COMMISSION OF THE EUROPEAN COMMUNITIES

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Amended proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Directive 2001/83/EC on the Community code relating to medicinal products for human use

Amended proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products

(presented by the Commission pursuant to Article 250 (2) of the EC Treaty)

2001/0253 (COD)

Amended proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Directive 2001/83/EC on the Community code relating to medicinal products for human use

(Text with EEA relevance)

1. BACKGROUND

Proposal sent to the Council and Parliament COM(2001) 404 final -2001/0253(COD)under Article 175(1) of the EC Treaty:	26 November 2001
Opinion of the European Economic and Social Committee:	18 September 2002
Position of the European Parliament - first reading:	23 October 2002

2. OBJECTIVE OF THE COMMISSION PROPOSAL

Regulation 2309/93 makes provision for the evaluation of the Community procedures for the authorisation and supervision of medicinal products which entered into force in 1995. In the light of the experience acquired from 1995 to 2000, and the Commission's analysis in its report "on the operation of the procedures for granting marketing authorisations for medicinal products" (COM (2001) 606 final, 23.10.2001), it appeared necessary to adapt Regulation 2309/93 and Directives 2001/83/EC and 2001/82/EC on the Community code relating to medicinal products for human use and for veterinary use.

Generally speaking, four main objectives are particularly relevant:

(1) to guarantee a high level of public health protection, particularly by providing patients, as swiftly as possible, with innovative and reliable products and by increasing market surveillance by reinforcing monitoring and pharmacovigilance procedures;

(2) to complete the internal market in pharmaceutical products while taking account of the implications of globalisation, and to establish a regulatory and legislative framework that favours the competitiveness of the European pharmaceuticals sector;

(3) to meet the challenges of the future enlargement of the European Union;

(4) to rationalise and simplify the system, thus improving its overall consistency and visibility, and the transparency of procedures.

Lastly, with regard to veterinary medicinal products, the proposals intend to specifically address the problem of availability of such medicinal products.

3. COMMISSION OPINION ON PARLIAMENT'S AMENDMENTS

3.1. Amendments accepted by the Commission: 2, 13, 24, 25, 33, 35, 42, 43, 44, 47, 48, 50, 57, 58, 61, 67, 68, 70, 82, 83, 84, 88, 89, 93, 97, 110, 120 (first part), 125, 130 and 158.

The Commission can accept the following amendments with the wording proposed by the European Parliament.

– Amendment 2, which introduces into recital 2 the reference to a "safe" movement of medicinal products:

"Recital 2:

*Community legislation is a major milestone in the achievement of the objective of the free **and safe** movement of medicinal products for human use and the elimination of obstacles to trade in such products. However, in the light of the experience acquired, new measures have proved necessary to eliminate the remaining obstacles to free movement*."

– Amendment 13, that deletes in the definition of "radionuclide kit" the word "radionuclide". To maintain coherence with certain provisions of the Directive, it is necessary to align the provisions of Article 6(2) and of Article 7:

"Title of Article 1, point 8:

8) Kit.

Article 6(2):

*2. The authorisation referred to in paragraph 1 shall also be required for radionuclide generators, **kits**, radionuclide precursor radiopharmaceuticals and industrially prepared radiopharmaceuticals.*

"Article 7:

*A marketing authorisation shall not be required for a radiopharmaceutical prepared at the time of use by a person or by an establishment authorised, according to national legislation, to use such medicinal products in an approved health care establishment exclusively from authorised radionuclide generators, **kits** or radionuclide precursors in accordance with the manufacturer's instructions."*

– Amendment 24 reinforcing the means to respond to the threat of bioterrorist attacks:

"Article 5

***1.** Without prejudice to Regulation [(EEC) No 2309/93], a Member State may, in accordance with legislation in force and to fulfil special needs, exclude from the provisions of this Directive medicinal products supplied in response to a bona fide unsolicited order, formulated in accordance with the specifications of an authorised health care professional and for use by **an individual patient** under his direct personal responsibility.*

2. Member States may temporarily authorise the distribution of an unauthorised medicinal product in response to the suspected or confirmed spread of a pathogen which could cause harm.

Without prejudice to paragraph 1, Member States must lay down provisions removing criminal, civil and administrative liability from marketing authorisation holders, manufacturers and health professionals for any consequences resulting from the use of a medicinal product other than for the authorised indications or from the use of an unauthorised medicinal product, when such use is recommended by a competent authority in response to the suspected or confirmed spread of pathogenic agents which could cause harm. Such provisions shall apply whether or not national or Community authorisation has been issued."

– Amendment 25 regarding the documents to be submitted by the applicant on the constituents of the medicinal product:

"Article 8(3)(c):

*c) Qualitative and quantitative particulars of all the constituents of the medicinal product**, including the reference to its international non-proprietary name (INN) recognised by the WHO, where an INN for the medicinal product exists, or a reference to the relevant chemical name**;"*

– Amendment 33, according to which an applicant has to submit documents to proof that he/she will be able to meet certain pharmacovigilance obligations:

"Article 8(3)(n):

n) Proof that the applicant has the services of a qualified person responsible for pharmacovigilance and has equipment for the notification of any adverse reaction suspected of occurring either in the Community or in a third country."

– Amendment 35 that clarifies that the data protection period of 11 years constitutes the maximum time:

"Article 10(1), second subparagraph:

*The ten-year period referred to in the first subparagraph shall be extended to **a maximum** of eleven years if, during the first eight years of those ten years, the marketing authorisation holder obtains an authorisation for one or more new therapeutic indications which, during the scientific evaluation prior to their authorisation, are held to bring a significant clinical benefit in comparison with existing therapies."*

– Amendment 42, according to which the summary of the product characteristics shall contain certain information in the prescribed order:

"Article 11, introductory sentence:

*The summary of the product characteristics shall contain**, in the order indicated below,** the following information:*."

– Amendment 43, that reintroduces "major incompatibilities" into the summary of the product characteristics in the section on pharmaceutical particulars:

"Article 11(6), point 6.1a:

6.1a major incompatibilities."

– Amendment 44, that reintroduces a provision according to which homeopathic products authorised or registered before December 1993 do not need to be updated according to the new legislation:

"Article 13(1):

1. Member States shall ensure that homeopathic medicinal products manufactured and placed on the market within the Community are registered or authorised in accordance with Articles 14, 15 and 16, except where such medicinal products are covered by a registration or authorisation issued in accordance with national legislation up to 31 December 1993. ***Each Member State shall take due account of the registrations and authorisations issued by other Member States.***"

– Amendment 47 on the dossier to be submitted for a simplified registration of a homeopathic medicinal product:

"Article 15, second indent:

- dossier describing how the homeopathic stock or stocks is/are obtained and controlled, and justifying its/their ***homeopathic use,*** *on the basis of an adequate bibliography,*"

– Amendment 48 on certain particulars to be submitted in an application for simplified registration of a homeopathic medicinal product. It is acceptable to delete the reference to the method of dilution.

"Article 15, third indent:

- manufacturing and control file for each pharmaceutical form and a description of the method of ***potentisation****,"*

– Amendment 50, introducing a correction in the reference to Article 8(3):

"Article 18

Where a Member State is informed in accordance with point ***(l)*** *of Article 8(3) that another Member State has authorised a medicinal product which is the subject of a marketing authorisation application in the Member State concerned, it shall reject the application unless it has been submitted in compliance with Articles 27 to 39.*"

– Amendments 57 and 58 on the invalidity of a marketing authorisation where the authorised product is not effectively marketed:

"Article 24(2) and (3):

2. Any authorisation which is not followed within ***three years*** *of its issue by the actual placing on the market of the authorised product in the authorising Member State shall cease to be valid.*

The competent authority may, in exceptional circumstances and on public health grounds, grant a derogation from the provisions of the previous subparagraph. The derogation shall be duly justified.

3. When an authorised product previously placed on the market in the authorising Member State is no longer actually present on the market for a period of ***three*** *consecutive years, the authorisation for that product shall cease to be valid.*

The competent authority may, in exceptional circumstances and on public health grounds, grant a derogation from the provisions of the previous subparagraph. The derogation shall be duly justified."

– Amendment 61 according to which the rules of procedure of the co-ordination group are to be made public:

"Article 27(3):

3. The coordination group shall draw up, its own Rules of Procedure, which shall enter into force after a favourable opinion of the Commission. ***These Rules of Procedure shall be made public.***"

– Amendment 67, which is intended to ensure that the Committee appoints a rapporteur when the arbitration procedures are examined:

"Article 32(2):

2. In order to consider the matter, the Committee ***shall appoint*** *one of its members to act as the rapporteur. The Committee may also appoint individual experts to advise it on specific questions. When appointing experts, the Committee shall define their tasks and specify the time-limit for the completion of these tasks."*

– Amendment 68 according to which the committee shall specify the time limit for explanations by the applicant:

"Article 32(3), first subparagraph:

3. Before issuing its opinion, the Committee shall provide the applicant or the marketing authorisation holder with an opportunity to present written or oral explanations ***within a time-limit which it shall specify***."

– Amendment 70 which reduces the time limit for the Commission to prepare a draft decision from 30 to 15 days:

"Article 33, first subparagraph:

Within ***15*** *days of the receipt of the opinion the Commission shall prepare a draft of the decision to be taken in respect of the application, taking into account Community law****.***"

– Amendment 82 including into the package leaflet a specific invitation to consult health-care professionals in certain situations:

"Article 59(1)(e), indent (viii):

viii) a specific invitation to consult the doctor or the pharmacist, as appropriate, for any clarification on the use of the product;"

– Amendment 83 which adds the manufacturer's contact details to the information which must be included in the package leaflet:

"Article 59(1)(f), indent via):

via) the name and address of the manufacturer;"

– Amendment 84 on an assessment of the legibility and clarity of package leaflets:

"Article 59(3):

3. The legibility, clarity and ease of use for patients of the package leaflet shall be assessed in consultation with target patient groups."

– Amendment 88 on information on the manufacturer of a vial:

"Article 66(3), fourth indent:

*- the name **and address** of the manufacturer**,***"

– Amendment 89 on the labelling of homeopathic medicinal products:

"Article 68

*Without prejudice to the provisions of Article 69, homeopathic medicinal products shall be labelled in accordance with the provisions of this title and shall be identified by a reference on their labels, in clear and legible form, to their **potentised nature.***"

– Amendment 93 changing the heading of Title VII:

"Title VII:

Wholesale distribution of medicinal products "

– Amendment 97 which extends the application of Title VII to all homeopathic medicinal products by deleting the words "with the exception of those referred to in Article 14(1)":

"Article 85

The provision of this Title shall apply to homeopathic medicinal products."

– Amendment 110 on clarifying the notion of advertising in the context of professional and scientific meetings:

"Article 95

The provisions of Article 94(1) shall not prevent hospitality being offered, directly or indirectly, at events for purely professional and scientific purposes; such hospitality shall

*always be **strictly limited** to the main scientific objective of the meeting; it must not be extended to persons other than health professionals.*"

– The first part of amendment 120 clarifying how to calculate when the periodic safety update reports have to be presented:

"Article 104(6):

6, Unless other requirements have been laid down as a condition of the granting of authorisation, or subsequently as indicated in the guidelines referred to in Article 106(1), reports of all adverse reactions shall be submitted to the competent authorities in the form of a periodic safety update report, either immediately upon request or periodically as follows: six monthly for the first two years after ***the medicinal product was first placed on the market***, annually for the subsequent two years, and thereafter at three-yearly intervals. The periodic safety update reports shall include a scientific evaluation of the benefits and risks of the medicinal product."

– Amendment 125 on the possibility of unannounced inspections by the competent authorities:

"Article 111(1), second subparagraph:

The competent authority may ***also*** carry out ***unannounced*** inspections at the premises of manufacturers of active substances used as starting materials, or at the premises of marketing authorisation holders whenever it considers that there are serious grounds for suspecting non-compliance with the principles and guidelines of good management practice referred to in Article 47. These inspections may also be carried out at the request of a Member State, the Commission or the Agency."

– Amendment 130 according to which the Rules of Procedure of the Standing Committee shall be made publicy:

"Article 121(5):

*5. The Standing Committee shall adopt its own rules of procedure**, which shall be made public***."

– Amendment 158 according to which in the name of a homeopathic medicinal product, the scientific names can be supplemented, but not be replaced by an invented name:

"Article 69(1), 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(5); if the homeopathic medicinal product is composed of two or more stocks, the scientific names of the stocks on the labelling may be **supplemented** by an invented name."*

3.2. **Amendments accepted in part or principle by the Commission: 3, 5, 8, 11, 12, 14, 15, 18, 27, 30, 31, 32, 36, 46 (first part), 51, 52, 53 (first part), 55, 60, 63, 66, 69, 71 (second part), 80, 85, 86, 91, 92 (second part), 94, 95, 98, 99, 104, 106, 108, 114, 116 (first part), 121, 122, 140, 151, 156, 159, 167, 168, 185, 186 and 191**.

The Commission can accept in principle the following amendments:

– Amendment 3 introducing into recital 3 a reference to the high level of public health protection:

"Recital 3:

*It is therefore necessary to align the national laws, regulations and administrative provisions which contain differences with regard to the basic principles in order to promote the operation of the internal market****, while realising a high level of human health protection****."*

– Amendments 5 and 32 on the necessity to fulfil the relevant ethical criteria for all clinical trials submitted for a new medicinal product. Bearing in mind that these criteria have already been made obligatory by Directive 2001/20/EC, a similar provision in Directive 2001/83/EC is redundant. However, a recital can be introduced to refer to these ethical criteria:

"Recital 10a:

There is a need to provide for the ethical requirements of Directive 2001/20/EC of the European Parliament and the Council on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use to apply to all medicinal products authorised within the Community. In particular, with respect to clinical trials conducted outside the Community on medicinal products destined to be authorised within the Community, at the time of the evaluation of the application for authorisation, it will be verified that these trials were conducted respecting the principles of good clinical practice and the ethical requirements equivalent to the provisions of this Directive."

– Amendments 8 and 140 introduce a recital to justify the proposed provision to allow patients to obtain information on certain prescription medicinal products with regard to three illnesses. Rewording is required to ensure consistency with *Recital 16*, already proposed by the Commission, which relates to this same provision:

"Recital 16:

As part of the proper use of medicinal products, the rules on packaging should be adapted to take account of the experience acquired.

Recital 16a:

Patients legitimately need and expect information on medicinal products. With regard to medicinal products which require a prescription, in order to meet these needs and expectations, strict conditions must be applied to authorisation to access information on certain medicinal products in the interest of the patients. This information must not be in the form of advertising or direct promotion of medicinal products subject to prescription.*"*

– Amendment 11 on further clarifications of the definition of a medicinal product. A reformulation is needed to refer, in addition to pharmacological action, to immunological and metabolic action. This addition helps to better specify the definition of medicinal product and is in line with Article 1(2)(a) of Council Directive 93/42/EEC on medical devices:

"Article 1, point 2 b:

b) Any substance or combination of substances which may be used in human beings ***either*** *with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions* ***by exerting a pharmacological, immunological or metabolic action.****"*

– Amendment 12 deleting certain parts in the definition of a homeopathic medicinal product. A rewording is needed to reintroduce the reference to homeopathic stocks, which are an important step in producing a homeopathic medicinal product.

"Article 1, point 5

5) Homeopathic medicinal product:

Any medicinal product prepared from substances called homeopathic stocks in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia or, in absence thereof, by the pharmacopoeias currently used officially in the Member States. A homeopathic medicinal product may contain a number of principles."

– Amendment 14 introducing a definition of the local representative. A rewording is necessary to bring the notion in line with the wording already used in the text of the directive:

"Article 1, point 18a)

18a) Representative of the marketing authorisation holder:

The person, commonly known as local representative, designated by the marketing authorisation holder to represent him in the Member State concerned. Any delegation of activities to this person by the market authorisation holder shall not relieve the latter of his legal responsibility.*"*

– Amendment 15 introducing a definition of the risk/benefit balance. A rewording is necessary to distinguish between the effects on the patient and on the environment:

"Article 1, points 28, 29 and 30:

(28) Risks related to use of the medicinal product

- any risk relating to the quality, safety and efficacy of the medicinal product as regards the health of patients;

(29) Risks related to the environment

- any risk of unwanted effects on the environment;

(30) Risk/benefit balance:

An evaluation of the positive therapeutic effects of the medicinal product in relation to the risks as defined above.*"*

– Amendment 18 on the situation that a given product could fulfil the definition of different regulatory regimes. In order to improve the legal certainty, the provision of Article 2(2) needs to be maintained. But its objective can be clarified by amending Recital 7. A rewording of this recital allows equally taking account of amendments 20, 21, 22 and 23 on the exclusion of food, food supplements, medical devices and cosmetics from the scope of Directive 2001/83/EC. While it is unnecessary to add a provision in the operative part of the Directive, the underlying idea can be stated in a recital:

"Recital 7:

Particularly as a result of scientific and technical progress, the definitions and scope of Directive 2001/83/EC should be clarified in order to achieve high standards for the quality, safety and efficacy of medicinal products for human use. In order to take account, both of the emergence of new therapies and of the growing number of so-called "borderline" products between the medicinal product sector and other sectors, the definition of "medicinal product" should be modified so as to avoid any doubt as to the applicable legislation, when a product, whilst fully falling within the definition of a medicinal product, may also fall within the definition of other regulated products. ***With the same objective to clarify situations, where a given product comes under the definition of a medicinal product, but could also fulfil the definition of other regulated products, it is necessary, in case of doubt and in order to provide legal certainty, to state explicitely which provisions have to be complied with. Where a product comes clearly under the definition of other product categories, in particular food, food supplements, medical devices or cosmetics, this Directive does not apply.*** *It is also worth taking advantage of this opportunity to improve the consistency of the terminology of pharmaceutical legislation."*

– Amendments 27 and 30 on certain particulars and documents to be submitted with an application for marketing authorisation to be part of the dossier in all cases. The words "if applicable" are deleted so as to make the requirement applicable in all cases.

"Article 8(3)(g):

g) Reasons for any precautionary and safety measures to be taken for the storage of the medicinal product, its administration to patients and for the disposal of waste products, together with an indication of any potential risks presented by the medicinal product for the environment."

– Amendment 31 requiring the applicant to submit detailed information on pharmacovigilance and on risk-management systems. A rewording is necessary since risk-management systems are not necessary for all medicinal products:

"Article 8(3), point ia:

ia) A detailed description of the pharmacovigilance and, where appropriate, of the risk-management system which the applicant will introduce."

– Amendment 36 allowing an abridged application for a generic product in a Member State even if the reference product has not been authorised in that particular Member State, but only in another Member State. As this exception is intrinsically linked to the provision of Article 10(1), it should be introduced into this same paragraph rather than constituting a separate paragraph:

"Article 10(1), second indent:

The first indent shall also apply, if the reference medicinal product has not been authorised in the Member State where the application for the generic medicinal product is submitted. In this case, the applicant has to indicate in the application the name of the Member State where the reference medicinal product is or has been authorised. On request of the competent authority of the Member State where the application is submitted, the competent authority of the other Member State shall transmit within a period of one month, a copy of the dossier and of the marketing authorisation of the reference medicinal product."

– The first part of Amendment 46 on the sufficient degree of dilution. Where it can be accepted to replace the term "dilution" by "potentisation" a rewording is needed to keep the word "active principles" in line with the Directive's terminology.

"Article 14(1), third indent:

there is a sufficient degree of ***potentisation, which involves a sequential series of dilutions or succussions,*** *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 substances whose presence in an allopathic medicinal product results in the obligation to submit a doctor's prescription."*

– Amendment 51 on ways to make information on marketing authorisations available to the general public. A rewording is necessary as neither the marketing authorisation nor the summary of the product characteristics contain any confidential information whose publication could be objected by the authorisation holder:

"Article 21(3):

3. The competent authorities shall ***make publicly available without delay the marketing*** *authorisation together with the summary of the product characteristics* ***for each medicinal product which it has authorised****."*

– Amendment 52 and the first part of amendment 53 on making publicly available the assessment report and the scientific reasoning. The contents of these amendments can be integrated in Article 21(4), second subparagraph which has to be reformulated:

"Article 21(4), second subparagraph:

The competent authorities shall ***make publicly accessible without delay*** the assessment report, together with the reasons for their opinion, after deletion of information of a commercially confidential nature*."*

– Amendment 55 specifying the specific obligations under which a conditional marketing authorisation may be granted. The provision needs to be reworded as the specific mechanism could concern other issues than those explicitly listed:

"Article 22, first subparagraph:

In exceptional circumstances, and following consultation with the applicant, authorisation ***may be granted subject to a requirement to introduce specific procedures, in particular concerning product safety, notification of the relevant authorities of any incident related to its use and any action to be taken. Such authorisation may be granted only for objective, verifiable reasons. The maintenance of the authorisation is bound to the annual reassessment of these requirements."***

– Amendment 60 stressing the applicant's responsibility that the submitted data is correct and has not been falsified. A rewording is necessary since criminal sanctions cannot be foreseen in Directive 2001/83/EC dealing with pharmaceutical legislation.

"Article 26, third subparagraph:

The applicant or marketing authorisation holder is responsible for the veracity of the documents and the data submitted by him."

– Amendment 63 which shall clarify the notion of "serious potential risk to public health". The provision has to be reformulated as it needs to be clarified that the guidelines are to be adopted by the Commission.

"Article 29(1a):

1a. Guidelines to be adopted by the Commission shall define a serious potential risk to public health."

– Amendment 66 which reinforces the arbitration procedures. The Commission accepts the Parliament's amendment turning the current option to refer a matter to the Agency into an obligation, in the cases of referral where a Community interest is involved. However, to give full effect to such an obligatory referral it is necessary to clarify that such referral leads to a scientific opinion followed by a Commission decision as foreseen in Articles 33 and 34. For reasons of coherence, this similar clarification has to be introduced in the two other provisions on referral procedures. The referral procedure under Article 31 envisages inter alia changes of the marketing authorisation in order to take account of pharmacovigilance information. If this procedure is to be reinforced, Article 116 needs to be aligned so as to allow the competent authorities to take all necessary decisions, including, alongside the suspension and revocation, the variation of a marketing authorisation.

"Article 29(3) :

3. If the Member States fail to reach an agreement within the 60-day period laid down in paragraph 2, the Agency shall be immediately informed, with a view to the application of the procedure under Articles 32, ***33 and 34****. The Agency shall be provided with a detailed statement of the matters on which the Member States have been unable to reach agreement and the reasons for their disagreement. A copy shall be forwarded to the applicant.*

Article 30(1) :

1. If two or more applications submitted in accordance with Articles 8 and Articles 10 to 11 have been made for marketing authorisation for a particular medicinal product, and if Member States have adopted divergent decisions concerning the authorisation of the medicinal product or its suspension or withdrawal, a Member State, the Commission or the applicant or the marketing authorisation holder may refer the matter to the Committee on Human Medicinal Products, hereinafter referred to as "the Committee", for application of the procedure laid down in Articles 32, ***33 and 34****.*

Article 31(1), first subparagraph:

1. The Member States or the Commission or the applicant or the marketing authorisation holder ***shall****, in specific cases where the interests of the Community are involved, refer the matter to the Committee for application of the procedure laid down in Articles 32,* ***33 and 34*** *before any decision is reached on a request for a marketing authorisation or on the suspension or withdrawal of an authorisation, or on any other variation to the terms of a marketing authorisation which appears necessary, in particular to take account of the information collected in accordance with Title IX.*

"Article 116:

The competent authorities shall suspend, revoke ***or vary*** *an authorisation to place a medicinal product on the market if the view is taken that the product is harmful under normal conditions of use, or that it lacks therapeutic efficacy, or that the risk/benefit balance is not positive under the authorised conditions of use, or that its qualitative and quantitative composition is not as declared. Therapeutic efficacy is lacking when it is concluded that therapeutic results cannot be obtained from the medicinal product.*

An authorisation shall also be suspended, revoked ***or varied*** *where the particulars supporting the application as provided for in Article 8 or Articles 10 to 11 are incorrect or have not been amended in accordance with Article 23, or where the controls referred to in Article 112 have not been carried out. "*

– Amendment 69 which cuts down the deadline within which the Agency has to transmit the final opinion to the Commission from 30 to 15 days. A rewording is necessary to keep the reference to the marketing authorisation holder:

"Article 32(5), first subparagraph:

Within ***15 days*** *of its adoption, the Agency shall forward the final opinion of the Committee to the Member States, to the Commission and to the applicant or the marketing* ***authorisation holder*** *together with a report describing the assessment of the medicinal product and stating the reasons for its conclusions."*

– The second part of amendment 71 on the report to be drawn up on the functioning of the Directive. A rewording is necessary to include the Council alongside the European Parliament:

"Article 38(2):

2. No later than [date], the Commission shall publish a report on the experience acquired on the basis of the procedures described in this Chapter and shall propose any amendments which may be necessary to improve those procedures. ***This report shall be forwarded to the European Parliament and to the Council.****"*

– Amendment 80 which adds the competent authorities to the list of those to whom patients may report adverse reactions. However, this needs to be reworded in order to specify which competent authorities are being referred to:

"Article 59(1)(d):

d) a description of the adverse reactions which may occur under normal use of the medicinal product and, if necessary, the action to be taken in such a case; the patient should be expressly asked to communicate any adverse reaction which is not mentioned in the package leaflet to his doctor or pharmacist and the authority ***responsible for pharmacovigilance****;"*

– Amendment 85 on assessments to be carried out on mock-ups of the outer packaging with target patient groups. However, a rewording of this provision is necessary in order to align it with point (j) of Article 8(3), as proposed by the Commission, according to which the applicant only has to provide mock-ups, but no specimens.

"Article 61(1):

1. One or more mock-ups of the outer packaging and the immediate packaging of a medicinal product, together with the draft package leaflet, shall be submitted to the authorities competent for authorising marketing when the marketing authorisation is requested. ***The results of assessments carried out in cooperation with target patient groups shall also be provided to the competent authority.***"

– Amendment 86 sets out how and in what languages the leaflet should be drawn up, with a view to ensuring legibility. A subparagraph regarding the possibility that several languages might be used needs to be added.

"Article 63(2):

2. The package leaflet must be written and designed to be clear and understandable enabling the users to act appropriately, when necessary with the help of health professionals. The package leaflet must be clearly legible in the official language or languages of the Member State where the medicinal product is placed on the market.

The first subparagraph shall not prevent the package leaflet from being printed in several languages, provided that the same information is given in all the languages used*."*

– Amendment 91 which replaces the statement "without approved therapeutic indications" on the label, and, where appropriate, in the package leaflet for homeopathic medicinal products registered under the simplified registration procedure, with the statement "without specific therapeutic indications". However, this needs to be reworded to make it clear that a registered homeopathic medicinal product cannot have any therapeutic indication whatsoever, neither general, nor specific:

"Article 69(1), eleventh subparagraph:

- homeopathic medicinal product "without therapeutic indications".

– The second part of amendment 92 sets out a period of protection for data provided in the context of an application for a change of classification of a medicinal product. However, it needs to be reworded to limit the duration of the period of protection and to clarify it. Therefore, a new *Article 74a* should be added:

"Article 74a

Where a change of classification of a medicinal product has been authorised on the basis of significant pre-clinical tests and clinical trials, the competent authority shall not refer to the results of those tests or trials when examining an application by another applicant for or holder of marketing authorisation for a change of classification of the same substance for two years after the initial change was authorised."

– Amendment 94 lays down a requirement for distributors importing in parallel a medicinal product originating from another Member State to inform the holder of the marketing organisation of their intention. However, rewording is needed to clarify the provision and to add a requirement to also inform the competent authorities in the Member State to which the product will be imported. A new *paragraph 2a* must be added to *Article 76*:

"Article 76(2a):

2a. Any distributor, not being the marketing authorisation holder, who imports a product from another Member State shall notify the marketing authorisation holder and the competent authority in the Member State to which the product will be imported of his/her intention to import it."

– Amendment 95 lays down a requirement for the marketing authorisation holder and, within the limits of their responsibilities, the distributors to provide suitable supplies. However, rewording is needed to include this provision in Article 81, which already lays down public service obligations. It is also necessary to exclude pharmacists from this obligation, and to limit it to the needs of patients in the Member State where the supplies are kept. The application of the principles of proportionality and protection of public health, and the fact that such provisions must be implemented in compliance with the rules of the EC Treaty should also be taken into account. A new subparagraph has therefore been inserted into *Article 81* after the first subparagraph and the second subparagraph has been reworded:

"Article 81:

With regard to the supply of medicinal products to pharmacists and persons authorised or entitled to supply medicinal products to the public, Member States shall not impose upon the holder of a distribution authorisation which has been granted by another Member State, any obligation, in particular public service obligations, more stringent than those they impose on persons whom they have themselves authorised to engage in equivalent activities.

The holder of a marketing authorisation for a medicinal product and the distributors of the said medicinal product in a Member State shall, within the limits of their responsibilities, ensure appropriate supplies of that medicinal product so that the needs of patients in the Member State in question are covered.

The arrangements for implementing this Article *should, moreover, be justified on grounds of public health protection and be proportionate in relation to the objective of such protection,* ***in compliance with the Treaty rules, particularly those concerning the free movement of goods and competition****."*

– Amendment 98, which introduces into the wording of Title VIII the concept of "information". However, rewording appears appropriate in order to refer to "information" in general and not only to "Communication of information":

"Title VIII

ADVERTISING ***AND INFORMATION"****.*

– Amendment 99, which is intended to make the definition of advertising more precise by distinguishing it from information. However, rewording is needed to clarify this provision. Information is already defined in Article 88(2), as proposed by the Commission:

"Article 86(1), introductory sentence:

1. For the purposes of this Title, "advertising of medicinal products" shall include any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products; it shall include in particular:"

– Amendment 104, which stipulates certain topics to be covered by the report to be submitted by the Commission on the experience with the pilot-case on information to patients. It needs to be reworded though, in particular to clarify that the list is not exhaustive:

"Article 88(7a):

7a. The evaluation of the information pilot project shall include, among other things:

– *overall quality of the information presented,*

– *accuracy of the information,*

– *dissemination of the information,*

– *accessibility of the information."*

– Amendments 106 and 191 on the reference to the international non-proprietary name. A rewording is necessary to combine the wording of both amendments :

"Article 89(2):

2. Member States may decide that the advertising of a medicinal product to the general public may, notwithstanding paragraph 1, include only the name of the medicinal product ***or its international non-proprietary name, where this exists, or the trademark*** *if it is intended solely as a reminder."*

– Amendment 108 allowing a reference to the trademark in advertising under certain conditions. A rewording is necessary to align the provisions with the one covering the advertising of a medicinal product to the general public (Article 89(2)) :

"Article 91(2):

2. Member States may decide that the advertising of a medicinal product to persons qualified to prescribe or supply such products may, notwithstanding paragraph 1, include only the name of the medicinal product, ***or its international non-proprietary name, where this exists, or the trademark****, if it is intended solely as a reminder."*

– Amendment 114, which makes it compulsory for Member States to take measures to require doctors and other health care professionals to report adverse reactions. Rewording is needed to make such a provision obligatory, while maintaining the wording of the Commission's proposal:

"Article 101, paragraph 2:

The Member States ***shall impose*** *specific requirements on doctors and other health care professionals, in respect of the reporting of suspected serious or unexpected adverse reactions."*

– The first part of amendment 116 which lays down a requirement to publish information concerning pharmacovigilance. Rewording is needed to avoid referring to the Register and to preserve wording that is more accessible to public:

"Article 102, paragraph 2:

2. Member States shall ensure that suitable information collected within this system is communicated to the other Member States and the Agency. This information shall be recorded in the database referred to in point (j) of the second paragraph of Article 51 of Regulation (EEC) 2309/93 and shall be permanently and ***immediately accessible to the public****."*

– Amendment 121 on the communication of pharmacovigilance information by the authorisation holder to the public:

"Article 104(8):

8. The marketing authorisation holder shall not be authorised to communicate information on pharmacovigilance issues to the public without the consent of the competent authority."

– Amendments 122 and 159 impose an obligation on the holder of a marketing authorisation to inform the competent authorities of any imminent cessation of sales or withdrawal of a medicinal product from the market. Rewording is needed to bring this provision into line with the measure set out in the proposal for a Regulation amending Regulation 2309/93:

"Article 104a:

The marketing authorisation holder ***shall notify the competent authorities of any imminent temporary or definitive cessation of sales of a medicinal product. He/ she shall ensure that, except in exceptional circumstances, the notification is carried out at least two months prior to the cessation of sales of the product.****"*

– Amendment 151 on the classification of a medicinal product by the reference Member State in the case of a mutual recognition procedure. However, a rewording is necessary to make clear that the classification remains part of the summary of the product characteristics:

"Article 11, point 10

10) Classification in accordance with ***Article 70(1). The classification by the reference Member State shall be taken seriously into account when the mutual recognition procedure referred to in Articles 27 to 39 for obtaining marketing authorisation for a medicinal product is applied."***

– Amendment 156, which is intended to make the definition of a generic medicinal product more precise. However, this needs to be reworded to take into account the scientific definition commonly accepted by the Member States within the informal "notice to the applicant" group:

"Article 10(2)(b):

b) generic medicinal product shall mean a medicinal product which has the same qualitative and quantitative composition in active principles and the same pharmaceutical form, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability tests. ***The different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance are considered as the same active substance, unless they differ significantly in properties with regard to safety and/or efficacy.*** *The various* ***solid*** *immediate-release oral pharmaceutical forms are deemed to be one and the same pharmaceutical form. Bioavailability studies may not be required of the applicant if he/she can demonstrate that the product meets the criteria of Annex I."*

– Amendments 167 and 168 explicitly set out that the provisions for generic medicinal products also cover similar biological medicinal products. Such medicinal products cannot always be considered to be generic medicinal products under the definition in Article 10(2)(b), but are nonetheless not required to provide a full dossier. Relevant studies which take the place of bioavailability studies must be included in the dossier. The amendment needs to be reworded so that it reflects the conditions for such medicinal products, in particular by adding a paragraph on them to *Article 10*:

*"**Article 10(3a):***

3a. 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, the results of appropriate pre-clinical tests and clinical trials related to these conditions must be provided. The results of other tests and trials from the reference medicinal product's dossier shall not be provided."

– Amendments 185 and 186 which change the period of validity of the marketing authorisation. The European Parliament proposes that the Commission's proposal to abolish the requirement of five-yearly renewal be amended. It is proposed that a requirement to renew the first marketing authorisation after five years be introduced. After this renewal, the marketing authorisation would be considered to be valid indefinitely. *Recital 13* and *Article 24(1)* are therefore amended. Rewording is needed to more precisely

set out the context of the first evaluation and to avoid increasing the amount of time needed to complete such a procedure:

"Recital 13:

Marketing authorisations ***for new medicinal products must initially be limited to five years'*** *validity.* ***After the first renewal, the marketing authorisation shall be considered to be valid indefinitely. Furthermore, any authorisation not used for three consecutive years, that is, it has not led to the actual placing on the market of a medicinal product during that period, should be considered invalid in order, in particular, to avoid the administrative burden linked to maintaining such authorisations.***

Article 24(1):

1. Without prejudice to paragraphs 2 and 3, authorisation shall be valid for ***five years****.*

This authorisation may be renewed after five years on the basis of a comparative reassessment of the risk/benefit balance. When, after five years, the marketing authorisation is renewed, the holder shall provide a consolidated version of the dossier on the quality, safety and efficacy of the medicinal product which includes all the modifications made during its five years of validity.

The application for renewal shall be submitted to the competent authority at least six months before the authorisation's validity lapses.

After this renewal, the marketing authorisation shall be valid indefinitely."

3.3. Amendments not accepted by the Commission: 1, 4, 6, 8, 9, 10, 16, 19, 26, 28, 29, 34, 38, 39, 40, 41, 45, 46 (second part), 49, 53 (second part), 54, 56, 59, 62, 64, 65, 71 (first sentence), 72, 73, 74, 75, 76, 77, 78, 79, 81, 87, 92 (first part), 96, 100, 101, 102, 103, 105, 107, 111, 113, 115, 116 (second part), 117, 118, 119, 120 (second part), 123, 124, 126, 127, 129, 131, 132, 134, 135, 136, 141, 153, 154, 155, 157, 172, 173, 176, 179, 181, 182, 189, 190, 196, 198 and 202.

– The Commission does not accept amendment 1, which defines medicinal products as opposed to other consumer goods. Specifying this is not necessary to make the provisions in the proposal clearer, nor does it reflect any of its provisions.

– The Commission does not accept amendment 4, which introduces a specific reference to the objectives set out in Articles 152 and 153 of the EC Treaty. This reference is not justified from a legal point of view, as the Commission's proposal is based on Article 95 of the EC Treaty.

– The Commission does not accept amendment 6, which states in a recital that the quality requirements for medicinal products are different according to whether the medicinal product is intended for adults or for children. This cannot be accepted, as there can be no difference between quality, safety and efficacy requirements for medicinal products depending on their target population.

– The Commission does not accept amendments 8 and 9, which set out the provisions concerning providing patients with information. The proposed recitals do not reflect the contents of the provision on information in Article 88(2).

– The Commission does not accept amendment 10, which introduces a recital on the environmental classification of medicinal products. This recital is not reflected by any measure in the proposal.

– The Commission does not accept amendments 16 and 73, which lay down a requirement for generic medicinal products authorised by the Member States to be identified with the same denomination. This provision cannot be applied since these measures are also applicable to generic medicinal products authorised under national procedures.

– The Commission does not accept amendment 19, which grants the Agency the power to determine the scope of the proposed Directive. Firstly, this must be the prerogative of the national authorities entrusted with applying it. Secondly, and within the framework of the mutual recognition procedure, if several Member States are in disagreement, the Agency's corresponding scientific committee will issue an opinion in the context of arbitration proceedings.

– The Commission does not accept amendment 26, which adds to Article 8, on the requirements for preparing the dossier for the application for authorisation, a requirement for an assessment of the risk/benefit balance in respect of the release of the product as waste into the environment. This provision already exists and is included under paragraph 3, point g of the same Article.

– The Commission does not accept amendment 28, which introduces a reference to all tests, regardless of who carried them out. The provision in the proposal is intended to cover all tests and trials which are necessary and useful for the application for authorisation, without specifying who carries them out. There is no need for this reference.

– The Commission does not accept amendment 29, which introduces requirements to, firstly, specify the tests for adults and for children, and secondly, provide for tests comparing the new medicinal product to be authorised with existing medicinal products in the same therapeutic class This requirement cannot be a part of the assessment with a view to granting marketing authorisation. Such assessments must be based solely on the criteria of quality, safety and efficacy. The competent authorities in Member States compare efficacy in order to determine the price and the amount refunded. Such assessments should only be carried out in such a context.

– The Commission does not accept amendments 34, 39, 134 and 202, which introduce the possibility of conducting the tests and trials needed for authorisation, submitting the application for authorisation, and authorising generic medicinal products during the ten-year period of data protection. It is also proposed that the application of "Bolar" type clauses be extended to cover generic medicinal products, the submission of the application for authorisation and of samples, the granting of authorisation, and exports during the period in which the reference medicinal product is covered by a patent or a supplementary protection certificate. These derogations from the rights deriving from the protection of data and from intellectual property rights are detrimental to the balance proposed by the Commission in its original proposal. It is important to maintain this balance between a ten-year period of data protection for innovative medicinal products and a "Bolar" type clause for generic medicinal products in order to allow the tests and trials needed for authorisation to be carried out during the period in which they are protected by intellectual property rights. As for the last part of amendment 34, which introduces a reference to medicinal products which are biosimilar to biological medicinal products, the principle of referring to this type of product is acceptable but should be specified directly in Article 10.

– The Commission does not accept amendment 38, which lays down a requirement to provide appropriate tests and trials if one or more of the active principles in a generic medicinal product is changed. There is no need for this reference as the modified provision already makes this a requirement.

– The Commission does not accept amendment 40, which introduces an additional period of three-years data protection for data submitted with regard to authorising new indications for a medicinal product, which has already been authorised. The provision would lead to a disproportionate extension of the data protection period and would provoke, in addition, disharmonisation between generic medicines and the reference products, which would obtain these protected new indications. The amendment needs to be considered together with the second part of amendment 92, which the Commission has accepted and which provides for a protection of data submitted with regard to changing the classification of an already authorised medicinal product.

– The Commission does not accept amendment 41, which reduces of period of time required to establish a "well-established medicinal use" from ten years to eight years. There is no justification for such a reduction. To the contrary, given that scientific literature replaces pre-clinical tests and clinical trials, a ten-year period is indispensable.

– The Commission does not accept amendment 45, which extends the option of simplified registration to homeopathic products administered by any route of administration that is described in the Pharmacopoeia or is used officially in the Member States. Such an extension of the simplified registration procedure is not justified. It must be limited to homeopathic medicinal products administered orally or externally. The risk related to other routes of administration must be accompanied by proven efficacy.

– The Commission does not accept the second part of amendment 46, which grants the Commission the option of adapting to technical progress the conditions which apply to homeopathic medicinal products which are eligible for the simplified registration procedure. These provisions are already included in the Commission's proposal. There is therefore no need to repeat them in this provision.

– The Commission does not accept amendment 49, which reduces of period of time required to draw up an assessment report from the 120 days proposed by the Commission to 90 days. It must be ensured that the amount of time for assessing the medicinal product is sufficient, and for this reason, the 120-day period must be maintained.

– The Commission does not accept the second part of amendment 53, which lays down a requirement to state the grounds for each indication of the medicinal product being assessed when publishing the assessment report. There is no need to stipulate such a requirement as this practice is already followed by the competent authorities.

– The Commission does not accept amendment 54, which lays down a requirement to publish the authorisation granted, the summary of product characteristics, the assessment report and the comments on this report for each medicinal product authorised. This provision is already set out in the proposed Directive.

– The Commission does not accept amendment 56, which introduces a requirement to take account of scientific and technical progress, after authorisation, and Community law. There is no need for such a reminder as Community law or scientific developments are to be taken into account for all medicinal products which are already authorised.

– The Commission does not accept amendments 59, 131 and 157, which lay down a requirement for the Commission to conduct studies comparing new medicinal products authorised by the Commission and examining the application of Council Directive 89/105/EEC relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems. Such studies, though desirable, do not fall within the scope of legislation on authorisation, surveillance and pharmacovigilance of medicinal products.

– The Commission does not accept amendment 62, which extends the scope of the mutual recognition procedure to homeopathic medicinal products registered under the simplified procedure. There is no need to specify this as Article 39 of the proposal for a Directive already sets out in detail the provisions of the mutual recognition procedure which apply to this kind of medicinal product.

– The Commission does not accept amendments 64 and 65, which make it obligatory to inform the Agency's scientific committee when Member States have arrived at different decisions regarding the authorisation, suspension, withdrawal or requests to harmonise the summary of characteristics of a medicinal product. These procedures must not appear to be automatic. Discretion is needed to verify their usefulness on a case-by-case basis. Not allowing this would risk creating an excessive number of procedures which the Agency would not be able to process.

– The Commission does not accept the first sentence of amendment 71, which introduces a requirement for the Commission to take account of the need to standardise the procedures which apply to pre-clinical tests and clinical trials in the context of the general report on the application of the mutual recognition procedure. Legislation which specifically addresses the harmonisation of national procedures for conducting these tests already exists (Directive 2001/20/EC relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use).

– The Commission does not accept amendment 72, which replaces the term "common name" with "international non-proprietary name" in the context of information which must obligatorily be included on the packaging. There is no need for this provision since the definition of "common name" in Article 1 already refers to "international non-proprietary name".

– The Commission does not accept amendment 74, which requires an obligatory blank space to be left on the packaging of the medicinal product for stating the dosage. The space on the external packaging of medicinal products is already quite limited. Requiring additional space would result in a reduction of the space available for other obligatory information.

– Commission does not accept amendments 75, 76 and 103, which require the competent authorities to set up a website containing information on the medicinal product and to include its address on the packaging and the package leaflet. Pharmaceutical legislation makes no provision for any requirement to publish information on websites.

– The Commission does not accept amendment 77, which requires a warning concerning disposal of unused medicinal products or waste materials from medicinal products to be placed on the packaging. This requirement is already set out in a provision of the proposed Directive.

– The Commission does not accept amendment 78, which lays down a requirement to include certain information on the packaging or the package leaflet in braille, or certain typefaces, or in other formats, on request. This requirement would be disproportionate with regard to the goal to be achieved and could be detrimental to the normal format for the indications. The prescribing agent and the pharmacist must be capable of providing blind or visually impaired patients with the necessary information in an appropriate form.

– The Commission does not accept amendment 79, which sets out certain requirements for the competent authorities in the Member States with regard to creating a database and making the data it contains accessible to all patients. Such provisions are the responsibility of the Member States, which decide on the best means for guaranteeing access to certain information for all patients. The proposal for a regulation amending Regulation 2309/93 already provides for the creation of a database on all medicinal products authorised by the Community and by the Member States.

– The Commission does not accept amendment 81, which sets out a requirement to state on the packaging that the medicinal product was authorised recently and asking for all adverse reactions to be reported. The date on which a medicinal product was authorised is already to be stated on the packaging, and asking for adverse reactions to be reported should apply to all medicinal products, not only to new ones. Moreover, specifically asking for reports solely on such medicinal products could call into question the fact that they have undergone a full assessment and authorisation procedure.

– The Commission does not accept amendment 87, which modifies the wording of the purpose of the guidelines on the legibility of the information on the label and in the package leaflet. There is no need for such a change, as the goal of the Commission's proposal is already clearly to check the legibility of the packaging and the leaflets.

– The Commission does not accept the first part of amendment 92, which lays down a requirement for the competent authorities to examine the classification of the medicinal product during the authorisation procedure. Such a provision is already set out in the Commission's proposal.

– The Commission does not accept amendments 96 and 132, which impose obligations on pharmacists. Pharmaceutical legislation does not set out in detail the provisions governing pharmacists' professional activity.

– The Commission does not accept amendment 100, which lays down an obligation for advertising to be consistent with all the information which accompanies the marketing authorisation or is related to it. Advertising is to be checked only on the basis of a summary of the product's characteristics which reflects the scientific assessment as approved by the competent authority.

– The Commission does not accept amendments 101, 102, 173, 182 and 198, which either delete or amend the Commission's proposal regarding the provision of information to patients regarding prescription medicinal products for certain conditions, subject to certain requirements and controls, and for a three-year trial period. The Commission is of the opinion that its proposal should be maintained in order to ensure that patients are provided with certain information which is legitimate but limited solely to certain conditions during the first stage of trials. For the same reasons, the Commission does not accept amendment 113 which introduces a new chapter on the provision of information, and which would

make it possible to provide comparative information on all authorised medicinal products, diseases or therapies.

– The Commission does not accept amendment 105, which reforms what information should be brought to the attention of patients in the context of advertising for certain medicinal products. This provision is not appropriate in the context of advertising for non-prescription medicinal products.

– The Commission does not accept amendment 107, which replaces the term "state of health" with "health" in the provisions with which advertising must comply. The original terminology in the Commission's proposal was more precise.

– The Commission does not accept amendment 111, which extends the possibilities of co-promotion to co-marketing activities by the holder of the marketing authorisation and one or more companies nominated by him/her. Co-promotion can in no way cover the placing on the market of the medicinal product. This is to be done solely by the holder of the marketing authorisation, who is in all cases solely responsible for this activity.

– The Commission does not accept amendment 115, which asks a specific service of the Commission to put forward legislative proposals on pharmacovigilance. The distribution of work and services within the Commission is the responsibility of the Commission itself.

– The Commission does not accept the second part of amendment 116, nor amendments 123 and 124, which provide for access to pharmacovigilance information on authorised medicinal products. This information on authorised medicinal products is already referred to in point e) of the second paragraph of Article 51 of Regulation 2309/93, as provided for in the second paragraph of Article 102 and amended by the first part of amendment 116.

– The Commission does not accept amendment 117, which sets out an obligation to provide guaranteed public financing for activities related to pharmacovigilance. Decisions on financing national pharmacovigilance activities lie solely within the competence of Member States.

– The Commission does not accept amendment 118, which deletes the reference to exceptional circumstances for cases where electronic communication of pharmacovigilance data is not possible. This provision must be maintained and, as proposed by the Commission, limited solely to exceptional circumstances.

– The Commission does not accept amendment 119, which also includes patients as a source of information on adverse reactions that is forwarded directly to the holder of the marketing authorisation. Such direct communication between patients and marketing authorisation holders would not result in reliable and potentially usable information. Such information must be filtered by health professionals or by officials from the competent authority.

– The Commission does not accept the second part of amendment 120, which defines the areas of competence for the Agency's pharmacovigilance working group. This group is not explicitly created by Regulation 2309/93 and, as a result, no legal obligations can be laid down. As for the last part of the amendment, which sets out that all periodic safety update reports must be accessible to the public in a Register, the obligation to provide public access is already set out in Article 102(2).

– The Commission does not accept amendment 126, which lays down an obligation to consider the scientific assessment of the risk/benefit balance to be the first stage in the analysis of the medicinal product's relative efficacy. The purpose of a risk/benefit balance is, and must continue to be, to scientifically assess the benefits and the risks of the medicinal product in question on an individual basis, and not to compare that medicinal product with others.

– The Commission does not accept amendment 127, which lays down a requirement for the competent authorities to inform the prosecuting authorities if they find that data submitted by an applicant has been falsified. Such provisions do not fall under pharmaceutical law, but rather under Member States' administrative or criminal law.

– The Commission does not accept amendment 129, which introduces four new Articles requiring Member States to apply the criteria of independence, transparency and data protection in national activities concerning authorisation and scientific assessment. In the Commission's opinion, these are areas of national competence, and pharmaceutical law relates to the procedures regarding marketing authorisation, surveillance and pharmacovigilance for medicinal products, not to the internal administrative rules of each Member State.

– The Commission does not accept amendments 135 and 136, which lay down a specific requirement to take appropriate consideration of the sexes, particularly in clinical trials. The criteria of differences between the sexes is already taken into account in the scientific guidelines prepared with regard to the international harmonisation of the guidelines that the Community applies to its evaluation procedures.

– The Commission does not accept amendment 141, which introduces a recital regarding three objectives which must underlie all national policies concerning the control of social expenditure. The main aims of the pharmaceutical legislation are already expressed in the recitals of the Commission's proposal.

– The Commission does not accept amendments 153 and 154, which propose that a new category of medicinal product, "herbal health product", be introduced. There is no need to add such a category of products to the legislation. The new proposal on traditional herbal-based medicinal products already includes the definitions for this type of medicinal product.

– The Commission does not accept amendment 155, which removes the requirement to include the various strengths, pharmaceutical forms, routes of administration and forms of presentation of the same medicinal product in the same marketing authorisation. This clarification is needed from a legal point of view.

– The Commission does not accept amendment 172, which adds a recital referring to the pharmacovigilance data collected by the agencies of third countries and by the World Health Organisation. This recital is not reflected by any measure in the proposed Directive.

– The Commission does not accept amendment 176, which adds a new requirement with regard to the documents to be included in applications for marketing authorisations regarding "long-term tests" for medicinal products for long-term treatment. This wording is too vague. Medicinal products must, in all cases, undergo tests which are appropriate for the use for which they are authorised.

– The Commission does not accept amendment 179, which introduces an option for the Member States to lay down specific rules on the evaluation of homeopathic medicinal products. Such a derogation cannot be accepted. The legislation already allows for this, but limits it to the rules which apply to pre-clinical tests and clinical trials.

– The Commission does not accept amendment 181, which replaces Article 94 with a text that makes stricter the conditions under which medicinal products may be promoted to persons qualified to prescribe or supply them. Nevertheless, the proposed wording is too restrictive and makes such promotion impracticable.

– The Commission does not accept amendments 189 and 190, which lay down a requirement to refer to clinical information using natural frequencies in the relevant part of the summary of product characteristics and to include the research designs. The summary of product characteristics, which contains the results of the scientific assessment, is not the appropriate place for this information.

– The Commission does not accept amendment 196, which introduces a specific exception to patent rights, allowing for the production of medicinal products intended for export to third countries, at the request of the authorities of the third country in question, when it is covered by a patent. First, as drafted, this amendment does not meet the strict conditions on possible exceptions to patent rights set by the WTO Agreement on Trade Related Intellectual Property Rights. Secondly, such provision does not have a place in the legislation governing the placing on the market of medicinal products within the Community.

4. AMENDED PROPOSAL

Pursuant to Article 250(2) of the EC Treaty, the Commission amends its proposal in the aforementioned terms.

2001/0254 (COD)

Amended proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products

(Text with EEA relevance)

1. BACKGROUND

Transmission of the proposal to the Council and to the European Parliament
- COM(2001) 404 final – 2001/0254 (COD) -
by virtue of article 175, paragraph 1 of the Treaty: 26 November 2001

Opinion of the European Economic and Social Committee: 18 September 2002

Opinion of the European Parliament – first reading: 23 October 2002

2. OBJECTIVE OF THE COMMISSON PROPOSAL

Regulation 2309/93 provides for the possibility of an evaluation of the Community procedures for the authorisation and the supervision of medicinal products, which entered into force in 1995. In view of the experience gained during 1995 and 2000 and the analysis performed by the Commission in its report 'on the operation of the Community procedures for the marketing authorisation of medicinal products (COM(2001) 606 final of 23.10.2001)' it appeared necessary to amend Regulation 2309/93 and Directives 2001/83/EC and 2001/82/EC laying down the Community codes in relation to medicinal products for human and veterinary use.

In general, four major objectives appear to be particularly relevant.

(1) to assure a high level of public health protection, notably by making safe, innovative products available as quickly as possible, and by an increased supervision of the market through the strengthening of inspection procedures and of pharmacovigilance;

(2) to complete the single market for pharmaceutical products taking into account the stakes of globalisation and to establish a regulatory and legislative framework that favours the competitiveness of European industry;

(3) to respond to the challenges of the future enlargement of the European Union;

(4) to rationalise and simplify the system as well as to improve its overall coherence and visibility and the transparency of its procedures.

Finally with respect to veterinary medicines, the proposals aim specifically to take into account the problem of the availability of medicinal products for veterinary use.

3. OPINION OF THE COMMISSION ON THE AMENDMENTS ADOPTED BY THE PARLIAMENT

3.1. Amendments accepted by the Commission: 1, 15, 19, 20, 21, 22, 24, 28, 29, 31, 33, 34, 35, 39, 46 and 49.

The Commission can accept the following amendments with the wording proposed by the European Parliament. For certain provisions, other than those targeted by the amendments, incoherence with other provisions, or with the corresponding provisions in the proposal for a Directive relating to medicinal products for human use and in the Regulation laying down Community procedures for the authorisation and supervision and pharmacovigilance of medicinal products for human and veterinary use and establishing a European Medicinal Products Agency, have been removed by amending the wording, where necessary.

– Amendment 1 aimed at introducing a reference to the need to protect public health:

"Recital 3:

It is therefore necessary to align the national laws, regulations and administrative provisions which contain differences with regard to the basic principles in order to promote the operation of the internal market, ***without adversely affecting public health****."*

– Amendment 15 aimed at requiring the applicant to submit documents as proof that he/she will be able to meet certain pharmacovigilance obligations:

"*Article 12, paragraph 3, point na:*

Proof that the applicant has the services of a qualified person responsible for pharmacovigilance and has equipment for the notification of any adverse reaction suspected of occurring either in the Community or in a third country.*"*

– Amendment 19 aimed at specifying the order of the items to be mentioned in the summary of product characteristics:

"Article 14, introductory sentence:

*The summary of the product characteristics shall contain****, in the order indicated below,*** *the following information:*"

– Amendment 20 aimed at further specifying the incompatibilities concerned by the provision:

"Article 14, paragraph 6, point 6.1:

major *incompatibilities;*"

– Amendment 21 aimed at strengthening the need for Member States to take due account of registrations and authorisations of homeopathic veterinary medicinal products issued in other Member States:

"Article 16, paragraph 1:

Member States shall ensure that homeopathic veterinary medicinal products manufactured and marketed within the Community are registered or authorised in accordance with the provisions of Article 17(1) and (2), and Articles 18 and 19. ***Each Member State shall take due account of the registrations and authorisations issued by other Member States***:"

– Amendment 22 aimed at defining the strength relating to effect of homeopathic medicinal products and to delete the reference to allopathic medicines, as this reference is incoherent with the proposal to allow the simplified registration procedure also for homeopathic veterinary medicinal products for food-producing species and the proposals regarding prescription requirements:

"Article 17, paragraph 1, point (c):

there is a sufficient degree of ***potentisation, which involves a sequential series of dilutions or succussions,*** *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."*

– Amendment 24 aimed at further defining the strength relating to effect of homeopathic medicinal products, as far as the method of manufacturing is concerned:

"Article 18, indent 3:

- manufacturing and control file for each pharmaceutical form and a description of the method of ***potentisation****,"*

– Amendment 28 aimed at altering the period of validity of the marketing authorisation in the case where this has not been followed by the placing on the market of the medicinal product. The same provision is introduced in the case of previously authorised medicinal products, which have not been on the market for a certain period. A derogation clause is introduced:

"Article 28, paragraph 2:

Any authorisation which is not followed within ***three years*** *of its issue by the actual marketing of the authorised veterinary medicinal product in the authorising Member State shall cease to be valid.*

The competent authority may, in exceptional circumstances, grant a derogation from the provisions of the previous subparagraph. The derogation shall be duly justified.

Article 28, paragraph 3:

When an authorised veterinary medicinal product previously placed on the market in the authorising Member State is no longer actually present on the market in that Member State for ***three*** *consecutive years, the authorisation* ***for that veterinary medicinal product*** *shall cease to be valid.*

The competent authority may, in exceptional circumstances, grant a derogation from the provisions of previous subparagraph. The derogation shall be duly justified*."*

– Amendment 29 aimed at making public the rules of procedure for the co-ordination group in charge of decentralised procedures for marketing authorisation:

"Article 31, paragraph 3:

The co-ordination group shall draw up its own rules of procedure, which shall enter into force after a favourable opinion of the Commission. ***These rules of procedure shall be made public.****"*

– Amendment 31 aimed at providing a timetable for the work to be undertaken to harmonise the summary of product characteristics for veterinary medicinal products authorised for not less than ten year in the Community:

"Article 34, paragraph 2, subparagraph 4:

The Commission, acting in collaboration with the Agency, and taking into consideration the views of interested parties, shall agree the final list ***and timetable****."*

– Amendment 33 aimed at making it obligatory for the committee to appoint a rapporteur for the assessment of a referral:

"*Article 36, paragraph 2:*

In order to consider the matter, the Committee ***shall*** *appoint one of its members to act as rapporteur. The Committee may also appoint* ***independent*** *experts to advise it on specific questions. When appointing* ***such*** *experts, the Committee shall define their tasks and specify the time-limit for the completion of these tasks."*

– Amendment 34 aimed at providing a time limit for oral or written explanations by the applicant or marketing authorisation holder in the case of referrals made in accordance with Articles 33 or 34:

"Article 36, paragraph 3, first subparagraph:

Before issuing its opinion, the Committee shall provide the applicant or the marketing authorisation holder with an opportunity to present written or oral explanations ***within a time limit which it will specify****."*

– Amendment 35 aimed at shortening the time limit for the decision making process. In order to align the wording with amendment 70 proposed by the European Parliament to amend Article 33 of Directive 2001/83/EC for medicinal products for human use, accepted by the Commission, which is aimed at reducing the corresponding time limit for the Commission to prepare a draft decision from 30 to 15 days, that same amendment is also introduced in Article 37, first subparagraph:

"Article 36, paragraph 5, first subparagraph:

Within ***15 days*** *of its adoption, the Agency shall forward the final opinion of the Committee to the Member States, the Commission and the applicant or the marketing authorisation holder together with a report describing the assessment of the veterinary medicinal product and the reasons for its conclusions.*

Article 37, first subparagraph:

*Within **15** days of receipt of the opinion, the Commission shall prepare a draft of the decision to be taken in respect of the application, taking into account Community law."*

– Amendment 39 aimed at specifying the order of the items to be mentioned in the package leaflet:

"Article 61, paragraph 2, introductory wording:

*The package leaflet shall be approved by the competent authorities. It shall contain**, in the order indicated,** at least the following information, which shall conform to the particulars and documents provided pursuant to Articles 12 to 13d and the approved summary of product characteristics:"*

– Amendment 46 aimed at specifying that inspections can be carried out without prior notification. Alignment with the corresponding amendment 125 proposed by the European Parliament to amend Article 111 of Directive 2001/83/EC for medicinal products for human use, accepted by the Commission:

"Article 80, paragraph 1, subparagraph 2:

*The competent authority may **also** carry out **unannounced** inspections at the premises of manufacturers of active substances used as starting materials for veterinary medicinal products, and of the premises of the marketing authorisation holder whenever it considers that there are serious grounds for suspecting non-compliance with the provisions of Article 51. Such inspections may also be carried out at the request of another Member State, the Commission or the Agency."*

– Amendment 49 aimed at the publication of the rule of procedure of the Standing Committee for veterinary medicinal products:

"Article 89, paragraph 5:

*The Standing Committee shall adopt its own rules of procedure**, which shall be made public**."*

3.2. Amendments accepted in part or in principle by the Commission: 4, 5, 8, 9, 11, 14, 18, 26, 32, 36, 41, 42, 43, 48, 52, 53, 57, 58, 65, 68.

Certain provisions other than those targeted by the amendments accepted in principle have been reformulated to take account of faulty cross-references, alignment with the corresponding provisions for medicinal products for human use and linguistic corrections.

– The Commission can accept in principle amendments 4 and 41 aimed at providing a precision of the definition of a homeopathic veterinary medicinal product and its identification:

"Article 1, point 8:

Homeopathic veterinary medicinal product

Any veterinary medicinal product prepared from substances called homeopathic stocks in accordance with a homeopathic manufacturing procedure described by the European

Pharmacopoeia or, in absence thereof, by the pharmacopoeias currently used officially in the Member States.

A homeopathic veterinary medicinal product may contain a number of active principles.

Article 64, paragraph 2, indent 1:

- the scientific name of the stock or stocks followed by the degree of dilution, using the symbols of the pharmacopoeia used in accordance with point (8) of Article 1; if the homeopathic veterinary medicinal product is composed of more than one stock, the scientific names of the stocks may be ***supplemented*** *on the labelling by an invented name,*"

– The Commission can accept in principle amendment 5 aimed at providing a precision of the definition of the risks with the use of veterinary medicinal products and the benefit/risk ratio:

"Article 1, points 19, 19a and 19b:

(19) Risks related to the use of the product:

- any risk relating to the quality, safety and efficacy of the veterinary medicinal product as regards animal or human health;

(19a) Risks related to the environment:

- any risk of unwanted effects on the environment;

(19b) Benefit/risk ratio:

An evaluation of the positive therapeutic effects of the veterinary medicinal product in relation to the risks as defined above."

– The Commission can accept in principle amendments 8 and 9 aimed at strengthening the exceptional nature of the use of veterinary medicinal products outside the authorised use for non-food producing species in a Member State, while allowing for the possibility to have access to such products authorised in other Member States. However, a rewording is necessary, as veterinary medicinal products are authorised for an animal species. In exceptional circumstances, for a non food-producing species, if a product is authorised in another country, free import/export of veterinary medicinal products by veterinarians could be possible if the Member States have put in place appropriate measures for the import and control of such products:

"Article 10, paragraph 1:

If there is no authorised medicinal product in a Member State for a condition affecting ***a non food-producing species****, the veterinarian may,* ***by way of exception,*** *particularly in order to avoid causing unacceptable suffering to the animal concerned, under his/her personal responsibility, treat the animal(s) with:*

(a) a veterinary medicinal product authorised in the Member State concerned under this Directive or under Regulation (EC) No …/…. [laying down Community procedures for the authorisation and supervision and pharmacovigilance of medicinal products for human and veterinary use and establishing a European Medicinal Products

Agency] for use with another animal species, or for another condition in the same species; or

(b) if there is no product as referred to in point (a),

(i) either a medicinal product authorised for human use in the Member State *concerned in accordance with Directive 2001/83/EC of the European Parliament and of the Council** or under Regulation (EC) No …/…. [laying down Community procedures for the authorisation and supervision and pharmacovigilance of medicinal products for human and veterinary use and establishing a European Medicinal Products Agency]; or*

(ii) a veterinary medicinal product authorised in another Member State in accordance with this Directive for use in the same species for the condition in question or for another condition. Member States shall take specific measures to control such use; or

(c) if there is no product as referred to in point (b) and within the limits of the law of the Member State concerned, a veterinary medicinal product prepared extemporaneously by a person authorised to do so under national legislation in accordance with the terms of a veterinary prescription.

**** OJ L 311, 28.11.2001, p.67.***

Article 10, paragraph 2:

*By way of derogation from Article 11, the provisions of paragraph 1 shall also apply to the treatment by a veterinarian of an animal belonging to the equidae family provided that it has been declared, under Commission Decision 93/623/EEC** ***and Commission Decision 2000/68/EC**, as never having been intended for the production of foodstuffs.*

Article 10, paragraph 3:

By way of derogation from Article 11, and in accordance with the procedure referred to in Article 89(2), the Commission shall establish a list of ***substances*** *essential for the treatment of equidae and for which the withdrawal period shall be not less than six months according to the control mechanisms laid down in Decision 93/623/EEC** ***and Commission Decision 2000/68/EC****.*

** OJ L 298, 3. 12. 1993, p. 45, ** OJ L 23, 28.1.2000, p. 72."*

– The Commission can accept in part amendment 11 aimed at providing a precision of the exceptional circumstances under which the use of veterinary medicinal products outside the authorised use for food producing species in a Member State is permitted, while allowing for the possibility to have access to such products authorised in other Member States. However, a rewording is necessary, as veterinary medicinal products are authorised for an animal species. In addition, Member States are obliged to control any import/export of veterinary medicinal products by veterinarians. Alignment with the corresponding text in Article 10 should also be reintroduced. Furthermore, the qualification by means of suitability of veterinary medicinal products is subjective, and such wording, can not be introduced in Community legislation:

"Article 11, paragraph 1:

By way of exception, if there is no authorised medicinal product in a Member State for a condition affecting a food-producing species, the veterinarian responsible may under his/her personal responsibility, in particular to avoid unacceptable suffering, treat the animals concerned on a particular holding with*:*

(a) a veterinary medicinal product authorised in the Member State concerned under this Directive or under Regulation (EC) No .../.... [laying down Community procedures for the authorisation and supervision and pharmacovigilance of medicinal products for human and veterinary use and establishing a European Medicinal Products Agency] for use with another animal species, or for another condition in the same species; or

(b) if there is no product as referred to in point (a),

(i) either, a medicinal product authorised for ***human*** *use in the Member State concerned in accordance with Directive 2001/83/EC or under Regulation (EC) No .../.... [laying down Community procedures for the authorisation and supervision and pharmacovigilance of medicinal products for human and veterinary use and establishing a European Medicinal Products Agency]; or*

(ii) a veterinary medicinal product authorised in another Member State in accordance with this Directive for use in the same species for the condition in question or for another condition. ***Member States shall take specific measures to control such use****; or*

(c) if the product or products as referred to in point (b) is/are not available and within the limits of the law of the Member State concerned, of a veterinary medicinal product prepared extemporaneously by a person authorised to do so under national legislation in accordance with the terms of a veterinary prescription."

– The Commission can accept in principle amendments 14 and 68 aimed at adding a requirement to supply information in the application dossier on the pharmacovigilance system intended for a veterinary medicinal product and specific tests relating to the potential environmental risks posed by the veterinary medicinal product. However, sophisticated pharmacovigilance management systems are not necessary for all veterinary medicinal products and the requirement should therefore be required only where appropriate. Furthermore, the tests required to assess the potential risks to the environment are already included under the item safety tests. However, the provision relating to the potential environmental risks that the veterinary medicinal product may pose may be reformulated to take account of amendment 5:

"Article12, paragraph 3, point g:

Reasons for any precautionary and safety measures to be taken for the storage of the veterinary medicinal product, its administration to animals and for the disposal of waste products, together with an indication of any potential risks presented by the veterinary medicinal product for the environment and the health of humans, animals or plants;

Article12, paragraph 3, point ja:

A detailed description of the pharmacovigilance system and, where appropriate, the risk management system, which the applicant will introduce;"

– The Commission can accept in part amendment 18 aimed at providing an extension of the period allowed for development of products for use in additional food-producing species, from three to five years, with the view of making use of an extended period of exclusivity. However, the extension of the exclusivity period to new significant therapeutic indications and non-food producing species can not be accepted, as this would be counterproductive to the aim of the provision, namely provide an incentive for products for an extended number of minor food producing species, which are at the core of the problem with availability of veterinary medicines:

"Article 13, paragraph 4:

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 [date] the ten-year period provided for in the first 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.*

This period cannot, 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 food-producing species*** *shall be granted only if the marketing authorisation holder had also been at the origin of the maximum residue limits established for the species covered by the authorisation."*

– The Commission can accept in principle amendment 26 aimed at providing for a way to make information on marketing authorisations available to the general public. A rewording is however necessary as neither the marketing authorisation nor the summary of product characteristics contain any confidential information the publication of which the marketing authorisation holder can contest. In addition, the Commission proposes to modify the provisions in line with the corresponding amendments 51 and 52 and the first part of amendment 53 proposed by the European Parliament to amend Article 21, paragraph 3 and second subparagraph of paragraph 4 of Directive 2001/83/EC for medicinal products for human use, accepted in principle by the Commission:

"*Article 25, paragraph 3:*

The competent ***authority*** *shall* ***make publicly available without delay*** *a copy of the marketing authorisation together with the summary of product characteristics* ***for each veterinary medicinal product, which it has authorised.***

Article 25, paragraph 4, second subparagraph:

The competent authority shall make publicly accessible without delay *the assessment report* ***together with the*** *reasons for its opinion after deleting any information of commercially confidential nature."*

– The Commission can accept in principle amendment 32 aimed at providing for an obligatory referral of cases of risks to human or animal health or the environment where a Community interest is involved to allow for a scientific assessment of the question at Community level. However, to give full effect to such an obligatory referral it is necessary to clarify that such referral leads to a scientific opinion followed by a Commission decision as foreseen in Articles 37 and 38. For reasons of coherence, this similar clarification has to be introduced in the two other provisions on referral procedures. The referral procedure under Article 35 envisages inter alia changes of the marketing authorisation in order to take account of pharmacovigilance information. If this procedure is to be reinforced, Article 83 needs to be aligned so as to allow the competent authorities to take all necessary decisions, including, alongside the suspension and revocation, the variation of a marketing authorisation:

"Article 33, paragraph 3:

*If within the period of 60 days the Member States fail to reach an agreement, the Agency shall be immediately informed with a view to application of the procedure laid down in Article 36**, 37 and 38**. The Agency shall be provided with a detailed description of the matters on which agreement could not be reached and the reasons for the disagreement. The applicant shall be provided with a copy of this information.*

Article 34, paragraph 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 withdrawal of authorisation, a Member State, or the Commission, or the marketing-authorisation holder may refer the matter to the Agency for application of the procedure laid down in Article 36**, 37 and 38**.*

Article 35, paragraph 1, subparagraph 1:

*The Member States or the Commission or the applicant or holder of the marketing authorisation **shall**, in specific cases where the interests of the Community are involved, refer the matter to the Committee for the application of the procedure laid down in Article 36**, 37 and 38** before reaching a decision on a request for a marketing authorisation or on the suspension or withdrawal of an authorisation, or on any other variations to the terms of a marketing authorisation which appear necessary, so as to take account in particular of the information collected in accordance with Title VII.*

Article 83, paragraph 1, introductory wording:

*The competent authorities of the Member States shall suspend**, revoke or vary** marketing authorisation when it is clear that:*

Article 83, paragraph 2, introductory wording:

*Authorisation shall be suspended**, revoked or varied** where it is established that:* "

– The Commission can accept in principle amendment 36 aimed at providing for the transfer of the future report on the functioning of the proposed decentralised system for authorisation of veterinary medicinal products to the European Parliament. However, the Council will also receive this report and should thus be added to the provision:

"Article 42, paragraph 2:

The Commission shall publish, no later than [date], a report on experience gained on the basis of the procedures provided for in this chapter and shall propose any amendments necessary to improve the procedures. ***This report shall be forwarded to the European Parliament and the Council."***

– The Commission can accept in principle amendments 42 and 43 aimed at providing for a possibility to minimise the prescribed amount of medicines to the actual need in certain cases and provisions for the dispensing of veterinary medicinal products authorised for food producing species, for which a precision is needed. However, the placement of the provisions of amendment 42 on prescriptions is incongruent with the provisions of Article 66 dealing with sales of medicines and is better placed in Article 67, as an additonal subparagraph, and vice versa for amendment 43, which should be placed in Article 66 relating to the dispensing of veterinary medicinal products. Furthermore, there is a need to limit the dispensing rights by other professions than veterinarians and pharmacists as concerns treatments of bacterial infections:

"Article 66, paragraph 2a:

Member States may permit on their territory the dispensing of veterinary medicinal products for food producing animals, for which a veterinary prescription is required, by or under the supervision of a registered *person providing guarantees with respect to qualifications, record-keeping and reporting as appropriate* ***in accordance with national legislation. The Member States shall notify this arrangement to the*** *Commission. This provision shall not apply to the dispensing of veterinary medicinal products for the oral or parenteral treatment of bacterial infections.*

Article 67, paragraph 1, point (d):

officinal formulae, as defined in Article 3(2)(b), intended for food-producing animals

Article 67, paragraph 1, second and third subparagraphs:

Member States shall take all necessary measures to ensure that, where medicinal products are supplied solely on prescription, the quantity prescribed and supplied shall be restricted to the minimum amount required for the treatment or therapy concerned.

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 less than seven years."

– The Commission can accept in principle amendment 48 as far as the second part is concerned, aimed at prohibiting the direct advertising to the general public of veterinary medicinal products containing psychotropic or narcotic substances. These substances have a very specific status according to international law. However the first part of the amendment on the prohibition of advertising to the public of veterinary medicinal products available only after a veterinary prescription is not accepted, as it ignores that there is at present no general Community legislation on advertising of veterinary medicinal products on which such measures could be based:

"Article 85, paragraph 2a:

Member States shall prohibit the advertising to the general public of veterinary medicinal products which contain psychotropic or narcotic substances, such as those covered by the United Nations Conventions of 1961 and 1971."

– The Commission can accept in principle amendments 52 and 53 aimed at allowing for the use of homeopathic veterinary medicinal products in exceptional circumstances where there is no authorised veterinary medicinal product for the treatment of a particular condition. The proposed provision for non-food producing animals is in line with the possibility to use medicinal products for human use in exceptional circumstances, and should therefore be aligned with that provision. However, the provision aimed at introducing the possibility for extra-label use of homeopathic veterinary medicinal products for food-producing animals is acceptable only if appropriately controlled by the competent authorities. The recording of all treatments for food producing animals is furthermore necessary under other Community legislation and has therefore to be maintained. The provision should be amended in this sense:

"Article 16, paragraph 2a:

By way of derogation from Article 10, homeopathic veterinary medicinal products may be administered to non-food producing animals under the responsibility of a veterinarian.

Article 16, paragraph 2b:

By way of derogation from Article 11(1) and 11(2), Member States shall permit administration of homeopathic veterinary medicinal products intended for food producing species for which the active constituents are included in Annex II of Council Regulation (EEC) No 2377/90 under the responsibility of a veterinarian. Member States shall take appropriate measures to control the use of veterinary homeopathic medicinal products registered or authorised in another Member State in accordance with this Directive for use in the same species."

– The Commission can accept in principle amendments 57 and 58 aimed at changing the period of validity of the marketing authorisation. In effect the European Parliament proposes to amend the Commission's proposal which aims to remove the requirement to renew the authorisation after 5 years. The European Parliament proposes to introduce a requirement to renew the authorisation five years after the first marketing authorisation. After this first renewal, the authorisation will be considered as valid for an unlimited period. *Recital 13* and *Article 28, paragraph 1,* are therefore amended. A rewording is necessary, however, to specify better the context of the first evaluation as well as to avoid adding time limits for such a procedure.

"Recital 13:

Marketing authorisation ***for new veterinary medicinal products*** *should be* ***limited initially to five years. After this first renewal, the marketing authorisation shall be considered as valid for an unlimited period****. Furthermore, any authorisation not used for* ***three*** *consecutive years, that is to say, one which has not led to the placing on the market of a medicinal product in the Community during that period, should be considered invalid, in order, in particular, to avoid the administrative burden linked to maintaining such authorisations.*

Article 28, paragraph 1:

Without prejudice to paragraphs 2 and 3, ***the marketing authorisation shall be valid for five years.***

This authorisation may be renewed after five years on the basis of a reassessment of benefit/risk ratio. When, after five years, the marketing authorisation is renewed, the holder shall submit a consolidated dossier on the quality, safety and efficacy of the veterinary medicinal product with all the variations introduced during the five years of validity. The application for renewal shall be submitted at least six months prior to the date of expiry of the authorisation.

After this renewal, the marketing authorisation shall be valid for an unlimited duration."

– The Commission can accept in principle amendment 65 aimed at allowing for a derogation from the need for established maximum residue limits for pharmacologically active substances in veterinary medicinal products for the Equidae species, provided the target species is limited to those animals never having been intended to be used for the production of food-stuffs. However, it is not acceptable to allow this exemption for active substances to be included in veterinary medicinal products, for which alternative products are available. Likewise it is not acceptable to allow for marketing authorisations of products which contain substances included in Annex IV of Regulation (EEC) No 2377/90, as this would preclude the possibility to restrict import of foodstuffs containing such substances from third countries. Therefore, the provision has to be restricted and reworded as follows and a clarifying paragraph added to Article 12 dealing with the application for marketing authorisation:

"Article 6, paragraph 3:

By way of derogation from paragraph 1, a veterinary medicinal product containing pharmacologically active substances not included in Annexes I, II or III of Regulation (EEC) No 2377/90 may be authorised for the particular animals of the Equidae species, which have been declared, under Commission Decision 93/623/EEC* and Commission Decision 2000/68/EC**, as never having been intended for the production of foodstuffs. The active substances of such veterinary medicinal products shall not be included in Annex IV of Council Regulation (EEC) No 2377/90 or intended for use in the treatment of conditions for which a veterinary medicinal product is authorised in the Community.

Article 12, paragraph 1, third subparagraph:

In the case of veterinary medicinal products referred to in Article 6(3), a marketing authorisation may be applied for without a valid application in accordance with Regulation (EEC) No 2377/90. All scientific documentation necessary for the demonstration of the quality, safety and efficacy according to paragraph 3 shall be submitted."

– The Commission proposes to modify Article 1, point 2(b), to clarify the definition of a veterinary medicinal product by making reference to pharmacological, immunological and metabolic action. This modification is in line with amendment 11 proposed by the European Parliament to amend Article 1, point 2b, of Directive 2001/83/EC for medicinal products for human use, which has been accepted in principle by the Commission:

”*Article 1, point 2(b):*

which may be administered to or *used in animals* ***either*** *with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions* ***by exerting a pharmacological, immunological or metabolic action.****”*

– The Commission proposes to introduce a definition of the local representative in Article 1, point 17a. This modification is in line with the wording of amendment 14 proposed by the European Parliament of Directive 2001/83/EC for medicinal products for human use which has been accepted in principle by the Commission:

”*Article 1, point 17a:*

Representative of the marketing authorisation holder:

The person, commonly known as local representative, designated by the marketing authorisation holder to represent him/her in the Member State concerned. Any delegation of activities to this person by the marketing authorisation holder shall not relieve the latter of his/her legal responsibility.*”*

– The Commission proposes to modify Article 12, paragraph 3, point c, in line with the corresponding amendment 25 proposed by the European Parliament to amend Article 10, paragraph 1 of Directive 2001/83/EC for medicinal products for human use, accepted by the Commission. This amendment regards information to be submitted by the applicant the on constituents of the medicinal product:

“*Article 12, paragraph 3, point c:*

*Qualitative and quantitative particulars of all the constituents of the veterinary medicinal product****, including the reference to its international non-proprietary name (INN) recognised by the WHO, where an INN name exists, or a reference to the relevant chemical name;****”*

– The Commission proposes to modify Article 13, paragraph 1, and to add a subparagraph between the first and second subparagraphs, in line with the corresponding amendment 36 proposed by the European Parliament to amend Article 10, paragraph 1 of Directive 2001/83/EC for medicinal products for human use, accepted in principle by the Commission. This amendment would allow for an abridged application for a generic product in a Member State even if the reference product has not been authorised in that particular Member State, but only in another Member State:

“Article 13, paragraph 1, second subparagraph:

The first subparagraph shall also apply, if the reference medicinal product has not been authorised in the Member State where the application for the generic medicinal product is submitted. In this case, the applicant has to indicate in the application the name of the Member State where the reference medicinal product is or has been authorised. On request of the competent authority of the Member State where the application is submitted, the competent authority of the other Member State shall transmit within a period of one month, a copy of the dossier and of the marketing authorisation of the reference medicinal product.*”*

– The Commission proposes to modify Article 13, paragraph 2, point (b), aimed at providing a more precise definition of a generic medicinal product, in line with the scientific definition informally accepted by the Member States. The proposal is in coherence with amendment 156 proposed by the European Parliament to amend Article 10, paragraph 2 of Directive 2001/83/EC for medicinal products for human use, which the Commission accepted in principle, subject to reformulation to take account of the existing definition:

"*Article 13, paragraph 2, point (b):*

generic medicinal product shall mean a medicinal product which has the same qualitative and quantitative composition in terms of active substances, the same pharmaceutical form, and whose bioequivalence with the reference medicinal product has been demonstrated by means of appropriate bioavailability tests. ***The different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance are considered as the same active substance, unless they differ significantly in properties with regard to safety and/or efficacy.*** *Bioavailability tests may not be required of the applicant if he/she can demonstrate that the medicinal product meets the criteria set out in Annex I."*

– The Commission proposes a new paragraph 3a in Article 13 to specify the documentation requirements for biological generic veterinary medicinal products. These medicinal products can not always be classified as generic medicinal products in the sense of the definition provided for in Article 13, paragraph 2, point (b), but should not require the submission of a complete dossier in all cases. The documentation shall nevertheless include all necessary documents and particulars with respect to the safety tests and the preclinical and clinical trials to replace the bioavailability studies. The proposal is in coherence with amendments 167 and 168 proposed by the European Parliament to amend Article 10 of Directive 2001/83/EC for medicinal products for human use, which the Commission accepted in principle, subject to reformulation as indicated above, by the introduction of a separate paragraph:

"*Article 13, paragraph 3a:*

In the case that a biological veterinary medicinal product similar to a reference biological veterinary medicinal product does not fulfil all the conditions of the definition of generic medicinal product, the results of appropriate pre-clinical and clinical trials linked to these conditions shall be submitted. The results of other tests, referred to in the dossier of the reference medicinal product, are not required to be submitted.*"*

– The Commission proposes to modify Article 23, paragraph 3, to provide for correct reference to Article 12:

"*Article 23, paragraph 3:*

may similarly check, in particular through consultation of a national or Community reference laboratory, that the analytical method used for detecting residues presented by the applicant in accordance ***with point (j)*** *of Article 12(3) is satisfactory;"*

– The Commission proposes to modify Article 30, subparagraph 4, to align the wording with the corresponding amendment 60 proposed by the European Parliament to amend Article 26 of Directive 2001/83/EC for medicinal products for human use, accepted by the Commission subject to rewording, to introduce the explicit responsibility of the applicant

or marketing authorisation holder for the correctness of data submitted in support of an application for marketing authorisation:

"*Article 30, subparagraph 4:*

The applicant or marketing authorisation holder is responsible for the veracity of the documents and the data submitted by him/her.

– The Commission proposes to modify Article 33, paragraph 1, to add a paragraph 1a aimed at the introduction of a provision to clarify the notion of a potential serious risk to human or animal health or the environment. This modification is in line with the corresponding amendment 63 proposed by the European Parliament to amend Article 29 of Directive 2001/83/EC for medicinal products for human use, which the Commission accepted subject to rewording to take account of the need for any guidance proposed to be adopted by the Commission:

"*Article 33, paragraph 1a:*

Guidelines to be adopted by the Commission shall define a serious risk to human or animal health or the environment.*"*

– The Commission proposes to modify Article 58, paragraph 1, point (a) and Article 61, paragraph 2, points (a) and (b) to be in line with the corresponding proposal to amend Directive 2001/83/EC for medicinal products for human use. It is also proposed to modify Article 61, paragraph 1 by adding a second subparagraph, for reasons of coherence with the corresponding amendment 86 proposed by the European Parliament to amend Article 63 of Directive 2001/83/EC for medicinal products for human use, to allow for the inclusion of information in several languages on the same package leaflet, provided the information in all the languages is identical:

"Article 58, paragraph 1, point (a):

the name of the medicinal product ***followed by*** *its strength* ***and*** *pharmaceutical form, if the medicinal product is available in several strengths and/or pharmaceutical forms****; the common name shall be included where the product contains only one active substance and if its name is an invented name****;*

Article 61, paragraph 1:

*The inclusion of a package leaflet in the packaging of veterinary medicinal products shall be obligatory unless all the information required by this Article can be conveyed on the immediate packaging and the outer packaging. Member States shall take all appropriate measures to ensure that the package leaflet relates solely to the veterinary medicinal product with which it is included. The package leaflet shall be worded in terms that are comprehensible to the general public and in the official language or languages of the Member State in which the medicinal product is marketed****.***

The provisions of the first subparagraph do not preclude the possibility that the package leaflet is written in several languages, on condition that the information is identical in all the languages.

Article 61, paragraph 2, point (a):

*name or corporate name and permanent address or registered place of business of the marketing authorisation holder and of the manufacturer and**, where appropriate**, of the local representative designated by the marketing authorisation holder in the Member State;*

Article 61, paragraph 2, point (b)

*name of the veterinary medicinal product **followed by its strength and pharmaceutical form. The common name shall be included where the product contains only one active substance and if its name is an invented name. Where the medicinal product is authorised according to the procedure provided for in Articles 31 to 43 under different names in the Member States concerned, a list of the names authorised in each Member State;"***

– The Commission proposes to modify Articles 64, paragraph 2, to be coherent with the requirement in Article 17, paragraph 1, point (b), that no specific therapeutic indication may appear either on the labelling or on any information relating to the homeopathic veterinary medicinal product and to align the wording with the corresponding amendment 89 proposed by the European Parliament to amend Article 68 of Directive 2001/83/EC for medicinal products for human use:

"Article 64, paragraph 2, introductory wording:

*In addition to the clear mention of the words 'homeopathic veterinary medicinal product **without approved therapeutic indications' and to the reference to the potentised nature of the product,** 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:"*

– The Commission proposes to modify Article 72, paragraph 2, to make it obligatory for Member States to impose specific requirements to report adverse reactions to veterinary medicinal products. This modification is proposed to achieve coherence with amendment 114 on pharmacovigilance issues proposed by the European Parliament to amend Article 101 of Directive 2001/83/EC for medicinal products for human use, which have been accepted by the Commission subject to reformulation:

"*Article 72, paragraph 2:*

*The Member States **shall** impose specific requirements on veterinary practitioners and other health care professionals in respect of the reporting of suspected serious or unexpected adverse reactions and human adverse reactions."*

– The Commission proposes to modify Article 73, third paragraph, to clarify the provisions on public access to information on veterinary medicinal products. This modification is proposed to achieve coherence with amendment 116 on pharmacovigilance issues proposed by the European Parliament to amend Article 102 of Directive 2001/83/EC for medicinal products for human use, which have been accepted by the Commission subject to reformulation, to avoid reference to the data base but allowing the widest possible public access to the information:

"*Article 73, third paragraph:*

Member States shall ensure that ***appropriate*** *information collected within this system is forwarded to the other Member States and the Agency. This information shall be recorded in the database referred to in point (j) of the second paragraph of Article 51 of Regulation (EEC) No 2309/93 and shall be permanently accessible to* ***the public without delay.****"*

– The Commission proposes to modify Article 75, paragraph 5, to clarify how to calculate when the periodic safety update reports have to be presented, and to add a new paragraph 7 on the communication of pharmacovigilance information by the marketing authorisation holder to the public. These modifications are proposed to achieve coherence with amendments 120 and 121 on pharmacovigilance issues proposed by the European Parliament to amend Article 104 of Directive 2001/83/EC for medicinal products for human use, which have been accepted by the Commission:

"*Article 75, paragraph 5:*

Unless other requirements have been laid down as a condition for the granting of authorisation, ***or subsequently as indicated in the guidance referred to in Article 77(1),*** *records of all adverse reactions shall be submitted to the competent authorities in the form of a periodic safety update report, either immediately upon request or periodically as follows: six monthly for the first two years after* ***the veterinary medicinal product was first placed on the market****, annually for the subsequent two years, and thereafter at three-yearly intervals. The periodic safety update reports shall include a scientific evaluation of the benefits and risks* ***of*** *the veterinary medicinal product.*

Article 75, paragraph 7:

The marketing authorisation holder shall not be authorised to communicate information on pharmacovigilance issues to the public without the consent of the competent authority.*"*

– The Commission proposes to add a new Article 75a aimed at providing a requirement on the part of the marketing authorisation holder to inform the competent authorities of any cessation of the marketing of a veterinary medicinal product for reasons other than safety concerns. A time limit for the provision of such information should also be introduced. These modifications are proposed to achieve coherence with amendments 122 and 159 proposed by the European Parliament to amend the Directive 2001/83/EC, which have been accepted in principle by the Commission, subject to reformulation in line with the revised proposal to amend Regulation (EEC) No 2309/93:

"Article 75a:

The marketing authorisation holder shall also inform the competent authorities of any possible suspension, temporary or permanent, of the marketing of the veterinary medicinal product. This notification shall take place, unless there are exceptional circumstances, at least two months before the cessation of the marketing of the product."

– The Commission proposes to modify Article 84, paragraph 1, point (a), to reflect that the provisions of this article apply to already authorised veterinary medicinal products:

"Article 84, paragraph 1, point (a):

it is clear that the benefit/risk assessment of the veterinary medicinal product is, under the authorised conditions of use, unfavourable, particular regard being had to the benefits for animal health and welfare and to the safety and health benefits for the consumer, when the ***authorisation*** *concerns a veterinary medicinal product for zootechnical use."*

3.3. Amendments not accepted by the Commission: 2, 3, 7, 10, 13, 16, 17, 23, 25, 27, 30, 37, 38, 40, 44, 45, 47, 56, 59, 60, 62, 63, 64, 66, 67 and 69.

- The Commission cannot accept amendment 2 in recital 8 aimed at restricting authorisation of veterinary medicinal products for food producing animals to therapeutic purposes, as the prohibition of other uses is not within the scope of the legislation related to pharmaceutical products.

- The Commission cannot accept amendment 3 in a new recital aimed at a request by the European Parliament to the Commission to develop a standard environmental classification system for veterinary medicinal products. According to the Commission, this proposal is not necessary, as each new veterinary medicinal product is evaluated with respect to environmental risk assessment in the overall benefit/risk profile of that particular product. There is furthermore a problem with the availability of veterinary medicinal products which has to be underscored.

- The Commission cannot accept amendment 7 aimed at limiting the marketing authorisation of a veterinary medicinal product to a single pharmaceutical form. This change is not acceptable as the concept of an authorisation covers the original authorisation and any extensions to additional strengths, pharmaceutical forms and presentations. The addition of a pharmaceutical form is authorised in accordance with Regulation 541/95 on variations (implemented in accordance with Article 39).

- The Commission cannot accept amendment 10 aimed at allowing veterinarians unlimited access to treatment of all animals of the Equidae species, even with substances prohibited for use in food producing animals (annex IV). However, the provision is being modified to take account of the necessity to include Equidae for breeding and production within the scope of the provisions relating to Equidae excluded from production of foodstuffs in accordance with Commission Decision 2000/68/EC (see section 3.2. amendments 8 and 9).

- The Commission cannot accept amendment 13 aimed at providing a zero withdrawal period for all homeopathic veterinary medicinal products with a concentration of the active principle of equal or less than one part per million. This level of active principle is not referred to elsewhere in the Directive and even substances included in homeopathic veterinary medicinal products may be hazardous to human health.

- The Commission cannot accept amendment 16 aimed at limiting the data protection period for products containing new substances, not previously included in veterinary medicinal products in the European Union, to eight years. This amendment shifts the balance between protecting innovation and reinforcing generic competition which is included in the Commission proposal.

- The Commission cannot accept amendment 17 aimed at extending the period of data protection for veterinary medicinal products containing new active substances to 15 years for products for smaller species and laying hens if the applicants places the product on the

market within two years of authorisation. A definition of a smaller species is not possible at Community level, as this will vary from region to region in the Community. Furthermore 15 years is too long in comparison with the Commission proposal of 10 years as a general period for data protection. The proposal of the Commission to extend the data protection period directly to 13 years for products for bees and fish was made because it is unlikely that such products can be used in other species. The same conditions cannot be applied to laying hens and other species. Furthermore, the proposal by the European Parliament to qualify the amendment by a clause on placing on the market will not provide any additional safeguard with respect to the availability of veterinary medicinal products.

– The Commission cannot accept amendment 23 aimed at allowing active substances of human or animal origin to be included in homeopathic veterinary medicinal products provided that they comply with the monograph on homeopathic preparations of the European pharmacopoeia. For such substances there are additional essential requirements to be complied with, such as absence of adventitious agents and a risk assessment with respect to TSE.

– The Commission cannot accept amendment 25 aimed at deleting requirements for safety tests for homeopathic veterinary medicinal products for food-producing species if the substance is included in Annex II of Regulation (EEC) No 2377/90. There is no scientific justification to deviate from the harmonised standards as contained in the Directive for testing of the safety and efficacy of homeopathic veterinary medicinal products for food-producing species.

– The Commission cannot accept amendment 27 aimed at adding a reference to Community law to the requirement on marketing authorisation holders after an authorisation has been issued. Marketing authorisation holders have in any case to abide by Community law.

– The Commission cannot accept amendment 30 aimed at making a referral obligatory in the cases where divergent decisions have been taken in respect of marketing authorisations. The reasons of taking divergent decisions can vary significantly and may not pose a risk to human or animal health or the environment. Hence, it is necessary in these situations to maintain the discretion foreseen in the current provisions.

– The Commission cannot accept amendment 37 aimed at providing a reference to containers and a space on the label of the medicinal product to provide for the possibility to write additional information. The definition chosen for the container is the immediate packaging, which is already in the text. The extra label space is not feasible for all products, as there may be a problem of space. If there is a need of extra information, it should be solved by other means to provide the information.

– The Commission cannot accept amendment 38 aimed at amending the wording related to specific precautions for the disposal of veterinary medicinal products and making it a requirement to return all unused medicinal product to the pharmacy. The first part of the proposed wording does not add anything to the provision as proposed by the Commission. The proposal to return all unused products to the pharmacy is not workable in practice, as veterinary medicinal products are also delivered by other distribution channels. Furthermore there is no harmonised distribution system for veterinary medicinal products in the Community.

– The Commission cannot accept amendment 40 aimed at introducing a reference to article 59 in article 64. Article 59 is not relevant for homeopathic veterinary medicinal products as all information relating to these products are listed in Article 64.

– The Commission cannot accept amendment 44 aimed at reducing the period for compulsory prescription only status for veterinary medicinal products containing new active substances to four years under certain circumstances. The need to strengthen the provisions of pharmacovigilance cannot be limited to the first four years after authorisation.

– The Commission cannot accept amendments 45 and 69 aimed at providing guarantees of independent funding of activities of the national authorities in the field of pharmacovigilance, as this is a question of national competence.

– The Commission cannot accept amendment 47 aimed at providing for a relative effectiveness assessment of a veterinary medicinal product. The risk /benefit ratio for one medicinal product is related to the authorisation of that specific product and not to other products.

– The Commission cannot accept amendment 56 aimed at introducing four new articles to impose on Member States certain criteria of independence, transparency and confidentiality to be applied in the framework of the scientific evaluation and authorisation of veterinary medicinal products. The Commission considers that pharmaceutical legislation provides for a framework for procedures for marketing authorisation, surveillance and control of medicinal products and not for internal administrative procedures in the national competent authorities.

– The Commission cannot accept amendment 59 aimed at introducing a derogation for the application of Regulation (EEC) No 2377/90 on maximum residue limits (MRLs), to allow veterinarians, in exceptional circumstances, to treat food-producing animals with medicinal products containing substances not included in Annex I, II, or III of that Regulation, provided that he/she specifies a withdrawal period. The Commission considers that this derogation would have serious implications for consumer safety and for the future of the veterinary pharmaceutical industry, if veterinarians were given the possiblity to use any medicinal product in any species. No residue control possibilities would exist for such use and the incentive for the pharmaceutical industry to develop new products would be diminished. The veterinarian would furthermore not have sufficient information to establish a withdrawal period, as these are based on the preexistence of MRLs for at least one food-producing species.

– The Commission cannot accept amendment 60 aimed at introducing a definition of food-producing animals in the Directive. The Commission considers that such a definition does not fall within the scope of the pharmaceutical legislation.

– The Commission cannot accept amendment 62 aimed at introducing a reference in Article 11 to the absence of validated scientific data, as a prerequisite for the application of administrative withdrawal periods. The Commission considers that such reference is superflouous to the contents of the paragraph, which gives a minimum administrative withdrawal period that shall always be respected when the provisions of this Article are applied.

– The Commission cannot accept amendments 63 and 66 aimed at introducing a change in the provisions concerning the possibilities of the Member States to control the use of veterinary medicinal products intended for food-producing animals but not authorised in the Member State. The Commission considers that it is of paramount importance that a national control system is put in place. The importation of veterinary medicinal products from other Member States have to be strictly controlled by the authorities, as the entire marketing authorisation system would otherwise be undermined.

– The Commission cannot accept amendment 64 aimed at introducing a new recital on freedom of choosing an alternative therapy, despite differences in legal status of such therapies in Member States. The Commission considers that such a recital does not correspond to any provision of the proposal and thus, cannot be included in the proposal.

– The Commission cannot accept amendment 67 aimed at introducing a new definition of a veterinary prescription to allow only authorised veterinarians to prescribe medicinal products for use in animals. The Commission considers that this definition is too detailed and restricted. It may be envisaged that other authorised professionals may be allowed to prescribe particular types of medicinal products under national law. Furthermore, the meaning of representative samples and good veterinary practice in this context is unclear.

4. MODIFIED PROPOSAL

In conformity with Article 250, paragraph 2, of the EC treaty, the Commission has modified its proposal along the lines indicated.