P5_TA-PROV(2002)0505

Community code relating to medicinal products for human use ***I

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[1]),

– 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	Amendments by Parliament
Amendment 1 RECITAL –1 (new)	
	(-1) Medicinal products are not commodities like other goods.
Amendment 2 RECITAL 2	
(2) Community legislation is a major milestone in the achievement of the	(2) Community legislation is a major milestone in the achievement of the

[1] OJ C 75 E, 26.3.2002, p. 216.

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

Amendment 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***.

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 medicinal products in the Community.	(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 ***should not compromise public health objectives. The highest level of human health and consumer protection should be ensured, as stated in Articles 152 and 153 of the Treaty.***

Amendment 5
RECITAL 10 a (new)

	(10a) Medicinal products should be approved only where the underlying clinical trials meet the ethical requirements laid down in European Parliament and Council Directive 2001/20/EC of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical

practice in the conduct of clinical trials on medicinal products for human use([1]).

([1]) OJ L 121, 1.5.2001, p. 34.

Amendment 135
RECITAL 11a (new)

(11a) Article 3(2) of the Treaty obliges the Community to recognise and integrate gender aspects in all policy areas. For pharmaceutical legislation, this means that differences between the sexes in terms of the efficacy and safety of medicinal products should be evaluated in clinical trials and patients informed of the results. The Commission should adapt the technical guidelines for applicants and holders of marketing authorisation accordingly.

Amendment 185
RECITAL 13

(13) The validity of marketing authorisations should ***no longer*** be limited to five years. On the other hand, market surveillance should be stepped up. In addition, any authorisation which does not lead to the actual placing on the market of a medicinal product should cease to be valid.	(13) The validity of marketing authorisations ***for new medicinal products*** should ***initially*** be limited to five years***.*** On the other hand, market surveillance should be stepped up. In addition, any authorisation which does not lead to the actual placing on the market of a medicinal product should cease to be valid.

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	(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

Community register of the results of those inspections.	has proved necessary to reinforce the Community provisions on inspections and to compile a Community register of the results of those inspections.

Amendment 172
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 European and non-European regulatory agencies and the WHO.*** In the field of pharmacovigilance, account should be taken of the facilities offered by new information technologies to improve exchanges between Member States.

Amendment 173
RECITAL 16

(16) As part of the proper use of medicinal products, the rules on packaging should be adapted to take account of the experience acquired. ***On the other hand, information relating to certain medicinal products is authorised under strict conditions in the interests of patients and in order to meet their legitimate needs and expectations. Such information should not be equated with direct advertising or marketing of prescription medicines***	(16) As part of the proper use of medicinal products, the rules on packaging should be adapted to take account of the experience acquired.

Amendment 8
RECITAL 16 a (new)

	(16a) Patients have a legitimate need for and right to information on medicinal products, including those available on prescription.

Amendment 9
RECITAL 16 b (new)

(16b) 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.

Amendment 10
RECITAL 16 c (new)

(16c) The Commission should investigate whether it is possible to develop a standardised environmental classification system for medicinal products and, if the Commission finds an appropriate model, it should submit a proposal to that effect to the European Parliament before the end of 2003.

Amendment 141
RECITAL 16 d (new)

(16d) Member States' concern to manage their expenditure on medicinal products should not detract from the three goals of a dynamic information society, a high level of health protection for all EU citizens and the legitimate need of patients for more information.

Amendment 11
ARTICLE 1, POINT 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.

Amendment 12/rev.
ARTICLE 1, POINT 1, POINT (ba) (new)
Article 1, point 5 (Directive 2001/83/EC)

(ba) Point (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 principles."

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

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

"(8) Kit"

Amendment 153
ARTICLE 1, POINT 1, POINT (b c) (new)
Article 1, point 10 a (Directive 2001/83/EC)

(bc) The following point (10a) is added:

'(10a) Herbal health product:

Any product that contains herbal or plant derived substances which restore, correct or modify physiological functions and does not pose a health risk at the dosage delivered.'

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

(bd) The following point (18a) 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."

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

(ca) Point (28) is replaced by the following text and the following point (28a) is added:

"28. Risks related to use of the medicinal product

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

- any risk of undesirable effects on the environment.

28a. Risk/benefit balance:

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

Amendment 16
ARTICLE 1, POINT 1a (new)
Article 1 a (new) (Directive 2001/83/EC)

1a. The following Article 1a is inserted:

"Article 1a

Generic medicinal products 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."

Amendment 18
ARTICLE 1, POINT 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 Community legislation.	***Deleted***

Amendment 19
ARTICLE 1, POINT 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.

Amendment 20
ARTICLE 1, POINT 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 European Parliament and Council Regulation (EC) No 178/2002 of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety([1])."
	([1]) OJ L 31, 1.2.2002, p. 1.

Amendment 154
ARTICLE 1, POINT 3, POINT (b b) (new)
Article 3, point 6 b (Directive 2001/83/EC)

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

"(6b) Herbal health products"

Amendment 21
ARTICLE 1, POINT 3, POINT (b c) (new)
Article 3, point 6 c (new) (Directive 2001/83/EC)

(bc) The following point (6c) is added:

"(6c) Medical devices and their accessories as covered by Council Directives 90/385/EC of 20 June 1990([1]) and 93/42/EC of 14 June 1993([2]) as amended and European Parliament and Council Directive 98/79/EC of 27 October 1998([3]) on condition that such devices and accessories do not exert a pharmacological action."

([1]) OJ L 189, 20.7.1990, p. 17.
([2]) OJ L 169, 12.7.1993, p. 1.
([3]) OJ L 331, 7.12.1998, p. 1.

Amendment 22
ARTICLE 1, POINT 3, POINT (b d) (new)
Article 3, point 6 d (new) (Directive 2001/83/EC)

(bd) The following point (6d) is added:

"(6d) Food supplements as defined in European Parliament and Council Directive 2002/46/EC of 10 June 2002([1])."

([1]) OJ L 183, 12.7.2002, p. 51.

Amendment 23
ARTICLE 1, POINT 3, POINT (b e) (new)
Article 3, point 6 e (new) (Directive 2001/83/EC)

(be) The following point (6e) is added:

"(6e) Cosmetic products as defined in Council Directive 76/768/EEC of 27 July 1976([1])."

([1]) OJ L 262, 27.9.1976, p. 169.

Amendment 24
ARTICLE 1, POINT 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 shall 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.

Amendment 155
ARTICLE 1, POINT 5, POINT (a)
Article 6, paragraph 1, subparagraph 2 (Directive 2001/83/EC)

The various strengths, pharmaceutical forms, administration routes, presentations, and any variation under Article 35 shall be	The various strengths, pharmaceutical forms, administration routes, presentations, and any variation under Article 35 shall be

authorised under the first subparagraph ***and shall be considered as part of the same authorisation***.	authorised under the first subparagraph.

Amendment 25
ARTICLE 1, POINT 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***;

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

	(aa) The following point (ca) is added:
	(ca) An assessment of the risk/benefit balance in respect of the release of the product as waste into the environment.

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

	(ab) 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 for the disposal of waste products, together with an indication of any potential risks presented by the medicinal product for the environment."

Amendment 28
ARTICLE 1, POINT 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 conducted either by the applicant himself, on his behalf, or with his support, or in any other relevant manner***:

Amendments 136 and 29
ARTICLE 1, POINT 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 stage III in which the new medicinal product is compared with previously authorised medicinal products used to treat the same or a similar condition in order to demonstrate that the new medicinal product is more efficacious; clinical trials of stage II and III shall include a statistically sufficient number of women of all age groups concerned if the medicinal product is to be used to treat female patients; women-specific diseases and therapies shall be taken into account when designing the studies. The trials shall evaluate whether the medicinal product is effective for the respective indications, tolerated by women of all age groups, the appropriate dosage and which contra-indications and side-effects exist***;

Amendment 30
ARTICLE 1, POINT 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.

Amendment 31
ARTICLE 1, POINT 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.

Amendment 32
ARTICLE 1, POINT 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. 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.

Amendment 176
ARTICLE 1, POINT 6, POINT (b)
Article 8, paragraph 3, point (ic) (new) (Directive 2001/83/EC)

"(ic) Results of appropriate long-term tests on medicinal products intended for long-term use."

Amendment 33
ARTICLE 1, POINT 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 the equipment necessary for the notification of any adverse reaction suspected of occurring either in the Community or in a third country."

Amendments 34, 202 and 167
ARTICLE 1, POINT 7
Article 10, paragraph 1, subparagraph 1 (Directive 2001/83/EC)

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	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.

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. ***The marketing authorization of a generic medicinal product can be granted only after ten years have elapsed from the first authorisation of the reference medicinal product. A generic medicinal 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 medicinal product. In the case of a biosimilar medicinal product, pre-clinical tests and clinical trials shall be necessary.***

Amendment 35
ARTICLE 1, POINT 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 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.

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

Amendment 36
ARTICLE 1, POINT 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.

Amendment 156
ARTICLE 1, POINT 7
Article 10, paragraph 2, point (b) (Directive 2001/83/EC)

(b) generic medicinal product shall mean a medicinal product which has the same qualitative and quantitative composition in active ***principles*** and the same pharmaceutical form, ***and whose bio equivalence with the reference medicinal product has been demonstrated by appropriate bio availability tests. The various immediate-release oral pharmaceutical forms are deemed to be one and the same pharmaceutical form. Bio-availability studies may not be required of the applicant if he can demonstrate that the product meets the criteria of Annex I***.	(b) generic medicinal product shall mean a medicinal product which has the same qualitative and quantitative composition in active ***substance(s) (chemically identical in terms of isomer, complex, crystal polymorphic form, simple ester or salt form of the active moiety) and the same pharmaceutical form, and is bio-equivalent to the reference medicinal product, unless it differs significantly from the original product as regards safety and efficacy.***

Amendment 168
ARTICLE 1, POINT 7
Article 10, paragraph 2, point (b a) (new) (Directive 2001/82/EC)

	(ba) A biosimilar medicinal product shall mean 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 efficacy has been proven by means of appropriate pre-clinical tests and clinical trials.

Amendment 38
ARTICLE 1, POINT 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	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

medicinal product, and the results of pre-clinical tests ***or*** clinical trials shall be provided.	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 shall be conducted.***

Amendment 134
ARTICLE 1, POINT 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 protection certificates for the medicinal products.	4. Conducting the necessary tests and trials, ***the submission of an application, the submission of samples in accordance with Article 19, as well as the granting of a marketing authorisation for a generic medicinal product*** with a view to application of paragraphs 1, 2 and 3 ***as well as for export,*** shall not be regarded as contrary to patent rights or to complementary protection certificates for those ***reference*** medicinal products.

Amendment 196
ARTICLE 1, POINT 7
Article 10, paragraph 4, subparagraph 1 a (new) (Directive 2001/83/EC)

	Manufacturing shall be allowed if the medicinal product is intended for export to a third country that has issued a compulsory licence for that product, or where a patent is not in force and if there is a request to that effect of the competent public health authorities of that third country.

Amendment 40
ARTICLE 1, POINT 7
Article 10, paragraph 4 a (new) (Directive 2001/83/EC)

	4a. In addition to the provisions laid down in paragraph 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.

Amendment 42
ARTICLE 1, POINT 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:"

Amendment 190
ARTICLE 1, POINT 9, POINT (a a) (new)
Article 11, paragraph 5 (Directive 2001/83/EC)

(aa) The introductory wording of point 5 is replaced by the following:

"5. Clinical particulars using natural frequencies (number needed to treat/number needed to harm):"

Amendment 189
ARTICLE 1, POINT 9, POINT (a b) (new)
Article 11, paragraph 5, point 5.10 a (new) (Directive 2001/83/EC)

(ab) The following point 5.10a is added:

"5.10a. Research designs (test plans) for clinical trials"

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

6.-1. major incompatibilities,

Amendment 151
ARTICLE 1, POINT 9, POINT (c)
Article 11, point 10 (Directive 2001/83/EC)

(10) Classification in accordance with	(10) Classification in accordance with

Article 70.	***Article 70(1) of the reference Member State shall be taken seriously into account when the mutual recognition procedure for gaining the marketing authorisation for a medicinal product (Title III, Chapter 4) is applied.***

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

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

Amendment 45
ARTICLE 1, POINT 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,"

Amendment 46
ARTICLE 1, POINT 12, POINT (-aa) (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 potentisation, 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 principles 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 this indent by the procedure referred to in Article 121(2)."

Amendment 47
ARTICLE 1, POINT 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,"

Amendment 48
ARTICLE 1, POINT 12 b (new)
Article 15, indent 3 (Directive 2001/83/EC)

(12b) 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 potentisation,"

Amendment 179
ARTICLE 1, POINT 14, POINT (b)
Article 16, paragraph 2 (Directive 2001/83/EC)

(b) ***In*** paragraph 2, ***"toxicological" and pharmacological"*** is replaced by ***"pre-clinical"***

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

"Member States shall introduce or retain in their territory specific rules for the

	proof of quality, safety and efficacy of homeopathic medicinal products other than those referred to in Article 14(1), taking into account the provisions of paragraph 1 and in accordance with the criteria laid down for homeopathic medicinal products in Annex I.
	Member States shall notify the Commission of the specific rules in force."

Amendment 49
ARTICLE 1, POINT 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.***

Amendment 50
ARTICLE 1, POINT 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.

Amendment 51
ARTICLE 1, POINT 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 deletion of information of a commercially confidential nature.***

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

	The competent authorities shall make publicly accessible without delay, in the register referred to in paragraph 3, the assessment report together with the reasons for their opinion, after deletion of information of a commercially confidential nature.

Amendment 53
ARTICLE 1, POINT 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.***

Amendment 54
ARTICLE 1, POINT 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 made accessible to the public on the Agency's website.

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

In exceptional circumstances, and following	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.	consultation with the applicant, an authorisation ***may be granted subject to an obligation to establish special mechanisms for assessing the safety of the medicinal 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 in the register referred to in Article 21(3), together with deadlines and date of fulfilment.***

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

	(19a) In Article 23, the first paragraph is replaced by the following:
	"After a marketing authorisation has been issued, the holder must, in respect of the methods of manufacture and control provided for in Article 8(3)(d) and (h), take account of scientific and technical progress and introduce any changes that may be required to enable the medicinal product to be manufactured and checked by means of generally accepted scientific methods, with due regard for Community law."

Amendment 186
ARTICLE 1, POINT 21
Article 24, paragraph 1 (Directive 2001/83/EC)

1. Without prejudice to paragraphs 2 and 3, a marketing authorisation shall be valid indefinitely.	1. Without prejudice to paragraphs 2 and 3, a marketing authorisation ***for new medicines*** shall ***initially*** be valid ***for five years. This authorisation shall be renewed five years after the marketing authorisation on the basis of a comparative re-evaluation by the competent authorities of the updated risk/ benefit balance. After this renewal, the marketing authorisation shall be valid*** indefinitely***.***
	When the marketing authorisation is

	renewed after five years, its Annexes I to III shall compulsorily be updated.
	The re-assessment procedure must be completed no later than thirty days before the initial marketing authorisation expires. The Agency shall inform the authorisation holder as soon as possible of the results of the assessment.

Amendment 57
ARTICLE 1, POINT 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.

Amendment 58
ARTICLE 1, POINT 21
Article 24, paragraph 2, subparagraph 1 a (new) (Directive 2001/83/EC)

	The competent authority may, in exceptional circumstances, grant a derogation from the provisions of subparagraph 1. The derogation shall be duly justified.

Amendment 157
ARTICLE 1, POINT 21
Article 24, paragraph 3, 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.

Amendment 59
ARTICLE 1, POINT 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 Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems[1] in all Member States and in the candidate countries and, on the basis of the findings, the European Parliament may call on the Commission to reconsider the principles underlying that Directive and, if appropriate, consider reviewing it.

([1]) OJ L 40, 11.2.1989, p. 8.

Amendment 60
ARTICLE 1, POINT 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.

Amendment 61
ARTICLE 1, POINT 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.***

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

1. With a view towards the grant of a	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.	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. ***A dossier for homeopathic medicinal products shall contain the specific information and documents referred to in Articles 14, 15 and 16.***

Amendment 63
ARTICLE 1, POINT 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. ***What constitutes a serious risk to public health shall be defined in guidelines.***

Amendment 64
ARTICLE 1, POINT 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.

Amendment 65
ARTICLE 1, POINT 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.***

Amendment 66
ARTICLE 1, POINT 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.

Amendment 67
ARTICLE 1, POINT 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.

Amendment 68
ARTICLE 1, POINT 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 shall specify***.

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

5. 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.	5. 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.

Amendment 70
ARTICLE 1, POINT 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."

Amendment 71
ARTICLE 1, POINT 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***

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

Amendment 72
ARTICLE 1, POINT 37, POINT (a)
Article 54, point (a) (Directive 2001/83/EC)

(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;***	(a) the name of the medicinal product followed by its strength and pharmaceutical form (baby, child or adult as appropriate); ***the international non-proprietary name or, if one does not exist,*** the common name***,*** shall be included;

Amendment 73
ARTICLE 1, POINT 37, POINT (aa) (new)
Article 54, point (aa) (new) (Directive 2001/83/EC)

	(aa) The following point (aa) is inserted:
	"(aa) in the case of generic medicinal products, the same denomination of the internationally approved chemical name of the active substances and the name of the producer;"

Amendment 74
ARTICLE 1, POINT 37, POINT (b a) (new)
Article 54, point (e) (Directive 2001/83/EC)

	(ba) Point (e) is replaced by the following:
	"(e) the method and, if necessary, the route of administration. Space must be provided for a pharmacist to indicate the prescribed dose for the patient concerned;"

Amendment 75
ARTICLE 1, POINT 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;"

Amendment 76
ARTICLE 1, POINT 37, POINT (c b) (new)
Article 54, point (h a) (new) (Directive 2001/83/EC)

(cb) 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;"

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

(cc) 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;"

Amendment 78
ARTICLE 1, POINT 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 Article 54(a) 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 on the packaging or on the PIL, in large print (minimum font size 16). The full text of the PIL shall be available, free of charge, in other formats on request, (such as large print, braille, audio tape and electronic format).”

Amendment 79
ARTICLE 1, POINT 38 b (new)
Article 56 a (new)(Directive 2001/83/EEC)

(38 b) The following Article 56a is inserted:

"Article 56 a

The competent national authority shall 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 shall 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 shall be established to ensure as wide a dissemination of information as possible. Complete product information shall be made available on request on the web site and helpline, in the following alternative formats: large print (minimum font size 16), braille, audio tape and electronic format."

Amendment 80
ARTICLE 1, POINT 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	(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;	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***;

Amendment 81
ARTICLE 1, POINT 40 (new)
Article 59, paragraph 1, point (d a) (new) (Directive 2001/83/EC)

	(da) for every new medicinal product during the first five years after it is placed on the market, the indication 'newly authorised medicinal product, please report adverse reactions'.

Amendment 82
ARTICLE 1, POINT 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;

Amendment 83
ARTICLE 1, POINT 40
Article 59, paragraph 1, point (f), point (vi a) (new) (Directive 2001/83/EC)

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

Amendment 84
ARTICLE 1, POINT 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.

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

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

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

Amendment 86
ARTICLE 1, POINT 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."

Amendment 87
ARTICLE 1, POINT 44
Article 65, point (c) (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;***

Amendment 88
ARTICLE 1, POINT 44 a (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,"

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

(44b) 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."

Amendment 158
ARTICLE 1, POINT 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 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,

Amendment 91
ARTICLE 1, POINT 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,"

Amendment 92
ARTICLE 1, POINT 47 a (new)
Articles 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 considered essential to the approval of the application, 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."

Amendment 93
ARTICLE 1, POINT 48
Title VII, heading (Directive 2001/83/EC)

Title VII	Title VII
Distribution of medicinal products	***Wholesale*** distribution of medicinal products

Amendment 94
ARTICLE 1, POINT 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."

Amendment 95
ARTICLE 1, POINT 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 wholesale distributors registered in those 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 paragraph 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."

Amendment 96
ARTICLE 1, POINT 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 the continuity and quality of service.

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

providing pharmaceutical care.

2d. Medicinal products may be supplied only by a pharmacist who possesses a diploma or certificate as referred to in Council Directive 85/432/EEC of 16 September 1985 concerning the coordination of provisions laid down by Law, Regulation or Administrative Action in respect of certain activities in the field of pharmacy([1]).”

([1]) OJ L 253, 24.9.1985, p. 34.

Amendment 97
ARTICLE 1, POINT 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."

Amendment 182
ARTICLE 1, POINT 52 b (new)
Title VIIa (new) (Directive 2001/83/EC)

(52b) The following Title VIIa is inserted:

"TITLE VIIa

INFORMATION

Article 85a

The provision of reliable comparative information on diseases, therapeutic strategies and medicinal products shall be authorised in the interest of patients in order to respond to their legitimate needs. 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."

Amendment 98
ARTICLE 1, POINT 52 c (new)
Title VIII, title (Directive 2001/83/EC)

(52c) The title of TITLE VIII is replaced by the following:

"TITLE VIII

ADVERTISING AND COMMUNCATION OF INFORMATION"

Amendment 99
ARTICLE 1, POINT 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 marketing, 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:

Amendment 198
ARTICLE 1, POINT 53, POINT (b)
Article 86, paragraph 2, indent 4 (Directive 2001/83/EC)

- information relating to human health or diseases, provided that there is no reference, even indirect, to medicinal products***, and without prejudice to Article 88(2) of this Directive.***	- information relating to human health or diseases, provided that there is no reference, even indirect, to medicinal products.

Amendment 100
ARTICLE 1, POINT 53 a (new)
Article 87, paragraph 2 (Directive 2001/837EC)

(53a) In Article 87, 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."

Amendment 101
ARTICLE 1, POINT 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.

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

6a. By (date) the Commission shall, following consultations with consumer and patient organisations and other interested parties, present a report outlining a comprehensive consumer/patient information strategy to ensure good quality, objective, reliable and non-promotional information on medicinal products and other treatments.

It shall look specifically at ways in which websites and telephone helplines are or can be used to provide information on a range of treatments, including medicinal products, 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.

Amendment 103
ARTICLE 1, POINT 54
Article 88, paragraph 7 a (new) (Directive 2001/83/EEC)

7a. The Commission shall examine the possibility of encouraging every national authority to have a website that functions as a portal and provides objective information on medicinal products and health issues in general.

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

7b. The evaluation of the information pilot project shall include:

- overall quality of information presented,

- accuracy, as assessed by independent scientific and medical experts,

- dissemination, including the methods used and what proportion of the potential patient population 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 the development and assessment of the information.

Amendment 105
ARTICLE 1, POINT 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 medicinal product which is to be used on the advice of a medical practitioner."

Amendments 106 and 191
ARTICLE 1, POINT 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 ***and its international non-proprietary name, where this exists, or the trademark*** if it is intended solely as a reminder.

Amendment 107
ARTICLE 1, POINT 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;

Amendment 108
ARTICLE 1, POINT 57
Article 91, paragraph 2 (Directive 2001/83/EC)

2. Member States may decide that the	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.	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.

Amendment 181
ARTICLE 1, POINT 57a (new)
Article 94 (Directive 2001/83/EC)

	(57a) Article 94 is replaced by the following:
	"Article 94
	1. Where medicinal products are being promoted to persons qualified to prescribe or supply them, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such persons
	2. Hospitality at sales promotion shall be strictly limited to the main purpose of the meeting and must not be extended to persons other than health professionals.
	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. Medical sales representatives may not offer any inducement prohibited under paragraph 1 or contrary to paragraph 2."

Amendment 110
ARTICLE 1, POINT 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."

Amendment 111
ARTICLE 1, POINT 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 outer packaging of medicinal products.***

Amendment 113
ARTICLE 1, POINT 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."

Amendment 114
ARTICLE 1, POINT 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.

Amendment 115/rev.
ARTICLE 1, POINT 61 a (new)
Article 101, paragraph 2 a (new) (Directive 2001/83/EC)

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

"The 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 five years of marketing of a newly authorised medicinal product, considering enhanced roles for patients and health professionals to ensure a more efficient and effective response to potential problems."

Amendment 116
ARTICLE 1, POINT 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 immediately*** accessible to ***the public in the register referred to in Article 21(3), in accordance with European Parliament and Council Regulation (EC) No 1049/2001 of 30 May 2001 regarding public access to European Parliament, Council and Commission documents.([1])*** ***In addition, marketing authorisation holders shall have selected read and print access to data on their own medicinal products.***

([1]) OJ L 145, 31.5.2001, p. 43.

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

	62a. The following Article 102a is inserted:
	"Article 102a
	In order to ensure the total independence of the competent authorities, at least the activities connected with pharmacovigilance, the operation of communication networks and market surveillance shall receive public funding commensurate with the tasks conferred upon such authorities."

Amendment 118
ARTICLE 1, POINT 64
Article 104, paragraph 1, subparagraph 2 (Directive 2001/83/EC)

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

Amendment 119
ARTICLE 1, POINT 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.

Amendment 120
ARTICLE 1, POINT 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),	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.	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 the Agency's pharmacovigilance working group. Both the periodic safety update reports and the scientific evaluations must be publicly accessible in the register referred to in Article 21(3).***

Amendment 121
ARTICLE 1, POINT 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.

Amendments 159 and 122
ARTICLE 1, POINT 64 (new)
Article 104 a (new) (Directive 2001/83/EC)

	Article 104a ***The marketing authorisation holder shall ensure that the competent authorities are the first to be informed of an imminent cessation of sales and withdrawal of a medicinal product from the market, and only then shall the public or shareholders be informed.***

Amendment 123
ARTICLE 1, POINT 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.***

Amendment 124
ARTICLE 1, POINT 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 register referred to in Article 21(3).

Amendment 125
ARTICLE 1, POINT 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.

Amendment 126
ARTICLE 1, POINT 66
Article 116, paragraph 1 a (new) (Directive 2001/83/EC)

	The analysis of the risk/benefit balance

must be considered a first stage in the study of the medicinal product's relative and/or actual efficacity.

Amendment 127
ARTICLE 1, POINT 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.

Amendment 129
ARTICLE 1, POINT 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.

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. 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 (EC) No 1049/2001.
	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. 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 efficacity, adverse reactions and contra-indications on the basis of the information already approved for the package leaflet."

Amendment 130
ARTICLE 1, POINT 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***.

Amendment 131
ARTICLE 1, POINT 69
Article 122 a (new) (Directive 2001/83/EEC)

	Article 122a
	The Commission shall 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 shall address the comparison of these products in the context of transparency in respect of prices and reimbursement.

Amendment 132
ARTICLE 1, POINT 69 a (new)
Article 127 a (new) (Directive 2001/83/EC)

(69a) The following Article 127a is inserted:

"Article 127a

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