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***II
RECOMMENDATION FOR SECOND READING

on the common position adopted by the Council with a view to adopting a European Parliament and Council directive amending Directive 2001/83/EC on the Community code relating to medicinal products for human use
(10950/03/2003 – C5-0464/2003 – 2001/0253(COD))

Committee on the Environment, Public Health and Consumer Policy

Rapporteur: Françoise Grossetête

Symbols for procedures

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

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

Amendments to a legislative text

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

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PROCEDURAL PAGE

At its sitting of 23 October 2002 Parliament adopted its position at first reading on the proposal for a European Parliament and Council directive amending Directive 2001/83/EC on the Community code relating to medicinal products for human use (COM(2001) 404 – 2001/0253(COD)).

At the sitting of 9 October 2003 the President of Parliament announced that the common position had been received and referred to the Committee on the Environment, Public Health and Consumer Policy (10950/3/2003 – C5-0464/2003).

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

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

At the latter meeting it adopted the draft legislative resolution by 47 votes to 1, with 8 abstentions.

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

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

DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

on the common position adopted by the Council with a view to adopting a European Parliament and Council directive amending Directive 2001/83/EC on the Community code relating to medicinal products for human use
(10950/3/2003 – C5-0464/2003 – 2001/0253(COD))

(Codecision procedure: second reading)

The European Parliament,

– having regard to the Council common position (10950/3/2003 – C5-0464/2003),

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

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

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

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

– having regard to the recommendation for second reading of the Committee on the Environment, Public Health and Consumer Policy (A5-0446/2003),

1. Amends the common position as follows;

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

Council common position	Amendments by Parliament
	Amendment 1 Recital 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.***

[1] Texts Adopted, 23.10.2002, P5_TA(2002) 0505.
[2] OJ C 75 E, 26.3.2002, p. 216.
[3] Not yet published in OJ.

Justification

Retabling of Amendment 4 adopted at first reading on 23 October 2002.

Amendment 2
Recital 8

(8) Wherever it is proposed to change the scope of the centralised procedure, it should no longer be possible to opt for the mutual-recognition procedure or the decentralised procedure in respect of medicinal products which contain new active substances ***and for which the therapeutic indication is the treatment of acquired immune deficiency syndrome, cancer, neurodegenerative disorder or diabetes***.	(8) Wherever it is proposed to change the scope of the centralised procedure, it should no longer be possible to opt for the mutual-recognition procedure or the decentralised procedure in respect of medicinal products which contain new active substances.

Justification

This amendment reinstates the original Commission proposal.

Amendment 3
Recital 16 a (new)

	(16a) Following consultations with consumers', patients', doctors' and pharmacists' organisations, the Commission should submit to the European Parliament a report on the information currently available to patients.
	It should look specifically at ways in which websites and telephone helplines are 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 report referred to in the first subparagraph should also include details of

the arrangements which the Pharmaceutical Committee is putting forward with a view to ensuring that patients can obtain information.

Justification

A wide range of information concerning medicinal products is available from a variety of sources (websites, specialist brochures, etc.). All this information must be assessed. The Commission should consider ways of validating the information which already exists, taking account of liability issues and in consultation with the various organisations concerned.

Partial retabling of Amendment 102 from first reading.

Amendment 4
Recital 16 a (new)

(16a) 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 May 2004.

Justification

Retabling of Amendment 10 adopted at first reading on 23 October 2002.

Amendment 5
Recital 18

(18) 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.	(18) 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.

Justification

Retabling of Amendment 172 adopted at first reading on 23 October 2002.

Amendment 6
Recital 19 a (new)

(19a) The European Union and its Member States are committed to implement the decision of 30 August 2003 of the General Council of the World Trade Organisation on the implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health as soon as possible. Nothing in this directive or in Regulation [2309/93, new name to be inserted] shall be considered to inhibit the implementation of this decision by the Member States.

Justification

This amendment is necessary to ensure legal certainty after the agreement on access to medicines for developing countries reached at the World Trade Organization (Decision WT/L/540 of the Council for TRIPS of 30 August 2003). The amendment is admissible because it reacts to a change of the legal situation which occurred since the first reading.

Amendment 7
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 ***or administered to*** 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

Reinstates Amendment 11 at first reading, adopted on 23 October 2002.

Amendment 8
ARTICLE 1, POINT 1 (I)
Article 1, points 28 and 28 a (new) (Directive 2001/83/EC)

	Points 28-30 shall be replaced by the following points:
"28. Risks relating to use of the medicinal product:	"28. Risks ***relating*** to use of the ***medicinal*** product
Any risk relating to the quality, safety or efficacy of the medicinal product as regards the ***health of patients;***	**-** any risk relating to the quality, safety ***or*** efficacy of the ***medicinal*** product as regards the ***patients' health or public health;***
	- any risk of ***undesirable*** effects on the environment;
29. Risks relating to the environment:	***29.*** Risk/benefit balance:
Any risk of ***unwanted*** effects on the environment;	An evaluation of the positive therapeutic effects of the ***medicinal*** product in relation to the risk as defined ***above."***
30. Risk-benefit balance:	
An evaluation of the positive therapeutic effects of the medicinal product in relation to the risks as defined ***in point 28."***	

Justification

Reinstating Amendment 15 from first reading, adopted on 23 October 2002. Pharmaceutical drugs or their residues may, after excretion to the environment, have adverse effects. These effects should be accepted if the pharmaceutical drug has a definitive therapeutic value. The adverse environmental effects of a new pharmaceutical drug can only be properly evaluated and accepted when balanced against its favourable therapeutic effects. Such an evaluation should be made by the pharmaceutical drug authority. No single patient should be obstructed from using the best possible therapeutic alternative. A proper risk/benefit evaluation, including consideration of possible environmental effects, can only be made within the framework of the pharmaceutical legislation. Environmental effects of drugs are not, and should not be, evaluated in other types of community legislation.

Amendment 9
ARTICLE 1, POINT 2
Article 2, paragraph 2 (Directive 2001/83/EC)

2. In cases of doubt, where a product falls within the definition of "medicinal product", this Directive shall apply, even in cases where the product also falls within the scope of other Community legislation.	***deleted***

Justification

This point was rejected at the first reading. While leaving the legal certainty of medicines unchanged, the proposal creates considerable legal uncertainty for large numbers of foods, food supplements, cosmetics and medical devices. It will not benefit industry, consumers and society.

Amendment 10
ARTICLE 1, POINT 7, POINT (a)
Article 8, paragraph 3, point (c a) (new) (Directive 2001/83/EC)

	(ca) An assessment of the risk/benefit balance in respect of the release of the product as waste into the environment;

Justification

Retabling of Amendment 26 adopted at first reading on 23 October 2002.

Amendment 11
ARTICLE 1, POINT 7, POINT (b)
Article 8, paragraph 3, point (i), introductory phrase (Directive 2001/83/EC)

(i) Results of:	(i) Results of ***all the following tests conducted either by the applicant himself, on his behalf, or with his support, or in any other relevant manner:***

Justification

Retabling of Amendment 28 adopted at first reading on 23 October 2002.

Amendment 12
ARTICLE 1, POINT 7
Article 8, paragraph 3, point (i), indent 3 (Directive 2001/83/EC)

- clinical trials.	– clinical trials ***in which the group of participants is roughly representative of the target patient group:***

Justification

This amendment retables Amendments 29 and 136 of first reading with reduced demands and a more balanced language. The Council has more or less ignored these ideas so far. The Parliament should insist on the basic ideas but take into account the concerns of the Commission and the Council. The demand for superiority trials made in first reading should be reduced to simple comparative trials.

Amendment 13
ARTICLE 1, POINT 7 (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.

Justification

Retabling of Amendment 32 adopted at first reading.

Amendment 14
ARTICLE 1, POINT 8
Article 10, paragraph 1, subparagraph 4 (a) (new) (Directive 2001/83/EC)

	The ten-year period referred to in the second 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 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

It is generally accepted that there should be an appropriate incentive, in terms of regulatory data protection, for companies to research and develop new indications for existing products. It is irrational, and arbitrary to provide regulatory data protection in respect of significant new indications only where products are the subject of compulsory assessment through the centralised system of approval. It creates unjustified discrimination between different patient groups to establish a system that incentivises research into new treatments for some diseases, but not others. It creates discrimination between companies specialising in different therapeutic fields that cannot be objectively justified and is unfair. This is the result of the current proposals set out in the draft Regulation and the Annex to the draft Regulation governing the centralised procedure. Such discrimination is only justified in relation to orphan indications in respect of which separate legislation exists. The reward for appropriate innovation should be uniform and harmonised and should not depend upon which authorisation procedure is used.

Amendment 15
ARTICLE 1, POINT 8
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 substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies. The different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance shall be considered to be the same active substance, unless they differ significantly in properties with regard to safety and/or efficacy. The various immediate-release oral pharmaceutical forms shall be considered to be one and the same pharmaceutical form. Bioavailability studies need not be required of the applicant if he can demonstrate that the generic medicinal product meets the relevant criteria as defined in the appropriate detailed guidelines.	(b) "generic medicinal product" shall mean a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies. The different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance shall be considered to be the same active substance, unless they differ significantly in properties with regard to safety and/or efficacy. ***In such cases, additional information providing proof of the safety and efficacy of the various salts, esters or derivatives of an authorised active substance must be supplied by the applicant.*** The various immediate-release oral pharmaceutical forms shall be considered to be one and the same pharmaceutical form. Bioavailability studies need not be required of the applicant if he

	can demonstrate that the generic medicinal product meets the relevant criteria as defined in the appropriate detailed guidelines.

Amendment 16
ARTICLE 1, POINT 8
Article 10, paragraph 4 (Directive 2001/83/EC)

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

Amendment 17
ARTICLE 1, POINT 8
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 non-cumulative 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

Scientific research with regard to known substances is considerably reduced by insufficient data exclusivity provisions in the current legislation. As already agreed upon in first reading, it is important to create incentives for the whole pharmaceutical industry to carry out such research. This is valuable from a public health and industrial perspective, as it will

encourage in particular the numerous small and medium size companies located in Europe to carry out relevant scientific work.

Amendment 18
ARTICLE 1, POINT 8
Article 10, paragraph 5 (Directive 2001/83/EC)

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

Justification

Partial retabling of Amendment 134 from first reading, as regards exports.

The Bolar provision, as incorporated into the common position adopted by the Council, provides scope for certain activities, but fails to make specific references to generic and biosimilar medicinal products, in respect of which the provisions set out in paragraphs 1 to 4 are not identical. This amendment clarifies that position.

The addition of the phrase 'relating to those provisions' will rule out any confusion concerning 'the consequential practical requirements'.

Should these restrictions be retained, they would greatly reduce the development capacity of the European generic pharmaceuticals industry.

Amendment 19
ARTICLE 1, POINT 9 (a) (new)
Article 10c (a) (new) (Directive 2001/83/EC)

	The following new Article 10ca shall be added:
	1. Member states shall, no later than four weeks after the entry into force of this directive, establish a procedure to enable the grant of compulsory licences, on the basis of the Decision of 30 August 2003 of the General Council of the World Trade Organisation on the Implementation of

Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health.

2. Such licences will be granted when an application is made pursuant to a notification made by an eligible importing Member of the World Trade Organisation in accordance with conditions set in paragraph 1(b) and paragraph 2(b) of the Decision of 30 August 2003.

3. Before granting the licence, verification shall be made whether the notification to the WTO TRIPS Council effectively meets the conditions set thereto in the Decision of 30 August 2003.

4. The compulsory licences issued must contain the following specific conditions:

(a) Only the amount of patented products necessary to meet the needs of the WTO Member(s) having made the notification to the TRIPS Council may be manufactured under the licence.

(b) The entirety of the products manufactured under the licence must be exported to the country/countries having made (a) notification(s) to the TRIPS Council in accordance with paragraph 2(a) and paragraph 2(b) of the Decision of 30 August 2003 with regard to the product covered by the compulsory licence.

(c) Products made pursuant to the compulsory licence shall be clearly identified, through specific labelling or marking, as being produced pursuant to the Decision of 30 August 2003. The products must be distinguished from those made by the patent holder through special packaging and/or special colouring/shaping of the products themselves, provided that such distinction is feasible and does not have a significant impact on price.

(d) Before shipment begins, the holder of the compulsory license shall post on a website the following information :

(i) the quantities being supplied to the destination(s) specified in the compulsory licence;

(ii) the distinguishing features of the product(s) as referred to in subparagraph d;

5. Once the compulsory licence has been granted, the WTO TRIPS Council will be notified of the grant of the licence, including the specific conditions attached to it. The information provided shall include the name and address of the licensee, the product(s) for which the licence has been granted, the quantity(ies) for which it has been granted, the country(ies) to which the product(s) is (are) to be supplied and the duration of the licence. The notification shall also indicate the address of the website where the information required to be made public by the licensee is posted.

6. In determining the adequate remuneration to be paid to the right holder, the economic value to the country/countries of destination shall be taken into account.

7. The compulsory licence will be granted in full respect of the relevant requirements of Article 31 of the TRIPS Agreement, taking into account paragraph 5 of the Doha Declaration on the TRIPS Agreement and Public Health.

8. The conditions established under this article will be adapted to the annual review as foreseen under point 8 of the Decision of 30 August 2003 (WT7L/540) on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, by the procedure mentioned in Art. 121 of this directive.

Justification

The amendment is rewording and elaboration of Amendment 196 that was adopted in the first reading. The rewording and elaboration is needed because of and in line with the Decision of

30 August 2003 (WT7L/540) on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health.

Amendment 20
ARTICLE 1, POINT 12
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.***

Justification

Retabling of Amendment 44 adopted at first reading on 23 October 2002.

Amendment 21
ARTICLE 1, POINT 13, POINT (-a) (new)
Article 14, paragraph 1, indent 1 (Directive 2001/83/EC)

	(-a) In Article 14, paragraph 1, the first indent shall be replaced by the following:
	"- they are administered by a route of administration described in the European Pharmacopoeia or in the absence thereof in a Pharmacopoeia currently used in a Member State,"

Justification

The quality and safety of a particular pharmaceutical form are guaranteed by rules of good production practice. Additional safety is ensured by the requirement to comply with the criteria laid down in monographs in official pharmacopoeias. These cover all pharmaceutical forms, such as nasal sprays, injections and eye drops, which are treated differently in different Member States. (Amendment 45 at first reading)

Amendment 22
ARTICLE 1, POINT 13, POINT (-a a) (new)
Article 14, paragraph 1, indent 3 (Directive 2001/83/EC)

(-aa) In Article 14(1), the third indent in the first subparagraph shall be 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, both 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)."

Justification

Amendment 46 of the adopted text of the EP first reading is reintroduced. It is important to introduce the process essential to the preparation of medicines for homeopathic use, potentisation, at this point in the document. The pharmaceutical process involved in producing these products involves more than just simple dilution.

The word 'both' is added after 'allopathy', to prevent any misunderstanding about the fact that a medicinal product may not contain more than one part per 10 000 of the mother tincture also only applies to active principles whose presence in an allopathic medicinal product results in the obligation to submit a doctor's prescription, as is the case with 1/100th of the smallest dose used in allopathy.

Amendment 23
ARTICLE 1, POINT 15, POINT (b)
Article 16, paragraph 2 (Directive 2001/83/EC)

(b) ***in paragraph 2, "toxicological and pharmacological tests" shall be replaced by "pre-clinical tests";***

(b) ***Paragraph 2 shall be 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."***

Justification

Retabling of Amendment 179 adopted at first reading on 23 October 2002.

Amendment 24
ARTICLE 1, POINT 16
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 a marketing authorisation for medicinal products is completed within ***210*** days after the submission of a valid application.	1. Member States shall take all appropriate measures to ensure that the procedure for granting a marketing authorisation for medicinal products is completed within ***150*** days after the submission of a valid application, ***including 80 days for scientific data analysis and preparation of the assessment report by the rapporteur.***

Justification

Reinstates Amendment 49 at first reading, adopted on 23 October 2002.

Amendment 25
ARTICLE 1, POINT 19
Article 21, paragraph 4, subparagraph 2 (Directive 2001/83/EC)

The competent authorities shall make publicly accessible without delay the assessment report, together with the reasons for their opinion, after deletion of any information of a commercially confidential nature.	The competent authorities shall make publicly accessible without delay the assessment report, together with the reasons for their opinion, after deletion of any information of a commercially confidential nature. ***The justification shall be provided separately for each indication applied for.***

Justification

Retabling of Amendment 53 adopted at first reading on 23 October 2002.

Amendment 26
ARTICLE 1, POINT 20
Article 22 (Directive 2001/83/EC)

In exceptional circumstances and following consultation with the applicant, the authorisation may be granted subject to a requirement for the applicant to ***introduce specific procedures***, in particular concerning the safety of the medicinal product, notification to the competent authorities of any incident relating to its use, and action to be taken. This authorisation may be granted only for objective, verifiable reasons and must be based on one of the grounds set out in Annex I. Continuation of the authorisation shall be linked to the annual reassessment of these conditions.	In exceptional circumstances and following consultation with the applicant, the authorisation may be granted subject to a requirement for the applicant to ***meet certain conditions***, in particular concerning the safety ***and efficacy*** of the medicinal product, notification to the competent authorities of any incident relating to its use, and action to be taken. This authorisation may be granted only for objective, verifiable reasons and must be based on one of the grounds set out in Annex I. Continuation of the authorisation shall be linked to the annual reassessment of these conditions. ***The list of these conditions shall be made publicly accessible without delay, together with deadlines and date of fulfilment.***

Justification

Retabling of Amendment 55 adopted at first reading on 23 October 2002.

Amendment 27
ARTICLE 1, POINT 21
Article 23, paragraph 3 (Directive 2001/83/EC)

In order that the risk-benefit balance may be continuously assessed, the competent authority may at any time ask the holder of the marketing authorisation to forward data ***demonstrating that*** the risk-benefit balance ***remains favourable***.	In order that the risk-benefit balance may be continuously assessed, the competent authority may at any time ask the holder of the marketing authorisation to forward ***all the*** data ***required to assess*** the risk-benefit balance.

Justification

Rewording of the new Council proposal.

Amendment 28
ARTICLE 1, POINT 24
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.

Justification

Retabling of Amendment 60 adopted at first reading on 23 October 2002.

Amendment 29
ARTICLE 1, POINT 26
Article 30, paragraph 1 (Directive 2001/83/EC)

1. If two or more applications submitted in accordance with Articles 8, 10, 10a, 10b, 10c and 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 revocation, a Member State, the Commission or the applicant or the marketing authorisation holder ***may*** refer the matter to the Committee for Medicinal Products for Human Use, hereinafter referred to as "the Committee", for the application of the procedure laid down in Articles 32, 33 and 34.	1. If two or more applications submitted in accordance with Articles 8, 10, 10a, 10b, 10c and 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 revocation, a Member State, the Commission or the applicant or the marketing authorisation holder ***shall*** refer the matter to the Committee for Medicinal Products for Human Use, hereinafter referred to as "the Committee", for the application of the procedure laid down in Articles 32, 33 and 34.

Justification

This amendment retables Amendment 66 adopted at first reading on 23 October 2002 and ensures consistency with the following articles which have been amended.

Amendment 30
ARTICLE 1, POINT 40, POINT (a)
Article 54, point (a) (Directive 2001/83/EC)

(a) the name of the medicinal product followed by its strength and pharmaceutical form, and, if appropriate, whether it is intended for babies, children or adults; 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, and, if appropriate, whether it is intended for babies, children or adults; ***the international non-proprietary name (INN) or, if one does not exist,*** the common name***,*** shall be included;

Justification

Retabling of Amendment 72 adopted at first reading. The name of the medicinal product may be both the invented name and the INN. It is therefore better that the INN, which is known all over the world, should be used so that no dispute is possible.

Amendment 31
ARTICLE 1, PARAGRAPH 40, POINT (b a) (new)
Article 54, point (e) (Directive 2001/83/EC)

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

Justification

Reinstates Amendment 74 at first reading, adopted on 23 October 2002.

Amendment 32
ARTICLE 1, POINT 40, POINT (c a) (new)
Article 54, point (j) (Directive 2001/83/EC) (new)

	(ca) Point (j) of Directive 2001/83/EC shall be 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

Reinstating Amendment 77 from first reading adopted on 23 October 2002. 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 33
ARTICLE 1, POINT 41
Article 55(b) (new) (Directive 2001/83/EC)

The competent national authority shall establish a publicly accessible database, independent of pharmaceuticals companies, containing updated package leaflets for all pharmaceutical products licensed for sale or dispensing on the territory of the Member State concerned. That database shall be structured in such a way as to make a comparison of the information available for all medicinal products possible. That database shall be fully accessible to all citizens, including disabled persons.

Justification

Retabling of Amendment 79 adopted at first reading on 23 October 2002.

Amendment 34
ARTICLE 1, POINT 41 a (new)
Article 56 (Directive 2001/83/EC)

(41a) Article 56 shall be 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)."

Justification

Retabling of Amendment 78 from first reading. The information about the medicinal product must also be readily accessible for blind and partially-sighted people.

Amendment 35
ARTICLE 1, POINT 43
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'.

Justification

Retabling of Amendment 81 adopted at first reading.

Amendment 36
ARTICLE 1, POINT 43
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'.

Justification

Retabling of Amendment 81 adopted at first reading on 23 October 2002.

Amendment 37
ARTICLE 1, POINT 43
Article 59, paragraph 1, point (e) (Directive 2001/83/EC)

(e) 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;	(e) 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 ***or the competent authority***; ***during the first five years after the authorisation of a medicinal product, patients shall be informed that they can exceptionally communicate adverse reactions in writing or in electronic format directly to the authorities in charge of pharmacovigilance or to an organisation that acts as a filter. The postal address of the authority or its internet website for filling in online formulars shall be provided.***

Justification

Retabling of Amendment 80 adopted at first reading.

This amendment makes it possible for patients to report side-effects direct and unfiltered to the competent authority (particularly EMEA or the agency concerned). This is not without importance, bearing in mind that at present only a fraction of all side-effects are reported.

Amendment 38
ARTICLE 1, POINT 50, POINT (a a) (new)
Article 69, paragraph 1, indent 11 (Directive 2001/83/EC)

	(aa) the eleventh indent shall be replaced by the following:
	"- homeopathic medicinal product registered without specific therapeutic indications,"

Justification

The disclaimer "without approved therapeutic indications" on a package of a homeopathic medicinal product is confusing and discriminating. The simplified registration does not allow a therapeutic indication. The proposal is based on emotional arguments rather than logic and

science.

Amendment 39
ARTICLE 1, POINT 53
Article 74 a (Directive 2001/83/EC)

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

Justification

Reinstates Amendment 92 at first reading, adopted on 23 October 2002.

Amendment 40
ARTICLE 1, POINT 56
Article 81, subparagraph 2 (Directive 2001/83/EC)

The holder of a marketing authorisation for a medicinal product and the distributors of the said medicinal product actually placed on the market in a Member State shall, within the limits of their responsibilities, ensure ***appropriate*** and continued supplies of that medicinal product so that the needs of patients in the Member State in question are covered.	The holder of a marketing authorisation for a medicinal product and the distributors of the said medicinal product actually placed on the market in a Member State shall, within the limits of their responsibilities, ensure ***uninterrupted*** and continued supplies of that medicinal product ***to pharmacists and persons authorised to supply medicinal products*** so that the needs of patients in the Member State in question are covered.

Justification

Partial retabling of Amendment 95 from first reading.

Amendment 41
ARTICLE 1, POINT 56
Article 81, paragraphs 1 a, 1 b and 1 c (new) (Directive 2001/83/EC)

	1a. The pharmacist shall be present at the

pharmacy and shall always be contactable.

1b. The pharmacist shall manage the pharmacy in such a way as to guarantee the continuity and quality of service.

1c. The pharmacist shall supervise all work performed in the context of producing and providing pharmaceutical care.

Justification

Reintroduction of Amendment 96 of the adopted text by the European Parliament in first reading. To prevent confusion, paragraph 1d has been left out.

Amendment 42
ARTICLE 1, POINT 60 a (new)
Article 87, paragraph 2 (Directive 2001/83/EC)

60a. Article 87(2) shall be replaced by the following:

"2. All aspects of the advertising for a medicinal product must be consistent with the product information appended to the marketing authorisation and with any additional related information."

Justification

Retabling of Amendment 100 adopted at first reading.

Amendment 43
ARTICLE 1, POINT 61
Article 88, paragraph 6 a (new) (Directive 2001/83/EC)

TITLE VIII: INFORMATION AND ADVERTISING

6a. By (date) the Commission shall, following consultations with patients' and consumers' organisations, doctors' and pharmacists' organisations, Members States and other interested parties, present to the European Parliament and the Council a report on current practice with regard to information provision - particularly on the Internet - and its risks

and benefits for patients.

Following analysis of the above data, the Commission shall, if appropriate, put forward proposals setting out an information strategy to ensure good quality, objective, reliable and non-promotional information on medicinal products and other treatments and shall address the question of the information source's liability.

Amendment 44
ARTICLE 1, POINT 62 b (new)
Article 89, paragraph 1, point (b), indent 2 a (new) (Directive 2001/83/EC)

- 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.

Justification

Retabling of Amendment 105 adopted at first reading.

Amendment 45
ARTICLE 1, POINT 70
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

Retabling of Amendment 114 from first reading.

Amendment 46
ARTICLE 1, POINT 70
Article 101, paragraph 2 a (new) (Directive 2001/83/EC)

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-care professionals to ensure a more effective and appropriate response to potential problems.

Justification

Retabling of Amendment 115 from first reading.

Amendment 47
ARTICLE 1, POINT 71 a (new)
Article 102 a (new) (Directive 2001/83/EC)

71a) The following Article 102a shall be 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

Reinstates Amendment 117 at first reading, adopted on 23 October 2002.

Amendment 48
ARTICLE 1, POINT 73
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.	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 ***after it was first placed on the market***, 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 risk-benefit balance of the medicinal product.	The periodic safety update reports shall include a scientific evaluation of the risk-benefit balance of the medicinal product.
	Both the periodic safety update reports and the scientific evaluation of the risk-benefit balance shall be publicly accessible.

Justification

In its amended proposal, the Commission opted for this formulation in order to improve the first part of Amendment 120 adopted by the EP at first reading. It lays down a single reference time for the whole Community, even if the marketing of a centrally authorised medicinal product begins at different times in the individual Member States on the basis of price and reimbursement negotiations. Regrettably, the Council did not accept this formulation. However, it should be reinserted in order to ensure that the regular six-monthly pharmacovigilance reports during the first two years are not reduced to an empty exercise if there is a delay in starting to market the product.

Amendment 49
ARTICLE 1, POINT 73
Article 107, paragraph 2 a (new) (Directive 2001/83/EC)

	Evaluation reports of pharmacovigilance data, together with related Committee opinions and final measures taken, shall be publicly accessible.

Justification

Retabling of Amendment 124 adopted at first reading on 23 October 2002.

Amendment 50
ARTICLE 1, POINT 74
Article 111, paragraph 1, subparagraph 1 (Directive 2001/83/EC)

1. The competent authority of the Member State concerned shall ensure, by means of repeated inspections, and if necessary unannounced inspections, that the legal requirements governing medicinal products are complied with.	1. The competent authority of the Member State concerned shall ensure, by means of repeated inspections, and if necessary unannounced inspections, ***and where appropriate by asking an official medicinal product test laboratory or a laboratory designated for that purpose to carry out tests on samples,*** that the legal requirements governing medicinal products are complied with.

Justification

This amendment seeks to coordinate the pharmaceutical products package. (See Article 57(g) of the Regulation laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products.)

Amendment 51
ARTICLE 1, POINT 74
Article 111, paragraph 1, point (b) (Directive 2001/83/EC)

(b) take samples;	(b) take samples ***with a view to independent tests being carried out by an official medicinal products test laboratory or a laboratory designated for that purpose by a Member State***;

Justification

This amendment seeks to coordinate the pharmaceutical products package. (See Article 57(g) of the Regulation laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products.)

Amendment 52
ARTICLE 1, POINT 81
Article 126 a, paragraph 4 (Directive 2001/83/EC)

4. The Commission shall set up a register of medicinal products authorised under paragraph 1. Member States shall notify the Commission if any medicinal product is authorised, or ceases to be authorised, under paragraph 1, including the name or corporate name and permanent address of the authorisation holder. The Commission shall amend the register of medicinal products accordingly and make this register available on their website.	4. The Commission shall set up a ***publicly accessible*** register of medicinal products authorised under paragraph 1. Member States shall notify the Commission if any medicinal product is authorised, or ceases to be authorised, under paragraph 1, including the name or corporate name and permanent address of the authorisation holder. The Commission shall amend the register of medicinal products accordingly and make this register available on their website. ***Steps shall be taken to ensure that all the documents made publicly accessible by the competent authorities in the Member States can be consulted via the Commission's website.***

Justification

New amendment following the insertion of this article by the Council.

Amendment 53
ARTICLE 1, POINT 81
Article 126 b (new) (Directive 2001/83/EC)

	The Member States shall ensure that members of staff of the competent authority responsible for issuing authorisations, rapporteurs and experts concerned with the authorisation and surveillance of medicinal products have no financial or other interests in the pharmaceutical industry. These persons shall make an annual declaration of their financial interests.

Justification

Retabling of Amendment 129 adopted at first reading on 23 October 2002.

Amendment 54
ARTICLE 1, POINT 82 a (new)
Article 127 b (new) (Directive 2001/83/EC)

82a) The following Article 127b shall be inserted:

"Article 127b

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

Justification

Reinstates Amendment 132 at first reading, adopted on 23 October 2002.

EXPLANATORY STATEMENT

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

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

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

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

Research and development also help to lay the foundations for health protection. We all know that innovation comes at a price. It is 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. This is why the amendment on data protection adopted at first reading has been retabled.

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

Lastly, the issue of information must not be overlooked. The rapporteur, who did not endorse the Commission's initial proposal at first reading, would therefore like the matter to be discussed in greater detail in the future.