producing animals through a non-prescription route which guarantees food safety and traceability, such Member States should be allowed to continue to operate those systems. In the absence of a harmonised definition of 'veterinary prescription' and in the absence of a harmonised definition of a 'veterinary medicine', subsidiarity must prevail.

It is inappropriate to force a Member State which regards a vitamin supplement as a veterinary medicine to reclassify it as a prescription-only medicine (POM) necessitating a clinical examination of the animal by a veterinary surgeon. Another Member State may not regard the same material as a 'medicine' and in others, the concept of a 'prescription' may not require a clinical examination of the animal by a veterinary surgeon. These definitions would need to be harmonised to avoid a serious distortion of competition in the Single Market.

The idea of developing a 'list' of exempted medicines of the Common Position will not work, as correspondence from the Commission confirms that any such list will contain very few products. The effect will be to destroy the safe and effective non-prescription distribution routes that currently exist in Member States such as Ireland, the Netherlands and the UK as it is anticipated that the 'list' will not contain internal parasiticides, external parasiticides or routine vaccines.

Amendment 28
ARTICLE 1, POINT 41 (b)
Article 67, paragraph 2, subparagraph 2 (Directive 2001/82/EC)

In addition, a prescription shall be required for new veterinary medicinal products containing an active substance which has been authorised for use in a veterinary medicinal product for fewer than ***five years.***	In addition, a prescription shall be required for new veterinary medicinal products containing an active substance which has been authorised for use in a veterinary medicinal product for fewer than ***four years unless, having regard to the information and particulars provided by the applicant, or experience acquired in the practical use of the veterinary medicinal product, the competent authorities are satisfied that none of the criteria referred to in points (a) to (d) of the first paragraph apply***.

Justification

Reinstates Amendment 44 of First Reading, adopted on 23 October 2002. This amendment complements Amendment 43. Where Member States operate non-prescription distribution routes, it is essential that the licensing authorities have the discretion to assign products to a non-prescription route based on their professional assessment of the product. As an example, it may be appropriate to assign a new teat dip to a non-prescription route at the point of licensing. In order to stimulate innovation and competition, this discretion is appropriate. Indeed, it may be essential in order to allow a new entrant to the market to compete on equal terms with existing products.

The four-year period represents the end of the intense in-use monitoring (pharmacovigilance) period for a new product (Article 75(5)) and therefore represents a more logical time-point.

Amendment 29
ARTICLE 1, POINT 46 (a) (new)
Article 73 a (new) (Directive 2001/82/EC)

46a. The following Article 73a shall be inserted:

Article 73a

'In order to guarantee the total independence of the competent authorities, at least the activities connected with pharmacovigilance, the operation of communication networks and market surveillance shall receive public funding commensurate with the tasks conferred upon such authorities.'

Justification

Reinstates Amendment 45 at first reading, adopted on 23 October 2002.

Amendment 30
ARTICLE 1, POINT 52
Article 80, paragraph 1, subparagraph 1 (Directive 2001/82/EC)

′1. The competent authority of the Member State concerned shall ensure, by means of repeated inspections and, if necessary, unannounced inspections, that the legal requirements relating to veterinary medicinal products are complied with.	′1. The competent authority of the Member State concerned shall ensure, by means of repeated inspections and, if necessary, unannounced inspections, ***and also, if necessary, by asking an official laboratory for the control of medicinal products or a laboratory designated for this purpose to conduct tests on samples,*** that the legal requirements relating to veterinary medicinal products are complied with.

Justification

The aim of this amendment is to coordinate the set of measures connected with the legislation on pharmaceutical products. See Article 57 of the Regulation laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products.

Amendment 31
ARTICLE 1, POINT 52
Article 80, paragraph 1, point (b) (Directive 2001/82/EC)

(b) take samples***;***	b) take samples ***with a view to an independent analysis by an official laboratory for the control of medicinal products or by a laboratory designated for this purpose by a Member State.***

Justification

The aim of this amendment is to coordinate the set of measures connected with the legislation on pharmaceutical products. See Article 57 of the Regulation laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products.

Amendment 32
ARTICLE 1, POINT 54 (A) (ii)
Article 83, paragraph 1, point (a) a (new) (Directive 2001/82/EC)

	'(aa)The analysis of the risk/benefit balance shall be considered a first stage in the study of the relative and/or actual efficacy of a veterinary medicinal product.'

Justification

This amendment reinstates Amendment 47 adopted at first reading.

Amendment 33
ARTICLE 1, POINT 60 a (NEW)
Article 95 a (new) (Directive 2001/82/EC)

	The following Article 95 a shall be inserted:
	'Article 95 a
	Member States shall have an obligation to ensure that unused medicinal products or waste and packagings from used veterinary medicinal products are delivered to the collection systems which exist in the Member States. In Member States which do

not have appropriate collection systems, unused veterinary medicinal products shall be returned to the point of purchase.'

Justification

Reinstates the gist of part of Amendment 38 to Article 58(1)(j) adopted at first reading on 23 October 2002.

EXPLANATORY STATEMENT

Medicines are not like other products. They are not sold or consumed in the way ordinary, everyday products are sold and consumed. Their use is unique, and everyone expects their medicine to be safe and effective.

It is possible to find an optimum balance between competitiveness, research, health system requirements and the development of generic medicines. This, at any rate, is the main aim here.

While the Council appears to have abided by this balance which Parliament sought to achieve at first reading, there remain major differences of opinion on key issues.

The definition of the term medicinal product must not allow for any confusion with what are known as 'borderline products'. The rapporteur therefore wishes to clarify this definition and intends to put forward proposals regarding the definition of the terms generic medicinal product and biogeneric medicinal product.

Research and development also help to lay the foundations for health protection. We all know that innovation comes at a price. It is therefore our duty to prevent European industry from being relegated to the second division in the global league and from trailing behind the United States and Asia, as that would be a disaster for Europe. This is why the amendment on data protection adopted at first reading has been retabled.

Other issues such as the duration of testing or making public monies available for pharmacovigilance work are important matters on which Parliament has already given its opinion.