

# EUROPEAN PARLIAMENT

1999



2004

---

*Session document*

FINAL  
**A5-0340/2002**  
**PAR 1**

9 October 2002

**\*\*\*I**

## **REPORT**

on the proposal for a European Parliament and Council directive amending  
Directive 2001/83/EC on the Community code relating to medicinal products  
for human use  
(COM(2001) 404 – C5-0592/2001 – 2001/0253(COD))

Part 1: Motion for a resolution  
Draft legislative resolution  
Explanatory Statement

Committee on the Environment, Public Health and Consumer Policy

Rapporteur: Françoise Grossetête

### ***Symbols for procedures***

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

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

### ***Amendments to a legislative text***

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

## CONTENTS

	<b>Page</b>
PROCEDURAL PAGE .....	4
DRAFT LEGISLATIVE RESOLUTION .....	5
EXPLANATORY STATEMENT .....	84

### **Published separately**

Opinions of other committees.....	Part 2 – A5-0340/2002
-----------------------------------	-----------------------

## PROCEDURAL PAGE

By letter of 26 November 2001 the Commission submitted to Parliament, pursuant to Article 251(2) and Articles 95 and 152 of the EC Treaty, the proposal for a European Parliament and Council directive amending Directive 2001/83/EC on the Community code relating to medicinal products for human use (COM(2001) 404 - 2001/0253 (COD)).

At the sitting of 13 December 2001 the President of Parliament announced that she had referred this proposal to the Committee on the Environment, Public Health and Consumer Policy as the committee responsible and the Committee on Budgets, the Committee on Budgetary Control, the Committee on Legal Affairs and the Internal Market, the Committee on Industry, External Trade, Research and Energy and the Committee on Agriculture and Rural Development for their opinions (C5-0592/2001).

The Committee on the Environment, Public Health and Consumer Policy had appointed Françoise Grossetête rapporteur at its meeting of 13 September 2001.

It considered the Commission proposal and draft report at its meetings of 26 February, 3 June, 9 September and 2 October 2002.

At the last meeting it adopted the draft legislative resolution by 36 votes to 9, with 5 abstentions.

The following were present for the vote: Caroline F. Jackson, chairman; Mauro Nobilia, Alexander de Roo and Anneli Hulthén, vice-chairmen; Françoise Grossetête, rapporteur; Per-Arne Arvidsson, María del Pilar Ayuso González, Juan José Bayona de Perogordo (for Marialiese Flemming, pursuant to Rule 153(2)), Hans Blokland, Armonia Bordes (for Laura González Álvarez), David Robert Bowe, John Bowis, Philip Bushill-Matthews (for Martin Callanan), Dorette Corbey, Chris Davies, Avril Doyle, Anne Ferreira, Karl-Heinz Florenz, Pernille Frahm, Cristina García-Orcoyen Tormo, Robert Goodwill, Marie Anne Isler Béguin, Piia-Noora Kauppi (for Ria G.H.C. Oomen-Ruijten, pursuant to Rule 153(2)), Christa Kläß, Bernd Lange, Peter Liese, Giorgio Lisi (for Eija-Riitta Anneli Korhola), Torben Lund, Jules Maaten, Minerva Melpomeni Malliori, Patricia McKenna, Eryl Margaret McNally (for Catherine Stihler, pursuant to Rule 153(2)), Jorge Moreira da Silva, Rosemarie Müller, Riitta Myller, Giuseppe Nisticò, Béatrice Patrie, Marit Paulsen, Fernando Pérez Royo (for Kathleen Van Brempt), Frédérique Ries, Didier Rod (for Hiltrud Breyer), Dagmar Roth-Behrendt, Guido Sacconi, Karin Scheele, Horst Schnellhardt, Inger Schörling, Jonas Sjöstedt, María Sornosa Martínez, Astrid Thors and Antonios Trakatellis.

The opinions of the Committee on Budgets, the Committee on Budgetary Control, the Committee on Industry, External Trade, Research and Energy and the Committee on Agriculture and Rural Development are published separately (Part 2 – A5-0340/2002); the Committee on Legal Affairs and the Internal Market decided on 24 January 2002 not to deliver an opinion.

The report was tabled on 9 October 2002.

The deadline for tabling amendments will be indicated in the draft agenda for the relevant part-session.

## DRAFT LEGISLATIVE RESOLUTION

**European Parliament legislative resolution on the proposal for a European Parliament and Council directive amending Directive 2001/83/EC on the Community code relating to medicinal products for human use (COM(2001) 404 – C5-0592/2001 – 2001/0253(COD))**

**(Codecision procedure: first reading)**

*The European Parliament,*

- having regard to the Commission proposal to the European Parliament and the Council (COM(2001) 404<sup>1</sup>),
  - having regard to Article 251(2) and Articles 95 and 152 of the EC Treaty, pursuant to which the Commission submitted the proposal to Parliament (C5-0592/2001),
  - having regard to Rule 67 of its Rules of Procedure,
  - having regard to the report of the Committee on the Environment, Public Health and Consumer Policy and the opinions of the Committee on Budgets, the Committee on Budgetary Control, the Committee on Industry, External Trade, Research and Energy and the Committee on Agriculture and Rural Development (A5-0340/2002),
1. Approves the Commission proposal as amended;
  2. Asks to be consulted again should the Commission intend to amend the proposal substantially or replace it with another text;
  3. Instructs its President to forward its position to the Council and Commission.

Text proposed by the Commission <sup>2</sup>

Amendments by Parliament

---

Amendment 1  
RECITAL –1 (new)

***(-1) Medicinal products are not  
commodities like other goods.***

*Justification*

*Self-explanatory.*

---

<sup>1</sup> OJ C 75 E, 26.3.2002, p. 216.

<sup>2</sup> OJ C ....

Amendment 2  
RECITAL 2

(2) Community legislation is a major milestone in the achievement of the objective of the free 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.

(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.

*Justification*

*Although obviously there must be freedom of movement for medicinal products, it must also be safe.*

Amendment 3  
RECITAL 3

(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.

(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 prejudice to the objective of achieving a high level of public health.**

*Justification*

*Improvement of the operation of the internal market must not adversely affect the level of public health in the Member States.*

Amendment 4  
RECITAL 4

(4) The main purpose of any regulation on the production and distribution of medicinal products for human use **should be** to safeguard public health. **However, this objective should be achieved by means which do not hinder** the development of the pharmaceutical industry or trade in

(4) The main purpose of any regulation on the production and distribution of medicinal products for human use **is** to safeguard public health. The development of the pharmaceutical industry or trade in medicinal products in the Community **must not compromise public health objectives.**

medicinal products in the Community.

***The highest level of human health and consumer protection has to be insured, as stated in Articles 152 and 153 of the Treaty.***

*Justification*

*The proposed article 4 must be in accordance with Articles 152 and 153 of the Treaty.*

Amendment 5  
RECITAL 10 a (new)

***(10a) Medicinal products may be approved only where the underlying clinical trials meet the ethical requirements laid down by Directive 2001/20/EC on good clinical practice.***

*Justification*

*In order to guarantee compliance with Directive 2001/20/EC on clinical trials, applications for authorisation should be rejected if they do not meet the prescribed ethical criteria. Clinical trials in developing countries should not be possible for products which are primarily intended for Western markets.*

Amendment 6  
RECITAL 14

(14) The quality of medicinal products for human use produced or available in the Community should be guaranteed by requiring that the active substances used in their composition comply with the principles of good manufacturing practice in relation to those medicinal products. It has proved necessary to reinforce the Community provisions on inspections and to compile a Community register of the results of those inspections.

(14) The quality of medicinal products for human use produced or available in the Community should be guaranteed by requiring that the active substances used in their composition comply with the principles of good manufacturing practice in relation to those medicinal products, ***which differ depending on whether the medicinal product is intended for adults or children.*** It has proved necessary to reinforce the Community provisions on inspections and to compile a Community register of the results of those inspections.

*Justification*

*Children have a different metabolism from adults and require a different dosage and method of administering the medicine. Despite that, 50-90% of the medicinal products administered to children for therapeutic purposes have not been evaluated for paediatric use and all clinical trials have been carried out on adults.*

Amendment 7  
RECITAL 15

(15) Pharmacovigilance and, more generally, market surveillance and sanctions in the event of failure to comply with the provisions should be stepped up. In the field of pharmacovigilance, account should be taken of the facilities offered by new information technologies to improve exchanges between Member States.

(15) Pharmacovigilance and, more generally, market surveillance and sanctions in the event of failure to comply with the provisions should be stepped up ***in the light of international pharmacovigilance data collected by non-European regulatory agencies and WHO.*** In the field of pharmacovigilance, account should be taken of the facilities offered by new information technologies to improve exchanges between Member States.

*Justification*

*Identification of adverse drug reactions is an international issue that must involve collaboration of regional drugs agencies and pharmacovigilance centres.*

Amendment 8  
RECITAL 16 a (new)

***(16a) Whereas patients have a legitimate need and right for information about medicinal products, including those available on prescription.***

*Justification*

*The ban on advertising of prescription medicines should be reviewed to ensure it does not undermine the Treaty goal of improving public health, because it denies patients access to an important source of information concerning prescription medicines.*

*The European Parliament noted in its First Reading on the new Public Health Action Programme (2003-2008) (Trakatellis Report) that the Community should take into account the right of patients to receive simple, clear and scientifically sound information about their illnesses, available treatments and ways of improving their quality of life.*

Amendment 9  
RECITAL 16 a (new)

***(16a) Whereas the Commission and the Member States, acting through the Pharmaceutical Committee, should continue to consider methods of improving communication with patients and the general public concerning prescription medicinal products, including guidance for provision of information by persons responsible for placing medicinal products on the market.***

*Justification*

*The public, especially specific groups of patients, is actively seeking information about medicines and alternative treatments, provided also by industry. For the provision of this information appropriate systems of evaluation are needed.*

Amendment 10  
RECITAL 17 a (new)

***(17a) The Commission should investigate whether it is possible to develop a standardised environmental classification system for human medicinal products and, if the Commission finds an appropriate model, it should submit the relevant proposals to Parliament before the end of 2003.***

*Justification*

*An environmental classification system for medicinal products would provide the prescriber with valuable information in selecting specific products. The system should be designed so that there is no adverse effect on patient compliance in respect of prescribed medicines.*

Amendment 11

ARTICLE 1, PARAGRAPH 1, POINT (b)

Article 1, point 2, point (b) (Directive 2001/83/EC)

(b) Any substance or combination of substances which may be used in human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions.

(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 action.*

*Justification*

Amendment 12

ARTICLE 1, PARAGRAPH 1, POINT (ba) (new)

Article 1, point 5 (Directive 2001/83/EC)

***Point (5) is replaced by the following:***

***"Homeopathic medicinal product:***

***Medicinal product prepared from substances 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."***

*Justification*

Amendment 13  
ARTICLE 1, PARAGRAPH 1, POINT (b a) (new)  
Article 1, point 8 (Directive 2001/83/EC)

***(ba) The title of point (8) is replaced by the following:***

***"(8) Kit"***

*Justification*

*It is necessary to correct an error which is present in the codified version.*

Amendment 14  
ARTICLE 1, PARAGRAPH 1, POINT (b a) (new)  
Article 1, point 18 a (new) (Directive 2001/83/EC)

***The following point is added:***

***(18a) Local representative:***

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

*Justification*

Amendment 15  
ARTICLE 1, PARAGRAPH 1, POINT (c a) (new)  
Article 1, points 28 and 28 a (new) (Directive 2001/83/EC)

*Point (28) is replaced by the following text and (28a) (new) is added*

*"28. Risks related to use of the product*

*- any risk relating to the quality, safety and efficacy of the product as regards the patient's health or public health;*

*- any risk of unwanted effects on the environment.*

*28a. Risk/benefit balance:*

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

*Justification*

Amendment 16

ARTICLE 1, PARAGRAPH 1a (new)  
Article 1 a (new) (Directive 2001/83/EC)

*1a. The following Article 1a is inserted:*

*"Article 1a*

*Generic drugs must be identified in all Member States with the same denomination of the internationally approved chemical name of the active substances and the name of the producer."*

### *Justification*

*The same internationally approved chemical name will be useful to avoid confusion for patients and health operators also when they travel in other Member States of the Community. In addition, this will encourage patients to use generic drugs with a significant cut down of drug expenses.*

Amendment 17  
ARTICLE 1, PARAGRAPH 2  
Article 2, paragraph 1 (Directive 2001/83/EC)

***1. The provisions of this Directive shall apply to medicinal products for human use intended to be placed on the market in Member States and either prepared industrially or manufactured by a method involving an industrial process.*** ***deleted***

### *Justification*

*The current wording of the directive should be maintained. The new wording proposed – ‘manufactured by a method involving an industrial process’ - will lead to divergent interpretation, because there is no definition for an industrial process. Based on the provisions laid down in Art. 5 of Directive 2001/83/EC, existing practical solutions regulating the manufacturing of very small batches on a national level, e. g. the British provisions for ‘Dispensary Manufacturing’, the ‘Rules of Thousand Units’ (Germany), the Dutch ‘pharmacy delivery’ or the French ‘sous-traitance’ have to be maintained. Otherwise, it is not possible for a pharmacy to immediately meet the needs of patients presenting prescriptions by medical doctors for not currently prescribed homeopathic medicinal products.*

Amendment 18  
ARTICLE 1, PARAGRAPH 2  
Article 2, paragraph 2 (Directive 2001/83/EC)

***2. Whenever a substance or combination of substances falls within the definition of ‘medicinal product’, the provisions of this Directive shall apply, even in cases where the substance or combination of substances falls also within the scope of other*** ***deleted***

## **Community legislation.**

### *Justification*

*The proposal would include a series of products such as food products and medical devices which are already regulated by other Community legislation. This would create legal uncertainty.*

#### Amendment 19

#### ARTICLE 1, PARAGRAPH 2

Article 2, paragraph 2 a (new) (Directive 2001/83/EC)

***2a. In the event of doubt as to whether a product falls within the scope of this directive, the Agency shall determine whether the product concerned should be classified as a medicinal product as defined in this directive.***

### *Justification*

*The most serious objection to the proposed text of Article 2 is the overlapping between medicinal products and 'borderline products', to which on the one hand specific European rules apply for the purposes of marketing authorisation, such as food supplements, cosmetics and medical devices, and unregulated products which are supplied as having a certain medicinal effect but are not regarded as medicinal products as defined in this directive.*

*The Commission proposal is based on a hierarchy of legislation on medicinal products: in case of doubt as to whether a product is a medicinal product, the legislation on medicinal products (Directive 2001/83) applies. In relation to regulated products, this provision creates a lacuna, as the specific European legislation provides that Directive 2001/83 does not apply to these products. The registration procedure provided for by Directive 2001/83 is not suitable for unregulated products with a medical claim (e.g. dietary products).*

*This amendment provides for the addition of a negative list to the directive, explicitly listing the products which do not fall within the scope of Directive 2001/83 (Article 2(2)).*

*These firstly include the products in respect of which specific European market authorisation rules have been adopted, i.e. medical devices, cosmetics, biocides and food supplements. In addition, a directive concerning processed body materials is being drafted on the basis of Article 95 of the EC Treaty.*

*Secondly, products can be listed in the annex which are not medicinal products but which*

*may be placed on the market with a certain medicinal effect, such as dietary products and other food products.*

*Finally, this amendment provides for the institution of an authority at national level which is to determine in cases of doubt whether a product is a medicinal product and needs to be placed on the market in accordance with the procedure laid down by legislation on medicinal products.*

#### Amendment 20

ARTICLE 1, PARAGRAPH 3, POINT (b a) (new)  
Article 3, point 6 a (new) (Directive 2001/83/EC)

***(ba) The following point (6a) is added:***

***“(6a) Food as defined by Regulation No (EC) 178/2002 (Food Safety Authority).”***

#### *Justification*

*To avoid cumulation of directives for products already covered by specific rules.*

#### Amendment 21

ARTICLE 1, PARAGRAPH 3, POINT (b a) (new)  
Article 3, point 6 a (new) (Directive 2001/83/EC)

***Point (6a) (new) is added:***

***"Medical devices and their accessories as covered by Council Directives 90/385/EC, 93/42/EC as amended and 98/79/EC on condition that such devices and accessories do not exert a pharmacological action."***

#### *Justification*

#### Amendment 22

ARTICLE 1, PARAGRAPH 3, POINT (b b) (new)  
Article 3, point 6 b (new) (Directive 2001/83/EC)

***(bb) The following point (6b) is added:***

***“(6b) Food supplements as defined in Directive 2002/46 ”***

***Directive 2002/46.”***

*Justification*

*To avoid cumulation of directives for products already covered by specific rules.*

Amendment 23

ARTICLE 1, PARAGRAPH 3, POINT (b c) (new)  
Article 3, point 6 c (new) (Directive 2001/83/EC)

***(bc) The following point (6c) is added:  
“(6c) Cosmetic products as defined in  
Directive 76/768.”***

*Justification*

*To avoid cumulation of directives for products already covered by specific rules.*

Amendment 24

ARTICLE 1, PARAGRAPH 4  
Article 5 (Directive 2001/83/EC)

“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 ***his individual patients*** under his direct personal responsibility.”

“***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 a pathogen which could cause harm. Such provisions shall apply whether or not national or Community authorisation has been issued.”***

*Justification*

*Exceptional uses of medicinal products can be envisaged only on a case-by-case basis, for each patient requiring such a use.*

Amendment 25

ARTICLE 1, PARAGRAPH 6, POINT (a)

Article 8, paragraph 3, point (c) (Directive 2001/83/EC)

(c) Qualitative and quantitative particulars of all the constituents of the medicinal product;

(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;***

*Justification*

*Where it exists, the international non-proprietary name (INN) is the recognised international formulation of a medicinal product. Use of this name should be encouraged as a means of improving the rational prescription and use of medicinal products, with due regard for the principles laid down by the WHO.*

Amendment 26  
ARTICLE 1, PARAGRAPH 6, POINT (a)  
Article 8, paragraph 3, point (c a) (new) (Directive 2001/83/EC)

***(ca) A risk/benefit assessment concerning the release of the product as waste into the environment.***

*Justification*

*Attention should be paid to what becomes of medicinal products in the environment once they have been used and metabolised by users. When they are released as waste by natural routes, they end up in the soil and, in particular, in water. Epidemiological surveys are under way and questions are being asked as to the potential effects on the human endocrine metabolism.*

Amendment 27  
ARTICLE 1, PARAGRAPH 6, POINT (a a) (new)  
Article 8, paragraph 3, point (g) (Directive 2001/83/EC)

***(aa) Point (g) is replaced by the following:  
“(g) Reasons for any precautionary and safety measures to be taken for the storage of the medicinal product, its administration to patients and the disposal of waste products, together with an indication of any potential risks presented by the medicinal product for the environment.”***

*Justification*

*Such information must become mandatory.*

Amendment 28  
ARTICLE 1, PARAGRAPH 6, POINT (b)  
Article 8, paragraph 3, point (i), introductory phrase (Directive 2001/83/EC)

(i) Results of:

***(i) Results of all of the following tests undertaken either by the applicant himself, on his behalf, or with his support, or otherwise of relevance:***

*Justification*

*All tests undertaken by the applicant himself, on his behalf, or with his support or otherwise of relevance - irrespective of their result - should be submitted to ensure that the authorities have the full picture.*

Amendment 29

ARTICLE 1, PARAGRAPH 6, POINT b

Article 8, paragraph 3, point i, indent 3 (Directive 2001/83/EC)

- clinical trials.

***- clinical trials on medicinal products intended for adults and on medicinal products intended for paediatric use (including at least one clinical trial of phase III in which the new medicinal product was compared with previously authorised medicinal products used to treat the same or a similar condition using a superiority design).***

*Justification*

*50-90% of the medicinal products administered to children for therapeutic purposes have not been evaluated for paediatric use and all clinical trials have been carried out on adults. Clinical trials should help identify whether the new medicine is superior to those already authorised.*

Amendment 30

ARTICLE 1, PARAGRAPH 6, POINT (b)

Article 8, paragraph 3, point (i), indent 3 a (new) (Directive 2001/83/EC)

***- tests evaluating any potential risks presented by the medicinal product to the environment.***

*Justification*

*Since drugs are excreted from the user to public waste systems they reach the environment, often in biologically active form. To make a proper risk/ benefit assessment, the authority of pharmaceutical drugs need to have information on the results of risk assessment test of the*

*product they evaluate.*

Amendment 31

ARTICLE 1, PARAGRAPH 6, POINT (b)

Article 8, paragraph 3, point (i a) (new) (Directive 2001/83/EC)

***(ia) A detailed description of the in-house pharmacovigilance and risk-management system which the applicant has introduced.***

*Justification*

*Even where a firm is submitting an application for the first time, an internal pharmacovigilance system should have been in existence since the clinical trials were conducted. This system should be described in detail in the application for authorisation in order to encourage self-evaluation by the firm and enable the authorities to require improvements.*

Amendment 32

ARTICLE 1, PARAGRAPH 6, POINT (b)

Article 8, paragraph 3, point (i b) (new) (Directive 2001/83/EC)

***(ib) Proof that the clinical trials conducted with the medicinal product meet the ethical requirements of Directive 2001/20/EC on good clinical practice. As a rule, this excludes the recognition of clinical trials carried out in developing countries unless the medicinal product concerned primarily benefits the population of that country.***

### *Justification*

*In order to guarantee compliance with Directive 2001/20/EC on clinical trials, applications for authorisation should be rejected if they do not meet the prescribed ethical criteria. Clinical trials in developing countries should not be possible for products which are primarily intended for Western markets.*

#### Amendment 33

ARTICLE 1, PARAGRAPH 6, POINT (c a) (new)  
Article 8, paragraph 3, point (m a) (new) (Directive 2001/83/EC)

***(ca) The following point (ma) is added:***

***"(ma) 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."***

### *Justification*

*To ensure optimum knowledge of the provisions implemented in connection with pharmacovigilance, it is necessary for every applicant for a marketing authorisation to provide detailed information on his own system in advance.*

#### Amendment 34

ARTICLE 1, PARAGRAPH 7  
Article 10, paragraph 1, subparagraph 1 (Directive 2001/83/EC)

By way of derogation from point (i) of Article 8(3), and without prejudice to the law relating to the protection of industrial and commercial property, the applicant shall not be required to provide the results of pre-clinical tests or of clinical trials if he/she can demonstrate that the medicinal product has been a generic of a reference medicinal product authorised under Article 6 for not less than **ten** years in a Member State or in the Community.

By way of derogation from point (i) of Article 8(3), and without prejudice to the law relating to the protection of industrial and commercial property, the applicant shall not be required to provide the results of pre-clinical tests or of clinical trials if he/she can demonstrate that the medicinal product has been a generic of a reference medicinal product authorised under Article 6 for not less than **eight** years in a Member State or in the Community. ***A generic medicinal***

the Community.

***product authorised pursuant to this provision cannot be manufactured or placed on the market until ten years have elapsed from the first authorisation of the reference product. In the case of a biogeneric medicinal product, pre-clinical tests and/or clinical trials shall be necessary.***

*Justification*

Amendment 35

ARTICLE 1, PARAGRAPH 7

Article 10, paragraph 1, subparagraph 2 (Directive 2001/83/EC)

The ten-year period referred to in the first subparagraph shall be extended to 11 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.

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.

*Justification*

*Original Commission text with addition of the relevant part of ex. Amendment 132 as adopted.*

Amendment 36

ARTICLE 1, PARAGRAPH 7

Article 10, paragraph 1 a (new) (Directive 2001/83/EC)

***1a. If the reference medicinal product is absent from a Member State, another chosen Member State where the reference medicinal product has been authorised as laid down in Article 6 for at least ten years and in accordance with the provisions of Article 8 shall transmit to the requesting***

***Member State, within a period of 30 days, a copy of the dossier, the assessment report, the summary of product characteristics and the marketing authorisation for the reference medicinal product.***

*Justification*

*In some candidate countries, for historical or economic reasons, reference medicinal products have never been registered, or their marketing authorisation has expired without being renewed. The updating of authorisations for generic products according to European legal requirements in the candidate countries makes it necessary to be able to refer to a reference product. The absence of such a product could result in an obligation to withdraw from the market generic medicinal products which, however, meet quality, safety and efficacy requirements. To prevent such a situation from causing problems of access to generic medicinal products, it is important that it be possible to use a reference medicinal product present in another Member State as a reference when a new application for a generic and/or for the updating of existing generics is made.*

Amendment 37

ARTICLE 1, PARAGRAPH 7

Article 10, paragraph 2, point (b a) (new) (Directive 2001/83/EC)

***(ba) A biogeneric medicinal product is a medicinal product which possesses similar physico-chemical and biological properties and the same pharmaceutical form and whose equivalence to the reference medicinal product in terms of safety and/or efficacy has been proven by means of appropriate pre-clinical tests and/or clinical trials.***

### *Justification*

*It is important to add a definition. The nature of biogeneric medicinal products differs from that of generic medicinal products.*

#### Amendment 38

##### ARTICLE 1, PARAGRAPH 7

Article 10, paragraph 3 (Directive 2001/83/EC)

3. The first subparagraph of paragraph 1 shall not apply to changes in ***the active substance(s)***, therapeutic indications, strength, pharmaceutical form or route of administration vis-à-vis the reference medicinal product, and the results of pre-clinical tests or clinical trials shall be provided.

3. The first subparagraph of paragraph 1 shall not apply to changes in therapeutic indications, strength, pharmaceutical form or route of administration vis-à-vis the reference medicinal product, and the results of pre-clinical tests ***and/or*** clinical trials shall be provided. ***In the event of a change in the active substance(s), appropriate pre-clinical and clinical trials must be provided.***

### *Justification*

*The requirements that support licensing a generic medicinal product, which has a different active substance to the original medicine (i.e. a 'false' generic), should be separated from other possible changes. This is because a change in the active substance for a generic drug should be treated as a new medicinal product. Under these circumstances a comprehensive package of scientific data would be required to support licensing of the medicine, including patient clinical trial data. The legislation can be clarified by making this specific point. This would ensure that the new active substance has been proven to be safe and effective in a large population of patients.*

#### Amendment 39

##### ARTICLE 1, PARAGRAPH 7

Article 10, paragraph 4 (Directive 2001/83/EC)

4. Conducting the necessary tests and trials with a view to application of paragraphs 1, 2 and 3 ***to a generic medicinal product*** shall not be regarded as contrary to patent rights or to complementary

4. Conducting the necessary tests and trials ***on the active ingredient, submitting an application for marketing authorisation for a generic or biosimilar medicinal product, submitting samples pursuant to Article 19 and granting marketing authorisation for a generic medicinal***

protection certificates for the medicinal products.

**authorisation for a generic medicinal product** with a view to application of paragraphs 1, 2 and 3, **as well as for export, will not be regarded as contrary** to patent rights or to complementary protection certificates for **the reference** medicinal products **in question**.

#### *Justification*

*This amendment makes the Commission proposal more precise in that it describes exactly what development work may be carried out in connection with the authorisation procedure for a generic medicinal product. This will create legal certainty. Otherwise, generic medicinal products will continue to be developed outside the EU while the original is still under patent, with the consequent loss of jobs, investment and know-how.*

*A provision concerning exportation has been introduced for the following reasons:*

*- to improve access to medicinal products by facilitating exports of generic products so as to meet the health needs in a country which has granted a compulsory licence or which does not have a patents system,*

*-to ensure that the European generics industry can compete on the world market.*

#### Amendment 40

#### ARTICLE 1, PARAGRAPH 7

Article 10, paragraph 4 a (new) (Directive 2001/83/EC)

***4a. In addition to the provisions laid down in Article 10(1), where an application is made for a new indication for a well established substance, a period of three years of data exclusivity shall be granted, provided that significant pre-clinical or clinical studies were carried out in relation to the new indication.***

## *Justification*

*The current legislative provisions as well as the proposal of the European Commission do not foresee any data protection for pre-clinical test or clinical trials in relation to known substances. This has already considerably reduced the scientific work around known substances. It is therefore appropriate to install in the European Union a period of data exclusivity like in the United States where a three years period of data protection is granted by the competent authority provided it is linked to significant new clinical investigations.*

### Amendment 41 ARTICLE 1, PARAGRAPH 8 Article 10 a (Directive 2001/83/EC)

By way of derogation from point (i) of Article 8(3), and without prejudice to the law relating to the protection of industrial and commercial property, the applicant shall not be required to provide the results of pre-clinical tests and clinical trials if he/she can demonstrate that the component(s) of the medicinal product have been of well established medicinal use within the Community for at least the last ***ten years***, with recognised efficacy and an acceptable level of safety in terms of the conditions set out in Annex I. In that event, the test and trial results shall be replaced by appropriate scientific literature.

By way of derogation from point (i) of Article 8(3), and without prejudice to the law relating to the protection of industrial and commercial property, the applicant shall not be required to provide the results of pre-clinical tests and clinical trials if he/she can demonstrate that the component(s) of the medicinal product have been of well established medicinal use within the Community for at least the last ***eight years***, with recognised efficacy and an acceptable level of safety in terms of the conditions set out in Annex I. In that event, the test and trial results shall be replaced by appropriate scientific literature.

*Justification*

*This amendment ensures consistency with the other amendments tabled to Article 10(1).*

Amendment 42  
ARTICLE 1, PARAGRAPH 9, POINT (-a) (new)  
Article 11 (Directive 2001/83/EC)

***(-a) The introductory sentence is replaced by the following:***

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

*Justification*

*To ensure greater clarity as regards the summary of product characteristics, it is proposed that the order in which information must appear be laid down.*

Amendment 43  
ARTICLE 1, PARAGRAPH 9, POINT (b)  
Article 11, paragraph 6, point 6.-1 (Directive 2001/83/EC)

***6.-1. major incompatibilities,***

*Justification*

*This term appears in the codified directive and so should be reinstated.*

Amendment 44  
ARTICLE 1, PARAGRAPH 11  
Article 13, paragraph 1 (Directive 2001/83/EC)

1. Member States shall ensure that

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.

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 effected and of the authorisations issued by other Member States.***

#### *Justification*

*Member States must ensure that there is a certain amount of consistency and coordination.*

#### Amendment 45

ARTICLE 1, PARAGRAPH 12, POINT (-a) (new)  
Article 14, paragraph 1, indent 1 (Directive 2001/83/EC)

***(-a) In article 14, paragraph 1, the first indent is replaced by the following:***

***"- they are administered by a route of administration described in the European Pharmacopoeia or in absence thereof in a Pharmacopoeia currently used in a Member State,"***

## *Justification*

*Quality and safety of a pharmaceutical form is guaranteed by GMP rules. Additional safety is provided by the requirement to meet the criteria laid down in monographs in official Pharmacopoeias. They cover all pharmaceutical forms, as for example nasal sprays, injections and eye drops, which were treated in a different way in every Member State.*

### Amendment 46

ARTICLE 1, PARAGRAPH 12, POINT (-a) (new)  
Article 14, paragraph 1, indent 3 (Directive 2001/83/EC)

***(-a) In paragraph 1, the third indent is replaced by the following:***

***"- there is a sufficient degree of potentiation, which involves a sequential series of dilutions and 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; if new scientific evidence so warrants, the Commission may amend the present indent by the procedure referred to in Article 121 (2)."***

*Justification*

*It is important to introduce the process essential to the preparation of medicines for homeopathic use, potentiation, at this point in the document. The pharmaceutical process involved in producing these products involves more than just simple dilution.*

Amendment 47

ARTICLE 1, PARAGRAPH 12 a (new)  
Article 15, indent 2 (Directive 2001/83/EC)

***(12a) In Article 15, the second indent is replaced by the following:***

***"- 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,"***

*Justification*

*The use of 'nature' is unclear here. The word 'use' provides clearer meaning.*

Amendment 48

ARTICLE 1, PARAGRAPH 12 a (new)  
Article 15, indent 3 (Directive 2001/83/EC)

***(12a) In Article 15, the third indent is replaced by the following:***

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

*Justification*

*Potentiation includes the process of dilution.*

Amendment 49

ARTICLE 1, PARAGRAPH 15

Article 17, paragraph 1, subparagraph 1 (Directive 2001/83/EC)

1. Member States shall take all appropriate measures to ensure that the procedure for granting an authorisation to place a medicinal product on the market is completed within 150 days of a valid application, ***including 120 days for drawing up the assessment report and the summary of the product characteristics.***

1. Member States shall take all appropriate measures to ensure that the procedure for granting an authorisation to place a medicinal product on the market is completed within 150 days of a valid application, ***including 80 days for scientific data analysis and preparation of the report by the rapporteur.***

*Justification*

*Systematic acceleration of procedures compromises good quality assessment of marketing authorisations.*

*The time given to experts is presently limited (often about two months) due to administrative delays and time given to applicants to respond to questions.*

Amendment 50

ARTICLE 1, PARAGRAPH 15

Article 18 (Directive 2001/83/EC)

Where a Member State is informed in accordance with point ***(m)*** 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.

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.

*Justification*

*Consistency within text.*

Amendment 51  
ARTICLE 1, PARAGRAPH 18  
Article 21, paragraph 3 (Directive 2001/83/EC)

3. The competent authorities shall ***make available to any interested party*** a copy of the authorisation together with the summary of the product characteristics.

3. The competent authorities shall ***set up a Register making publicly accessible without delay*** a copy of the authorisation ***for any authorised medicinal product (through the centralised and decentralised procedure)***, together with the summary of product characteristics, ***after all commercially confidential information has been deleted.***

*Justification*

*In the spirit of EU Regulation 1049/2001 and the Charter of Fundamental Rights, and even if a given Member State has no national law providing for access to documents.*

Amendment 52  
ARTICLE 1, PARAGRAPH 18  
Article 21, paragraph 4, subparagraph 1 a (new) (Directive 2001/83/EC)

***The competent authorities shall make publicly available without delay, in the same Register as mentioned in Article 21(3), the assessment report together with the reasons for their opinion, after deletion of information of a commercially confidential nature.***

*Justification*

*In the spirit of EU Regulation 1049/2001 and the Charter of Fundamental Rights, and even if a given Member State has no national law providing for access to documents.*

Amendment 53

ARTICLE 1, PARAGRAPH 18

Article 21, paragraph 4, subparagraph 2 (Directive 2001/83/EC)

*At the request of any interested party*, the competent authorities shall ***make available*** the assessment report, together with the reasons for their opinion, after deletion of information of a commercially confidential nature.

The competent authorities shall ***publish*** the assessment report, together with the reasons for their opinion, after deletion of information of a commercially confidential nature. ***The justification shall be provided separately for each indication applied for.***

*Justification*

*In the interests of consistency with the regulation, the same wording should be used here. It is important to guarantee the greatest possible transparency.*

*If one or more of the indications applied for are not authorised, this provides important information for doctors and patients, since they are then better able to assess the risks of off-label use.*

Amendment 54

ARTICLE 1, PARAGRAPH 18

Article 21, paragraph 4 a (new) (Directive 2001/83/EC)

***4a. The marketing authorisation, the summary of product characteristics, the assessment report and the comments on this report shall be accessible to the general public on the agency's website.***

*Justification*

*Such access should improve information to patients.*

Amendment 55  
ARTICLE 1, PARAGRAPH 19  
Article 22, paragraph 1 (Directive 2001/83/EC)

In exceptional circumstances, and following consultation with the applicant, an authorisation may be granted subject to certain specific obligations to carry out further studies following the granting of authorisation.

In exceptional circumstances, and following consultation with the applicant, an authorisation ***could be granted subject to an obligation to establish special mechanisms for assessing the safety of the product, informing the competent authorities of any incident and taking all necessary measures immediately. The list of these obligations shall be made publicly accessible, without delay and in the same Register as mentioned in Article 21(3), together with deadlines and date of fulfilment***

*Justification*

*It is necessary to define more clearly the risk management plan and the criteria for granting authorisation in exceptional cases. In the spirit of EU Regulation 1049/2001 and the Charter of Fundamental Rights, and even if a given Member State has no national law providing for access to documents.*

Amendment 56  
ARTICLE 1, PARAGRAPH 19 a (new)  
Article 23, subparagraph 1 (Directive 2001/83/EC)

***(19a) In Article 23a, the first paragraph is replaced by the following:***

***'After an authorisation has been issued, the marketing authorisation holder must, with regard to the manufacturing and control methods referred to in Article 8(3)(d) and (h), take account of scientific and technical progress and make all the changes necessary to ensure that the medicinal product is manufactured and inspected in accordance with generally accepted scientific methods, with due***

*regard for Community law.'*

*Justification*

*Account must be taken of the Community legislation in force.*

Amendment 57

ARTICLE 1, PARAGRAPH 21

Article 24, paragraph 2 (Directive 2001/83/EC)

2. Any authorisation which is not followed within **two 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.

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.

*Justification*

*The proposed two-year time limit is not long enough to ensure appropriate management of the system, in particular owing to the divergences noted between Member States as regards market access for medicinal products.*

Amendment 58

ARTICLE 1, PARAGRAPH 21

Article 24, paragraph 2, subparagraph 1 a (new) (Directive 2001/83/EC)

***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.***

*Justification*

*Derogations should be possible in respect of specific medicinal products on public health grounds.*

Amendment 59  
ARTICLE 1, PARAGRAPH 21  
Article 24, paragraph 3 a (new) (Directive 2001/83/EC)

***3a. The Commission shall carry out a detailed study of the practical and effective application of the Transparency Directive (1989/105) in all Member States of the European Union and in the candidate countries and, on the basis of the findings, Parliament shall have the option of calling on the Commission to reconsider the principles underlying the said Directive and, if appropriate, consider a review of the Directive.***

*Justification*

*Application of the Transparency Directive (89/105) requires Member States to initiate pricing/reimbursement procedures within a period of no more than 180 days counting from the date of the marketing authorisation - which is never the case in some Member States. In certain Member States, it takes an average of two years before reimbursement is granted, and there have been cases where it has taken four years to place a product on the market.*

*The Transparency Committee set up to ensure that application of this directive is monitored has never actually succeeded in shortening the periods required in some Member States. The Commission has itself, on numerous occasions, expressed a wish to reconsider the foundations and principles of the directive.*

*The main problem is of course the de facto inequality between patients in Europe as regards access to treatments, as medicinal products, whilst properly authorised in the European Union, cannot be placed on some Member States' markets because their administrative processes are so slow.*

*Infringement proceedings are rare, as firms whose products are involved fear retaliation at the national level if the matter is referred to the Commission.*

Amendment 60  
ARTICLE 1, PARAGRAPH 22  
Article 26, paragraph 2 a (new) (Directive 2001/83/EC)

***Where a competent authority finds that the documents or data submitted are false, it shall demand that the applicant make the necessary corrections without delay, and within a time limit of two months. If the***

*time limit is not adhered to, the authority shall reject the application. If the authority finds that data has been falsified, it shall inform the prosecuting authorities without delay.*

*Justification*

*The vast majority of applications for authorisation contain correct documents and data. An action framework must be laid down for cases where incorrect data is submitted.*

Amendment 61  
ARTICLE 1, PARAGRAPH 24  
Article 27, paragraph 3 (Directive 2001/83/EC)

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

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.***

*Justification*

*There must be complete transparency with regard to these Rules of Procedure.*

Amendment 62  
ARTICLE 1, PARAGRAPH 24  
Article 28, paragraph 1, subparagraph 1 (Directive 2001/83/EC)

1. With a view towards the grant of a marketing authorisation for a medicinal product in more than one Member State, an applicant shall submit an application based on an identical dossier in these Member States. The dossier shall contain the information and documents referred to in Articles 8 and Articles 10 to 11. The documents submitted shall include a list of Member States concerned by the application.

1. With a view towards the grant of a marketing authorisation ***or registration*** for a medicinal product in more than one Member State, an applicant shall submit an application based on an identical dossier in these Member States. The dossier shall contain the information and documents referred to in Articles 8 and Articles 10 to 11. The documents submitted shall include a list of Member States concerned by the application.

application.

***A dossier for homeopathic medicinal products shall contain the specific information and documents referred to in Articles 14, 15 and 16.***

#### *Justification*

*The mutual recognition procedure is welcomed by patients, doctors and producers in order to integrate homeopathic medicinal products in the Internal Market. However this system is intended to cover especially Article 14 products (simplified registration). The technical term therefore consequently must be corrected in this Article.*

#### Amendment 63

#### ARTICLE 1, PARAGRAPH 24

Article 29, paragraph 1 a (new) (Directive 2001/83/EC)

***1a. Member States shall only be allowed to refuse to recognise an authorisation granted by another Member State if there is a serious potential risk to public health.***

***A serious risk to public health shall be defined in guidelines.***

### *Justification*

*The mutual recognition procedure has not been successfully used since applications tend to result in each Member State re-assessing the dossier from their own scientific perspective and this restricts acceptance of the application. Member States can open up a scientific assessment if they use the phrase 'serious grounds for supposing the product presents a risk to public health', which is the only way a product can be refused mutual recognition. But there is no definition of this phrase, indeed, references to grounds for objections are often referred to as 'matters' (Articles 29, 34), 'elements' (Article 29), 'reasons' (Articles 29, 32), 'questions' (Articles 27, 34), etc. There is no independent body to assess whether the concerns of the Member States are 'serious' and no route of appeal. A definition of what constitutes a serious risk to public health is needed to allow for transparency in decision making and the use of the MRP in the way that it was originally intended for the creation of a single European market.*

#### Amendment 64

#### ARTICLE 1, PARAGRAPH 24

#### Article 30, paragraph 1 (Directive 2001/83/EC)

1. If two or more applications submitted in accordance with Article 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 Article 32.

1. If two or more applications submitted in accordance with Article 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 **shall** refer the matter to the Committee on Human Medicinal Products, hereinafter referred to as "the Committee", for application of the procedure laid down in Article 32.

### *Justification*

*In the event of conflicting points of view, the Agency should have the opportunity to give a ruling.*

Amendment 65  
ARTICLE 1, PARAGRAPH 24  
Article 30, paragraph 2, subparagraph 3 (Directive 2001/83/EC)

The Commission or a Member State, in agreement with the Agency **and taking into account the views of interested parties, may refer these products in accordance with paragraph 1.**

The Commission or a Member State, in agreement with the Agency, **shall submit an application for harmonisation of the summary of product characteristics to the Committee, which shall advise on the changes to be made in the summary of product characteristics in accordance with the procedure laid down in Article 32.**

*Justification*

*Because of the impact of European case law (e.g. Decker & Kohll, Smits-Peerbooms, Vanbraekel), European integration in the field of health care and the free circulation of medicinal products has come a step closer. In order to make life easier for patients and social insurance bodies, harmonisation of therapeutic indications, posology, contra-indications, overdoses, driving of vehicles and operation of machinery, special precautions, incompatibilities, pregnancy and breast-feeding, interactions, storage, product life, pharmaceutical forms, methods of administration, supply and packaging would represent a positive contribution.*

Amendment 66  
ARTICLE 1, PARAGRAPH 24  
Article 31, paragraph 1, subparagraph 1 (Directive 2001/83/EC)

1. The Member States or the Commission or the applicant or the marketing authorisation holder **may**, 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 Article 32 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.

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 Article 32 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.

*Justification*

*In urgent situations, the Agency should have the opportunity to give a ruling.*

Amendment 67

ARTICLE 1, PARAGRAPH 24

Article 32, paragraph 2 (Directive 2001/83/EC)

2. In order to consider the matter, the Committee **may** appoint one of its members to act as 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.

2. In order to consider the matter, the Committee **shall** appoint one of its members to act as 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.

*Justification*

*Self-explanatory.*

Amendment 68

ARTICLE 1, PARAGRAPH 24

Article 32, paragraph 3, subparagraph 1 (Directive 2001/83/EC)

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.

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 will specify.***

*Justification*

*More detail is needed as regards the proposed time limit.*

Amendment 69  
ARTICLE 1, PARAGRAPH 24  
Article 32, paragraph 5, subparagraph 1 (Directive 2001/83/EC)

Within **30** 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.

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 **person applying for** the marketing authorisation, together with a report describing the assessment of the medicinal product and stating the reasons for its conclusions.

*Justification*

Amendment 70  
ARTICLE 1, PARAGRAPH 25, POINT (-a) (new)  
Article 33, paragraph 1 (Directive 2001/83/EC)

***(-a) The first paragraph is replaced by the following:***

***"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."***

### *Justification*

*This amendment aims at reducing the decision-making timelines which have been heavily criticised during the audit (cf. Evaluation of the Operation of Community Procedures for the Authorisation of Medicinal Products, section 5.1.14, page 110). The European Commission has proposed a modest reduction in one part of the process by shortening the duration of the consultation period of Member States from 28 days down to 15 days. However, even after this improvement the process could still take greater than 75 days, and reduction of other administrative steps is necessary and possible.*

#### Amendment 71

#### ARTICLE 1, PARAGRAPH 28

Article 38, paragraph 2 (Directive 2001/83/EC)

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.

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 will in particular take account of the need to standardise procedures applicable to clinical trials and pre-clinical tests. This report shall be forwarded to the European Parliament.***

### *Justification*

*The Bayer case has shown that standardisation of procedures for clinical and pre-clinical tests is necessary in order to improve safety for patients. Credible application of the centralised procedure for marketing medicinal products for human use requires that efforts be made to achieve such standardisation.*

#### Amendment 72

#### ARTICLE 1, PARAGRAPH 37, POINT (a)

Article 54, point (a) (Directive 2001/83/EC)

(a) the name of the medicinal product followed by its strength and pharmaceutical

(a) the name of the medicinal product followed by its strength and pharmaceutical

form (baby, child or adult as appropriate); the common name shall be included ***where the product contains only one active substance and if its name is an invented name;***

form (baby, child or adult as appropriate); ***the international non-proprietary name (INN) or, where this does not exist,*** the common name, shall be included;

*Justification*

*The packaging of medicinal products must above all take due account of patients' needs.*

Amendment 73

ARTICLE 1, PARAGRAPH 37, POINT (aa) (new)  
Article 54, point (aa) (new) (Directive 2001/83/EC)

***(aa) The following point (aa) is inserted:***

***"(aa) Generic drugs must be identified in all Member States with the same denomination of the internationally approved chemical name of the active substances and the name of the producer."***

*Justification*

*The same international approved chemical name will be useful to avoid confusion for patients and health operators also when they travel in other Member States of the Community. In addition, this will encourage patients to use generic drugs with a significant cut down of drug expenses.*

Amendment 74

ARTICLE 1, PARAGRAPH 37, POINT (b a) (new)  
Article 54, point (e) (Directive 2001/83/EC)

***(ba) Point (e) is replaced by the following:***

***"(e) the method of administration and, if necessary, the route of administration. Space must be provided on the packaging for a pharmacist to indicate the prescribed dose for the patient concerned;"***

*Justification*

*Will avoid the need for a pharmacist to cover over part of the packaging which could give a patient important information.*

Amendment 75

ARTICLE 1, PARAGRAPH 37, POINT (c a) (new)  
Article 54, point (f a) (new) (Directive 2001/83/EC)

***(ca) The following point (fa) is added:***

***"(fa) the address of the competent national authority's website on which information concerning the medicinal product is available shall be indicated on the packaging."***

*Justification*

*Such access to the website should mean patients are better informed about medicinal products.*

Amendment 76

ARTICLE 1, PARAGRAPH 37, POINT (c a) (new)  
Article 54, point (h a) (new) (Directive 2001/83/EC)

***(ca) The following point (ha) is added:***

***"(ha) the address of the competent national authority's website on which information concerning the medicinal product is available shall be indicated on the package leaflet."***

*Justification*

*Such access to the website should mean patients are better informed about medicinal products.*

Amendment 77  
ARTICLE 1, PARAGRAPH 37, POINT (c a) (new)  
Article 54, point (j) (Directive 2001/83/EC)

***(ca) Point (j) is replaced by the following:***

***"(j) a statement that unused medicinal products or waste materials from medicinal products should be returned to the pharmacy. A statement that unused medicinal products should not be discharged into the sewer;"***

*Justification*

*When drugs are excreted into public waste systems they will eventually reach the environment. Pharmacies should take care of unused pharmaceutical drugs from patients or customers, and subject them to destruction under environmentally safe conditions.*

Amendment 78  
ARTICLE 1, PARAGRAPH 38 a (new)  
Article 56 (Directive 2001/83/EC)

***(38a) Article 56 is replaced by the following:***

***"Article 56***

***The particulars referred to in Articles 54, 55 and 62 shall be easily legible, clearly comprehensible and indelible. The references made in Art 54 (a) of this Directive must be also expressed in Braille format on the packaging or in the Patient Information Leaflet (PIL) provided inside so that blind and partially-sighted people also have access to this vital information. Basic information such as product name, dosage, helpline telephone number and web site address must be included in the packaging or in the PIL, in large print (minimum font size 16). The full text of the PIL should be available, free of charge, in other formats on request, (such as large print, braille, audio tape and electronic***

*format)."*

### *Justification*

*The writing on the PIL leaflets and packaging is often too small for many partially sighted people to read. This can and does lead to patients endangering their health through wrongly taking medication. With a rapidly ageing population, age-related sight loss is an increasing problem. While Braille is understood by many lifelong blind people and is a vital lifeline for deaf-blind people, those who develop blindness and sight loss later in life do not tend to understand it. The use of Braille should therefore be coupled with the use of large print.*

### Amendment 79

ARTICLE 1, PARAGRAPH 38 b (new)  
Article 56 a (new)(Directive 2001/83/EEC)

***A new Article 56a is added:***

***"The competent national authority will establish a database, accessible free of charge through the internet, in which up to date content information for all pharmaceutical products licensed for sale or dispensing within the territory of that Member State is available. This database should be fully accessible to all citizens in such a way that disabled people can easily access pharmaceutical product information. For those without access to the internet, a telephone helpline service should be established to ensure as wide a dissemination of information as possible. Through the web site and helpline, complete product information should be made available on request, in the following alternative formats: Large Print (minimum font size 16) , Braille, Audio Tape and e-text. "***

### *Justification*

*This new Article would fall after A56 of the Directive and before point 39 of the Com doc. The packaging inside medicine packaging is by its nature small, so it would be difficult to fit all information on it. For this reason, the establishment of a web site, set up according to accepted standards of web-site accessibility and a helpline would be vital means for blind and partially sighted people to request information and to order the full Patient Information Leaflet (PIL) in alternative formats.*

### Amendment 80

#### ARTICLE 1, PARAGRAPH 40

Article 59, paragraph 1, point (d) (Directive 2001/83/EC)

(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;

(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 competent authority***;

### *Justification*

*Rules on recording adverse reactions should apply in the centralised and decentralised authorisation procedure. Up to now, European law provides that only medical professionals can report adverse reactions to the authorities. This has the advantage that standard medicinal terminology is used and the data can easily be compared. The disadvantage is that many doctors are too overworked to record and report large numbers of more minor reactions. Consequently, only a fraction of such reactions are currently reported. Patients should therefore be able to report such reactions directly to the authorities. The US Food and Drug Administration (FDA) introduced this scheme several years ago.*

### Amendment 81

#### ARTICLE 1, PARAGRAPH 40 a (new)

Article 59, paragraph 1, point (d a) (new) (Directive 2001/83/EC)

**40a. In Article 59(1), the following new point (da) is inserted after point (d):**

**“(da) for every new medicinal product in the first five years after it was first placed on the market, the indication ‘newly authorised medicinal product, please report adverse reactions.’”**

*Justification*

*Particularly in the case of new medicinal products, patients should be asked to report all adverse reactions so that the scale of problems occurring in practice can quickly be established.*

Amendment 82

ARTICLE 1, PARAGRAPH 40

Article 59, paragraph 1, point (e), point (vii a) (new) (Directive 2001/83/EC)

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

*Justification*

*Most of the Member States already use this approach. Medicines are special products and it is important to encourage citizens to ask health professionals for clarifications on their use when necessary.*

Amendment 83

ARTICLE 1, PARAGRAPH 40

Article 59, paragraph 1, point (f), point (vi a) (new) (Directive 2001/83/EC)

***(vi a) the name and address of the manufacturer;***

*Justification*

*These are important identification details.*

Amendment 84  
ARTICLE 1, PARAGRAPH 40  
Article 59, paragraph 2 a (new) (Directive 2001/83/EC)

***2a. The legibility, clarity and ease of use for patients of the package leaflet shall be assessed in consultation with target patient groups.***

*Justification*

*In order to ensure rational use of medicinal products, package leaflets need to be assessed with the participation of patient groups.*

Amendment 85  
ARTICLE 1, PARAGRAPH 40 a (new)  
Article 61, paragraph 1 (Directive 2001/83/EC)

***(40a) Article 61(1) is replaced by the following text:***

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

*Justification*

*Cf. the amendment relating to Article 59(2b) (new). The competent authorities must also be made aware of the assessments of proposed package leaflets by target patient groups.*

Amendment 86  
ARTICLE 1, PARAGRAPH 43, POINT (a a) (new)  
Article 63, paragraph 2 (Directive 2001/83/EC)

***(aa) Paragraph 2 is replaced by the following:***

***"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."***

*Justification*

*It is important to clarify in the legislation that the writing and design of patient leaflets should primarily serve the users in a way that it enables an appropriate use of the product. It is not sufficient to simply focus on clear and understandable terms, as this may still not ensure in the best possible way an appropriate acting.*

Amendment 87  
ARTICLE 1, PARAGRAPH 44  
Article 65, point © (Directive 2001/83/EC)

***(c) the legibility of particulars on the labelling and package leaflet;***

***(c) the design, writing and testing of effective labels and leaflets;***

*Justification*

*The primary purpose of guidelines in relation to a better understanding of labelling and package leaflets should refer to ways to verify the writing and testing of usable labels and leaflets. It is therefore appropriate to clarify the purpose of the envisaged guideline.*

Amendment 88  
ARTICLE 1, PARAGRAPH 44 b (new)  
Article 66, paragraph 3, indent 4 (Directive 2001/83/EC)

***(44a) The fourth indent in Article 66(3) is replaced by the following:***

***“- the name and address of the manufacturer,”***

*Justification*

*This information is important for the sake of clarity. The amendment is self-explanatory.*

Amendment 89  
ARTICLE 1, PARAGRAPH 44 a (new)  
Article 68 (Directive 2001/83/EEC)

***Article 68 is replaced by the following.***

***"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."***

*Justification*

*What characterises this category of medicinal product pharmaceutically is potentisation, the method of preparation which results in the dilute state of the active principle, or principles, contained in each medicine. The 'homeopathic nature' is more accurately linked to the reasons for prescription based on the principle of similars.*

Amendment 90  
ARTICLE 1, PARAGRAPH 45, POINT (a)  
Article 69, paragraph 1, indent 1 (Directive 2001/83/EC)

- the scientific name of the stock or stocks followed by the degree of dilution, making

- 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 replaced by an invented name,*

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, *an invented name may be given in addition to* the scientific names of the stocks on the labelling,

#### *Justification*

*For the sake of comprehensible information towards doctors and patients an invented name should be made possible. However, this invented name should only be made in addition to a full scientific declaration of active principles and ingredients.*

#### Amendment 91

ARTICLE 1, PARAGRAPH 45, POINT (a a) (new)  
Article 69, paragraph 1, indent 11 (Directive 2001/83/EC)

*(aa) The eleventh indent is replaced by the following:*

*"- homeopathic medicinal product without specific therapeutic indications,"*

#### *Justification*

*There is no point in an 'invented' name unless it is somehow to give a therapeutic indication as to which condition the remedy of combined stocks could be prescribed for. Remedies containing two or more stocks may have a supplementary 'invented name' added to the labelling.*

*If the symptoms of a patient's condition persist beyond the taking of a homeopathic remedy the patient should check with their doctor if they have not already done so. However, the patient should also refer back a registered homeopath for further diagnosis and treatment, as only the homeopath has the expertise to evaluate the effect of the homeopathic remedy being taken and to prescribe for the patient should the patient require further homeopathic treatment.*

#### Amendment 92

ARTICLE 1, PARAGRAPH 47 a (new)  
Article 74 a and 74 b (new) (Directive 2001/83/EC)

*(47a) The following Articles 74a and 74b are inserted:*

*"Article 74a*

*When an application is made by a marketing authorisation holder, the competent authorities shall examine and, as appropriate, amend the classification of a medicinal product by applying the criteria listed in Article 71."*

*"Article 74b*

*When an application includes significant pre-clinical tests or significant clinical trials, significant new analyses or significant new data generated at the request of the Competent Authority and deemed essential to the approval of the application, then the Competent Authority shall not refer to those tests, trials, analyses or data in the examination of an application by another marketing authorisation holder for a change of classification of the same substance during a period of 3 years after the authorisation."*

*Justification*

*The change of classification status may require considerable scientific work by the applicant. It is justifiable to provide for this work a data exclusivity provision.*

Amendment 93

ARTICLE 1, PARAGRAPH 48

Title VII, heading (Directive 2001/83/EC)

Title VII

Distribution of medicinal products

Title VII

**Wholesale** distribution of medicinal products

*Justification*

*(Ms Flemming and Mr Khanbhai) This is in line with the title of the former Council directive 92/25/EEC of 31 March 1992 on the 'wholesale distribution of medicinal products' for human use. In Article 77 wholesale distribution of medicinal products is defined as all*

*activities consisting of procuring, holding, supplying or exporting medicinal products, apart from supplying products to the public. Wholesale distribution, if not conducted by the marketing authorisation holder, requires a wholesale distribution authorisation. This authorisation is called 'distribution authorisation' in the Articles 78-81. Without the original title of chapter VII this definition is misleading and confusing.. Furthermore there is no reason to change the title because the retail distribution of medicinal products is not a subject of this chapter.*

*(Mr Nisticò) The change in the title creates legal uncertainty. The provisions laid down in this title are only referring to wholesale distribution of medicines, according to European legislation. The only sentence referring to distribution to the public is clearly distinguished in the text. The change in the heading will have the only effect of creating confusion as competencies are limited to wholesale distribution of medicinal products.*

#### Amendment 94

ARTICLE 1, PARAGRAPH 49, POINT (b a) (new)  
Article 76, paragraph 2 a (new) (Directive 2001/83/EC)

***(ba) The following paragraph 2a is added:***

***"2a. Any distributor, not being the marketing authorisation holder, who imports a product from another Member State shall notify the marketing authorisation holder of his intention to submit to a competent authority an application for a parallel import licence."***

#### *Justification*

*It is necessary to ensure that the marketing authorisation holder, who is responsible for his product, is made aware of parallel imports so as to ensure, where appropriate, that the safety, efficacy and quality criteria for the product are fully met, as recent examples have shown there to be problems with repackaging or the presentation of package leaflets.*

#### Amendment 95

ARTICLE 1, PARAGRAPH 49 a (new)  
Article 77, paragraph 3 a (new) (Directive 2001/83/EC)

***(49a) In Article 77, the following paragraph 3a is added:***

***"The holder of a marketing authorisation for a medicinal product shall provide an***

*uninterrupted supply of that medicinal product on the market of the Member State concerned to wholesaler distributors registered in these Member States, so that the provision of the medicinal product to patients through pharmacies and hospitals is ensured.*

*Within the limits of their respective responsibilities, wholesale distributors and manufacturing authorisation holders engaging in the wholesale distribution of their products pursuant to Article 77(3) shall provide an uninterrupted supply of such medicinal products to pharmacies and persons authorised to supply medicinal products to the public in the Member State concerned.*

*Pharmacies and persons authorised to supply medicinal products to the public shall also provide an uninterrupted supply of such medicinal products to the public in the Member State concerned."*

*Justification*

Amendment 96

ARTICLE 1, PARAGRAPH 50 a (new)

Article 81, paragraphs 2 a, 2 b, 2 c and 2d (new) (Directive 2001/83/EC)

*(50a) In Article 81, the following paragraphs 2a, 2b, 2c and 2d are inserted:*

*"2a. The pharmacist shall be present at the pharmacy and shall always be contactable.*

*2b. The pharmacist shall manage the pharmacy in such a way as to guarantee its continuity, service and quality.*

*2c. The pharmacist shall supervise all work performed in the context of producing and providing pharmaceutical care.*

*2d. Medicinal products as referred to in Article 1 of Directive 2001/83/EC may be supplied only by a pharmacist who*

*possesses a diploma or certificate as referred to in Directive 85/432/EEC.”*

*Justification*

*By no longer allowing general practitioners to supply medicinal products from their own pharmacies, the public can be guaranteed uniform quality standards in pharmaceutical care.*

Amendment 97

ARTICLE 1, PARAGRAPH 52 a (new)

Article 85 (Directive 2001/83/EC)

*(52a) Article 85 is replaced by the following:*

*"Article 85*

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

*Justification*

*There is no reason for different distribution requirements for homeopathic medicinal products which are subject to a special simplified registration procedure. In most Member States those products traditionally are distributed through the same channels as other pharmaceutical products. The minimum requirements laid down in Articles 76-85 do not exclude manufacturers from distributing their products through alternative distribution channels.*

Amendment 98

ARTICLE 1, PARAGRAPH 52 b (new)

Title VIII, title (Directive 2001/83/EC)

*52b. The title of TITLE VIII is replaced by the following:*

*“TITLE VIII*

*ADVERTISING AND  
COMMUNICATION OF  
INFORMATION”*

*Justification*

*To avoid confusion between two terms, information and advertising, which must be kept distinct.*

Amendment 99

ARTICLE 1, PARAGRAPH 53

Article 86, paragraph 1, introductory sentence (Directive 2001/83/EC)

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, consumption or awareness of the availability of medicinal products; **it** shall include in particular:

For the purposes of this Title, '**information on medicinal products**' shall include **objective reports on the composition, action, quality, indication, contra-indication and adverse reactions as well as the results of canvassing activity**, and "advertising of medicinal products" shall include any form of door-to-door **marketing**, canvassing activity or inducement designed to promote the prescription, supply, sale, consumption or awareness of the availability of medicinal products; **advertising** shall include in particular:

*Justification*

*For the sake of clarity, information and market canvassing should be excluded from the definition of advertising. Information should be given a positive definition of content so that it can be excluded from the advertising deemed inadmissible under the special provisions laid down in Article 88(2)(3) regarding information on certain medicinal products.*

Amendment 100

ARTICLE 1, PARAGRAPH 53 a (new)

Article 87, paragraph 2 (Directive 2001/83/EC)

**(53a) In Article 87 the paragraph 2 is replaced by the following:**

**"2. All parts of the advertising of a medicinal product must be consistent with the product information appended to the marketing authorisation as well as**

***additional related information."***

*Justification*

*Article 87(2) should be adapted to new rules applicable since the adoption of the new marketing authorisations procedures (Regulation n° 2309/93/EC). Documents appended to the marketing authorisation include the patient leaflet and the summary of products characteristics. Additional related information should also include the European Public Assessment Report.*

Amendment 101  
ARTICLE 1, PARAGRAPH 54  
Article 88, paragraph 2 (Directive 2001/83/EC)

***2. The communication of information on certain medicinal products is authorised under strict conditions in the interest of patients in order to respond to their legitimate needs. This provision applies to product information appended to the marketing authorisation as well as to additional related information.*** ***deleted***

***By way of derogation from the prohibition in paragraph 1(a), Member States shall authorise the dissemination of information relating to certain medicinal products authorised in the framework of the affections set out below, in order to respond to the expectations expressed by the patients' groups:***

***This dissemination of information shall be is carried out on the following conditions:***

***(a) the medicinal product shall be authorised and prescribed for the treatment of any of the following conditions:***

- acquired immune deficiency syndrome;***
- asthma and chronic broncopulmonary disorders;***
- diabetes;***

***(b) the information disseminated complies with the principles set out in this Title;***

***(c) implementation of this paragraph shall be conditioned by the setting-up of self-regulatory procedures by the pharmaceutical industry at Member State level;***

***(d) the information and its dissemination shall be in conformity with the principles of good practice which are adopted, after consultation with interested parties, in conformity with the procedure set out in Article 121(2).***

***(e) in order to monitor the implementation of the principles of good practice referred to above:***

***– the additional information related to the medicinal products shall be notified to the Agency. If the Agency does not object within thirty days following this notification, the information shall be deemed to be accepted;***

***– the Agency shall coordinate of the monitoring of the information on the medicinal products authorised in conformity with this Directive, in particular through the setting-up of a data base;***

***– on a yearly basis, the Agency shall prepare a report on the application of these principles of good practice;***

***(f) implementation of this paragraph shall be the subject of an evaluation and a detailed report no later than [date]. The Commission shall propose any changes required to improve its implementation.***

#### *Justification*

*(Bowis) Pharmaceutical companies already have the ability to explain their products on their own websites. Any further information system authorised by an independent body would raise questions of liability that might attach to that body and it would be better to leave the existing system as it is.*

*(Stihler) There is a need for patients and consumers to be able to obtain accurate, understandable and reliable information on the range of treatments, including medicines. But, what appears to be moves towards Direct to Consumer Advertising should be resisted. The*

*Commission, as an alternative, should look at how internet information could be validated, with thought to issues concerning liability.*

*The rationale behind the idea of a three disease trial is not entirely clear. On the one hand, those diagnosed with other diseases can reasonably argue that they are just as entitled to information. On the other hand, even a three disease trial would not give consumers and patients information on the range of therapies and could easily slip into direct to consumer advertising. Of greatest concern is the fact that the proposals would not give patients access information about different types of treatment additional to medicinal products.*

*(de Roo and Rod) Information on diseases or medicines coming from industry can not be anything but promotion, according to the WHO Ethical Criteria for Medicinal Drug Promotion.*

*Patients and consumers request comparative information on medicines that comes from independent sources. The proposed revision plays on smart words: information, communication, education. The proposed derogation is actually the first step forwards direct to consumers advertising of prescription medicines, nicely disguised as 'disease education'.*

*The proposed derogation will boost healthcare expenditures and compromise rational use of drugs for diabetes, aids and asthma.*

*(Ferreira) We take the view that the introduction of such information measures, even on a selective and experimental basis, cannot be authorised for the following reasons:*

- the provision of such information, or advertising, direct to patients results in a substantial increase in patient demand for specific, generally costly, active principles. For example, prescriptions for the 25 medicinal products advertised direct to consumers in the USA increased by 34% between 1998 and 1999, as compared with a 5.1% increase for all other medicinal products issued on prescription.*
- advertising medicinal products issued on prescription ultimately leads to increased use of medication. The demand for more expensive medicinal products could thus have an adverse effect on medical practice, and on doctor-patient relations.*
- the information intended for provision to the general public in this way is most often misleading, and the information actually disseminated tends to be poor.*
- we do not have any estimates for the impact such a measure would have on sickness insurance budgets. It would be paradoxical to take steps to bring expenditure on pharmaceuticals under control, when the budget for this sector would probably get out of hand as a result of the increases caused by information of this type or advertising. There would be a boomerang effect, with the medicinal products concerned becoming less accessible for the very groups of people at which they are targeted.*

*If, however, this proposal were to be accepted, we can already foresee that this measure, to be carried out within six years, will be assessed in a positive light and consequently that the go-ahead will be given for opening up other medicinal products to 'advertising'.*

*(Liese) There is a need of patients and consumers to be able to obtain accurate, understandable and reliable information on the range of treatments, including medicines. But, what appears to be moves towards Direct to Consumer Advertising should be resisted. The Commission, as an alternative, should look at how internet information could be validated, with thought to issues concerning liability.*

*The rationale behind the idea of a three disease trial is not entirely clear. On the one hand, those diagnosed with other diseases can reasonably argue that they are just as entitled to information. On the other hand, even a three disease trial would not give consumers and patients information on the range of therapies and could easily slip into direct to consumer advertising. Of greatest concern is the fact that the proposals would not give patients access information about different types of treatment additional to medicinal products.*

*(Van Brempt and de Keyser) The proposal of the Commission as a first step towards direct to consumer advertising of prescription medicines should be resisted. This proposed derogation cannot be anything but promotion and will boost healthcare expenditure and compromise rational use of drugs for diabetes, aids and asthma. The Commission, as an alternative, should develop an information and education strategy based on clearly defined standards.*

*(Lund) According to a number of studies, the Commission's proposal will lead to an increase in the consumption of medicinal products. The same studies also show that the pharmaceuticals industry is not capable of providing impartial information. An exemption in this area could in the long term pave the way for authorising advertising of all products along US lines, resulting in misinformation and increased consumption of medicinal products, to the detriment of consumers and patients alike. The population is already quite well-informed about products associated with the disorders referred to and the exemption is therefore unnecessary. Moreover, it would be difficult to administer in practice since it is impossible to distinguish between information and advertising when the source of the latter is the pharmaceuticals industry.*

*Information for patients concerning the medicinal product's effect, side-effects and effect in conjunction with the use of other medicinal products should be provided on an objective basis and by independent bodies.*

Amendment 102  
ARTICLE 1, PARAGRAPH 54  
Article 88, paragraph 6 a (new) (Directive 2001/83/EC)

***6a. By (date) the European Commission shall, following consultations with consumer and patient organisations and other interested parties, present a report outlining a comprehensive consumer/patient information and strategy ensuring good quality objectives reliable and non-promotional information about medicines and other treatments.***

***It shall look specifically at ways in which websites and telephone helplines are or can be used to give information on a range of treatments, including medicines, and, where official approval is given to this***

***information source, addressing the question of liability.***

***The Commission shall propose any changes to this article, which could enhance the extent and quality of information available to patients paying particular attention to solutions that would ensure that this information is available in formats which are accessible to patients with disabilities.***

***The report shall notify the European Parliament of the findings of the Pharmaceutical Committee on how to enhance the extent and quality of information available to patients.***

#### *Justification*

*Information to patients is essential to increase their awareness of possible treatments. Information must also be accessible to all people with disabilities including blind and partially sighted people. Sources of information therefore need to conform to clearly defined standards.*

*There is a need for consumers /patients to be able to obtain accurate, balanced, understandable and reliable information on medicine and non-medicine treatment. The European Commission should - instead of moving towards direct to consumer advertising of prescription medicines - develop an information and education strategy to ensure that consumers/patients receive objective, comparative and balanced information on medicines and other treatments.*

*General knowledge about medicines and a better understanding of prescription medicines and their safe and appropriate use should be enhanced. All patients including those who do not have access to the Internet must have equal possibilities to receive the information they seek. Information should be assessed with regard to the quality of its content and usefulness and not only with regard to the source of the information.*

#### Amendment 103

##### ARTICLE 1, PARAGRAPH 54

Article 88, paragraph 7 a (new) (Directive 2001/83/EEC)

***The European Commission shall look into the possibility of urging every national authority to have a website that functions***

***as a portal and provides objective information on pharmaceutical products and health issues in general.***

*Justification*

*The European Commission should urge the Member States to ensure that every European citizen has access to objective information and come to an agreement on objective quality criteria of these websites and the information provided.*

Amendment 104  
ARTICLE 1, PARAGRAPH 54  
Article 88, paragraph 7a (new) (Directive 2001/83/EC)

***Evaluation of the information pilot should assess:***

- overall quality of information presented,***
- accuracy, as assessed by independent scientific and medical experts,***
- dissemination - what methods have been used and what proportion of the potential patient population has received the information,***
- accessibility of the information for patients with different communication needs - e.g. blind or visually impaired people,***
- involvement of key stakeholders in development and assessment of the information.***

*Justification*

*In order to evaluate whether the trial project has any added value for the public and the health care some criteria must serve as a basis for this evaluation. It should evaluate the overall level and kind of public health benefit that has resulted from this pilot.*

Amendment 105

ARTICLE 1, PARAGRAPH 55, POINT (a a) (new)

Article 89, paragraph 1, point (b), indent 3 (Directive 2001/83/EC)

***(aa) In paragraph 1, the third indent of point (b) is replaced by the following:***

***“- an express and legible invitation to read carefully the instructions on the package leaflet or on the outer packaging, as the case may be, and a warning specifying that the product is a medicine which is to be used on the advice of a medical practitioner.”***

*Justification*

*Medicinal products are not products for everyday consumption, and users should be reminded of this.*

Amendment 106

ARTICLE 1, PARAGRAPH 55, POINT (b)

Article 89, paragraph 2 (Directive 2001/83/EC)

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 if it is intended solely as a reminder.

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 the trademark*** if it is intended solely as a reminder.

### *Justification*

*The name of the medicinal product, which is used for its registration, is part of the marketing authorisation: it has to be approved by the competent authorities. That (full) name of the medicinal product normally reflects or includes a brand name which, in order to maintain exclusive use, has been registered as a trademark by the marketing authorisation holder. The name of the medicinal product may therefore include a trademark. For reminder advertising it is appropriate to allow the use of either the full name of the medicine or of the trademark.*

#### Amendment 107

ARTICLE 1, PARAGRAPH 56, POINT (a)

Article 90, point (c) (Directive 2001/83/EC)

(c) suggests that the subject's **state of health** can be **immediately** improved by taking the medicinal product;

(c) suggests that the subject's **health** can be improved by taking the medicinal product;

### *Justification*

*The difficulties encountered in implementing the rules on advertising have meant that it has not been possible to prevent the dissemination of advertising which does not comply with the various criteria contained in Directive 2001/83/EC.*

*Moreover, it is not appropriate to go back to the initial wording contained in that directive, as it is difficult to define what is meant by 'the health (FR = *bonne santé normale*) of the subject'.*

#### Amendment 108

ARTICLE 1, PARAGRAPH 57

Article 91, paragraph 2 (Directive 2001/83/EC)

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, if it is intended solely as a reminder.

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 the trademark**, if it is intended solely as a reminder.

*Justification*

*The name of the medicinal product, which is used for its registration, is part of the marketing authorisation: it has to be approved by the competent authorities. That (full) name of the medicinal product normally reflects or includes a brand name which, in order to maintain exclusive use, has been registered as a trade mark by the marketing authorisation holder. The name of the medicinal product may therefore include a trademark. For reminder advertising, it is appropriate to allow the use of either the full name of the medicine or of the trademark.*

Amendment 109

ARTICLE 1, PARAGRAPH 57 a (new)

Article 94, paragraph 3 (Directive 2001/83/EEC)

***(57a) In article 94, paragraph 3 is replaced by the following:***

***“3. Persons qualified to prescribe or supply medicinal products shall not solicit or accept any inducement prohibited under paragraph 1 or contrary to paragraph 2. Member States shall develop appropriate regulations or a code of conduct to enforce paragraph 1, 2 and 3.”***

*Justification*

*It is necessary to take appropriate measures or agree on a code of conduct at Member State level, to enforce these paragraphs.*

Amendment 110

ARTICLE 1, PARAGRAPH 57 b (new)

Article 95 (Directive 2001/83/EC)

***(57b) Article 95 is replaced by the following:***

***"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."***

*Justification*

*Sales promotion activities have been in the spotlight in various Member States as they resulted in lack of independence of health professionals. The requirements therefore need to be tightened up.*

Amendment 111  
ARTICLE 1, PARAGRAPH 59  
Article 98, paragraph 3 (Directive 2001/83/EC)

***3. The Member States shall authorise the co-promotion of a medicinal product by the holder of the marketing authorisation and one or more companies nominated by him/her.***

***3. The provisions of this directive are without prejudice to the activities of co-promotion and co-marketing performed by the holder of the marketing authorisation, and one or more companies appointed by him/her. The details of the co-promoting and co-marketing companies may appear on the product outer box.***

*Justification*

*The amendment to Article 98 would clarify certain practical aspects of co-marketing and co-promotion arrangements.*

Amendment 112  
ARTICLE 1, PARAGRAPH 59 a (new)  
Article 99a (new) (Directive 2001/83/EC)

***59a. After Article 99, the following new Article 99a is inserted:***

***“Article 99a***

***1. The Member States shall maintain an institute which shall offer further training for health professionals independent of business interests and which shall also award a quality seal for scientifically***

*recognised further training offered by other institutions.*

*2. The Member States shall set up a complaints body for patients, health professionals and firms which shall receive reports on suspected or proven infringements of the provisions of this Title.*

*3. The Member States shall publish an annual report on the application of the provisions of this Title.”*

#### *Justification*

*On paragraph 1: in many Member States, pharmaceutical companies and industry associations offer further training for health professionals, the scientific independence of which is not always guaranteed. Consequently, this urgently needed further training should be either state-organised or at least state-approved.*

*On paragraph 2: it would be useful to set up a central body for complaints.*

*On paragraph 3: regular reports should be published in order to identify trends and positive and negative developments at an early stage. The annual reports can be used to identify best practice in this area.*

#### Amendment 113

ARTICLE 1, PARAGRAPH 60 a (new)  
Title VIII a (new) (Directive 2001/83/EC)

***(60a) The following Title VIIIa is added:***

#### ***"TITLE VIIIa INFORMATION***

##### ***Article 100a***

***The provision of reliable comparative information on diseases, therapeutic strategies and medicinal products is authorised in the interest of patients in order to respond to their legitimate needs. Any kind of communication on diseases, therapeutic strategies and medicinal products coming from a pharmaceutical company is considered as advertising, as defined in article 86, and is regulated by***

***Title VIII (articles 86 to 100)."***

*Justification*

*To recognise the need of patient information and to ensure the quality of this information through independence of information providers from the pharmaceutical industry.*

Amendment 114

ARTICLE 1, PARAGRAPH 61

Article 101, paragraph 2 (Directive 2001/83/EC)

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

The Member States ***shall require*** doctors and other health care professionals ***to report*** suspected serious or unexpected adverse reactions.

*Justification*

*Rules on registering adverse reactions should apply in the centralised and decentralised authorisation procedure. Up to now, European law provides that only medical professionals can report adverse reactions to the authorities. This has the advantage that standard medicinal terminology is used and the data can easily be compared.*

Amendment 115

ARTICLE 1, PARAGRAPH 61 a (new)

Article 101, paragraph 2 a (new) (Directive 2001/83/EC)

***(61a) In Article 101, the following paragraph 2a is added:***

***2a. The European Commission's Directorate General for Health and Consumer Protection shall bring forward proposals for improving the amount and quality of pharmacovigilance data in Europe, in particular during the first 5 years of marketing for a newly authorisation medicine, considering enhanced roles for patients and health professionals to ensure a more efficient and effective response to potential problems.***

*Justification*

*Self-explanatory.*

Amendment 116  
ARTICLE 1, PARAGRAPH 62  
Article 102, paragraph 2 (Directive 2001/83/EC)

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 accessible to all Member States.

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 without delay ***accessible to the public in the same Register as mentioned in Article 21(3), according to the EU Regulation 1049/2001 on access to documents.***

***In addition, selected read and print access for Marketing Authorisation Holders shall be ensured in relation to data on their own products.***

*Justification*

*Health professionals and the public are the parties most interested in information on adverse drug reactions. Such information falls within the definition of public document as mentioned in Regulation 1049/2001. In order to ensure the safety of patients in the EU, it is essential that an effective pharmacovigilance system is in place. The Commission proposes the introduction of a single EU data base for recording adverse drug reactions, which will increase the effectiveness of the current system. Industry should also be given selected access to the data on their own products in this data base, in order to allow coordinated action between the authorities and the Marketing Authorisation Holder on safety issues, and thus further increase the effective functioning of the system.*

Amendment 117  
ARTICLE 1, PARAGRAPH 62 a (new)  
Article 102 a (new) (Directive 2001/83/EC)

***62a. The following Article 102a is inserted:***

*inserted:*

*“Article 102a*

*In order to ensure the complete independence of the competent authorities, at least the activities connected with pharmacovigilance, the functioning of communication networks and market surveillance must receive public funding commensurate with the tasks conferred upon such authorities.”*

*Justification*

*The surveillance activities entrusted to the competent authorities will increase owing to the new tasks conferred upon them. So that such tasks can be carried out properly, provision must now be made for the public funding which is essential for this system to function well.*

Amendment 118

ARTICLE 1, PARAGRAPH 64

Article 104, paragraph 1 (Directive 2001/83/EC)

1. The marketing authorisation holder shall be required to maintain detailed records of all suspected adverse reactions occurring either in the Community or in a third country.

***Save in exceptional circumstances***, these reactions shall be communicated electronically in the form of a report according to the guidelines referred to in Article 106(1).

1. The marketing authorisation holder shall be required to maintain detailed records of all suspected adverse reactions occurring either in the Community or in a third country.

These reactions shall be communicated electronically in the form of a report according to the guidelines referred to in Article 106(1).

*Justification*

*The electronic communication of this information on reactions will speed up its processing and, where appropriate, dissemination enormously, which can be crucial in urgent cases.*

Amendment 119

ARTICLE 1, PARAGRAPH 64

Article 104, paragraph 2 (Directive 2001/83/EC)

2. The marketing authorisation holder shall be required to record all suspected serious adverse reactions which are brought to his attention by a health care professional and to report them immediately to the competent authority of the Member State on whose territory the incident occurred, and in no case later than 15 calendar days following the receipt of the information.

2. The marketing authorisation holder shall be required to record all suspected serious adverse reactions which are brought to his attention by a health care professional **or patients** and to report them immediately to the competent authority of the Member State on whose territory the incident occurred, and in no case later than 15 calendar days following the receipt of the information.

#### *Justification*

*The marketing authorisation holder for a medicinal product should be required to notify adverse reactions reported to him by patients as well.*

#### Amendment 120

#### ARTICLE 1, PARAGRAPH 64

#### Article 104, paragraph 6 (Directive 2001/83/EC)

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 **authorisation**, 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.

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 **it 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.

***This evaluation shall be reviewed by the pharmacovigilance working group of the Agency. Both the periodic safety update reports and the scientific evaluations must be publicly accessible in the same Register as mentioned in Article 21(3).***

### *Justification*

*The first placing on the market is a more suitable reference point because full pharmacovigilance starts then. If the granting of authorisation is retained as the reference point, the result could be that, in view of the lengthy negotiations on prices and repayments, a firm would not have to submit the first periodic report until around three years after the product was placed on the market. This cannot be the intention. Periodic safety update reports are key information when it comes to rational prescribing and rational use of medicines. Regulation 1049/2001 on access to documents shall apply to this kind of “public document”.*

### Amendment 121

#### ARTICLE 1, PARAGRAPH 64

Article 104, paragraph 7 a (new) (Directive 2001/83/EC)

***7a. The marketing authorisation holder shall not be authorised to communicate information on pharmacovigilance issues to the public without the consent of the Agency.***

### *Justification*

*This provision is aimed at ensuring that convergent information is communicated by the competent authorities and the marketing authorisation holder in the event of a problem being detected.*

### Amendment 122

#### ARTICLE 1, PARAGRAPH 64 a (new)

Article 104 a (new) (Directive 2001/83/EC)

***64a. After Article 104, the following new Article 104a is added:***

#### ***“Article 104a***

***The marketing authorisation holder shall ensure that the competent authorities are the first to be informed of an imminent sales stop and withdrawal of a medicinal product from the market, and only then the public or shareholders are informed.”***

*Justification*

*This clarification is necessary in the light of the Lipobay case, when the authorities were informed far too late.*

Amendment 123

ARTICLE 1, PARAGRAPH 64

Article 105, paragraph 1 (Directive 2001/83/EC)

1. The Agency, in collaboration with the Member States and the Commission, shall set up a data-processing network to facilitate the exchange of pharmacovigilance information regarding medicinal products marketed in the Community intended to allow all competent authorities to share the information at the same time.

1. The Agency, in collaboration with the Member States and the Commission, shall set up a data-processing network to facilitate the exchange of pharmacovigilance information regarding medicinal products marketed in the Community intended to allow all competent authorities to share the information at the same time. ***This information shall also be made available to interested persons in an appropriate form and free of charge in public databases.***

*Justification*

*Warnings of manufacturing defects or serious adverse reactions should be accessible to all interested persons.*

Amendment 124

ARTICLE 1, PARAGRAPH 64

Article 107, paragraph 2 a (new) (Directive 2001/83/EC)

***2a. Evaluation reports of pharmacovigilance data, together with related Committee opinions and final measures taken, shall be made publicly accessible in the same Register as mentioned in Article 21(3).***

*Justification*

*Pharmacovigilance measures can only be understood and implemented in practice if fully explained to health professionals and the public.*

*Improving prevention of side effects of drugs requires full transparency.*

Amendment 125

ARTICLE 1, PARAGRAPH 65 POINT (a)

Article 111, paragraph 1, subparagraph 2 (Directive 2001/83/EC)

The competent authority may carry out inspections at the premises of manufacturers of active substances used as starting materials, or of 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.

The competent authority may **also** carry out **unannounced** inspections at the premises of manufacturers of active substances used as starting materials, or of 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.

*Justification*

*Self-explanatory.*

Amendment 126

ARTICLE 1, PARAGRAPH 66

Article 116, subparagraph 1 a (new) (Directive 2001/83/EC)

***The analysis of the risk/benefit balance must be considered to be a first stage in the study of the medicinal product's relative and/or actual efficacy.***

*Justification*

*Studies should be provided for to investigate the efficacy of medicinal products. Efficacy is a*

*key factor as far as health is concerned, and studies must therefore be made.*

Amendment 127  
ARTICLE 1, PARAGRAPH 66  
Article 116, subparagraph 2 a (new) (Directive 2001/83/EC)

***Where the authority finds that data have been falsified, it shall inform the prosecuting authorities without delay.***

*Justification*

*The vast majority of applications for authorisation contain correct documents and data. An action framework must be laid down for cases where incorrect data is submitted.*

Amendment 128  
ARTICLE 1, PARAGRAPH 67 a (new)  
Article 118 a (new) (Directive 2001/83/EC)

***(67a) After Article 118, the following new Article 118a is inserted:***

***“Article 118a***

- 1. The Member States shall lay down the sanctions for infringements of this Directive or the rules laid down on the basis of this Directive and shall take all the necessary measures for its enforcement. These sanctions shall be effective, proportionate and have a deterrent effect. The Member States shall notify the corresponding provisions to the Commission no later than 31 December 2004 and shall immediately inform the Commission of any changes thereto.***
- 2. The Member States shall immediately inform the Commission of the opening of legal proceedings on the grounds of any infringements of this Directive.***
- 3. The Member States shall impose fines on the holders of marketing authorisation granted on the basis of this Directive if***

***certain obligations laid down as part of these authorisations have not been met. The Member States shall publish the names of the holders concerned and the amount of the fines imposed.”***

*Justification*

*Where authorisation holders do not comply with their obligations, they should be required to pay a fine and the public should be informed.*

Amendment 129

ARTICLE 1, PARAGRAPH 68 a (new)  
Title XI a (Directive 2001/83/EC)

***(68a) After Article 119, the following new Title XIa is inserted:***

***“Title XIa***

***Transparency***

***Article 119a***

***The Member States shall ensure that staff in their authorisation authorities, rapporteurs and experts concerned with the authorisation and surveillance of medicinal products have no financial or other interests in the pharmaceutical industry which could influence their impartiality. They shall require these persons to act independently and in the interest of the common good and to make an annual declaration of their financial interests.***

***All direct and indirect interests which could be linked with the pharmaceutical industry shall be recorded in a register to be kept by the authority, which may be consulted by the public.***

***Article 119b***

***In order to guarantee a high degree of transparency, the Member State authorities shall issue rules under which non-confidential regulatory, scientific or technical information on the authorisation***

*and surveillance of medicinal products shall be made available to the public.*

*Copies of all scientific information, with the exception of confidential information of a commercial nature, shall be sent to interested persons upon written request and against payment of the cost incurred in sending them. Regulatory information on applications for authorisation submitted, the stage reached in the procedure, interim decisions, authorisations and conditions shall be published in a clear form on the Internet. The model shall be Regulation 1049/2001 on public access to documents of the EU institutions.*

#### *Article 119c*

*The authority of each Member State shall maintain a database on the medicinal products whose marketing it has authorised, which may be used free of charge. Health professionals, firms and the public shall be granted access rights to the database with the appropriate restrictions in each case. The protection of business secrets and personal data shall be guaranteed. The database shall include a section on medicinal products authorised for children. Information for the public shall be worded in an appropriate and comprehensible manner.*

#### *Article 119d*

*The database shall make it possible to compare different medicinal products as to their effectiveness, adverse reactions and contra-indications on the basis of the information already approved for the package leaflet.”*

#### *Justification*

*The same rules on transparency should apply for the centralised and decentralised authorisation procedure in order to guarantee the safety of medicinal products throughout Europe, in particular with a view to enlargement to the east. For the sake of clarity, a separate title on transparency should be created.*

*In order to establish confidence in the independence and competence of the authorities, they must work as transparently as possible. This will also facilitate the debate on the effectiveness and safety of medicinal products among external scientists. Patients also have a right to easily understood and comprehensive information on the characteristics of the medicinal products with which they are being treated.*

*The authorities should have access to all data. Firms should be given the right to access data concerning their own products. Health professionals should have access to information couched in medical terminology, while patients require clear information in a language which can be understood by lay people. Access to the database should therefore be varied accordingly.*

*The database should also include information on which medicinal products are explicitly authorised for the treatment of children. Information aimed at the public should be couched in a language that can be understood by people with no medical knowledge.*

*The database will be of particular use to patients if it enables them to compare different medicinal products. As a first step, therefore, it should be made possible to compare effectiveness, adverse reactions and contra-indications on the basis of the information already authorised for the package leaflet. This is easily done from both a technical and legal point of view, because the information has already been approved for publication and cannot be alleged to be unfair or disputed by firms.*

Amendment 130

ARTICLE 1, PARAGRAPH 69

Article 121, paragraph 5 (Directive 2001/83/EC)

5. The Standing Committee shall adopt its own rules of procedure.

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

*Justification*

*There must be total transparency as regards such rules.*

Amendment 131

ARTICLE 1, PARAGRAPH 69

Article 122 a (new) (Directive 2001/83/EEC)

***The Commission should undertake a benchmarking study into the comparison of new medicinal products that are evaluated***

*by the EMEA and for which the Commission is granting a marketing authorisation. This study should address the comparison of these products in the context of transparency in dealing with prices and reimbursement ~~in order for the new medicinal products to have the same access for all patients all over the EU.~~*

#### *Justification*

*Major differences in prices for pharmaceutical products exist between the Member States. It is very important that the market for pharmaceutical products should become more transparent. This benchmarking study of the European Commission is the first step in this process.*

#### Amendment 132

ARTICLE 1, PARAGRAPH 69 a (new)  
Article 127 a (new) (Directive 2001/83/EC)

*(69a) The following Article 127a is added:*

#### *"Article 127a*

*Member States shall set up appropriate collection systems for unused or time-expired medicinal products via pharmacies."*

#### *Justification*

*Separate collection systems via pharmacies should be put in place to avoid that unused or time-expired medicinal products enter the ordinary waste stream. This amendment seeks to complement amendment 24 of the rapporteur.*

## EXPLANATORY STATEMENT

Medicines are not like other products. They are not sold or consumed in the way ordinary, everyday products are sold and consumed. Their use is unique, and everyone expects their medicine to be safe and effective. Safety and efficacy lie at the heart of the proposed directive. (*Safety and efficacy for patients and safety and security for the environment*)

The proposed revision will have implications for all concerned: the pharmaceutical industry, the generic medicines industry, doctors, pharmacists, veterinarians, distributors of medicinal products, national agencies and, of course, patients.

At first sight, the interests of these different categories may appear to clash. But there are many areas where their interests coincide, so that it is possible to find an optimum balance between competitiveness, research, health system needs and the development of generic medicines. This, at any rate, is the main aim here.

Revision of Europe's pharmaceutical legislation first of all requires an analysis of the current procedures for marketing authorisation so as to identify their shortcomings in order to be able to propose improvements, whilst keeping in mind the main thrust of this report: the protection of the health of all Europeans.

At present, there are two procedures for registering medicinal products: the centralised procedure, managed by the European Agency, under which authorisations valid for all EU Member States are issued, and the mutual recognition procedure, for which the Member States have jurisdiction. The current system seems to work satisfactorily. There is no need to alter the existing dual structure, and the main task is to optimise the way it works.

Under the centralised procedure, studies carried out in connection with applications to market medicinal products are too slow and inflexible. Whilst the safety and efficacy of a product are two concepts which constitute a sine qua non, the speed at which products of benefit to patients become available must be a third pillar in improving health protection. Is it possible to conceive of a situation where patients cannot access new products which will help cure them, because of excessively rigid administrative procedures? Improvements are also necessary as regards transparency, in particular concerning the Agency's expertise and its functioning.

Under the mutual recognition procedure, the time taken to obtain an authorisation is excessively long, but, above all, current practice shows that Member States are all too inclined not to recognise other Member States' marketing authorisations and scientific assessments. Strict ground rules will therefore need to be drawn up with all EU Member States.

The issuing of authorisation for a medicinal product does not, however, mean that checks are no longer needed on its efficacy and safety. We are all mindful of the recent examples of medicinal products withdrawn from the market on public health grounds. It is thus essential to step up pharmacovigilance requirements, i.e. the ongoing monitoring of a medicinal product, if the existence of European health system is to offer patients the best possible guarantees. Such monitoring activity will need to be taken into account properly when budgetary resources are allocated to the competent authorities.

In order to submit an application for marketing authorisation under the centralised or mutual recognition procedures, an applicant first needs to carry out extensive research in order to discover either new molecules or an innovative therapeutic use for an existing medicine. Research and development lay the foundations for health protection. We all know that innovation comes at a price. It is thus our duty to prevent European industry from being relegated to the second division in the global league and from trailing behind the United States and Asia, as that would be a disaster for Europe.

Obviously, we are aware of the usefulness of generic medicines and of the important role they play in Europe's health systems. We therefore welcome the approach taken by the Commission to make it easier for such medicines to gain access to the Community market. The term 'generic medicinal products' has been introduced for the first time. It is also proposed that the 'Bolar' system be introduced in the European Union.

Lastly, it is not possible to consider this proposal without addressing the subject of information and the Commission's proposal that the dissemination of information relating to certain medicinal products authorised for the following disorders: asthma, AIDS and diabetes, be authorised for an experimental five-year period.

As we have already stressed, the market for a medicinal product is unique, and the aim must not be to maximise sales volumes but to ensure that the product is used appropriately. It is therefore vital to maintain a very clear distinction between information and advertising. The Commission's proposal is ambiguous in this area. It is therefore essential to ensure that the information disseminated to patients is checked before it reaches them by impartial scientific bodies which receive public funding. In this context, all package leaflets should be made more legible and more comprehensible.

The significance of enlargement must also be emphasised. There is no hiding the fact that the revised text which will be adopted will apply also to the new Member States. Each new Member State will have an important role as a fully fledged player in the establishment and development of a Europe where health is to the fore and which we all wish to see come about.

# EUROPEAN PARLIAMENT

1999



2004

---

*Session document*

FINAL  
**A5-0340/2002**  
Par2

9 October 2002

**\*\*\*I**

## **REPORT**

on the proposal for a European Parliament and Council directive amending  
Directive 2001/83/EC on the Community code relating to medicinal products  
for human use  
(COM(2001) 404 – C5-0592/2001 – 2001/0253(COD))

Part 2: Opinions of the other committees

Committee on the Environment, Public Health and Consumer Policy

Rapporteur: Françoise Grossetête



## CONTENTS

	<b>Page</b>
OPINION OF THE COMMITTEE ON BUDGETS .....	4
OPINION OF THE COMMITTEE ON BUDGETARY CONTROL.....	10
OPINION OF THE COMMITTEE ON INDUSTRY, EXTERNAL TRADE, RESEARCH AND ENERGY .....	18
OPINION OF THE COMMITTEE ON AGRICULTURE AND RURAL DEVELOPMENT .....	37

### **Published separately:**

Motion for a resolution..... Part 1 – A5-0340/2002

Draft legislative resolution

Explanatory statement

21 June 2002

## **OPINION OF THE COMMITTEE ON BUDGETS**

for the Committee on the Environment, Public Health and Consumer Policy

on

1) the proposal for a European Parliament and Council regulation on laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products

(COM(2001) 404 – C5-0591/2001 – 2001/0252(COD))

2) the proposal for a European Parliament and Council directive on amending Directive 2001/83/EC on the Community code relating to medicinal products for human use

(COM(2001) 404 – C5-0592/2001 – 2001/0253(COD))

3) the proposal for a European Parliament and Council directive on amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products

(COM(2001) 404 – C5-0593/2001 – 2001/0254(COD))

Draftsman: Wilfried Kuckelkorn

### **PROCEDURE**

The Committee on Budgets appointed Wilfried Kuckelkorn draftsman at its meeting of 22 January 2002.

It considered the draft opinion at its meeting of 19 June 2002.

At the latter meeting it adopted the following amendments unanimously.

The following were present for the vote: Terence Wynn, chairman; Anne Elisabet Jensen vice-chairman; Wilfried Kuckelkorn, draftsman; Ioannis Averoff, Kathalijne Maria Buitenweg, Joan Colom i Naval, Den Dover, Göran Färm, Neena Gill, Catherine Guy-Quint, Jutta D. Haug, Juan Andrés Naranjo Escobar, Joaquim Píscarreta, Giovanni Pittella, Guido Podestà, Ralf Walter and Brigitte Wenzel-Perillo.

## SHORT JUSTIFICATION

On the basis of the financial statements annexed to the three proposals, and which foresee no significant budgetary impact, the rapporteur has concentrated his amendments on the proposal to adapt the operational structure of the agency.

With regard to the global contents of the proposal, of which the objective is to guarantee a high level of human and animal health protection through increased market surveillance and a stepping up of pharma-co-vigilance procedures, the rapporteur is concerned about the future costs that new activities entrusted to the Agency might generate for heading 3 of the Financial Perspective.

He therefore suggests requesting an evaluation following the entry into force of these new regulations in order to assess the needs of the agency and to possibly adjust the subsidy, taking in account the level of the fees.

In this context, he also wishes to recall the principles traditionally supported by the committee on budgets and which are reflected in the amendments:

- new initiatives (including enlargement) should not be financed through a reduction of existing policies;
- the budgetary authority decides on the amount of the subsidy within the annual procedure;
- the Agency implements Community policies (linked to the achievement of the internal market) and receives public funding to do so; therefore principles of budgetary transparency should be ensured;
- the Agency Management Board must adjust the draft work programme and draft budget of the subsidy decided by the budgetary authority which implies selecting priorities to be financed within the Agency's financing capacities.

## AMENDMENTS

The Committee on Budgets calls on the Committee on the Environment, Public Health and Consumer Policy, as the committee responsible, to incorporate the following amendments in its report:

**Proposal for a European Parliament and Council regulation on laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products (COM(2001) 404 – C5-0591/2001 – 2001/0252(COD))**

Text proposed by the Commission<sup>1</sup>

Amendments by Parliament

Amendment 1  
Recital 19 a (new)

***Whereas the agency's budget is composed of fees paid by the private sector and contributions paid out of the Community budget to implement Community policies.***

*Justification*

*The EMEA belongs to the second generation category of agencies partly financed by industry and partly by public funding. The rules and decisions at Community level (Financial Regulation, staff regulation, contribution to pensions, annual budgetary procedure), fully apply to it and should be recalled in the founding regulation.*

Amendment 2  
Recital 19 b (new)

***Whereas article 25 of the IIA foresees that the Financial Perspective will be adjusted in order to cover the new needs resulting from enlargement.***

*Justification*

*Expenditure resulting from enlargement will be financed by appropriate provisions in order to avoid jeopardising current policies.*

---

<sup>1</sup> OJ C 75E, 26.03.02 p. 189.

Amendment 3  
Article 60, paragraph 1

The revenues of the Agency shall consist of **a contribution** from the Community and the fees paid by undertakings for obtaining and maintaining a marketing authorisation and for other services provided by the Agency.

The revenues of the Agency shall consist of **contributions** from the Community and the fees paid by undertakings for obtaining and maintaining a marketing authorisation and for other services provided by the Agency. **The budgetary authority will re-examine when necessary the level of the contributions on the basis of an evaluation of needs and the level of fees.**

*Justification*

*It is necessary to refer to contributions in the plural since the EMEA receives two types of contributions: one is a balancing subsidy and the other is due to finance the orphan drugs programme. It is however clear, that the amount of the EU contributions will be determined each year in the budgetary procedure.*

Amendment 4  
Article 60, paragraph 3

By 15 February of each year at the latest, the Director shall draw up a preliminary draft **budget** covering the operational expenditure and the programme of work anticipated for the following financial year, and shall forward this preliminary draft to the Management Board **together with** an establishment plan.

By 15 February of each year at the latest, the Director shall draw up a preliminary draft **estimate** covering the operational expenditure and the **preliminary** programme of work anticipated for the following financial year, and shall forward this preliminary draft to the Management Board **including** an establishment plan.

*Justification*

*The recasting of the Financial Regulation foresees that the agencies' establishment plans are authorised by the budgetary authority. Moreover, the agencies are requested to follow the rules of the general budgetary procedure in accordance with the common statement of November 1995 referred to as "code of conduct" because they receive Community funding.*

Amendment 5  
Article 60, paragraph 6

The Management Board shall adopt the Agency's final budget before the beginning of the financial year, adjusting it where necessary to the Community subsidy and the Agency's other resources.

The Management Board shall adopt the Agency's final ***work programme and final*** budget before the beginning of the financial year, adjusting it where necessary to the Community subsidy and the Agency's other resources. ***Any modification of the establishment plan and of the budget shall be notified to the budgetary authority under the form of a rectifying budget.***

*Justification*

*For reasons of budgetary transparency, the agencies are requested to follow the rules of the budgetary procedure in accordance with the common statement of November 1995 referred to as "code of conduct"*

Amendment 6  
Article 61

Article 61

The structure and the ***amount*** of the fees referred to in Article 60(1) shall be established by the Council acting under the conditions provided for by the Treaty on a proposal from the Commission, following the latter's consultation of organisations representing the interests of the pharmaceutical industry at Community level.

Article 61

The structure and the ***level*** of the fees referred to in Article 60(1) shall be established by the Council acting under the conditions provided for by the Treaty on a proposal from the Commission, following the latter's consultation of organisations representing the interests of the pharmaceutical industry at Community level. ***The Management Board shall adjust the level of the fees each year in accordance with the EU inflation rate established by Eurostat.***

*Justification*

*In order to maintain the balance between private and public sources of funding the fees paid by industry should be adjusted to inflation.*

Amendment 7  
Article 69

Article 69

The Management Board shall, in the case of veterinary medicinal products which have limited markets, or in the case of veterinary medicinal products intended for diseases with a regional distribution, adopt the necessary administrative measures to provide help to pharmaceutical companies at the time of submission of their applications. These administrative measures shall include, in particular, the taking over responsibility for some translations by the Agency.

Article 69

***Administrative measures for*** veterinary medicinal products which have limited markets, or in the case of veterinary medicinal products intended for diseases with a regional distribution, ***are financed by*** pharmaceutical companies. ***At*** the time of submission of their applications ***the Management Board determines the percentage of co-financing for the Agency, in particular for translations.***

*Justification*

*If the industry asks for a service, it should pay for it as a principle. However, the Management Board may decide on a case by case basis the share of co-financing with the Agency.*

21 June 2002

## **OPINION OF THE COMMITTEE ON BUDGETARY CONTROL**

for the Committee on the Environment, Public Health and Consumer Policy

- on a proposal for a regulation for the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products.

(COM(2001) 0404 – C5-0591/2001 – 2001/0252 (COD))

- on a 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.

(COM(2001) 0404 – C5-0592/2001 – 2001/0253 (COD))

- on a 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

(COM(2001) 404 – C5-0593/2001 – 2001/0254 (COD))

Draftsman: Jan Mulder

### **PROCEDURE**

The Committee on Budgetary Control appointed Jan Mulder draftsman at its meeting of 21 February 2002.

It considered the draft opinion at its meetings of 15 April, 23 May and 19 June 2002.

At the last meeting it adopted the following amendments unanimously.

The following were present for the vote: Diemut R. Theato, chairman, Herbert Bösch, vice-chairman, María Antonia Avilés Perea, Jean-Louis Bourlanges, Mogens N.J. Camre, Helmut Kuhne, John Joseph McCartin (for Brigitte Langenhagen), Jan Mulder (for Antonio Di Pietro), Ole Sorensen and Bart Staes.

## SHORT JUSTIFICATION

The European Parliament is the discharge authority for only four of the agencies currently in existence<sup>1</sup>.

The committee on Budgetary Control has taken the view that this situation should be rectified progressively, as and when the founding regulations of the agencies come up for renewal.

One such opportunity now presents itself through the Commission's proposal to repeal Regulation (EEC) n°2309/93 and replace it by a new act modelled on the regulation in force but reflecting the adjustments to the consolidated directives. The two proposals for directives accompanying the proposed new regulation are being amended in order to respond to the challenges of enlargement and the advent of new therapies. However, they do not have any budgetary control implications. The attached amendments therefore concern only the recasting of the founding regulation of the European Agency for the Evaluation of Medicinal Products.

## AMENDMENTS

The Committee on Budgetary Control calls on the Committee on the Environment, Public Health and Consumer Policy, as the committee responsible, to incorporate the following amendments in its report:

Text proposed by the Commission<sup>2</sup>

Amendments by Parliament

### Amendment 1 Article 56, paragraph 2

2. Members of the Management Board, members of the Advisory Board, members of the Committees, rapporteurs and experts shall not have financial or other interests in the pharmaceutical industry which could affect their impartiality. They shall undertake to act in the public interest and in an independent manner. All indirect interests which could relate to this industry shall be entered in a register held by the Agency which the public may consult.

2. Members of the Management Board, members of the Advisory Board, members of the Committees, rapporteurs and experts shall not have financial or other interests in the pharmaceutical industry which could affect their impartiality. They shall undertake to act in the public interest and in an independent manner. All indirect interests which could relate to this industry shall be entered in a register held by the Agency which the public may consult ***on request, at***

---

<sup>1</sup> Centre for Development of Vocational Training, Thessaloniki.  
Foundation for Improvement of Living and Working Conditions, Dublin.  
Reconstruction Agency for Kosovo, Thessaloniki  
European Food Safety Authority

<sup>2</sup> OJ C not yet available.

*the Agency's offices.*

*The Agency's code of conduct shall provide for implementation of this article with particular reference to the acceptance of gifts.*

Members of the Management Board, members of the Advisory Board, members of the Committees, rapporteurs and experts who participate in meetings or working groups of the Agency shall declare, at each meeting, any specific interests which could be considered to be prejudicial to their independence with respect to the points on the agenda.

Members of the Management Board, members of the Advisory Board, members of the Committees, rapporteurs and experts who participate in meetings or working groups of the Agency shall declare, at each meeting, any specific interests which could be considered to be prejudicial to their independence with respect to the points on the agenda. *These declarations shall be available to the public.*

#### *Justification*

*The aim of this amendment is to introduce the appropriate level of openness and transparency, which is especially necessary in the pharmaceutical sector. Additionally an extra paragraph concerning the code of conduct needs to be added.*

#### Amendment 2 Article 58, paragraph 1

1. The Management Board shall *consist of four representatives of the Member States, four representatives of the European Parliament, four representatives of the Commission, and four representatives of patients and industry, appointed by the Commission.*

1. The Management Board shall *be composed of 14 members appointed by the Council in consultation with the European Parliament from a list drawn up by the Commission which includes a number of candidates substantially higher than the number of members to be appointed, plus a representative of the Commission. Four of the members shall have their background in organisations representing patients and industry.*

*The list drawn up by the Commission, accompanied by the relevant documentation, shall be forwarded to the European Parliament. As soon as possible and within three months of such communication, the European Parliament*

*may make its views available for consideration by the Council, which will then appoint the Management Board.*

*The members of the Board shall be appointed in such a way to secure the highest standards of competence, a broad range of relevant expertise and, consistent with these, the broadest possible geographic distribution within the Union.*

*The full members of the Management Board may arrange to be replaced by alternates.*

#### *Justification*

*To ensure coherence in the administrative organisation of the agencies, the above amendment is based on the procedure applicable to the Management Board of the European Food Safety Authority as laid down in Regulation (EC) No. 178/2002 (Article 25). Appropriate voice is given to interested parties (patients, industry). The Commission proposal to include representatives of Parliament and Council on the Management Board does not seem appropriate, considering the role of both Institutions in budgetary control and scrutiny.*

*Membership of the Management Board should be regarded as a personal appointment, rather than a responsibility which can be delegated to an "alternate" Member. It is therefore proposed to delete the provision allowing full Members to be replaced by an "alternate".*

#### *Amendment 3* *Article 60, paragraph 10*

*The Management Board, on a recommendation **by** the European Parliament, shall give a discharge to the Director in respect of the implementation of the budget.*

***On** a recommendation **from the Council**, the European Parliament, shall give a discharge to the Director in respect of the implementation of the **Agency's** budget.*

#### *Justification*

*Following the example of the more recent decisions setting up agencies, the regulation should provide that the European Parliament is the discharge authority. The amendment is based on the discharge provisions applying to the European Agency for Reconstruction (Kosovo agency) as laid down in its founding Regulation (EC) No. 2667/2000 of 5 December 2000, as well as those governing the European Food Safety Authority (Regulation (EC) No. 178/2002 of 28 January 2002). Moreover, this will probably be the discharge procedure applicable to the Aviation Safety Authority, which currently awaits a second reading by Parliament. .*

Amendment 4  
Article 60 a (new)

***Combating fraud***

1. ***In order to combat fraud, corruption and other unlawful activities the provisions of Regulation (EC) No 1073/1999 of the European Parliament and of the Council of 25 May 1999<sup>1</sup> concerning investigations conducted by the European Anti-Fraud Office (OLAF) shall apply without restriction.***
2. ***The Agency shall accede to the Interinstitutional Agreement of 25 May 1999 concerning internal investigations by the European Anti-Fraud Office (OLAF)<sup>2</sup> and shall issue, without delay, the appropriate provisions applicable to all the employees of the Agency.***

*Justification*

*The EMEA has already taken a decision with the agreement of its management board (dated 1 June 1999) concerning the terms and conditions for internal investigations in relation to the prevention of fraud, corruption and any illegal activity detrimental to the Communities' interests. This decision lays down the procedures governing cooperation with OLAF.*

*Nevertheless it would be more transparent for the agency's duty to cooperate with OLAF inquiries to be stated explicitly. It must be stated unequivocally that the Agency and all its employees are subject to the relevant Community provisions on combating fraud.*

*The amendment is based on amendments adopted by Parliament to both the Aviation Safety and Maritime Safety Agency regulations.*

Amendment 5  
Article 70

To ensure ***an appropriate*** level of transparency, the Management Board, on

To ensure ***a high*** level of transparency, the Management Board, on the basis of a

---

<sup>1</sup> OJ L 136, 31 May 1999.

<sup>2</sup> OJ L 136, 31 May 1999.

the basis of a proposal by the Executive Director, in agreement with the Commission, shall adopt rules to ensure the availability to the public of regulatory, scientific or technical information concerning the authorisation or supervision of medicinal products which is not of a confidential nature.

proposal by the Executive Director, in agreement with the Commission, shall adopt rules to ensure the availability to the public of regulatory, scientific or technical information concerning the authorisation or supervision of medicinal products which is not of a confidential nature.

***The internal rules of procedure of the Agency and its committees and working groups shall be made available to the public and published on the internet.***

#### *Justification*

*Especially in the pharmaceutical sector a high level of transparency of public services is necessary.*

AGENCY	DISCHARGE AUTHORITY	GIVEN TO
Centre for Development of Vocational Training <sup>1</sup> Thessaloniki (formerly Berlin) [1975] Foundation for Improvement of Living and Working Conditions <sup>2</sup> Dublin [1975]	European Parliament (on recommendation by Council)	Management Board
Reconstruction Agency for Kosovo (OBNOVA) <sup>3</sup> Thessaloniki [1999] European Food Safety Authority (EFSA) <sup>4</sup> Provisional seat: Brussels [2002]	European Parliament (on recommendation by Council)	Director
Environment Agency <sup>5</sup> Copenhagen [1990] European Training Foundation <sup>6</sup> Turin [1990] Monitoring Centre for Drugs and Drug Addiction <sup>7</sup> Lisbon [1993] Agency for the Evaluation of Medicinal Products <sup>8</sup> London [1993] Office for Harmonisation in the Internal Market <sup>9</sup> Alicante [1994] Community Plant Variety Office <sup>10</sup> Angers [1994] Translation Centre for Bodies of the EU <sup>11</sup> Luxembourg [1994] Agency for Safety and Health at Work <sup>12</sup> Bilbao [1995]	Management Board	Director

<sup>1</sup> Council Regulation 337/75 of 10.2.1975

<sup>2</sup> Council Regulation 1365/75 of 26.5.1975

<sup>3</sup> Council Regulation 2454/99 of 15.11.1999

<sup>4</sup> Regulation 178/92 of the European Parliament and the Council of 28.1.2002

<sup>5</sup> Council Regulation 1210/90 of 7.5.1990

<sup>6</sup> Council Regulation 1360/90 of 7.5.1990

<sup>7</sup> Council Regulation 302/93 of 8.2.1993

<sup>8</sup> Council Regulation 2309/93 of 23.7.1993

<sup>9</sup> Council Regulation 40/94 of 20.12.1993

<sup>10</sup> Council Regulation 2100/94 of 27.7.1994

<sup>11</sup> Council Regulation of 2965/94 of 28.11.1994

<sup>12</sup> Council Regulation 2062/94 of 18.7.1994

<sup>13</sup> Council Regulation 1035/97 of 2.6.1997

Monitoring Centre for Racism and Xenophobia <sup>13</sup> Vienna [1997]		
---	--	--

20 June 2002

**OPINION OF THE COMMITTEE ON INDUSTRY, EXTERNAL  
TRADE, RESEARCH AND ENERGY**

for the Committee on the Environment, Public Health and Consumer Policy

on the 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 (COM(2001) 404 – C5-0592/2001 – 2001/0253(COD))

Draftsman: Imelda Mary Read

**PROCEDURE**

The Committee on Industry, External Trade, Research and Energy appointed Imelda Mary Read draftsman at its meeting of 23 January 2002.

It considered the draft opinion at its meetings of 25 March, 28 May, 4 June and 19 June 2002.

At the latter/last meeting it adopted the following amendments by 37 votes to 4.

The following were present for the vote: Jaime Valdivielso de Cué, acting chairman; Imelda Mary Read, draftsman; Konstantinos Alyssandrakis, Danielle Auroi (for Nuala Ahern), María del Pilar Ayuso González (for Sir Robert Atkins), Luis Berenguer Fuster, Yves Butel, Massimo Carraro, Giles Bryan Chichester, Nicholas Clegg, Dorette Corbey (for Gérard Caudron), Concepció Ferrer, Francesco Fiori (for Christian Foldberg Røvsing), Colette Flesch, Christos Folias (for Marjo Matikainen-Kallström), Cristina García-Orcoyen Tormo (for Paul Rübig), Neena Gill (for Norbert Glante), Michel Hansenne, Hans Karlsson, Bashir Khanbhai, Werner Langen, Peter Liese (for Dominique Vlasto), Rolf Linkohr, Eryl Margaret McNally, Erika Mann, Giuseppe Nisticò (for Guido Bodrato), Reino Paasilinna, Paolo Pastorelli, Elly Plooij-van Gorsel, Samuli Pohjamo (for Willy C.E.H. De Clercq), John Purvis, Alexander Radwan (for Peter Michael Mombaur), Bernhard Rapkay (for Carlos Westendorp y Cabeza), Mechtild Rothe, Umberto Scapagnini, Esko Olavi Seppänen, Gary Titley, Claude Turmes, W.G. van Velzen, Alejo Vidal-Quadras Roca, Myrsini Zorba and Olga Zrihen Zaari.

## SHORT JUSTIFICATION

The main objectives underpinning the Commission's proposal to revise EU pharmaceutical legislation should be warmly welcomed. Ensuring a high level of health protection for EU citizens and access to safe, effective, affordable medicines are the essential goals, together with the establishment of a climate where all sectors of this industry in the EU can thrive.

The nature and complexity of the pharmaceutical industry, where profits are directly or indirectly from the public purse, and where pan-European liberalisation is either absent or poorly developed, mean that normal Internal Market expectations have not, so far, applied. To successfully liberalise this market, and for it to successfully compete globally, the regulatory regime needs to be clear, workable and soundly based. It must also be recognised that the pace of developments within the industry may overtake the legislation.

A myriad of different interests are involved within the industry. Balances must be found, for example between the generic and the in-patent parts of the industry. The views of patients and consumers also need to be considered, although the issue of the independence of patients organisations, and how far they accurately represent patients' views, must be addressed.

There are many well reasoned proposals from the Commission. For example, the opportunity to redefine a medicinal product to incorporate some new therapies is positive. However, this must not inadvertently incorporate treatments that are covered by their own specific legislation.

The proposal for a "Bolar" provision, allowing research into generic products whilst the reference product is still patent protected, is also welcome. Without this provision, research into generic products will still take place during the patent period, but will be undertaken in non-EU countries.

Given the level of harmonisation of national authorisation procedures, the different periods of data exclusivity in member states is an anomaly. The proposed harmonised period will bring greater certainty to the market and will assist in the move towards a fully operating Internal Market. However, there are some additional issues with the proposals for the extra year of data exclusivity, granted where a new indication is authorised.

The proposal to abolish the five year renewal process is welcome, reducing administrative and financial burdens on the industry, while preventing the loss from the market of rarely used medicines. However, the pharmacovigilance provisions proposed by the Commission need to be sufficient to ensure continued high levels of health protection.

The proposal to invalidate authorisation for products which have not been placed on the market for two years should not be supported. It will not assist in getting products to the market more quickly and at worst could result in Member States being unable to respond to an outbreak of a rare disease. The Commission should reconsider whether the existing proposals on pharmacovigilance and periodic safety update reports will be sufficient in ensuring health protection following the abolition of the five year renewal.

The Commission should also reconsider its proposal on advertising. There is a need for access

to accurate, understandable and reliable information on the range of treatments, including medicines. But, moves towards Direct to Consumer Advertising should be resisted. The Commission, as an alternative, should look at how internet information could be validated, addressing issues concerning liability.

In addition to establishing the rules for advertising medicines to the general public, it is vital that any relationship between pharmaceutical companies and medical practitioners be fully transparent.

Whatever amendments agreed in relation to advertising, it is imperative that the European Parliament also has a say in any future changes.

## AMENDMENTS

The Committee on Industry, External Trade, Research and Energy calls on the Committee on the Environment, Public Health and Consumer Policy, as the committee responsible, to incorporate the following amendments in its report:

Text proposed by the Commission<sup>1</sup>

Amendments by Parliament

### Amendment 1 Recital 14

(14) The quality of medicinal products for human use produced or available in the Community should be guaranteed by requiring that the active substances used in their composition comply with the principles of good manufacturing practice in relation to those medicinal products. It has proved necessary to reinforce the Community provisions on inspections and to compile a Community register of the results of those inspections.

(14) The quality of medicinal products for human use produced or available in the Community should be guaranteed by requiring that the active substances used in their composition comply with the principles of good manufacturing practice in relation to those medicinal products, ***which differ according to whether the medicinal product is intended for adults or for children***. It has proved necessary to reinforce the Community provisions on inspections and to compile a Community register of the results of those inspections.

### *Justification*

*Children's metabolism differs from that of adults and they need different doses and administration routes. In spite of this, 50 – 90% of pharmaceutical products administered to children for therapeutic purposes have never been evaluated for paediatric use and all*

<sup>1</sup> OJ C 75E, 26.3.2002, P.216.

*clinical trials have been carried out on adults.*

Amendment 2

ARTICLE 1, PARAGRAPH 1, POINT (c a) (new)  
Article 1, paragraph 5 (Directive 2001/83/EEC)

***(c a) Paragraph 5 is replaced by the following:***

***5. Homeopathic medicinal product***

***Any medicinal product prepared from substances 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 active principles.***

*Justification*

*Neither ‘products’ or ‘compositions’ are defined in the document while substances are clearly defined in Article 1(3). Substances sufficiently covers all the sources of homeopathic medicinal products. There is no need to refer to ‘homeopathic stocks’ as creation of these form part of the homeopathic manufacturing procedure outlined in the relevant pharmacopoeia. ‘Also’ is an unnecessary word in this sentence. The use of the word ‘active’ is in accord with its use in the phrase ‘active principle in amended Article 10 2 b. principle’ in amended Article 10 2 b.*

Amendment 3

ARTICLE 1, PARAGRAPH 1, POINT (b)  
Article 1, point 2, (b) (Directive 2001/83/EC)

Any substance or combination of substances which ***may*** be used in human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions

Any substance or combination of substances which ***is intended to be used in*** human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions ***by exerting a pharmacological action***

*Justification*

*The definition of a medicinal product must be more precise. Since “modifying physiological functions” is a property that belongs not solely to medicinal product, it cannot be the criteria*

*to define medicinal products and the scope of application of the legislation. The definition of a medicine needs therefore to refer to a more specific and more precisely defined property as in the above mentioned amendment.*

Amendment 4

ARTICLE 1, PARAGRAPH 1, POINT (c c) (new)  
Article 1, point 28 a (new) (Directive 2001/83/EEC)

***(cc) The following point is added:***

***“(28a) Risk/benefit balance:***

***An evaluation of the positive effects of the product in relation to the risk of unwanted effects as defined above.”***

*Justification*

*Self-explanatory.*

Amendment 5

ARTICLE 1, PARAGRAPH 3, POINT ba (new)  
Article 3, point 6 a (new) (Directive 2001/83/EEC)

***In Article 3, the following paragraph 6a is added:***

***“6a. This directive shall not apply to medical devices and their accessories.”***

*Justification*

*Medical devices are already fully covered by directives 90/385/EC and 93/42/EC (as amended) and by 93/79/EC. The inclusion of medical devices in the regulatory procedure for pharmaceutical products would not be appropriate in view of their different application and effect.*

Amendment 6

ARTICLE 1, PARAGRAPH 5, POINT (a)  
Article 6, paragraph 1, second subparagraph (Directive 2001/83/EEC)

The various strengths, pharmaceutical forms, administration routes, presentations, and any

The various strengths, pharmaceutical forms, administration routes, presentations, and any

variation under Article 35 shall be authorised under the first by ***and shall be considered as part of the same authorisation.***

variation under Article 35 shall be authorised under the first by.

#### *Justification*

*The proposed new definition of “marketing authorisation” would mean that a single global marketing authorisation would replace the individual marketing authorisations currently issued for different strengths and pharmaceutical forms. This concept would not contribute to Public Health, but it will impose major business hurdles on companies, particularly in terms of co-marketing agreements. It would also remove the possibility for important innovative advances in medicinal products development to be encouraged, recognised and protected through regulatory data protection. Such advances include the development of long acting dosage forms (reducing the number and frequency of doses needed to be taken) and the development of oral liquid and injectable forms of medicines (facilitating administration to patients unable to swallow tablets, e.g. some elderly patients and the unconscious). This amendment proposes that the definition of “marketing authorisation” proposed by the Commission be slightly modified.*

#### Amendment 7

#### ARTICLE 1, PARAGRAPH 5, POINT (b)

Article 6, paragraph 1 a (new) (Directive 2001/83/EEC)

The following paragraph 1a is inserted:

The marketing authorisation holder shall be responsible for marketing the medicinal product.

The following paragraph 1a is inserted:

The marketing authorisation holder shall be responsible for marketing the medicinal product. ***The holder is responsible for ensuring that the marketing of the medicinal product, whether done by himself, or by a third party, is in compliance with the provisions of this Directive.***

#### *Justification*

*This amendment takes account of the variety of channels and commercial agreements for the distribution of pharmaceuticals, and avoids legal uncertainty both for the consumers and the business partners by ensuring that these marketing schemes do not interfere with the responsibility related to certification processes.*

Amendment 8  
ARTICLE 1, PARAGRAPH 6, POINT (b)  
Article 8, paragraph 3, point (i), indent 3 (Directive 2001/83/EEC)

- clinical trials.

- clinical trials ***on medicinal products which are intended for adults and also on those intended for paediatric use.***

*Justification*

*50 – 90% of pharmaceutical products which are administered to children for therapeutic purposes have never been evaluated for paediatric use and all clinical trials have been carried out on adults.*

Amendment 9  
ARTICLE 1, PARAGRAPH 7  
Article 10, paragraph 1, second subparagraph (new) (Directive 2001/83/EEC)

1. By way of derogation from point (i) of Article 8(3), and without prejudice to the law relating to the protection of industrial and commercial property, the applicant shall not be required to provide the results of pre-clinical tests or of clinical trials if he/she can demonstrate that the medicinal product has been a generic of a reference medicinal product authorised under Article 6 for not less than ten years in a Member State or in the Community.

1. By way of derogation from point (i) of Article 8(3), and without prejudice to the law relating to the protection of industrial and commercial property, the applicant shall not be required to provide the results of pre-clinical tests or of clinical trials if he/she can demonstrate that the medicinal product has been a generic, of a reference medicinal product authorised under Article 6 for not less than ten years in a Member State or in the Community.

***However, in case of a biosimilar medicinal product, pre-clinical and clinical tests are needed in all cases.***

*Justification*

*The biological steps in creating a biosimilar medicinal products is, in contrast to generical chemical products, much more complicated. This is due to the fact that the side-effects of the by-products of the biosimilar medicinal products are unknown. Therefore in light of protecting the health safety of patients, pre-clinical and clinical tests are required in all cases..*

Amendment 10  
ARTICLE 1, PARAGRAPH 7, POINT 2, POINT (ba) (new)  
Article 10, paragraph 2, point (b a) (new) (Directive 2001/83/EEC)

***(b a) biosimilar medicinal product shall mean a non-generic biological medicinal product which has similar physicochemical and biological properties, same pharmaceutical form, and whose equivalent efficacy and safety profile with the reference biological medicinal product has been justified by appropriate preclinical tests and/or clinical trials.***

*Justification*

*Self-explanatory.*

Amendment 11  
ARTICLE 1, PARAGRAPH 7, POINT 4  
Article 10, paragraph 4 (Directive 2001/83/EEC)

4. Conducting the necessary tests and trials with a view to application of paragraphs 1, 2 and 3 to a generic medicinal product shall not be regarded as contrary to patent rights or to complementary protection certificates for those medicinal products.

4. Conducting the necessary tests and trials with a view to application of paragraphs 1, 2 and 3 to a generic ***or biosimilar*** medicinal product shall not be regarded as contrary to patent rights or to complementary protection certificates for those medicinal products.

*Justification*

*Self-explanatory.*

Amendment 12  
ARTICLE 1, PARAGRAPH 12, POINT (-a) (new)  
Article 14, paragraph 1, indent 3 (Directive 2001/83/EEC)

***In paragraph 1, the third indent is replaced by the following:***

***"- there is a sufficient degree of potentiation, which involves a sequential***

***series of dilutions and 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; if new scientific evidence so warrants, the Commission may amend the present indent by the procedure referred to in Article 121 (2)."***

*Justification*

*It is important to introduce the process essential to the preparation of medicines for homeopathic use, potentiation at this point in document. The pharmaceutical process involved in producing these products involves more than just simple dilution.*

Amendment 13

ARTICLE 1, PARAGRAPH 12 a (new)  
Article 15, indent 2 (Directive 2001/83/EEC)

***In article 15 the second indent is replaced by the following:***

***"- 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,"***

*Justification*

*The use "nature" is unclear in the original text. We propose the word "use" as giving clearer meaning. Potentiation includes the process of dilution and is defined by the Chichester proposed amendment to ARTICLE 11 (Directive 2001/82/EEC, Article 17).*

Amendment 14  
ARTICLE 1, PARAGRAPH 21  
Article 24, paragraph 2 (Directive 2001/83/EC)

***2. Any authorisation which is not followed within two 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.***

*Justification*

*This proposal does not understand the realities of pricing and reimbursement negotiations. If the proposal is designed to be a form of consumer protection following the abolition of the five yearly renewal, the Commission should review whether the existing proposals on pharmacovigilance and PSUR requirements offer a sufficient degree of protection.*

Amendment 15  
ARTICLE 1, PARAGRAPH 25, POINT (-a) (new)  
Article 33 (Directive 2001/83/EEC)

***(-a) In the first paragraph, "30 days" is replaced by "10 days";***

*Justification*

*This amendment aims at reducing the decision making timelines which have been heavily criticised during the audit (cf. Evaluation of the Operation of Community Procedures for the Authorisation of Medicinal Products; section 5.1.14, page 110). The European Commission has proposed a modest reduction in one part of the process by shortening the duration of the consultation period of Member States from 28 days down to 15 days. However, even after this improvement the process could still take greater than 75 days, and reduction of other administrative steps is necessary and possible.*

Amendment 16  
ARTICLE 1, PARAGRAPH 37, POINT (ca) (new)  
Article 54, point (j) (Directive 2001/83/EEC)

***(ca) Point (j) is replaced by the following:  
"(j) a statement that unused medicinal products or waste materials from medicinal products should be returned to the***

***pharmacy. A statement that unused medicinal products should not be discharged into the sewer; "***

*Justification*

*Unused medicinal products, residues and those past their expiry date must be returned to the chemist. They should not be discarded with other waste. They are a danger to public health and the environment.*

Amendment 17

ARTICLE 1, PARAGRAPH 38 a (new)  
Article 56 (Directive 2001/83/EEC)

***The following text is added to Article 56:***

***"The references made in Art 54 (a) of this Directive must be also expressed in Braille format on the packaging or in the Patient Information Leaflet (PIL) provided inside. Basic information such as product name, dosage, helpline telephone number and web site address must be included in the packaging or in the PIL, in large print (minimum font size 16). The full text of the PIL should be available, free of charge, in other formats on request, (such as large print, braille, audio tape and electronic format). This measure is to improve access to this vital information for blind and partially sighted people."***

*Justification*

*A new paragraph should be added to Article 56 of the Directive which would fall between point 38 and 39 of the COM doc. The writing on the PIL leaflets and packaging is often too small for many partially sighted people to read. This can and does lead to patients endangering their health through wrongly taking medication. With a rapidly ageing population, age-related sight loss is an increasing problem. While Braille is understood by many lifelong blind people and is a vital lifeline for deaf-blind people, those who develop blindness and sight loss later in life do not tend to understand it. The use of Braille should therefore be coupled with the use of large print.*

Amendment 18  
ARTICLE 1, PARAGRAPH 38 b (new)  
Article 56 a (new) (Directive 2001/83/EEC)

*A new Article 56a is added:*

***"The competent national authority will establish a database, accessible free of charge through the internet in which up to date content information for all pharmaceutical products licensed for sale or dispensing within the territory of that Member State. This database should be fully accessible to all citizens in such a way that disabled people can easily access pharmaceutical product information. For those without access to the internet, a telephone helpline service should be established to ensure as wide a dissemination of information as possible. Through the web site and helpline, complete product information should be made available on request, in the following alternative formats: Large Print (minimum font size 16) , Braille, Audio Tape and e-text. "***

*Justification*

*This new Article would fall after A56 of the Directive and before point 39 of the Com doc. The packaging inside medicine packaging is by its nature small, so it would be difficult to fit all information on it. For this reason, the establishment of a web site, set up according to accepted standards of web-site accessibility and a helpline would be vital means for blind and partially sighted people to request information and to order the full Patient Information Leaflet (PIL) in alternative formats..*

Amendment 19  
ARTICLE 1, PARAGRAPH 44 b (new)  
Article 68 (Directive 2001/83/EEC)

***Article 68 is replaced by the following.***

***"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."***

*Justification*

*What characterises this category of medicinal product pharmaceutically is potentisation, the method of preparation which results in the dilute state of the active principle, or principles, contained in each medicine. The 'homeopathic nature' is more accurately linked to the reasons for prescription based on the principle of similars .*

Amendment 20

ARTICLE 1, PARAGRAPH 45, POINT (a)

Article 69, paragraph 1, first indent (Directive 2001/83/EEC)

- 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 ***replaced*** by an invented name,

- 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,

*Justification*

*The scientific names of the included stocks should be included on the label. What is the point of an "invented" name unless it is somehow to give a therapeutic indication as to which condition the remedy of combined stocks could be prescribed for. For a medicine being registered under 14.1, there is no point to an invented name and the names of the stocks should be included. If the medicine is to be registered other than by 14.1 and an invented name may be part of the indications for therapeutic use then there is no objection. As a compromise therefore, remedies that contain two or more stocks could have a supplementary "invented name" added to the labelling.*

Amendment 21

ARTICLE 1, PARAGRAPH 45, POINT (b b) (new)

Article 69, paragraph 1, indent 12 (Directive 2001/83/EEC)

***- a warning advising the user to consult a doctor and a registered homeopath if the symptoms persist***

### *Justification*

*Although if the symptoms of a patient's condition persist beyond the taking of a homeopathic remedy the patient should check with their doctor if they have not already done so. However, if the patient has already taken homeopathic treatment they have clearly expressed a desire to try this kind of treatment and may already be consulting with a homeopath. Therefore we consider the patient should refer back to their doctor and a registered homeopath for further diagnosis and treatment. Only the homeopath has the expertise to evaluate the effect of the homeopathic remedy being taken and to prescribe for the patient should the patient require further homeopathic treatment. It is important that patients seek the help of registered practitioners of homeopathy for guarantees of safety and effectiveness.*

### Amendment 22

ARTICLE 1, PARAGRAPH 51 a (new)

Article 77, paragraph 3 a (new) (Directive 2001/83/EEC)

***3a. The marketing authorisation holder of a medicinal product shall provide uninterrupted supply of that medicinal product, marketed in the concerned Member State, to wholesaler distributors registered in these Member States, so that the provision of the medicinal product to patients through pharmacies and hospitals is ensured.***

### *Justification*

*There is evidence to suggest that manufacturers are withholding and/or restricting supply of prescription medicines to wholesalers in Member States. This is against the principle of the single, free internal market and is causing unacceptable disruption of the supply of essential medicines to patients.*

### Amendment 23

ARTICLE 1, PARAGRAPH 54, POINT 2

Article 88(2) (Directive 2001/83/EC)

***2. The communication of information on certain medicinal products is authorised under strict conditions in the interest of patients in order to respond to their legitimate needs. This provision applies to product information appended to the marketing authorisation as well as to***

***Delete***

*additional related information.*

*By way of derogation from the prohibition in paragraph 1(a), Member States shall authorise the dissemination of information relating to certain medicinal products authorised in the framework of the affections set out below, in order to respond to the expectations expressed by the patients' groups:*

*This dissemination of information shall be carried out on the following conditions:*

*(a) the medicinal product shall be authorised and prescribed for the treatment of any of the following conditions:*

- acquired immune deficiency syndrome;*
- asthma and chronic broncopulmonary disorders;*
- diabetes;*

*(b) the information disseminated complies with the principles set out in this Title;*

*(c) implementation of this paragraph shall be conditioned by the setting-up of self-regulatory procedures by the pharmaceutical industry at Member State level;*

*(d) the information and its dissemination shall be in conformity with the principles of good practice which are adopted, after consultation with interested parties, in conformity with the procedure set out in Article 121(2).*

*(e) in order to monitor the implementation of the principles of good practice referred to above:*

*– the additional information related to the medicinal products shall be notified to the Agency. If the Agency does not object within thirty days following this notification, the information shall be deemed to be accepted;*

*– the Agency shall coordinate of the*

*monitoring of the information on the medicinal products authorised in conformity with this Directive, in particular through the setting-up of a data base;*

*– on a yearly basis, the Agency shall prepare a report on the application of these principles of good practice;*

*(f) implementation of this paragraph shall be the subject of an evaluation and a detailed report no later than [date]. The Commission shall propose any changes required to improve its implementation.*

#### *Justification*

*There is a need for patients and consumers to be able to obtain accurate, understandable and reliable information on the range of treatments, including medicines. But, what appears to be moves towards Direct to Consumer Advertising should be resisted. The Commission, as an alternative, should look at how internet information could be validated, with thought to issues concerning liability.*

*The rationale behind the idea of a three disease trial is not entirely clear. On the one hand, those diagnosed with other diseases can reasonably argue that they are just as entitled to information. On the other hand, even a three disease trial would not give consumers and patients information on the range of therapies and could easily slip into direct to consumer advertising. Of greatest concern is the fact that the proposals would not give patients access information about different types of treatment additional to medicinal products.*

#### Amendment 24

#### ARTICLE 1, PARAGRAPH 54

Article 88, paragraph 3 (Directive 2001/83/EEC)

***3. Medicinal products may be advertised to the general public which, by virtue of their composition and purpose, are intended and designed for use without the intervention of a medical practitioner for diagnostic purposes or for the prescription or monitoring of treatment, with the advice of the pharmacist, if necessary.***

***Delete***

#### *Justification*

*Given that Article 88(1) prohibits 'the advertising to the general public medicinal products*

*which are available on medical prescription only ...', there is no need to stipulate in Article 88(3) that medicines not requiring a prescription may be advertised to the general public. This additional provision creates confusion.*

Amendment 25

ARTICLE 1, PARAGRAPH 54, POINT 7 a (new)

Article 88, point 6 a (new) (Directive 2001/83/EC)

***By (date) the European Commission shall present a report on information to patients, looking specifically at ways in which websites are or can be used to give information on a range of treatments, including medicines, and, where official approval is given to this information source, addressing the question of liability. The Commission shall propose any changes to this article, which could enhance the extent and quality of information available to patients.***

*Justification*

*Information to patients is essential to increase their awareness of possible treatments. Sources of information need to conform to clearly defined standards.*

Amendment 26

ARTICLE 1, PARAGRAPH 54

Article 88, paragraph 7 a (new) (Directive 2001/83/EEC)

***The European Commission shall look into the possibility of urging every national authority to have a website that functions as a portal and provides objective information on pharmaceutical products and health issues in general.***

*Justification*

*The European Commission should urge the Member States to ensure that every European citizen has access to objective information and come to an agreement on objective quality criteria of these websites and the information provided.*

Amendment 27  
ARTICLE 1, PARAGRAPH 57 a (new)  
Article 94, point 3 (Directive 2001/83/EEC)

***(57a) In article 94, paragraph 3 is replaced by the following:***

***3. Persons qualified to prescribe or supply medicinal products shall not solicit or accept any inducement prohibited under paragraph 1 or contrary to paragraph 2. Member States shall develop appropriate regulations or a code of conduct to enforce paragraph 1, 2 and 3.***

*Justification*

*It is necessary to take appropriate measures or agree on a code of conduct at Member State level, to enforce these paragraphs.*

Amendment 28  
ARTICLE 1, PARAGRAPH 59  
Article 98, paragraph 3 (Directive 2001/83/EEC)

3. The Member States shall authorise the co-promotion of a medicinal product by the holder of the marketing authorisation and one or more companies nominated by him/her.

***3. The provisions of this Directive are without prejudice to the activities of co-promotion and co-marketing performed by the holder of the marketing authorisation and one or more companies nominated by him/her. In the case of co-promotion, the details of the co-promoting company may appear on the product outer box.***

*Justification*

*This amendment aims at improving the information of the public.*

Amendment 29  
ARTICLE 1, PARAGRAPH 62  
Article 102, paragraph 2 (Directive 2001/83/EEC)

- Member States shall ensure that suitable information shall be recorded in the data

- Member States shall ensure that suitable information shall be recorded in the data

base referred to in point (j) of the second paragraph of Article 51 of Regulation (EEC) No. 2309/93 and shall be permanently accessible to all Member States

base referred to in point (j) of the second paragraph of Article 51 of Regulation (EEC) No. 2309/93 and shall be permanently accessible to all Member States

***In addition, selected read and print access for Marketing Authorisation Holders shall be ensured in relation to data on their own products.***

#### *Justification*

*In order to ensure the safety of patients in the EU, it is essential that an effective pharmacovigilance system is in place. The Commission proposes the introduction of a single EU data base for recording adverse drug reactions, which will increase the effectiveness of the current system. Industry should also be given selected access to the data on their own products in this data base, in order to allow coordinated action between the authorities and the Marketing Authorisation Holder on safety issues, and thus further increase the effective functioning of the system.*

Amendment by W.G. van Velzen

Amendment 30

ARTICLE 1, PARAGRAPH 69

Article 122 a (new) (Directive 2001/83/EEC)

***The Commission should undertake a benchmarking study into the comparison of new medicinal products that are evaluated by the EMEA and for which the Commission is granting a marketing authorisation. This study should address the comparison of these products in the context of transparency in dealing with prices and reimbursement.***

#### *Justification*

*Major differences in prices for pharmaceutical products exist between the Member States. It is very important that the market for pharmaceutical products should become more transparent. This benchmarking study of the European Commission is the first step in this process.*



20 June 2002

## **OPINION OF THE COMMITTEE ON AGRICULTURE AND RURAL DEVELOPMENT**

for the Committee on the Environment, Public Health and Consumer Policy on

the proposal for a Regulation of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the evaluation of medicinal products (COM(2001) 404 – C5- 0591/01 – COD010252)

the 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 (COM(2001) 404 – C5-0592/01 – COD010253)

the 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 (COM(2001) 404 – C5-0593/01 – COD 010254)

Draftsman: Robert William Sturdy

### **PROCEDURE**

The Committee on Agriculture and Rural Development appointed Robert William Sturdy draftsman at its meeting of 8 January 2002.

The committee considered the draft opinion at its meetings of 19 March 2002, 28 May 2002 and 19 June 2002.

At the last meeting it adopted the following conclusions unanimously.

The following were present for the vote: Joseph Daul, chairman; Albert Jan Maat, vice-chairman; Robert William Sturdy, rapporteur; Gordon J. Adam, Carlos Bautista Ojeda, Arlindo Cunha, Christel Fiebiger, Francesco Fiori, Christos Folias, Jean-Claude Fruteau, Georges Garot, Lutz Goepel, Willi Görlach, Liam Hyland, María Izquierdo Rojo, Elisabeth Jeggle, Salvador Jové Peres, Hedwig Keppelhoff-Wiechert, Heinz Kindermann, Dimitrios Koulourianos, Astrid Lulling (for Neil Parish), Véronique Mathieu, Hans-Peter Mayer (for Michl Ebner), Xaver Mayer, Karl Erik Olsson, Mikko Pesälä, Encarnación Redondo Jiménez and Agnes Schierhuber.

## SHORT JUSTIFICATION

The Commission's proposals for amending the regulatory framework for the approval of veterinary medicinal products in the EU acknowledge the lack of availability of veterinary medicines and are a positive step forward in addressing this problem.

The proposals recognise the need for veterinary medicinal products in ensuring the health and welfare of animals. They take into account animal health and welfare as well as public health, whereas previously the system has focussed exclusively on public health with little regard for the health and welfare of animals. A licensing system that takes into account both these requirements will bring back the much-needed balance, to the benefit of people and animals.

In recognising the lack of availability of veterinary medicines, the proposals give some welcome suggestions for improving the system of registration, allowing medicines to be approved efficiently while at the same time ensuring that only safe, efficacious and high-quality medicines reach the marketplace. An improved system would achieve this without an overly burdensome procedure – what the Commission has called “cutting red tape.”

The Commission's proposals offer special provisions to increase medicines availability for horses not intended for the human food-chain as well as other animals such as rabbits and ferrets.

The Commission's proposals offer extended data protection to increase the incentives for companies to invest in producing new medicines for animals. They offer special protection for medicines developed for fish and bees, which currently face the worst medicines availability crisis.

The proposals remove the administrative requirement to re-license products every five years, instead proposing a strengthening of the existing in-use monitoring and reporting system. This is coupled with proposals for extended record-keeping for treatment of animals destined for the food-chain, aimed at supporting full traceability throughout the EU.

Overall, the Commission's proposals will achieve the following:

- They will support the welfare and safety of humans. Consumers expect that animals, whose produce they eat, are free of disease; the public should be protected from diseases that can be passed on to humans; and farmers should be able to have access to registered and approved safe, efficacious and high-quality medicines should their animals fall ill.
- They will support the welfare of animals. By encouraging innovation they will encourage new treatments, enabling animals to have access to the medicines they need to stay healthy or be treated if they become sick.
- They will encourage and enable companies to continue to invest in research and development in order to bring new treatments to the market, and stay ahead of the spread or emergence of new diseases. Keeping research and development facilities in Europe will safeguard jobs and keep Europe as a centre of innovation.

The Commission's proposals aim at making practical improvements to the system for scrutinising, evaluating and approving veterinary medicinal products based on 20 years of experience of the current system. In general, they propose welcome measures to increase transparency and ease of use of the system, making it less burdensome, less cumbersome and less time-consuming while at the same time protecting the interests of members of society and animals.

However, the Commission's proposals have some major weaknesses that could undermine the practical effectiveness of the solutions proposed.

They do not reflect an understanding of the length of time it takes to obtain registration and to develop the data required for the extension of a marketing authorisation to different species and to different sicknesses, whether for a food-producing animal or not.

They do not fully recognise that the number-one focus must be solving the medicines availability crisis by getting products to the market at the same time as ensuring no lapse in existing provisions for human and animal safety.

They do take into account the fundamental nature of the animal-health markets. Due to the species-specific, regional and often sporadic nature of animal diseases, the markets are, in practice, tiny when compared to those for human pharmaceuticals.

Animal medicines must be licensed to similar standards of quality, safety and efficacy as human pharmaceutical products, yet the economic realities of the potential marketplaces mean that it may not be economically feasible to bring them to market. A great many veterinary medicinal products are "orphan drugs" when the criteria for human pharmaceutical products are applied in the same manner.

Therefore the draftsman would propose a series of amendments that would address these problems without compromising human health or animal health and welfare.

## AMENDMENTS

The Committee on Agriculture and Rural Development calls on the Committee on the Environment, Public Health and Consumer Policy, as the committee responsible, to incorporate the following amendments into its report:

Text proposed by the Commission<sup>1</sup>

Amendments by Parliament

---

### Regulation of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products

#### Amendment 1 Recital 10

(10) In the field of veterinary medicinal products, administrative measures should be provided for in order to take account of the specific features of this field, particularly those due to the regional distribution of certain diseases. The field of application of the centralised procedure should also include medicinal products used within the framework of Community provisions regarding prophylactic measures for epizootic diseases.

(10) In the field of veterinary medicinal products, administrative measures should be provided for in order to take account of the specific features of this field, particularly those due to the regional distribution of certain diseases. ***The Commission should develop, as a matter of urgency, a specific legal instrument to set out a policy for veterinary ‘orphan’ medicinal products, analogous to that developed for human medicines by Regulation (EC) No. 141/2000, and implemented by Regulation (EC) No 847/2000.*** The field of application of the centralised procedure should also include medicinal products used within the framework of Community provisions regarding prophylactic measures for epizootic diseases.

#### *Justification*

*There is a declining availability of veterinary medicinal products, particularly for minor species or minor diseases. This policy was one of the medium-term proposals for solutions published in the Communication from the Commission to the Council and European Parliament (“Availability of veterinary medicinal products”), 05.12.2000, COM(2000) 806. It*

---

<sup>1</sup> OJ C 75, 26.03.2002.

*is further supported by the statements contained within the “Whereas” clauses (9) and (10) of the proposal for a Directive amending Directive 2001/82/EC (2001/0254 (COD)).*

Amendment 2  
Article 28, paragraph 1

1. Each application for authorisation for a medicinal product for veterinary use shall specifically include all the information and documents referred to in Articles 12(3), 13a and 14 of Directive 2001/82/EC, and Annex I thereto. ***The information and documents are to take account of the unique, Community nature of the authorisation requested, and particularly of the use of a single name of the medicinal product.***

The application shall be accompanied by the fee payable to the Agency for the examination of the application.

1. Each application for authorisation for a medicinal product for veterinary use shall specifically include all the information and documents referred to in Articles 12(3), 13a and 14 of Directive 2001/82/EC, and Annex I thereto.

The application shall be accompanied by the fee payable to the Agency for the examination of the application.

*Justification*

*There should be more flexibility in the requirement for one trademark for all of Europe. This is becoming increasingly difficult to achieve, diverts time and resources and may delay product coming to market and after Enlargement may become impossible.*

Amendment 3  
Article 31, paragraph 2

2. Within 15 days of receipt of the opinion referred to in paragraph 1, the applicant may provide written notice to the Agency that he/she wishes to appeal. In that case the applicant shall forward the detailed grounds for his/her appeal to the Agency within 60 days of receipt of the opinion.

2. Within 15 days of receipt of the opinion referred to in paragraph 1, the applicant may provide written notice to the Agency that he/she wishes to appeal. In that case the applicant shall forward the detailed grounds for his/her appeal to the Agency within 60 days of receipt of the opinion.

Within 60 days of receipt of the grounds for appeal, the Committee for Veterinary Medicinal Products shall re-examine its opinion in accordance with the conditions laid down in the second subparagraph of Article 55(1). The conclusions reached on the appeal shall be annexed to the final opinion.

Within 60 days of receipt of the grounds for appeal, the Committee for Veterinary Medicinal Products shall re-examine its opinion in accordance with the conditions laid down in the second subparagraph of Article 55(1). ***If the grounds for appeal include new data, not available at the time of the original submission, then this period will be extended by 30 days.*** The conclusions reached on the appeal shall be annexed to the final opinion.

#### *Justification*

*If new data has become available since the submission, and could help solve the issue, then there should be an appeal procedure with extra time granted to assess the new data. See also Article 55(1).*

#### Amendment 4 Article 33, paragraph 1, point b

(b) in the case of zootechnical veterinary medicinal products and growth promoters, when the safety and welfare of the animals and/or consumer safety ***and benefits in terms of health*** have not been sufficiently taken into account;

(b) in the case of zootechnical veterinary medicinal products and growth promoters, when the safety and welfare of the animals and/or consumer safety have not been sufficiently taken into account;

#### *Justification*

*It is unreasonable to assume that veterinary medicinal products administered to animals might directly benefit human health. A more reasonable approach is to require veterinary medicinal products not to damage human health. Reference to benefits in terms of health should therefore be deleted.*

#### Amendment 5 Article 35, paragraphs 2 and 3

2. ***Any*** authorisation ***which is not followed by the actual placing on the market of*** the veterinary medicinal product

2. ***The marketing*** authorisation ***holder shall state in each periodic safety update report submitted in accordance***

authorised on the Community market ***within two years of authorisation shall cease to be valid.***

***with Article 44 whether*** the veterinary medicinal product authorised ***is actually*** on the Community market.

***3. When an authorised veterinary medicinal product previously placed on the market is no longer actually present on the market for two consecutive years, the authorisation for the product shall cease to be valid.***

***Delete***

#### *Justification*

*Requiring the marketing authorisation holder to include information in the reports required under Article 44(3) will achieve the same objective without forcing products off the market if they are not required, or cannot be marketed or manufactured for a 2-year period.*

#### Amendment 6 Article 35, paragraph 5

5. When an application is lodged for a marketing authorisation in respect of veterinary medicinal products of major interest, ***particularly*** from the point of view of animal health ***and from the viewpoint of therapeutic innovation***, the applicant may request an accelerated assessment procedure. Due reasons are to be given for the request.

5. When an application is lodged for a marketing authorisation in respect of veterinary medicinal products of major interest from the point of view of animal health, the applicant may request an accelerated assessment procedure. Due reasons are to be given for the request. ***The Veterinary Committee shall consider in particular the application of this procedure in respect of medicinal products which meet the specific needs of smaller species or minor uses, and also of laying hens. In such cases the Agency, pursuant to the provisions of Regulation (EC) No 297/95, shall apply a reduction in the fees relating to authorisation.***

If the Committee for Veterinary Medicinal Products accepts the application, the time-limits laid down in the first subparagraph of Article 28(3) shall be reduced to 150 days.

If the Committee for Veterinary Medicinal Products accepts the application, the time-limits laid down in the first subparagraph of Article 28(3) shall be reduced to 150 days.

#### *Justification*

*The value of the procedure concerned in the case of smaller species or minor uses should be more clearly stated.*

Amendment 7  
Article 52

The Agency may give a scientific opinion, in the context of cooperation with the World Health Organisation, for the assessment of certain medicinal products for human use intended exclusively for the markets of non-member countries. For this purpose, on the recommendation of the World Health Organisation, a request shall be submitted to the Agency, in accordance with the provisions of Article 6. The Committee for Human Medicinal Products shall be responsible for drawing up the Agency's opinion, in accordance with the provisions of Articles 6 to 9. The provisions of Article 10 shall not apply.

The Agency may give a scientific opinion, in the context of cooperation with the World Health Organisation, for the assessment of certain medicinal products for human use intended exclusively for the markets of non-member countries. For this purpose, on the recommendation of the World Health Organisation, a request shall be submitted to the Agency, in accordance with the provisions of Article 6. The Committee for Human Medicinal Products shall be responsible for drawing up the Agency's opinion, in accordance with the provisions of Articles 6 to 9. ***The Agency may give a scientific opinion in the context of cooperation with the Office International des Epizooties, for the assessment of certain medicinal products for veterinary use intended exclusively for the markets of third countries. For this purpose a request shall be submitted to the Agency, in accordance with the provisions of Article 28. The Committee for Veterinary Medicinal Products shall be responsible for drawing up the Agency's opinion, in accordance with the provisions of Articles 28, 29, 30 and 31.*** The provisions of Article 10 ***or Article 32*** shall not apply.

*Justification*

*This is proposed for the human pharmaceuticals but is equally needed by the veterinary sector. It removes the requirement to obtain a full marketing authorisation just for the purpose of facilitating registration in Third Countries with no intention of marketing in the EU.*

Amendment 8  
Article 55, paragraph 1

1. Where, in accordance with the provisions of this Regulation, the Committee for Human Medicinal Products or the Committee for Veterinary Medicinal Products is required to evaluate a medicinal product, it shall appoint one of its members to act as rapporteur for the coordination of the evaluation. The Committee concerned may appoint a second member to act as co-rapporteur.

If there is an appeal against one of its opinions, the Committee concerned shall appoint a different rapporteur and, where necessary, a different co-rapporteur from those appointed for the initial opinion. This appeal procedure may deal only with the points of the opinion initially identified by the applicant and may be based **only on the** scientific data available at the time the Committee adopted the initial opinion.

1. Where, in accordance with the provisions of this Regulation, the Committee for Human Medicinal Products or the Committee for Veterinary Medicinal Products is required to evaluate a medicinal product, it shall appoint one of its members to act as rapporteur for the coordination of the evaluation **taking into consideration any proposal from the applicant for the choice of rapporteur**. The Committee concerned may appoint a second member to act as co-rapporteur.

If there is an appeal against one of its opinions, the Committee concerned shall appoint a different rapporteur and, where necessary, a different co-rapporteur from those appointed for the initial opinion. This appeal procedure may deal only with the points of the opinion initially identified by the applicant and may be based on scientific data **not** available at the time the Committee adopted the initial opinion.

*Justification*

*If new data has become available since the submission, and could help solve the issue, then there should be an appeal procedure with extra time granted to assess the new data. See also Article 31.*

Amendment 9  
Article 70

To ensure an appropriate level of transparency, the Management Board, on the basis of a proposal by the Executive Director, in agreement with the Commission, shall adopt rules to ensure the availability to the public of regulatory, scientific or technical information

To ensure an appropriate level of transparency, the Management Board, on the basis of a proposal by the Executive Director, in agreement with the Commission, **and after consultation with interested parties**, shall adopt rules to ensure the availability to the public of

concerning the authorisation or supervision of medicinal products which is not of a confidential nature.

regulatory, scientific or technical information concerning the authorisation or supervision of medicinal products which is not of a confidential nature.

*Justification*

*The applicant / marketing authorisation holder should be involved in the decisions.*

Amendment 10  
Article 72, paragraph 1

***1. Only one authorisation may be granted to a particular applicant for a specific medicinal product.***

***Delete***

***However, for*** objective verifiable reasons relating to public health or the availability of medicinal products to health professionals and/or patients, the Commission may authorise the same applicant to submit more than one application to the Agency for that medicinal product.

***1. For*** objective verifiable reasons relating to public health or the availability of medicinal products to health professionals and/or patients, the Commission may authorise the same applicant to submit more than one application to the Agency for that medicinal product.

*Justification*

*The wording is too restrictive and makes it at the sole discretion of the Commission to grant or withhold permission for a copycat licence.*

Amendment 11  
ANNEX I, paragraph 4

***4. Medicinal products intended for veterinary use, containing a new active substance which was not included in the composition of any medicinal product for veterinary use authorised in the Community prior to the date of entry into force of this Regulation.***

***Delete***

*Justification*

*The flexibility to register in the markets where the disease and / or species occurs will ensure*

*that the medicines are registered in those markets. Compelling registration via the centralised procedure may mean the product is not registered at all.*

**Directive of the European Parliament and of the Council amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products**

Amendment 12  
ARTICLE 1, PARAGRAPH 5  
Article 5 (Directive 2001/82/EC)

1. No veterinary medicinal product may be placed on the market of a Member State unless a marketing authorisation has been issued by the competent authorities of that Member State in accordance with this Directive or a marketing authorisation has been granted in accordance with Regulation (EEC) No 2309/93.

The various strengths, *pharmaceutical forms, administration routes*, presentations and any amendment under Article 39 must be authorised under the first subparagraph and shall be considered part of the same authorisation.

1. No veterinary medicinal product may be placed on the market of a Member State unless a marketing authorisation has been issued by the competent authorities of that Member State in accordance with this Directive or a marketing authorisation has been granted in accordance with Regulation (EEC) No 2309/93.

The various strengths *and* presentations *of a single pharmaceutical formulation* and any amendment under Article 39 must be authorised under the first subparagraph and shall be considered part of the same authorisation.

*Justification*

*A marketing authorisation should only be defined down to the level of different formulations. Making a single marketing authorisation cover all presentations and products containing one particular active substance will undermine data protection provisions.*

Amendment 13  
ARTICLE 1, PARAGRAPH 7  
Article 10, paragraph 1 (Directive 2001/82/EC)

1. If there is no authorised medicinal product in a Member State for a condition affecting a species of pet animal or animals kept in zoos or circuses, the veterinarian may, particularly in order to avoid causing unacceptable suffering to the animal concerned, under his/her personal responsibility, treat the animal(s) with:

1. If there is no authorised medicinal product in a Member State for a condition affecting a species of pet animal or animals kept in zoos or circuses *or on fur farms*, the veterinarian may, particularly in order to avoid causing unacceptable suffering to the animal concerned, under his/her personal responsibility, treat the animal(s) with:

### *Justification*

*These articles lay down ‘cascade’ provisions, which in the proposal are divided between two articles, with Article 10 applying to pets, zoo and circus animals and horses, while Article 11 applies to food-producing animals. However, animals also exist and receive medication which do not fall into any of these categories. Among them are animals on fur farms, which should also be mentioned in Article 10. Alternatively, Article 10 could simply refer to ‘non-food-producing animals’.*

#### Amendment 14

#### ARTICLE 1, PARAGRAPH 7

Article 13, paragraph 1 (Directive 2001/82/EC)

1. By way of derogation from point (j) of the first subparagraph of Article 12(3), and without prejudice to the law relating to the protection of industrial and commercial property, the applicant shall not be required to provide the results of the safety and residue tests or of the pre-clinical and clinical trials if he/she can demonstrate that the medicinal product is a generic of a reference medicinal product authorised within the meaning of Article 5 for not less than ten years in a Member State or the Community.

However, the ten-year period provided for in the first subparagraph is extended to **13** years in the case of veterinary medicinal products for **fish or bees**.

1. By way of derogation from point (j) of the first subparagraph of Article 12(3), and without prejudice to the law relating to the protection of industrial and commercial property, the applicant shall not be required to provide the results of the safety and residue tests or of the pre-clinical and clinical trials if he/she can demonstrate that the medicinal product is a generic of a reference medicinal product authorised within the meaning of Article 5 for not less than ten years in a Member State or the Community.

However, the ten-year period provided for in the first subparagraph is extended to **15** years in the case of veterinary medicinal products for **smaller species and laying hens, provided that the applicant places the medicinal product on the market in the course of the first two years following authorisation.**

### *Justification*

*The duration of the industrial-property protection period for medicinal products should be extended to a minimum of 15 years in order to enable the industry to derive full benefit from such products.*

Amendment 15  
ARTICLE 1, PARAGRAPH 7  
Article 13, paragraph 4 (Directive 2001/82/EC)

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 **three** years following the granting of the initial marketing authorisation.

4. In the case of veterinary medicinal products intended for one or more species and containing a new active substance that has not been authorised in the Community by [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 species **or other significant new therapeutic indication**, if it is authorised within the **eight** years following the granting of the initial marketing authorisation.

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

The extension of one, two or three years of further data protection also applies to any initial marketing authorisation relative to two, three or four food-producing species, respectively.

This period cannot, however, exceed a total of 13 years, ***for a marketing authorisation for four or more food-producing species.***

The extension of the ten-year period to 11, 12, or 13 years 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 extension of one, two or three years of further data protection also applies to any initial marketing authorisation relative to two, three or four food-producing species, respectively.

This period cannot, however, exceed a total of 13 years.

The extension of the ten-year period to 11, 12, or 13 years ***in relation to 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.

#### *Justification*

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

Amendment 16  
ARTICLE 1, PARAGRAPH 8  
Article 13 c (Directive 2001/82/EC)

***After marketing authorisation has been granted, the*** marketing authorisation holder may allow use to be made of the pharmaceutical, safety and residues, preclinical and clinical documentation contained in the file with a view to examining a subsequent application for a veterinary medicinal product having the same qualitative and quantitative composition in active substances and the same pharmaceutical form.

***The*** marketing authorisation holder may allow use to be made of the pharmaceutical, safety and residues, preclinical and clinical documentation contained in the file with a view to examining a subsequent ***or parallel*** application for a veterinary medicinal product having the same qualitative and quantitative composition in active substances and the same pharmaceutical form.

*Justification*

*Companies increasingly need to cooperate to develop animal medicines, or to bring them to market in all Member States. Penalising one partner with a delayed marketing authorisation will not encourage this. Being able to co-launch is important*

Amendment 17  
ARTICLE 1, PARAGRAPH 9  
Article 14, point (1) (Directive 2001/82/EC)

(1) Name of the veterinary medicinal product followed by the strength and the pharmaceutical form;

(1) Name of the veterinary medicinal product followed by the strength and ***optionally*** the pharmaceutical form;

*Justification*

*If the name of the product becomes too long then it will be impossible to fit it onto labels of small packs. The 'pharmaceutical form' is not always necessary in the name.*

Amendment 18  
ARTICLE 1, PARAGRAPH 17  
Article 27, paragraph 3 (Directive 2001/82/EC)

***3. In order to allow the continuous evaluation of the relationship between the benefits and the risks, the marketing authorisation holder shall also forthwith forward to the***

***Delete***

**competent authorities any new information which might entail the amendment of the contents of the file or of the approved summary of the product characteristics. In particular, he/she shall forthwith inform the competent authorities of any prohibition or restriction imposed by the competent authorities of any country in which the veterinary medicinal product is marketed or of any rejection of an application for authorisation submitted in a third country.**

*Justification*

*Non-EU countries may use different criteria to accept or reject products that bear no relation to the authorisation process in the EU, unless 'equivalence' has been demonstrated with the EU through the establishment of a mutual recognition agreement.*

Amendment 19

ARTICLE 1, PARAGRAPH 18

Article 28, paragraphs 2 and 3 (Directive 2001/82/EC)

- |  |  |
|--|--|
| <p><b>2. Any authorisation that is not followed within two years of its issue by the actual marketing of the authorised veterinary medicinal product in the authorising Member State shall cease to be valid.</b></p>  | <p><b>2. The marketing authorisation holder shall state in each periodic safety update report submitted in accordance with article 75(5) whether there is actual marketing of the authorised veterinary medicinal product in the authorising Member State during the period covered by the report.</b></p> |
| <p><b>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 a period of two consecutive years, the authorisation shall cease to be valid.</b></p> | <p><b>Delete</b></p>   |

*Justification*

*Requiring the marketing authorisation holder to include information in the reports required under Article 75(5) will achieve the same objective without forcing products off the market if*

*they are not required, or cannot be marketed or manufactured for a 2-year period.*

Amendment 20  
ARTICLE 1, PARAGRAPH 21  
Article 34, paragraph 2 (Directive 2001/82/EC)

2. With a view to promote the harmonisation of veterinary medicinal products authorised for not less than ten years in the Community, and to strengthen the efficiency of the provisions of Article 11, the Member States shall send to the coordination group, no later than [date], a list of veterinary medicinal products for which a harmonised summary of product characteristics should be prepared.

The coordination group shall agree on a list of medicinal products, on the basis of proposals sent by the Member States, and shall forward this list to the Commission.

The medicinal products in this list are subject to the provisions in Paragraph 1 following a timetable established in cooperation with the Agency.

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

2. With a view to promote the harmonisation of veterinary medicinal products authorised for not less than ten years in the Community, and to strengthen the efficiency of the provisions of Article 11, the Member States shall send to the coordination group, no later than [date], a list of veterinary medicinal products for which ***the relevant marketing authorisation holders have agreed that*** a harmonised summary of product characteristics should be prepared.

The coordination group shall agree on a list of medicinal products, on the basis of proposals sent by the Member States, and shall forward this list to the Commission.

The medicinal products in this list are subject to the provisions in Paragraph 1 following a timetable established in cooperation with the Agency ***and the interested parties.***

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

*Justification*

*Harmonisation should be sought, but not at the expense of indications lost from the product label, especially given the current medicines availability crisis. Harmonisation will be resource-intensive; a practical timetable is necessary.*

Amendment 21  
ARTICLE 1, PARAGRAPH 44  
Article 67, point (a), point (ii) (a)\* (Directive 2001/82/EC)

**(a)\* veterinary medicinal products for food-producing animals;** **Delete**

*Justification*

*Existing national product distribution systems and food-residue monitoring programmes in the Member States are all shown to be safe and effective. Due to different interpretations of the term “medicine” and the different professional rules existing in each Member State for “prescribing,” this proposal will not create a harmonised European situation. It will override national sovereignty and will be very damaging to the interests of animal welfare, farmers and thousands of rural businesses which are registered to supply certain categories of animal medicines in some Member States.*

*The existing law provides for protection for the consumer of foodstuffs from the treated animal – this clause should be reinstated (the Commission’s proposal calls for a deletion!)*

*Extending the existing timeframe from 5 to 7 years will restrict access to medicines without corresponding benefits. The four-year period represents the end of the intense in-use monitoring (pharmacovigilance) period for a new product (Article 75.5). The “unless” clause should be reinstated, as it allows individual cases to be assessed on their merits.*

Amendment 22  
ARTICLE 1, PARAGRAPH 44  
Article 67, point (b) (Directive 2001/82/EC)

(b) "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*."

(b) "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 *four years unless, having regard to the information and particulars provided by the applicant, or experience acquired in the practical use of the veterinary medicinal product, the competent authorities are satisfied that none of the criteria referred to in (a) to (d) of the first paragraph apply.*"

*Justification*

*Extending the existing timeframe from 5 to 7 years will restrict access to medicines without*

*corresponding benefits. The four-year period represents the end of the intense in-use monitoring (pharmacovigilance) period for a new product (Article 75.5). The “unless” clause should be reinstated, as it allows individual cases to be assessed on their merits.*

Amendment 23  
ARTICLE 1, PARAGRAPH 44  
Article 67, point (c) (Directive 2001/82/EC)

(c) those products in respect of which special precautions must be taken by the veterinarian in order to avoid any unnecessary risk to:

- the target species,
- the person administering the products to the animal,
- ***the consumer of foodstuffs obtained from the treated animal,***
- the environment;

(c) those products in respect of which special precautions must be taken by the veterinarian in order to avoid any unnecessary risk to:

- the target species,
- the person administering the products to the animal,
- delete***
- the environment;

*Justification*

*See Amendment 21.*

Amendment 24  
ARTICLE 1, PARAGRAPH 44  
Article 67, point (e) (Directive 2001/82/EC)

(e) magistral or officinal formulae intended for animals.

In addition, a prescription shall be required for new veterinary medicinal product containing an active substance which has been authorised for use in a veterinary medicinal product for less than ***seven years.***

(e) magistral or officinal formulae intended for animals.

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

*Justification*

*See Amendment 21.*

Amendment 25  
ARTICLE 1, PARAGRAPH 45  
Article 69 (Directive 2001/82/EC)

Member States shall ensure that the owners or keepers of food-producing animals can provide proof of purchase, possession and administration of veterinary medicinal products to such animals for a period of five years after **slaughter**.

Member States shall ensure that the owners or keepers of food-producing animals can provide proof of purchase, possession and administration of veterinary medicinal products to such animals for a period of five years after **medication**.

*Justification*

*Keeping records for five years after medication will ensure perfectly well that an animal's medical history can be traced, for example if medicine residues are found in the animal or in food products derived from it. In practice, residues ought not to be found once the withdrawal period for the medicine has elapsed.*