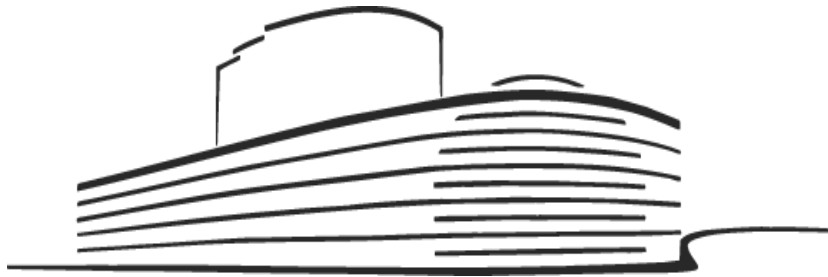


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P5_TA-PROV(2003)0573

Members' Statute

European Parliament resolution on the Statute for Members of the European Parliament

The European Parliament,

- having regard to the Council and Commission statements made in Parliament on 17 December 2003,
 - having regard to Article 190(5) of the Treaty establishing the European Community and Article 108(4) of the Treaty establishing the European Atomic Energy Community,
 - having regard to its decision of 3 June 2003¹ and its resolution of 4 June 2003² on the adoption of a Statute for Members of the European Parliament,
 - having regard to the Bureau decision of 28 May 2003 concerning the new rules governing the reimbursement of Members' expenses,
 - having regard to Rule 37(2), (3), (4) and (5) of the Rules of Procedure,
- A. whereas, in its letter of 25 June 2003, the Council pointed out that there were still significant differences between the respective positions of the Council and of Parliament, which were preventing it from giving its approval,
- B. whereas, in its letter of 21 November 2003, the Council emphasised that, almost twenty-five years after the first elections by direct universal suffrage and six years after the establishment of the necessary legal basis by the Treaty of Amsterdam, it was important that the Statute for Members of the European Parliament now be adopted, and that it wished to step up dialogue in order to achieve compromise solutions that would be acceptable to both institutions,
1. Calls on the Council to inform Parliament as soon as possible (preferably before the end of the Italian Presidency and, in any event, by 15 January 2004) whether it is in a position to accept the proposed compromise and to approve the Statute for Members of the European Parliament should the decision which Parliament adopted on 3 and 4 June 2003 be amended accordingly;
 2. Believes that an overall compromise on the Statute for Members of the European Parliament could comprise the following points:
 - (a) the part of the Statute relating to secondary law should be examined separately and autonomously from that relating to primary law and they should be approved on the basis of the institutional provisions applying to each of them;

¹ P5_TA(2003)0236.

² P5_TA(2003)0241.

- (b) as regards the part relating to primary law, Member States should be asked to revise those provisions of the Protocol on privileges and immunities of the European Communities of 8 April 1965 which concern Members of the European Parliament, using the Statute adopted on 3 and 4 June 2003 as a model;
 - (c) consequently, and subject to a favourable opinion from the Council, Articles 4, 5, 6, 7, 8 and 38(2), recitals 7, 15, 16, 17, 18, 20, 21, 30, 31, 32, 33, 34 and the words '*or only in respect of residual matters not covered by primary law*' in recital 14 should be deleted;
 - (d) Members should be entitled to an old-age pension as from the age of 63;
 - (e) consequently, and subject to a favourable opinion from the Council, in Article 20(1), '60' should be replaced with '63';
 - (f) the provision concerning the Community tax to which the Members' allowance is to be made subject is without prejudice to the Member States' power to make this allowance subject to national tax law provisions, provided that any double taxation is avoided (compromise reached under the Belgian Presidency);
 - (g) consequently, and subject to a favourable opinion from the Council, a new paragraph 1a should be inserted after paragraph 1 of Article 18 to read: '*Paragraph 1 shall be without prejudice to the Member States' power to make this allowance subject to national tax law provisions, provided that any double taxation is avoided*';
 - (h) the new rules governing the reimbursement of Members' expenses should enter into force at the same time as the Statute;
3. Instructs its President to forward this resolution to the Council and the Commission.

P5_TA-PROV(2003)0574

Tax on commercial diesel fuel *

European Parliament legislative resolution on the proposal for a Council directive amending Directive 92/81/EEC and Directive 92/82/EEC to introduce special tax arrangements for diesel fuel used for commercial purposes and to align the excise duties on petrol and diesel fuels (COM(2002) 410 – C5-0409/2002 – 2002/0191(CNS))

(Consultation procedure)

The European Parliament,

- having regard to the Commission proposal to the Council (COM(2002) 410)¹,
 - having regard to Article 93 of the EC Treaty, pursuant to which the Council consulted Parliament (C5-0409/2002),
 - having regard to Rule 67 of its Rules of Procedure,
 - having regard to the report of the Committee on Economic and Monetary Affairs and the opinion of the Committee on the Environment, Public Health and Consumer Policy, the Committee on Industry, External Trade, Research and Energy and Committee on Regional Policy, Transport and Tourism (A5-0383/2003),
1. Rejects the Commission proposal;
 2. Calls on the Commission to withdraw its proposal and submit a new one;
 3. Instructs its President to forward its position to the Council and the Commission.

¹ OJ C 291 E, 26.11.2002, p. 221.

P5_TA-PROV(2003)0575

Environmental liability ***II

European Parliament legislative resolution on the Council common position for adopting a European Parliament and Council directive on environmental liability with regard to the prevention and remedying of environmental damage (10933/5/2003 – C5-0445/2003 – 2002/0021(COD))

(Codecision procedure: second reading)

The European Parliament,

- having regard to the Council common position (10933/5/2003 – C5-0445/2003)¹,
 - having regard to its position at first reading² on the Commission proposal to Parliament and the Council (COM(2002) 17)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 Legal Affairs and the Internal Market (A5-0461/2003),
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 46
Article 4, paragraph 3

<i>3. This Directive shall be without prejudice to the right of the operator to limit his liability in accordance with national legislation implementing the Convention on Limitation of Liability for Maritime Claims (LLMC), 1976, including any future amendment to the Convention, or the Strasbourg Convention on Limitation of</i>	<i>Deleted</i>
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¹ OJ C 277 E, 18.11.2003, p. 10.

² *Texts Adopted*, 14.5.2003, P5_TA(2003)0211.

³ OJ C 151 E, 25.6.2002, p. 132.

***Liability in Inland Navigation (CLNI),
1988, including any future amendment to
the Convention.***

Amendment 12
Article 6, paragraph 2, point (e)

(e) itself take the necessary remedial measures.

(e) itself take the necessary remedial measures, ***as a last resort.***

Amendment 22
Article 14, paragraph 2

2. The Commission, before* shall present a report on the effectiveness of the Directive in terms of actual remediation of environmental damages, on the availability at reasonable costs and on conditions of insurance and other types of financial security for the activities covered by Annex III. In the light of that report, the Commission may submit proposals for mandatory financial security.

2. Five years after the entry into force of this Directive, the Commission shall report to the European Parliament and the Council on the measures adopted by the Member States pursuant to paragraph 1. If no appropriate instruments or markets for insurance or other forms of financial security have been established, the Commission shall, in the light of that report, submit proposals for a harmonised compulsory financial guarantee for water and soil damage based on a gradual approach. After a two-year assessment period, this provision shall apply to the remediation of damages caused to species and natural habitats.

2a. A ceiling may be established for the financial guarantee by case and by location, to be determined in accordance with a sliding scale drawn up by the Member States, taking into account in particular the risks of the activities carried out and the annual turnover.

2b. Member States may decide not to apply this provision to low risk activities and may consider establishing thresholds in relation to any insurance requirements under these provisions.

* ***Eight years after the entry into force of this Directive.***

Amendment 27
Article 18, paragraph 3, point (a)

(a) the application of Article 4(2) and (4) in relation to the exclusion of pollution covered by the international instruments listed in Annexes IV and V from the scope of this Directive, particularly in the light of experience gained within relevant international fora, such as the IMO and Euratom, and Conventions, and the extent to which these instruments have entered into force and/or have been implemented by Member States and/or have been modified, **and** taking account of all relevant instances of environmental damage resulting from such activities and the remedial action taken;

(a) the application of Article 4(2) and (4) in relation to the exclusion of pollution covered by the international instruments listed in Annexes IV and V from the scope of this Directive, particularly in the light of experience gained within relevant international fora, such as the IMO and Euratom, and Conventions, and the extent to which these instruments have entered into force and/or have been implemented by Member States and/or have been modified, taking account of all relevant instances of environmental damage resulting from such activities and the remedial action taken, **and considering the relationship between shipowners' liability and oil receivers' contributions;**

P5_TA-PROV(2003)0576

European Medicines Agency ***II

European Parliament legislative resolution on the common position adopted by the Council with a view to adopting a European Parliament and Council regulation laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (10949/2/2003 – C5-0463/2003 – 2001/0252(COD))

(Codecision procedure: second reading)

The European Parliament,

- having regard to the Council common position (10949/2/2003 – C5-0463/2003)¹,
 - having regard to its position at first reading² on the Commission proposal to Parliament and the Council (COM(2001) 404)³,
 - having regard to the amended proposal (COM(2002) 735)⁴,
 - 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 (A5-0425/2003),
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 12

(12) In order to reduce the cost for small and medium-sized enterprises of marketing medicinal products authorised by the centralised procedure, provisions should be adopted to allow for a reduction of fees,

(12) In order to reduce the cost for small and medium-sized enterprises of marketing medicinal products authorised by the centralised procedure, provisions should be adopted to allow for a reduction of fees,

¹ OJ C 297 E, 9.12.2003, p. 1.

² *Texts Adopted*, 23.10.2002, P5_TA(2002)0504.

³ OJ C 75 E, 26.3.2002, p. 189.

⁴ Not yet published in OJ.

deferring the payment of fees and offering administrative assistance in respect of these enterprises.

deferring the payment of fees, ***taking over responsibility for translations*** and offering administrative assistance in respect of these enterprises.

Amendment 41
Recital 14a (new)

(14a) The Community is required, pursuant to Article 178 of the Treaty, to take account of the development policy aspects of any measure and to promote the creation of conditions fit for human beings worldwide. Pharmaceutical law should continue to ensure that only efficacious, safe and top-quality medicinal products are exported, and the Commission should consider creating further incentives to carry out research into medicinal products against widespread tropical diseases.

Amendment 42
Recital 19a (new)

(19a) The Agency's budget should be composed of fees paid by the private sector and contributions paid out of the Community budget to implement Community policies.

Amendment 43
Article 3, paragraph 3, point (b)

(b) the summary of the product characteristics is in all relevant respects consistent with that of the medicinal product authorised by the Community; and

(b) the summary of the product characteristics is in all relevant respects consistent with that of the medicinal product authorised by the Community ***except for those parts of the summary of product characteristics referring to indications or dosage forms which are still covered by patent law at the time the generic medicine was marketed;*** and

Amendment 44
Article 3, paragraph 5

5. *Not earlier than ...**, the Commission, having consulted the Agency, may present any appropriate proposal modifying point 3 of the Annex and the Council shall take a decision on that proposal by qualified majority.

5. *By ...**, **the following fifth and sixth indents shall be added to point 3 of the Annex:**

- auto-immune diseases and other immune dysfunctions;

- viral diseases.

Thereafter, the Commission, having consulted the Agency, may present any appropriate proposal modifying point 3 of the Annex and the Council shall take a decision on that proposal by qualified majority.

Amendment 8
Article 5, paragraph 3

3. At the request of the Executive Director of the Agency or the Commission representative, the Committee for Medicinal Products for Human Use shall also draw up an opinion on any scientific matter concerning the evaluation of medicinal products for human use. The Committee shall take due account of any requests by Member States for an opinion.

3. At the request of the Executive Director of the Agency or the Commission representative, the Committee for Medicinal Products for Human Use shall also draw up an opinion on any scientific matter concerning the evaluation of medicinal products for human use. The Committee shall take due account of any requests by Member States for an opinion. ***The Committee shall also formulate an opinion whenever there is disagreement in the assessment of medicinal product through the mutual recognition procedure. The opinion of the Committee shall be made publicly accessible.***

Amendment 45
Article 6, paragraph 1, subparagraph 1

1. Each application for the authorisation of a medicinal product for human use shall specifically and completely include the particulars and documents as referred to in Articles 8(3), 10, 10a, 10b or 11 of, and Annex I to, Directive 2001/83/EC. These particulars and documents shall take account of the unique, Community nature of the

1. Each application for the authorisation of a medicinal product for human use shall specifically and completely include the particulars and documents as referred to in Articles 8(3), 10, 10a, 10b or 11 of, and Annex I to, Directive 2001/83/EC. ***The documents must include a statement to the effect that clinical trials carried out outside***

authorisation requested and, otherwise than in exceptional cases relating to the application of the law on trade marks, shall include the use of a single name for the medicinal product.

the EU meet the ethical requirements of Directive 2001/20/EC. These particulars and documents shall take account of the unique, Community nature of the authorisation requested and, otherwise than in exceptional cases relating to the application of the law on trade marks, shall include the use of a single name for the medicinal product.

Amendment 46

Article 6, paragraph 3, subparagraphs 1a and 1b (new)

The duration of the analysis of the scientific data in the file concerning the application for marketing authorisation must be at least 80 days, except in cases where the rapporteur and co-rapporteur declare that they have completed their assessment before that time.

On the basis of a duly reasoned request, the Committee for Human Medicinal Products may call for the duration of the analysis of the scientific data in the file concerning the application for marketing authorisation to be extended.

Amendment 11

Article 14, paragraph 7, subparagraph 1

7. Following consultation with the applicant, an authorisation may be granted subject to certain specific obligations, to be reviewed annually by the Agency.

7. Following consultation with the applicant, an authorisation may be granted subject to certain specific obligations, to be reviewed annually by the Agency. *The list of these obligations shall be made publicly accessible.*

Amendment 12

Article 14, paragraph 11

11. Medicinal products for human use which have been authorised in accordance with the provisions of this Regulation shall benefit from *the provisions on protection in Article 10 of Directive 2001/83/EC.*

Notwithstanding the first subparagraph, medicinal products for human use

11. *Without prejudice to the law on the protection of industrial and commercial property,* medicinal products for human use which have been authorised in accordance with the provisions of this Regulation shall benefit from *an eight-year period of protection and a ten-year period of marketing protection, in which connection*

appearing in the Annex to this Regulation shall benefit from a ten-year period of protection, which shall be extended to a maximum of 11 years if, during the first eight years of those ten years, the marketing authorisation holder obtains an authorisation for one or more new therapeutic indications which, during the scientific evaluation prior to their authorisation, are held to bring a significant clinical benefit in comparison with existing therapies.

the latter period shall be extended to a maximum of 11 years if, during the first eight years of those ten years, the marketing authorisation holder obtains an authorisation for one or more new therapeutic indications which, during the scientific evaluation prior to their authorisation, are held to bring a significant clinical benefit in comparison with existing therapies.

Amendment 47
Article 20, paragraph 7

7. The Agency shall, upon request, inform any person concerned of the final decision.

7. The Agency shall, upon request, inform any person concerned of the final decision ***and make the decision publicly accessible immediately after it has been taken.***

Amendment 48
Article 22, paragraph 1

The Agency, acting in close cooperation with the national pharmacovigilance systems established in accordance with Article 102 of Directive 2001/83/EC, shall receive all relevant information concerning suspected adverse reactions to medicinal products for human use which have been authorised by the Community in accordance with this Regulation. Where appropriate, the Committee for Medicinal Products for Human Use shall, in accordance with Article 5 of this Regulation, draw up opinions on the measures necessary.

The Agency, acting in close cooperation with the national pharmacovigilance systems established in accordance with Article 102 of Directive 2001/83/EC, shall receive all relevant information concerning suspected adverse reactions to medicinal products for human use which have been authorised by the Community in accordance with this Regulation. Where appropriate, the Committee for Medicinal Products for Human Use shall, in accordance with Article 5 of this Regulation, draw up opinions on the measures necessary. ***These opinions shall be made publicly accessible.***

Amendment 49
Article 24, paragraph 3, subparagraph 2

Unless other requirements have been laid down as a condition for the granting of the marketing authorisation by the Community, these records shall be submitted, in the form of a periodic safety update report, to the

Unless other requirements have been laid down as a condition for the granting of the marketing authorisation by the Community, these records shall be submitted, in the form of a periodic safety update report, to the

Agency and Member States immediately upon request or at least every six months **during the first two years following authorisation** and once a year for the following two years. Thereafter, the reports shall be submitted at three-yearly intervals, or immediately upon request.

Agency and Member States immediately upon request or at least every six months **after authorisation until the placing on the market. Periodic safety update reports shall also be submitted immediately upon request or at least every six months during the first two years following the initial placing on the Community market** and once a year for the following two years. Thereafter, the reports shall be submitted at three-yearly intervals, or immediately upon request.

Amendment 50
Article 26, paragraph 3

The Agency, in consultation with Member States and the Commission, shall set up a data-processing network for the rapid transmission of information to the competent Community authorities in the event of an alert relating to faulty manufacture, serious adverse reactions and other pharmacovigilance data regarding medicinal products authorised in accordance with Article 6 of Directive 2001/83/EC.

The Agency, in consultation with Member States and the Commission, shall set up a data-processing network for the rapid transmission of information to the competent Community authorities in the event of an alert relating to faulty manufacture, serious adverse reactions and other pharmacovigilance data regarding medicinal products authorised in accordance with Article 6 of Directive 2001/83/EC. **Such data shall be made publicly accessible, if relevant, after evaluation.**

Amendment 18
Article 30, paragraph 3

3. At the request of the Executive Director of the Agency or the Commission representative, the Committee for Medicinal Products for Veterinary Use shall also draw up opinions on any scientific matters concerning the evaluation of veterinary medicinal products. The Committee shall take due account of any requests from Member States for an opinion.

3. At the request of the Executive Director of the Agency or the Commission representative, the Committee for Medicinal Products for Veterinary Use shall also draw up opinions on any scientific matters concerning the evaluation of veterinary medicinal products. The Committee shall take due account of any requests from Member States for an opinion. **The Committee shall also formulate an opinion whenever there is disagreement in the assessment of a veterinary medicinal product through the mutual recognition procedure. The opinion of the Committee shall be made publicly accessible.**

Amendment 51
Article 39, paragraph 2, subparagraph 2

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

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

Amendment 52
Article 45, paragraph 7

7. The Agency shall, upon request, inform any person concerned of the final decision.

7. The Agency shall, upon request, inform any person concerned of the final decision ***and make the decision publicly accessible, immediately after it has been taken.***

Amendment 53
Article 47, paragraph 1

The Agency, acting in close cooperation with the national pharmacovigilance systems established in accordance with Article 73 of Directive 2001/82/EC, shall receive all relevant information about suspected adverse reactions to veterinary medicinal products which have been authorised by the Community in accordance with this Regulation. Where appropriate the Committee for Medicinal Products for Veterinary Use shall, in accordance with Article 30 of this Regulation, draw up opinions on the measures necessary.

The Agency, acting in close cooperation with the national pharmacovigilance systems established in accordance with Article 73 of Directive 2001/82/EC, shall receive all relevant information about suspected adverse reactions to veterinary medicinal products which have been authorised by the Community in accordance with this Regulation. Where appropriate the Committee for Medicinal Products for Veterinary Use shall, in accordance with Article 30 of this Regulation, draw up opinions on the measures necessary. ***These opinions shall be made publicly accessible.***

Amendment 54
Article 49, paragraph 3, subparagraph 2

Unless other requirements have been laid down as a condition for the granting of the marketing authorisation by the Community, these records shall be submitted, in the form of a periodic safety update report, to the

Unless other requirements have been laid down as a condition for the granting of the marketing authorisation by the Community, these records shall be submitted, in the form of a periodic safety update report, to the

Agency and Member States immediately upon request or at least every six months **during the first two years following authorisation** and once a year for the following two years. Thereafter, the reports shall be submitted at three-yearly intervals, or immediately upon request.

Agency and Member States immediately upon request or at least every six months **after authorisation until the placing on the market. Periodic safety update reports shall also be submitted immediately upon request or at least every six months during the first two years following the initial placing on the Community market** and once a year for the following two years. Thereafter, the reports shall be submitted at three-yearly intervals, or immediately upon request.

Amendment 55

Article 57, paragraph 1, subparagraph 2, point (b)

(b) transmitting on request and making available assessment reports, summaries of product characteristics, labels and package leaflets or inserts for these medicinal products;

(b) transmitting on request and making **publicly** available assessment reports, summaries of product characteristics, labels and package leaflets or inserts for these medicinal products;

Amendment 56

Article 57, paragraph 1, subparagraph 2, point (ga) (new)

(ga) providing scientific advice on the use of antibiotics in food-producing animals in order to minimise the occurrence of bacterial resistance in the Community; this advice shall be updated when needed;

Amendment 57

Article 57, paragraph 1, subparagraph 2, point (k)

(k) creating a database on medicinal products, to be accessible to the general public, and **giving technical assistance for its maintenance**; the information provided to the public shall be worded in an appropriate and comprehensible manner;

(k) creating a database on medicinal products, to be accessible to the general public, and **ensuring that it is updated, and managed independently of pharmaceutical companies; the database shall facilitate the search for information already authorised for package leaflets; it shall include a section on medicinal products authorised for the treatment of children**; the information provided to the public shall be worded in an appropriate and comprehensible manner;

Amendment 58
Article 57, paragraph 2, subparagraph 1a (new)

Where appropriate, the database shall also include references to data on clinical trials currently being carried out or already completed, contained in the clinical trials database provided for in Article 11 of Directive 2001/20/EC. The Commission shall, in consultation with the Member States, issue guidelines on data fields which could be included and which may be accessible to the public.

Amendment 59
Article 61, paragraph 1, subparagraph 1

1. Each Member State shall appoint, for a three-year term which may be renewed, one member and one alternate to the Committee for Medicinal Products for Human Use and one member and one alternate to the Committee for Medicinal Products for Veterinary Use.

1. Each Member State shall, *after consultation of the Management Board*, appoint for a three-year term which may be renewed, one member and one alternate to the Committee for Medicinal Products for Human Use and one member and one alternate to the Committee for Medicinal Products for Veterinary Use.

Amendment 31
Article 62, paragraph 1, subparagraph 1

1. Where, in accordance with the provisions of this Regulation, the Committee for Medicinal Products for Human Use, or the Committee for Medicinal Products for Veterinary Use is required to evaluate a medicinal product, it shall appoint one of its members to act as rapporteur for the coordination of the evaluation. The Committee concerned may appoint a second member to act as co-rapporteur.

1. Where, in accordance with the provisions of this Regulation, the Committee for Medicinal Products for Human Use, *the Committee on Herbal Medicinal Products* or the Committee for Medicinal Products for Veterinary Use is required to evaluate a medicinal product, it shall appoint one of its members to act as rapporteur for the coordination of the evaluation. The Committee concerned may appoint a second member to act as co-rapporteur.

Amendment 32
Article 62, paragraph 2, subparagraph 1

2. Member States shall transmit to the Agency the names of national experts with proven experience in the evaluation of

2. Member States shall transmit to the Agency the names of national experts with proven experience in the evaluation of

medicinal products who would be available to serve on working parties or scientific advisory groups of the Committee for Medicinal Products for Human Use or the Committee for Medicinal Products for Veterinary Use, together with an indication of their qualifications and specific areas of expertise.

medicinal products who would be available to serve on working parties or scientific advisory groups of the Committee for Medicinal Products for Human Use, ***the Committee on Herbal Medicinal Products*** or the Committee for Medicinal Products for Veterinary Use, together with an indication of their qualifications and specific areas of expertise.

Amendment 33
Article 64, paragraph 3

3. Each year, the Executive Director shall submit a draft work programme for the coming year to the Management Board for approval, making a distinction between the Agency's activities concerning medicinal products for human use and those concerning veterinary medicinal products.

3. Each year, the Executive Director shall submit ***a draft report covering the activities of the Agency in the previous year and*** a draft work programme for the coming year to the Management Board for approval, making a distinction between the Agency's activities concerning medicinal products for human use, ***those concerning herbal medicinal products*** and those concerning veterinary medicinal products.

The draft report covering the activities of the Agency in the previous year shall include information about the number of applications evaluated within the Agency, the time taken for completion of the evaluation and the medicinal products authorised, rejected or withdrawn.

Amendment 60
Article 65, paragraph 1

1. The Management Board shall consist of one representative of each Member State ***and four representatives of the Commission.***

1. The Management Board shall consist of one representative of each Member State, ***two representatives of the Commission and two representatives of the European Parliament.***

In addition, two representatives of patients' organisations, one representative of doctors' organisations and one representative of veterinarians' organisations shall be appointed by the Council in consultation with the European Parliament on the basis of a list drawn up

by the Commission which includes appreciably more names than there are posts to be filled. The list drawn up by the Commission shall be forwarded to the European Parliament, together with the relevant background documents. As quickly as possible, and within three months of notification, the European Parliament may submit its views for consideration to the Council, which shall then appoint the Management Board.

The members of the Management Board shall be appointed in such a way as to guarantee the highest levels of specialist qualifications, a broad spectrum of relevant expertise and the broadest possible geographic spread within the European Union.

Amendment 61
Article 67, paragraph 4

4. Activities relating to pharmacovigilance, to the operation of communications networks and to market surveillance shall receive adequate public funding.

4. Activities relating to pharmacovigilance, to the operation of communications networks and to market surveillance shall receive public funding *commensurate with the tasks conferred.*

Amendment 37
Article 73, subparagraph 1a (new)

The Agency shall set up a register pursuant to Article 2(4) of Regulation (EC) No 1049/2001 to make available all documents that are publicly accessible pursuant to this Regulation.

Amendment 62
Article 88a (new)

Article 88a

The periods of protection foreseen in Articles 14(11) and 39(10) do not apply to reference medicinal products for which an application for authorisation has been submitted before the date referred to in

Article 89(2).

Amendment 63
Annex, point 3a (new)

***3a. Medicinal products that are designated
as orphan medicinal products pursuant to
Regulation (EC) No 141/2000.***

P5_TA-PROV(2003)0577

Community code on medicinal products for human use *II**

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 (10950/03/2003 – 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)¹,
 - having regard to its position at first reading² on the Commission proposal to Parliament and the Council (COM(2001) 404)³,
 - having regard to the amended Commission proposal (COM(2003) 163)⁴,
 - 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.

¹ OJ 297 E, 9.12.2003, p. 41.

² *Texts Adopted*, 23.10.2002, P5_TA(2002) 0505.

³ OJ C 75 E, 26.3.2002, p. 216.

⁴ Not yet published in OJ.

Amendment 60
RECITAL 7

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

(7) Particularly as a result of scientific and technical progress, the definitions and scope of Directive 2001/83/EC should be clarified in order to achieve high standards for the quality, safety and efficacy of medicinal products for human use. In order to take account both of the emergence of new therapies and of the growing number of so-called "borderline" products between the medicinal product sector and other sectors, the definition of "medicinal product" should be modified so as to avoid any doubt as to the applicable legislation when a product, whilst fully falling within the definition of a medicinal product, may also fall within the definition of other regulated products. ***This definition should specify the type of action that the medicinal product may exert on physiological functions. This enumeration of actions allows in addition to cover medicinal products such as gene therapy, radiopharmaceutical products as well as certain medicinal products for topical use.*** Also, in view of the characteristics of pharmaceutical legislation, provision should be made for such legislation to apply. With the same objective of clarifying situations, where a given product comes under the definition of a medicinal product but could also fall within the definition of other regulated products, it is necessary, in case of doubt and in order to ensure legal certainty, to state explicitly which provisions have to be complied with. Where a product comes clearly under the definition of other product categories, in particular food, food supplements, medical devices, biocides or cosmetics, this Directive should not apply. It is also appropriate to improve the consistency of the terminology of pharmaceutical legislation.

Amendment 61
RECITAL 14a (new)

(14a) Biological medicinal products similar to a reference medicinal product do not usually meet all the conditions to be considered as a generic medicinal product mainly due to manufacturing process characteristics, raw materials used, molecular characteristics and therapeutic modes of action. When a biological medicinal product does not meet all the conditions to be considered as a generic medicinal product, the results of appropriate tests should be provided in order to fulfil the requirements related to safety (pre-clinical tests) or to efficacy (clinical tests) or to both.

Amendment 56
RECITAL 16a (new)

(16a) Environmental impact must be assessed and, on a case-by-case basis, specific arrangements to limit it must be envisaged. In any event this impact should not constitute a criterion for refusal of a marketing authorisation.

Amendment 63
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 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 or administered to human beings ***either*** with a view to restoring, correcting or modifying physiological functions ***by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.***

Amendment 64
ARTICLE 1, POINT 1, POINT (i)
Article 1, points 28, 29 and 30 (Directive 2001/83/EC)

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*;

29. *Risks relating to the environment*:

Any risk of unwanted effects on the environment;

30. Risk-benefit balance:

An evaluation of the positive therapeutic effects of the medicinal product in relation to the risks as defined in point 28;

28. Risks *related* to use of the medicinal product:

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

- *any risk of undesirable effects on the environment*;

29. Risk/benefit balance:

An evaluation of the positive therapeutic effects of the medicinal product in relation to the risk as defined in point 28, *first indent*.

Amendment 65
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*.

2. In cases of doubt, where, *taking into account all its characteristics*, a product *may fall* within the definition of a "medicinal product" *and within the definition of a product covered by other Community legislation the provisions of this Directive shall apply*.

Amendment 57
ARTICLE 1, POINT 7, POINT (a)
Article 8, paragraph 3, point (c a) (new) (Directive 2001/83/EC)

(ca) Evaluation of the potential environmental risks posed by the medicinal product. This impact shall be assessed and, on a case-by-case basis, specific arrangements to limit it shall be envisaged.

Amendment 66
ARTICLE 1, POINT 7, POINT (b)
Article 8, paragraph 3, point (ib) (new) (Directive 2001/83/EC)

(ib) A statement to the effect that clinical trials carried out outside the European Union meet the ethical requirements of Directive 2001/20/EC.

Amendment 14
ARTICLE 1, POINT 8
Article 10, paragraph 1, subparagraph 3a (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 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 58
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

(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***

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.

providing proof of the safety and/or 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 67

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 and the related detailed guidelines.* The results of other tests and trials from the reference medicinal product's dossier shall not be provided.

Amendment 68

ARTICLE 1, POINT 8

Article 10, paragraph 4a (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 one year of data exclusivity shall be granted, provided that significant pre-

clinical or clinical studies were carried out in relation to the new indication.

Amendment 69

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.
In case of registrations, Article 28 and Article 29, paragraphs 1 to 3 shall apply.

Amendment 70

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 ***a maximum of*** 210 days *of* the submission of a valid application.

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.***

Amendment 72
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 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.**

Amendment 73
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; **where the product contains up to three active substances, the international non-proprietary name (INN) shall be included, or, if one does not exist, the common name shall be included;**

Amendment 74
ARTICLE 1, POINT 40, POINT (ba) (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 shall be provided for the prescribed

dose to be indicated."

Amendment 75

ARTICLE 1, POINT 40, POINT (ca) (new)
Article 54, point (j) (Directive 2001/83/EC)

(ca) Point (j) shall be replaced by the following:

"(j) specific precautions relating to the disposal of unused medicinal products or waste derived from medicinal products, where appropriate, as well as reference to any appropriate collection system in place;"

Amendment 76

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

(41a) Article 56 shall be replaced by the following:

"Article 56

The name of the medicinal product, as referred to in Article 54, point (a) must also be expressed in Braille format on the packaging. The marketing authorisation holder shall ensure that the package information leaflet is made available on request from patients' organisations in formats appropriate for the blind and partially-sighted."

Amendment 83

ARTICLE 1, POINT 56
Article 81, paragraph 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

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.

medicinal product *to pharmacies and persons authorised to supply medicinal products* so that the needs of patients in the Member State in question are covered.

Amendment 77/rev
ARTICLE 1, POINT 61a (new)
Title VIIIa and Article 88a (new) (Directive 2001/83/EC)

(61a) The following text is inserted after Article 88:

"TITLE VIIIa:

INFORMATION AND ADVERTISING

Article 88a

Within three years the Commission shall, following consultations with patients' and consumers' organisations, doctors' and pharmacists' organisations, Member 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 59
ARTICLE 1, POINT 71a (new)
Article 102 a (new) (Directive 2001/83/EC)

(71a) The following Article shall be inserted:

"Article 102a

The management of funds earmarked for pharmacovigilance, the functioning of

communication networks and market surveillance shall be subject to constant supervision by the competent authorities in order to guarantee their independence.”

Amendment 78

ARTICLE 1, POINT 73

Article 104, paragraph 6, subparagraph 1 (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 for the granting of *the marketing* 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, immediately upon request or *at least every six months after authorisation and until the placing on the market. Periodic safety update reports shall also be submitted immediately upon request or at least every six months during the first two years following the initial placing on the market and once a year for the following two years. Thereafter, the reports shall be submitted at three-yearly intervals, or immediately upon request.*

Amendment 79

ARTICLE 1, POINT 74(a)

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 Medicines Control Laboratory or a laboratory designated for that purpose to carry out tests on samples*, that the legal requirements governing medicinal products are complied with.

Amendment 80
ARTICLE 1, POINT 74(a)
Article 111, paragraph 1, subparagraph 5, point (b) (Directive 2001/83/EC)

(b) take samples;

(b) take samples *including with a view to independent tests being carried out by an Official Medicines Control Laboratory or a laboratory designated for that purpose by a Member State;*

Amendment 81/rev
ARTICLE 1, POINT 81
Article 126a, 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.

Amendment 82
ARTICLE 1, POINT 81a (new)
Article 126b (new) (Directive 2001/83/EC)

(81a) The following Article 126b is inserted:

"Article 126b

In order to guarantee independence and transparency, 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 which could affect their impartiality. These persons shall make an annual declaration of their financial

interests.

In addition, the Member States shall ensure that the competent authority makes publicly accessible its rules of procedure and those of its committees, agendas for its meetings and records of its meetings, accompanied by decisions taken, details of votes and explanations of votes, including minority opinions."

Amendment 84

ARTICLE 1, POINT 82a (new)

Article 127b (new) (Directive 2001/83/EC)

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

"Article 127b

Member States shall ensure that appropriate collection systems are in place for medicinal products that are unused or have expired."

Amendment 62

ARTICLE 1a (new)

Article 1a

The periods of protection foreseen in Article 1, point 8, that modifies Article 10(1), do not apply to reference medicinal products for which an application for authorisation has been submitted before the date of transposition referred to in Article 2(1).

P5_TA-PROV(2003)0578

Community code on veterinary medicinal products ***II

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

(Codecision procedure: second reading)

The European Parliament,

- having regard to the Council common position (10951/3/2003 – C5-0465/2003)¹,
 - having regard to its position at first reading² on the Commission proposal to Parliament and the Council (COM(2001) 404)³,
 - having regard to the amended proposal (COM(2003) 163)⁴,
 - having regard to Article 251(2) of the EC Treaty,
 - having regard to Rule 80 of its Rules of Procedure,
 - having regard to the recommendation for second reading of the Committee on the Environment, Public Health and Consumer Policy (A5-0444/2003),
1. Amends the common position as follows;
 2. Instructs its President to forward its position to the Council and Commission.

Council common position

Amendments by Parliament

Amendment 37
RECITAL 14a (new)

14a. Biological medicinal products similar to a reference medicinal product do not usually meet all the conditions to be considered as a generic medicinal product mainly due to manufacturing process characteristics, raw materials used, molecular characteristics and therapeutic

¹ *Texts Adopted*, 23.10.2002, P5_TA(2003)0506.

² OJ C 297 E, 9.12.2003, p. 72.

³ OJ C 75 E, 26.3.2002, p. 234.

⁴ Not yet published in OJ.

modes of action. When a biological product does not meet all the conditions to be considered as a generic medicinal product, the results of appropriate tests should be provided in order to fulfil the requirements related to safety (pre-clinical tests) or to efficacy (clinical tests) or to both.

Amendment 34
RECITAL 21a (new)

21a. The environmental impact must be studied and consideration must be given on a case by case basis to specific provisions seeking to limit it.

Amendment 39
ARTICLE 1, POINT 1, POINT (b)
Article 1, point 2, point (b) (Directive 2001/82/EC)

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

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

Amendment 5
ARTICLE 1, POINT 1, POINT (g)
Article 1, point 19 (new) (Directive 2001/82/EC)

(g) point 19 shall be replaced by the following:

(g) point 19 shall be replaced by the following, ***and the following point 19a shall be added:***

'19. Risks relating to ***the*** use of the product:

"19. Risks relating to use of the product:

Any risk relating to the quality, safety ***or*** efficacy of the veterinary medicinal product as regards animal or human health. ';

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

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

19a. Risk/benefit balance:

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

Amendment 40

ARTICLE 1, POINT 2

Article 2, paragraph 2 (Directive 2001/82/EC)

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

2. In cases of doubt, where, ***taking into account all its characteristics***, a product ***may fall*** within the definition of a "medicinal product" ***and within the definition of a product covered by other Community legislation, the provisions of this Directive shall apply.***

Amendment 41

ARTICLE 1, POINT 4

Article 6, paragraph 3 (Directive 2001/82/EC)

3. By way of derogation from paragraph 1, a veterinary medicinal product containing pharmacologically active substances not included in Annexes I, II or III to Regulation (EEC) No 2377/90 may be authorised for particular animals of the equidae family that have been declared, in accordance with Commission Decision 93/623/EEC of 20 October 1993 establishing the identification document (passport) accompanying registered equidae*, as not being intended for slaughter for human consumption. Such veterinary medicinal products shall neither include active substances that appear in Annex IV to Regulation (EEC) No 2377/90 nor be intended for use in the treatment of conditions, as detailed in the authorised Summary of Product Characteristics, for which a veterinary medicinal product is authorised for animals of the equidae family.

3. By way of derogation from paragraph 1, a veterinary medicinal product containing pharmacologically active substances not included in Annexes I, II or III to Regulation (EEC) No 2377/90 may be authorised for particular animals of the equidae family that have been declared, in accordance with Commission Decision 93/623/EEC of 20 October 1993 establishing the identification document (passport) accompanying registered equidae* ***and Commission Decision 2000/68/EC of 22 December 1999 amending Decision 93/623/EC and establishing the identification of of equidae for breeding and production on *****, as not being intended for slaughter for human consumption. Such veterinary medicinal products shall not include active substances that appear in Annex IV to Regulation (EEC) No 2377/90, nor be intended for use in the treatment of conditions, as detailed in the authorised Summary of Product Characteristics, for which a veterinary medicinal product is authorised for animals of the equidae family.

* OJ L 298, 3.12.1993, p. 45. **Decision as amended by Commission Decision 2000/68/EC** (OJ L 23, 28.1.2000, p. 72).

* OJ L 298, 3.12.1993, p. 45.

** OJ L 23, 28.1.2000, p. 72.

Amendment 42
ARTICLE 1, POINT 6
Article 10, paragraph 2 (Directive 2001/82/EC)

2. By way of derogation from Article 11, paragraph 1 of this Article shall also apply to the treatment by a veterinarian of an animal belonging to the equidae family provided that it has been declared, in accordance with *Commission Decision 93/623/EEC*, as not being intended for slaughter for human consumption.

2. By way of derogation from Article 11, ***the provisions of*** paragraph 1 of this Article shall also apply to the treatment by a veterinarian of an animal belonging to the equidae family provided that it has been declared, in accordance with *Decision 93/623/EEC and Decision 2000/68/EC*, as not being intended for slaughter for human consumption.

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

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

Amendment 43
ARTICLE 1, POINT 6
Article 12, paragraph 3, point (j), indent 2a (new) (Directive 2001/82/EC)

- tests assessing the potential risks posed by the medicinal product for the environment. This impact should be studied and consideration should be given on a case by case basis to specific provisions seeking to limit it.

Amendment 35
ARTICLE 1, POINT 6
Article 13, paragraph 2, point (b) (Directive 2001/82/EC)

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

(b) 'generic medicinal product' shall mean a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies. The different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance shall be considered to be the same active substance, unless they differ significantly in properties with regard to safety and/or efficacy. ***In such cases, additional information intended to provide proof of the safety and/or 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 44
ARTICLE 1, POINT 6
Article 13, paragraph 4 (Directive 2001/82/EC)

4. Where a biological veterinary medicinal product which is similar to a reference biological veterinary medicinal product does not meet ***certain*** conditions in the definition of generic medicinal products, owing, in particular, to differences in manufacturing processes of the biological veterinary medicinal product and the reference biological veterinary medicinal product, the results of appropriate pre-clinical tests or clinical trials relating to these conditions

4. Where a biological veterinary medicinal product which is similar to a reference biological veterinary medicinal product does not meet ***the*** conditions in the definition of generic medicinal products, owing, in particular, to differences ***relating to raw materials or*** in manufacturing processes of the biological veterinary medicinal product and the reference biological veterinary medicinal product, the results of appropriate pre-clinical tests or clinical trials relating to

must be provided. The results of other tests and trials from the reference medicinal product's dossier shall not be provided.

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 and the related detailed guidelines.*** The results of other tests and trials from the reference medicinal product's dossier shall not be provided.

Amendment 45

ARTICLE 1, POINT 8

Article 16, paragraph 1 (Directive 2001/82/EC)

1. Member States shall ensure that homeopathic veterinary medicinal products manufactured and placed on the market within the Community are registered or authorised in accordance with Articles 17, 18 and 19, except where such veterinary medicinal products are covered by a registration or authorisation granted in accordance with national legislation on or before 31 December 1993.

1. Member States shall ensure that homeopathic veterinary medicinal products manufactured and placed on the market within the Community are registered or authorised in accordance with Articles 17, 18 and 19, except where such veterinary medicinal products are covered by a registration or authorisation granted in accordance with national legislation on or before 31 December 1993. ***In the case of homeopathic medicinal products registered in accordance with Article 17, Article 32 and Article 33, paragraphs 1 to 3 shall apply.***

Amendment 46

ARTICLE 1, POINT 12

Article 21, paragraph 1, subparagraph 1 (Directive 2001/82/EC)

1. Member States shall take all appropriate measures to ensure that the procedure for granting a marketing authorisation for a veterinary medicinal product is completed within ***210 days after*** the submission of a valid application.

1. Member States shall take all appropriate measures to ensure that the procedure for granting a marketing authorisation for a veterinary medicinal product is completed within ***a maximum of 210 days of*** the submission of a valid application.

Amendment 47

ARTICLE 1, POINT 17

Article 28, paragraph 2, subparagraph 2 (Directive 2001/82/EC)

To this end, the marketing authorisation holder shall submit a consolidated ***version of***

To this end, the marketing authorisation holder shall submit a consolidated ***list of all***

the file in respect of quality, safety and efficacy, including all variations introduced since the marketing authorisation was granted, at least six months before the marketing authorisation ceases to be valid in accordance with paragraph 1.

documents submitted in respect of quality, safety and efficacy, including all variations introduced since the marketing authorisation was granted, at least six months before the marketing authorisation ceases to be valid in accordance with paragraph 1. ***The competent authority may require the applicant to submit the listed documents at any time.***

Amendment 48

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

(iii a) Point (f) shall be replaced by the following:

“(f) The species of animal for which the veterinary medicinal product is intended; the method and, if necessary, the route of administration. Space shall be provided for the prescribed dose to be indicated;”

Amendment 49

ARTICLE 1, POINT 32, POINT (a), POINT (iva) (new)
Article 58, paragraph 1, point (j) (Directive 2001/82/EC)

(iv a) Point (j) shall be replaced by the following:

“(j) specific precautions relating to the disposal of unused medicinal products or waste derived from veterinary medicinal products, where appropriate, as well as a reference to any appropriate collection system in place;”

Amendment 36

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

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

"Article 73a

The management of funds intended for activities connected with pharmacovigilance, the operation of communication networks and market surveillance shall be under the permanent control of the competent authorities in order to guarantee the independence of these authorities."

Amendment 50

ARTICLE 1, POINT 48

Article 75, paragraph 5, subparagraph 1 (Directive 2001/82/EC)

5. Unless other requirements have been laid down as a condition of the **grant** of authorisation or subsequently as indicated in the guidelines referred to in Article 77(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.

5. Unless other requirements have been laid down as a condition for the **granting of the marketing** authorisation or subsequently as indicated in the guidelines referred to in Article 77(1), reports of all adverse reactions shall be submitted to the competent authorities in the form of a periodic safety update report, immediately upon request or **at least every six months after authorisation until the placing on the market. Periodic safety update reports shall also be submitted immediately upon request or at least every six months during the first two years following the initial placing on the market and once a year for the following two years.** Thereafter, **the reports shall be submitted** at three-yearly intervals, or **immediately upon request.**

Amendment 52

ARTICLE 1, POINT 52, POINT (a)

Article 80, paragraph 1, subparagraph 1 (Directive 2001/82/EC)

1. The competent authority of the Member State concerned shall ensure, by means of repeated inspections and, if necessary, unannounced inspections, that the legal requirements relating to veterinary medicinal products are complied with.

1. The competent authority of the Member State concerned shall ensure, by means of repeated inspections and, if necessary, unannounced inspections, **and where appropriate, by asking an Official Medicines Control Laboratory or a laboratory designated for that purpose to conduct tests on samples,** that the legal requirements relating to veterinary medicinal

products are complied with.

Amendment 51

ARTICLE 1, POINT 52, POINT (a)

Article 80, paragraph 1, subparagraph 5, point (b) (Directive 2001/82/EC)

(b) take samples;

(b) take samples *with a view to an independent analysis by an Official Medicines Control Laboratory or by a laboratory designated for this purpose by a Member State.*

Amendment 53

ARTICLE 1, POINT 60a (new)

Article 95a (new) (Directive 2001/82/EC)

(60a) The following Article 95a shall be inserted:

“Article 95 a

Member States shall ensure that appropriate collection systems are in place for veterinary medicinal products that are unused or expired.”

Amendment 38

ARTICLE 1a (new)

Article 1a

The periods of protection foreseen in Article 1, point 6, that modifies Article 13, do not apply to reference medicinal products for which an application for authorisation has been submitted before the date of transposition referred to in Article 2(1).

P5_TA-PROV(2003)0579

Traditional herbal medicinal products *II**

European Parliament legislative resolution on the Council common position for adopting a European Parliament and Council directive amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use (12754/1/2003 – C5-0519/2003 – 2002/0008(COD))

(Codecision procedure: second reading)

The European Parliament,

- having regard to the Council common position (12754/1/2003 – C5-0519/2003)¹,
 - having regard to its position at first reading² on the Commission proposal to Parliament and the Council (COM(2002) 001)³,
 - having regard to the amended proposal (COM(2003) 161)⁴,
 - 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 (A5-0452/2003),
1. Amends the common position as follows;
 2. Instructs its President to forward its position to the Council and the Commission.

¹ Not yet published in OJ.

² Texts Adopted, 21.11.2002, P5_TA(2002)0561.

³ OJ C 126 E, 28.5.2002, p. 263.

⁴ Not yet published in OJ.

Amendment 1
RECITAL 11a (new)

(11a) This Directive allows non-medicinal herbal products, fulfilling the criteria of food legislation, to be regulated under food legislation in the Community.

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

1. A list of herbal substances, preparations and combinations thereof shall be established in accordance with the procedure referred to in Article 121(2). The list shall contain with regard to each herbal substance the indication, the specified strength and the posology, the route of administration and any other information necessary for the safe use of the herbal substance.

1. A list of herbal substances, preparations and combinations thereof shall be established in accordance with the procedure referred to in Article 121(2) ***for their use in traditional herbal medicinal products***. The list shall contain, with regard to each herbal substance, the indication, the specified strength and the posology, the route of administration and any other information necessary for the safe use of the herbal substance ***as a traditional medicinal product***.

P5_TA-PROV(2003)0580

Measuring instruments ***II

European Parliament legislative resolution on the Council common position adopting a European Parliament and Council directive on measuring instruments (9681/4/2003 – C5-0417/2003 – 2000/0233(COD))

(Codecision procedure: second reading),

The European Parliament,

- having regard to the Council common position (9681/4/2003 – C5-0417/2003),¹
 - having regard to its position at first reading² on the Commission proposal to Parliament and the Council (COM(2000) 566)³,
 - having regard to the amended proposal (COM (2002) 37))⁴,
 - 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 Industry, External Trade, Research and Energy (A5-0458/2003),
1. Amends the common position as follows;
 2. Instructs its President to forward its position to the Council and the Commission.

Council common position

Amendments by Parliament

Amendment 1
Recital 5

(5) Member States should ***retain the option to*** prescribe legal metrological control. Where legal metrological control is prescribed, measuring instruments complying with common performance requirements should be used.

(5) Member States should, ***as a general rule,*** prescribe legal metrological control. Where legal metrological control is prescribed, ***only*** measuring instruments complying with common performance requirements should be used.

¹ OJ C 252 E, 21.10.2003, p. 1.

² OJ C 65 E, 14.3.2002, p. 34.

³ OJ C 62 E, 27.2.2001, p. 1.

⁴ OJ C 126 E, 28.5.2002, p. 368.

Amendment 2
Recital 5a (new)

(5a) The principle of optionality introduced by this Directive, implying that Member States may exercise their right to decide whether or not to regulate any of the instruments covered by this Directive, will be applicable only to the extent that this clause will not cause unfair competition.

Amendement 4
Recital 12a (new)

(12a) The conformity assessment of sub-assemblies should respect the provisions of this Directive. If sub-assemblies are traded separately and independently of an instrument, the exercise of conformity assessment should be undertaken independently of the instrument concerned.

Amendment 5
Recital 13

(13) The state of the art in measurement technology is subject to constant evolution which may lead to changes in the needs for conformity assessments. Therefore, for each category of measurement there must be an appropriate procedure or a choice between different procedures of equivalent stringency. The procedures adopted are as required by Council Decision 93/465/EEC of 22 July 1993 concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the "CE" marking, which are intended to be used in the technical harmonisation Directives. However, derogations may have to be made for these modules in order to reflect specific aspects of metrological control. Provision should be made for the "CE" marking to be affixed during the fabrication process.

(13) The state of the art in measurement technology is subject to constant evolution which may lead to changes in the needs for conformity assessments. Therefore, for each category of measurement ***and, where appropriate, sub-assemblies***, there must be an appropriate procedure or a choice between different procedures of equivalent stringency. The procedures adopted are as required by Council Decision 93/465/EEC of 22 July 1993 concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the "CE" marking, which are intended to be used in the technical harmonisation Directives. However, derogations may have to be made for these modules in order to reflect specific aspects of metrological control. Provision should be made for the "CE" marking to be affixed

during the fabrication process.

Amendment 6
Recital 13a (new)

(13a) Continued development in measurement technology as well as concerns expressed by stakeholders about certification, stress the need for ensuring consistent conformity assessment procedures for industrial products, as requested by the Council Resolution adopted on 10 November 2003.¹

¹ *OJ C 282, 25.11.2003, p. 3.*

Amendment 29
Recital 18

(18) Member States may consider it appropriate to require measuring instruments which they have subjected to legal metrological control, and sub-assemblies which function in relation to them, to continue to meet the appropriate national requirements in use. The national specifications which remain should not interfere with the provisions of this Directive on "putting into use".

(18) National specifications concerning the appropriate national requirements in use should not interfere with the provisions of this Directive on "putting into use".

Amendment 30
Recital 19a (new)

(19a) The activity of the Measuring Instruments Committee should include proper consultations with representatives of interested parties;

Amendment 8
Article 1a (new)

Article 1a

1. Member States may prescribe the use of measuring instruments mentioned in Article 1 for measuring tasks for reasons of public interest, public health, public safety,

public order, protection of the environment, levying of taxes and duties, protection of consumers and fair trading, where they consider it justified.

2. Where Member States do not prescribe such use, they shall communicate the reasons thereof to the Commission and the other Member States.

Amendment 9
Article 2, paragraph 1

This Directive establishes the requirements *which* the devices and systems referred to in Article 1 have to satisfy, with a view to their being placed on the market and/or put into use for those tasks *for which a Member State prescribes legal metrological control.*

This Directive establishes the requirements *which* the devices and systems referred to in Article 1 have to satisfy, with a view to their being placed on the market and/or put into use for those tasks *mentioned in the first paragraph of Article 1 a.*

Amendment 10
Article 3, point (c)

(c) "legal metrological control" means the control of the measurement tasks for the field of application of a measuring instrument, *prescribed by the Member States* for reasons of public interest, public health, public safety, public order, protection of the environment, levying of taxes and duties, protection of the consumers and fair trading;

(c) "legal metrological control" means the control of the measurement tasks *intended* for the field of application of a measuring instrument, for reasons of public interest, public health, public safety, public order, protection of the environment, levying of taxes and duties, protection of the consumers and fair trading;

Amendment 31
Article 3, point (i)

(i) "normative document" means a document containing technical specifications adopted by the Organisation Internationale de Métrologie Légale (OIML).

(i) "normative document" means a document containing technical specifications adopted by the Organisation Internationale de Métrologie Légale (OIML), *subject to the procedure stipulated in Article 13(1).*

Amendment 13
Article 4, subparagraph 1a (new)

1a. Sub-assemblies and measuring instruments may be assessed independently and separately for the purpose of establishing conformity.

Amendment 14
Article 7, paragraphs 2 to 4

2. Member States ***requiring legal metrological control*** shall take all appropriate measures to ensure that measuring instruments *be* placed on the market and/or put into use only if they satisfy the requirements of this Directive.

3. A Member State ***requiring legal metrological control*** may require a measuring instrument to satisfy provisions governing its putting into use that are justified by local climatic conditions. In such a case, the Member State shall choose appropriate upper and lower temperature limits from Table 1 of Annex I and, in addition, may specify humidity conditions (condensing or non-condensing) and whether the intended location of use is open or closed.

4. When different accuracy classes are defined for a measuring instrument:

(a) the instrument-specific annexes under the heading "Putting into use" may indicate the accuracy classes to be used for specific applications.

(b) in all other cases a Member State ***requiring legal metrological control*** may determine the accuracy classes to be used for specific applications within the classes defined, subject to allowing the use of all accuracy classes on its territory.

In either case *falling* under (a) or (b), measuring instruments of a better accuracy class may be used *if* the owner *so chooses*.

2. Member States shall take all appropriate measures to ensure that measuring instruments *be* placed on the market and/or put into use only if they satisfy the requirements of this Directive.

3. A Member State may require a measuring instrument to satisfy provisions governing its putting into use that are justified by local climatic conditions. In such a case, the Member State shall choose appropriate upper and lower temperature limits from Table 1 of Annex I and, in addition, may specify humidity conditions (condensing or non-condensing) and whether the intended location of use is open or closed.

4. When different accuracy classes are defined for a measuring instrument:

(a) the instrument-specific annexes under the heading "Putting into use" may indicate the accuracy classes to be used for specific applications.

(b) in all other cases a Member State may determine the accuracy classes to be used for specific applications within the classes defined, subject to allowing the use of all accuracy classes on its territory.

In either case *falling* under (a) or (b), measuring instruments of a better accuracy class may be used *if* the owner *so chooses*.

Amendment 15
Article 8, subparagraph 1

Conformity assessment of a measuring instrument with the relevant essential requirements shall be carried out by the application, at the choice of the manufacturer, of one of the conformity assessment procedures listed in the instrument-specific annex. The manufacturer shall provide, where appropriate, technical documentation for specific instruments or groups of instruments as set out in *Annex III*.

Conformity assessment of a measuring instrument with the relevant essential requirements shall be carried out by the application, at the choice of the manufacturer, of one of the conformity assessment procedures listed in the instrument-specific annex. The manufacturer shall provide, where appropriate, technical documentation for specific instruments or groups of instruments as set out in *Article 8a*.

Amendment 16
Article 8a (new)

Article 8a

TECHNICAL DOCUMENTATION

- 1) The technical documentation shall render the design, manufacture and operation of the measuring instrument intelligible and shall enable an assessment of its conformity with the appropriate requirements of this Directive.***
- 2) The technical documentation shall be sufficiently detailed to ensure :***
 - the definition of the metrological characteristics,***
 - the reproducibility of the metrological performances of produced instruments when properly adjusted using appropriate intended means, and***
 - the integrity of the instrument.***
- 3) The technical documentation shall include insofar as relevant for assessment and identification of the type and/or instrument:***
 - 3.1. a general description of the instrument;***
 - 3.2. conceptual design and manufacturing drawings and plans of components, sub-assemblies, circuits, etc;***
 - 3.3. manufacturing procedures to ensure consistent production;***

3.4. if applicable, a description of the electronic devices with drawings, diagrams, flow diagrams of the logic and general software information explaining their characteristics and operation;

3.5. descriptions and explanations necessary for the understanding of paragraphs 3.2, 3.3 and 3.4, including the operation of the instrument;

3.6. a list of the standards and/or normative documents referred to in Article 10, applied in full or in part;

3.7. descriptions of the solutions adopted to meet the essential requirements where the standards and/or normative documents referred to in Article 10 have not been applied;

3.8. results of design calculations, examinations, etc;

3.9. the appropriate test results, where necessary, to demonstrate that the type and/or instruments comply with:

(a) the requirements of the Directive under declared rated operating conditions and under specified environmental disturbances

(b) the durability specifications for gas-, water-, heat-meters as well as for liquids other than water.

3.10. the EC-type examination certificates or EC design examination certificates in respect of instruments containing parts identical to those in the design.

4) The manufacturer shall specify where seals and markings have been applied.

5) The manufacturer shall indicate the conditions for compatibility with interfaces and sub-assemblies, where relevant.

Amendment 17
Article 9, paragraph 2

2. Member States shall apply the criteria set

2. Member States shall apply the criteria set

out in **Annex II** for the designation of such bodies. Bodies that meet the criteria laid down in the national standards which transpose the relevant harmonised standards, the references of which have been published in the Official Journal, shall be presumed to meet the corresponding criteria. Member States shall publish the references to these national standards.

If a Member State has not introduced national legislation **regulating a measuring instrument**, it retains the right to designate and notify a body for tasks relating to that instrument.

out in **Article 9a** for the designation of such bodies. Bodies that meet the criteria laid down in the national standards which transpose the relevant harmonised standards, the references of which have been published in the Official Journal, shall be presumed to meet the corresponding criteria. Member States shall publish the references to these national standards.

If a Member State has not introduced national legislation **for tasks mentioned under Article 1a**, it retains the right to designate and notify a body for tasks relating to that instrument.

Amendment 18
Article 9, paragraph 3, indent 1

– ensure that the body continues to meet the criteria set out in **Annex II**,

– ensure that the body continues to meet the criteria set out in **Article 9a**,

Amendment 19
Article 9a (new)

Article 9a

**CRITERIA TO BE SATISFIED BY
DESIGNATED BODIES**

Set out below are the criteria that Member States shall apply for the designation of bodies according to Article 9(1).

1. The body, its director and staff involved in conformity assessment tasks shall not be the designer, manufacturer, supplier, installer or user of the measuring instruments that they inspect, nor the authorised representative of any of them. In addition, they may not be not directly involved in the design, manufacture, marketing or maintenance of the instruments, nor represent the parties engaged in these activities. The preceding criterion does not, however, preclude in any way the possibility of exchanges of technical information between the manufacturer and the body for the

purposes of conformity assessment.

2. The body, its director and staff involved in conformity assessment tasks shall be free from all pressures and inducements, in particular financial inducements, that might influence their judgement or the results of their conformity assessment, especially from persons or groups of persons with an interest in the results of the assessments.

3. The conformity assessment shall be carried out with the highest degree of professional integrity and requisite competence in the field of metrology.

Should the body subcontract specific tasks, it shall first ensure that the subcontractor meets the provisions of this Directive, and in particular of this Article. The body shall keep the relevant documents assessing the subcontractor's qualifications and the work carried out by him under this Directive at the disposal of the notifying authority.

4. The body shall be able to carry out all the conformity assessment tasks for which it has been designated, whether these tasks are carried out by the body itself or on its behalf and under its responsibility. It shall have at its disposal the necessary staff and have access to the necessary facilities for carrying out the technical and administrative tasks entailed in conformity assessment in a proper manner.

5. The body's staff shall have:

- sound technical and vocational training, covering all conformity assessment tasks for which the body was designated;*
- satisfactory knowledge of the rules in respect of the tasks which it carries out, and adequate experience of such tasks;*
- the ability required to draw up the certificates, records and reports to demonstrate that the tasks were carried out.*

6. The impartiality of the body, its director and staff shall be guaranteed. The remuneration of the body shall not depend on the results of the tasks it carries out. The remuneration of the body's director and staff shall not depend on the number of tasks carried out, nor on the results of such tasks.

7. The body shall take out civil liability insurance, if its civil liability is not covered by the Member State under national law.

8. The body's director and staff shall be bound to observe professional secrecy with regard to all information obtained in the course of exercising their duties pursuant to this Directive, except vis-à-vis the authority of the Member State which has designated it.

Amendment 20

Article 10, paragraph 2, subparagraph 1

Member States shall presume conformity with the essential requirements referred to in Annex I and in the relevant instrument-specific Annexes in respect of a measuring instrument that complies with the normative document referred to in Article 13(1)(a), whose references have been published in the Official Journal of the European Union, C series.

Member States shall presume conformity with the essential requirements referred to in Annex I and in the relevant instrument-specific Annexes in respect of a measuring instrument that complies with the **corresponding parts of the normative documents and lists** referred to in Article 13(1)(a), whose references have been published in the Official Journal of the European Union, C series.

Amendment 21

Article 10, paragraph 3

3. A manufacturer may choose to use any technical solution that complies with the essential requirements referred to in Annex I and in the relevant instrument-specific Annexes. **However, only by applying those methods** mentioned in the relevant standards **and** documents referred to in paragraphs 1 and 2 **is the presumption of conformity ensured.**

3. A manufacturer may choose to use any technical solution that complies with the essential requirements referred to in Annex I and in the relevant instrument-specific Annexes **(MI-001 to MI-010). In addition, to benefit from the presumption of conformity, the manufacturer has to correctly apply solutions mentioned either** in the relevant **European harmonised**

standards, **or in the corresponding parts of the normative documents and lists**, referred to in paragraphs 1 and 2.

Amendment 22

Article 13, paragraph 1, point (a)

(a) identify normative documents drawn up by OIML and indicate parts thereof compliance with which gives rise to a presumption of conformity with the corresponding essential requirements of this Directive;

(a) identify normative documents drawn up by OIML and, **in a list**, indicate **the** parts thereof compliance with which gives rise to a presumption of conformity with the corresponding essential requirements of this Directive;

Amendment 23

Article 13, paragraph 1, point (b)

(b) publish the references of the document referred to in point (a) in the Official Journal of the European Union, C series.

(b) publish the references of the **normative documents and the list** referred to in point (a) in the Official Journal of the European Union, C series.

Amendment 24

Article 13, paragraph 2

2. On request by a Member State or on its own initiative, the Commission, acting in accordance with the procedure referred to in Article 12(3), may take any appropriate measure to amend instrument-specific annexes in respect of:

– **the inclusion of sub-assemblies**,

– the maximum permissible errors (MPEs) and accuracy classes,

– the rated operating conditions,

– the critical change values,

– disturbances,

– **the list of conformity assessment procedures**,

2. On request by a Member State or on its own initiative, the Commission, acting in accordance with the procedure referred to in Article 12(3), may take any appropriate measure to amend instrument-specific annexes **(MI-001 to MI-010)** in respect of:

– the maximum permissible errors (MPEs) and accuracy classes,

– the rated operating conditions,

– the critical change values,

– disturbances,

Amendment 25

Article 19

Instruments in use

Member States may require measuring instruments subject to legal metrological control to continue to meet appropriate in-service requirements.

Deleted

Amendment 26

Article 23

The European Parliament and the Council invite the Commission to report, before *, on the implementation of this Directive ***and, in particular, on the application of Articles 1 and 2 thereof, inter alia*** on the basis of reports provided by the Member States, and, where appropriate, to submit a proposal for amendments.

The European Parliament and the Council invite the Commission to report, before *, on the implementation of this Directive, inter alia, on the basis of reports provided by the Member States, and, where appropriate, to submit a proposal for amendments.

Amendment 27

Article 23, paragraph 1a (new)

The European Parliament and Council invite the Commission to evaluate if conformity assessment procedures for industrial products are properly applied and, where appropriate, to propose amendments in order to ensure consistent certification.

Amendment 32

Annex

***JOINT DECLARATION
OF THE EUROPEAN PARLIAMENT,
THE COUNCIL AND THE
COMMISSION***

The Council and the European Parliament undertake to act expeditiously in accordance with their respective rules of procedure, on a proposal from the Commission, concerning a full set of coherent conformity assessment procedures (Council Decision

*93/465/EEC), as indicated in the
Competitiveness Council Resolution
adopted on 10 November 2003. The
Commission has the intention to submit
the necessary proposals as foreseen in its
2004 legislative programme, after
consulting the interested parties.*

P5_TA-PROV(2003)0581

Motor vehicles: seats, their anchorages and head restraints ***I

European Parliament legislative resolution on the proposal for a European Parliament and Council directive amending Council directive 74/408/EEC relating to motor vehicles with regards to the seats, their anchorages and head restraints (COM(2003) 361 – C5-0283/2003 – 2003/0128(COD))

(Codecision procedure: first reading)

The European Parliament,

- having regard to the Commission proposal to the European Parliament and the Council (COM(2003) 361)¹,
 - having regard to Article 251(2) and Article 95 of the EC Treaty, pursuant to which the Commission proposal was submitted to the European Parliament (C5-0283/2003),
 - having regard to Rule 67 of the Rules of Procedure,
 - having regard to the report of the Committee on Regional Policy, Transport and Tourism (A5-0418/2003),
1. Approves the Commission proposal as amended;
 2. Calls on the Commission to refer the matter to Parliament again if it intends 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 3
RECITAL 8a (new)

(8a) Research shows that the risks of side-facing seats for passengers in category M₃ vehicles have not been sufficiently assessed. It is necessary to examine these risks using methods such as those used for testing car safety in order to arrive at a balanced risk assessment. The Commission should commission such tests and forward the results to the European Parliament by 31

¹ Not yet published in OJ.

December 2004.

Amendment 1

ARTICLE 1, POINT 2

Article 3a, paragraph 1 (Directive 74/408/EEC)

1. With effect from [1 July 2004], Member States shall prohibit the installation of side-facing seats on new types of vehicles of *categories M₁, N₁, M₂ and M₃ of class III or B.*

1. With effect from [1 July 2004], Member States shall prohibit the installation of side-facing seats on new types of vehicles of *categories M₁, and N₁ as well as category M₂ of class B.*

Amendment 2

ARTICLE 1, POINT 2

Article 3a, paragraph 2 (Directive 74/408/EEC)

2. With effect from [1 January 2006], Member States shall prohibit the installation of side-facing seats on new vehicles of *categories M₁, N₁, M₂ and M₃ of class III or B.*

2. With effect from [1 January 2006], Member States shall prohibit the installation of side-facing seats on new vehicles of *categories M₁ and N₁ as well as category M₂ of class B.*

P5_TA-PROV(2003)0582

Motor vehicles: safety belts and restraint systems ***I

European Parliament legislative resolution on the proposal for a European Parliament and Council directive amending Council Directive 77/541/EEC on the approximation of the laws of the Member States relating to safety belts and restraint systems of motor vehicles (COM(2003) 363 – C5-0282/2003 – 2003/0130(COD))

(Codecision procedure: first reading)

The European Parliament,

- having regard to the Commission proposal to the European Parliament and the Council (COM(2003) 363)¹,
 - having regard to Articles 251(2) and 95 of the EC Treaty, pursuant to which the Commission submitted the proposal to Parliament (C5-0282/2003),
 - having regard to Rule 67 of its Rules of Procedure,
 - having regard to the report of the Committee on Regional Policy, Transport and Tourism (A5-0304/2003),
1. Approves the Commission proposal as amended;
 2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its 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

Amendment by Parliament

Amendment 1
ARTICLE 1, POINT 3a (new)
Annex XV Table (Directive 77/541/EEC)

3a. The table in Annex XV shall be replaced by the following:

¹ Not yet published in OJ.

Vehicle category	Forward facing seating positions				Rear facing seating positions	Side facing seating positions
	Outboard seating positions		Centre seating positions			
	Front	Other than front	Front	Other than front		
M_1	Ar4m	Ar4m	Ar4m	Ar4m	B, Br3, Br4m	
$M_2 \leq 3,5$ T	Ar4m, Ar4Nm	Ar4m, Ar4Nm	Ar4m, Ar4Nm	Ar4m, Ar4Nm	Br3, Br4m, Br4Nm	
$M_2 > 3,5$ T	Br3, Br4m, Br4Nm or Ar4m, Ar4Nm ☞	Br3, Br4m, Br4Nm or Ar4m, Ar4Nm ☞	Br3, Br4m, Br4Nm or Ar4m, Ar4Nm ☞	Br3, Br4m, Br4Nm or Ar4m, Ar4Nm ☞	Br3, Br4m, Br4Nm	
	See point 3.1.10 for conditions when a lap belt is permitted.	See point 3.1.10 for conditions when a lap belt is permitted.	See point 3.1.10 for conditions when a lap belt is permitted.	See point 3.1.10 for conditions when a lap belt is permitted.		
M_3	Br3, Br4m, Br4Nm or Ar4m, Ar4Nm ☞	Br3, Br4m, Br4Nm or Ar4m, Ar4Nm ☞	Br3, Br4m, Br4Nm or Ar4m, Ar4Nm ☞	Br3, Br4m, Br4Nm or Ar4m, Ar4Nm ☞	Br3, Br4m, Br4Nm	Br3, Br4m and Br4Nm
	See point 3.1.10 for conditions when a lap belt is permitted.	See point 3.1.10 for conditions when a lap belt is permitted.	See point 3.1.10 for conditions when a lap belt is permitted.	See point 3.1.10 for conditions when a lap belt is permitted.		
N_1	Ar4m, Ar4Nm	B, Br3, Br4m, Br4Nm or none # Point 3.1.8 and 9 lap belt required in exposed seating positions	B, Br3, Br4m, Br4Nm or A, Ar4m, Ar4Nm * Point 3.1.7 lap belt permitted if the windscreen is not in reference zone	B, Br3, Br4m, Br4Nm or none # Point 3.1.8 and 9 lap belt required in exposed seating positions	None	
N_2	B, Br3, Br4m, Br4Nm or A, Ar4m, Ar4Nm *	B, Br3, Br4m, Br4Nm or none #	B, Br3, Br4m, Br4Nm or A, Ar4m, Ar4Nm *	B, Br3, Br4m, Br4Nm or none #	None	
N_3	Point 3.1.7 lap belt permitted if the windscreen is not in reference zone and for driver's seat.	Point 3.1.8 and 9 lap belt required in exposed seating positions	Point 3.1.7 lap belt permitted if the windscreen is not in reference zone.	Point 3.1.8 and 9 lap belt required in exposed seating positions		

P5_TA-PROV(2003)0583

Motor vehicles: anchorages for safety-belts ***I

European Parliament legislative resolution on the proposal for a European Parliament and Council directive amending Council Directive 76/115/EEC on the approximation of the laws of the Member States relating to anchorages for motor-vehicle safety belts (COM(2003) 362 – C5-0286/2003 – 2003/0136(COD))

(Codecision procedure: first reading)

The European Parliament,

- having regard to the Commission proposal to the European Parliament and the Council (COM(2003) 362)¹,
 - having regard to Articles 251(2) and 95 of the EC Treaty, pursuant to which the Commission submitted the proposal to Parliament (C5-0286/2003),
 - having regard to Rule 67 of its Rules of Procedure,
 - having regard to the report of the Committee on Regional Policy, Transport and Tourism (A5-0305/2003),
1. Approves the Commission proposal as amended;
 2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its 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
ARTICLE 1, POINT 2 a (new)
Annex I, Item 4.3.2. (Directive 76/115/EEC)

2a. In Annex I, Item 4.3.2. shall be replaced by the following:

"4.3.2. The minimum number of safety belt anchorages for each seating position shall be as specified in Appendix 1."

¹ Not yet published in OJ.

Amendment 2
 ARTICLE 1, POINT 2 b (new)
 Annex I, Item 4.3.10a. (Directive 76/115/EEC)

2b. In Annex I, the following item is added:
"4.3.10a. In buses and coaches in category M₃, subcategories III and B, at each side facing seating position whose longitudinal vertical plane forms an angle of 45° to 135° with the median longitudinal plane of the vehicle, a padded divider at least 100 mm long and at least 100 mm high must be provided. Length and height extend from the H point after that point has been displaced horizontally into each plane passing vertically through the outermost point on the side of the seating position nearer to the front of the vehicle. The divider may be foldable so as to afford easy access to the seating position."

Amendment 3
 ARTICLE 1, POINT 2 c (new)
 Annex I, Item 5.4.6., Title (Directive 76/115/EEC)

2c. In Annex I, the title of Item 5.4.6. shall be replaced by the following:
"5.4.6. Test in the case of rearward and side facing seats"

Amendment 4
 ARTICLE 1, POINT 2 d (new)
 Annex I, Appendix 1, Table (Directive 76/115/EEC)

2d. In Appendix 1 of Annex I, the table shall be replaced by the following:

Vehicle category	Forward facing seating positions				Rear facing seating positions	Side facing seating positions
	Outboard		Centre			
	Front	Other	Front	Other		
M ₁	3	3 or 2 Ø	3 or 2 *	2	2	-
M ₂ ≤ 3,5 t	3	3	3	3	2	-

$M_2 > 3,5 t$	3 ☀	3 or 2 ☿	3 or 2 ☿	3 or 2 ☿	2	-
M_3	3 ☀	3 or 2 ☿	3 or 2 ☿	3 or 2 ☿	2	2 Δ
$N_1, N_2 \& N_3$	3	2 or 0 #	3 or 2 *	2 or 0 #	-	-

Amendment 5

ARTICLE 1, POINT 2 e (new)

Annex I, Appendix 1, key to table (Directive 76/115/EEC)

2e. In Appendix 1 of Annex I, the following symbol shall be added:

"Δ: refers to Item 4.3.10a. (special provision for side facing seating positions whose longitudinal vertical plane forms an angle of 45° to 135° with median longitudinal vertical plane of the vehicle)"

P5_TA-PROV(2003)0584

Freedom of movement and ownership of goods

European Parliament resolution on a legal framework for free movement within the internal market of goods whose ownership is likely to be contested (2002/2114(INI))

The European Parliament,

- having regard to its resolutions of 14 December 1995 on the return of plundered property to Jewish communities¹ and of 16 July 1998 on the restitution of property belonging to Holocaust victims²,
 - having regard to the European Convention on Offences relating to Cultural Property of 23 June 1985 and Council Directive 93/7/EEC of 15 March 1993 on the return of cultural objects unlawfully removed from the territory of a Member State³,
 - having regard to Rule 163 of its Rules of Procedure,
 - having regard to the report of the Committee on Legal Affairs and the Internal Market (A5-0408/2003),
- A. whereas early moves were made following the end of the Second World War to find and return looted property to its country of origin,
- B. whereas a very considerable amount of property has not been recovered by its owners or their successors,
- C. whereas litigants have often been confronted with difficult problems due to conflicts of law, varying prescriptive periods and other difficulties, and that this hampers or prevents access to swift and efficient resolution of the interests of all parties affected,
- D. whereas this is an important human and legal problem as victims continue to encounter legal and technical problems,
- E. whereas a public hearing was held on 18 March 2003,
- F. whereas this is a widespread European legal problem,
1. Welcomes the recognition among various governments that the unique problems associated with cultural goods (i.e. public or private property considered as constituting an artistic creation or cultural property) which were plundered in wartime through acts of violence, confiscation or by apparently legal transactions or auctions need to be addressed;

¹ OJ C 17, 22.1.1996, p. 199.

² OJ C 292, 21.9.1998, p. 166.

³ OJ L 74, 27.3.1993, p. 74.

2. Recognises that, although the problem of these goods is a matter of public knowledge, it has often proved remarkably difficult for private claimants to recover their property and to clarify their provenance;
3. Welcomes the efforts being made by third countries (especially the United States of America and the Russian Federation) to take parallel or reciprocal action;
4. Calls on the Commission, with due regard for Article 295 of the EC Treaty, to undertake a study by the end of 2004 on:
 - establishing a common cataloguing system, to be used by both public entities and private collections of art to gather together data on the situation regarding looted cultural goods and the exact status of existing claims;
 - developing common principles regarding access to public or private archives containing information on property identification and location and tying together existing databases of information about title to disputed properties;
 - identifying common principles on how ownership or title is established, prescription, standards of proof and rights to export or import property which has been recovered;
 - exploring possible dispute-resolution mechanisms that avoid lengthy and uncertain judicial procedures and take into account principles of fairness and equity;
 - the value of creating a cross-border coordination administrative authority to deal with disputes on title to cultural goods;
5. Calls on the Member States and the accession States to make all necessary efforts to adopt measures to ensure the creation of mechanisms which favour the return of the property referred to in this resolution and to be mindful that the return to rightful claimants of art objects looted as part of crimes against humanity is a matter of general interest for the purposes of Article 1 of Protocol 1 to the European Convention of Human Rights;
6. Calls on the Presidency of the European Union to assign this issue to a working group of the Council;
7. Instructs its President to forward this resolution to the Council, the Commission, the governments of the Member States and the accession States and the Council of Europe.

P5_TA-PROV(2003)0585

Legislative and work programme of the Commission for 2004

European Parliament resolution on the Commission's legislative and work programme for 2004 (COM(2003) 645 final)

The European Parliament,

- having regard to the conclusion of the interinstitutional agreement on better law-making between the European Parliament, the Council and the Commission,
 - having regard to the Commission's legislative and work programme (COM(2003) 645),
 - having regard to the presentation by the Commission of that programme on 18 November 2003 and the ensuing debate in the presence of Council,
 - having regard to the Brussels European Council of 12 and 13 December 2003,
 - having regard to Rule 57 and Rule 37(4) of the Rules of Procedure,
- A. whereas the annual legislative programme constitutes an indispensable interinstitutional instrument for coordinating, evaluating and monitoring the Union's activities in a transparent and efficient way,
- B. whereas transparency and predictability with regard to the European Union's legislative work are core principles of modern governance,
- C. whereas 2004 will be a significant and crucial year for the European Union, marked by major events, such as the most extensive enlargement the EU has ever known, the approval of a new Constitutional Treaty, the election of a new European Parliament in June, the arrival of Commissioners from the new Member States in May and the establishment of a new College of Commissioners in November,
- D. whereas more transparent and efficient legislative planning on the part of the European Union requires closer involvement of the Council in the interinstitutional legislative programming exercise; whereas the draft interinstitutional agreement on better law-making provides a basis for such enhanced interinstitutional coordination,
- E. whereas the Brussels European Council of 12-13 December 2003 opened the way for multiannual legislative programming by adopting a first Council triannual strategic programme in accordance with the conclusions of the 2002 Seville European Council,

General and institutional remarks

1. Takes note of the Commission's work and legislative programme and the political priorities outlined, namely the absorption of the accession of ten new Member States, stability and sustainable growth;

2. Notes that in view of the special institutional character of the year 2004 the Commission has limited the number of key initiatives to be presented in 2004 to those it considers absolutely necessary and feasible; notes that the proposals to be put forward match the political priorities, but takes the view, nevertheless, that the Commission has taken too little action in response to the calls made by the parliamentary committees;
3. Notes that the annual legislative and work programme contains a total of 275 legislative proposals and non-legislative acts, 128 of which directly correspond to the political priorities for 2004 but only 57 of which are legislative acts; notes that a substantial part of the programme for 2004 consists of proposals postponed from previous programmes;
4. Regrets that only about half of the proposals announced in the legislative and work programme for 2003 have actually been adopted by the Commission; hopes that the programme for 2004 is based on more realistic assumptions;
5. Notes that the European Parliament elections and the enlargement and subsequent renewal of the Commission in 2004 represent important challenges with regard to both the implementation of the legislative and work programme for 2004 and the interinstitutional dialogue on the preparation of the programme for 2005;
6. Calls upon its parliamentary committees to examine closely the proposals contained in the legislative and work programme with a view to identifying those proposals that still need to be dealt with under the current legislature;
7. Calls, in view of the imminent end of the current legislature, for close cooperation between the institutions with regard to the management of legislative procedures currently under examination; proposes, while fully respecting the Commission's and Council's rights and prerogatives, the following arrangements:
 - calls upon the Commission to present all proposals that require a decision before the end of the year 2004 in good time, given the time constraints arising from the fact that the electoral process will take place during the 2004 legislative year;
 - calls upon the Commission not to present any other new and far-reaching proposals shortly before the European elections, when Parliament cannot examine them properly owing to the electoral process;
8. Takes the view that, in 2004, it will be necessary to reach agreement with the Commission on an ad hoc procedure governing the various stages in the preparation and presentation of the next legislative programme;
9. Calls upon the Commission to comply with the timetables indicated in its legislative and work programme for the presentation of new proposals; insists, should the Commission envisage deviating from these timetables, on the need to consult the relevant parliamentary committee beforehand;
10. Takes the view that application of the interinstitutional agreement on better law-making will clear the way for wider-ranging coordination of legislative work among the three

institutions, and considers that the Council should be involved in an interinstitutional legislative programme;

11. Takes the view that the links between the Commission's programme and the Council's multiannual strategic programme drawn up in December 2003 are as yet far from clear; calls on the Commission and Council to explain precisely how these two planning processes go together;
12. Points out that the need to revise the institutional framework of the enlarged European Union and to continue the work of establishing a future Constitution for Europe represents one of the major challenges for 2004;
13. Notes that discussions and work are in progress in the Commission on the subject of future priorities for a revised financial framework for post-2006; takes the view that this debate is relevant, but that no decision should be taken at this stage, particularly in view of the imminence of the enlargement of the Union (1 May 2004) and the European elections (June 2004); believes that the decision should be taken by the future Commission once it has been formed and has determined its priorities, and that the final decision must be taken by the budgetary authority;

Enlargement, stability and the EU's role in the world

14. Welcomes the fact that on 1 May 2004 ten new Member States will join the European Union; agrees that this historic enlargement will provide a considerable boost to the EU's economic and political potential, but will also represent an enormous challenge for the EU and in particular for the Commission;
15. Recalls in this context the Commission's role in ensuring that the *acquis communautaire* is adhered to in the new Member States, with regard *inter alia* to the rules on the internal market, in the areas of employment and social protection policy, the environment and justice and home affairs;
16. Points to the importance of economic cohesion within the Union, and deplores the fact that the Commission has not yet presented Parliament with an Action Plan for after May 2004 concerning the efforts needed for the new Member States to catch up economically and converge with the EU 15;
17. Takes the view that the accession of 10 new Member States, the ongoing negotiations with Romania and Bulgaria, the report on the situation in Turkey and the opinion on Croatia's membership application together form the key political priority for 2004, but emphasises that, in the current tense and unstable international situation, the new framework created by an enlarged Union with new neighbourhood relations with countries to the east and in the Mediterranean will make closer coordination and tangible progress in the sphere of the CFSP essential with a view to the establishment of an area of security, peace, stability and prosperity, chiefly involving the Union's new neighbours; welcomes the adoption of a security strategy for the Union and calls on the Commission to implement policies which are consistent with that document;

18. Supports further development of the joint economic area, area of justice and security and research area with Russia, as well as the feasibility studies concerning stabilisation and association agreements with Bosnia-Herzegovina and Serbia-Montenegro;
19. Invites the Commission to devote particular attention to further developments and the progress of reform in Turkey, in particular in the run-up to the progress report for the December 2004 Council; in the aftermath of the recent terrible bomb attacks invites the Commission to maintain and even foster its engagement in Turkey in order to express the full solidarity of the European Union;
20. Welcomes the Commission's analysis regarding the need for a reinforced ESDP, and invites the Commission and Council to work ever more closely together and to follow the consultation and information procedures of the European Parliament; insists, furthermore, that the Commission inform the competent European Parliament committee regularly during the budget year about the ongoing implementation of the budget dedicated to external actions, and in particular provide information about specific problems of implementation, in order to avoid a repetition of the 2003 global transfer situation, which clearly demonstrates that political priorities set by Parliament in the budgetary procedure have not been implemented;
21. Regrets the fact that the Israeli-Palestinian conflict has disrupted and hampered the Barcelona integration process and applauds the ongoing efforts of the Commission and the High Representative for the CFSP to bring about peace in the region;
22. Emphasises the importance of the EU presence in Afghanistan; thanks the European Commission's delegation to Kabul for its efforts; calls for Community and Member State aid to be continued in order to meet the needs of the population;
23. Welcomes the recent communication from the Commission on the budgetisation of the European Development Fund (EDF); reiterates its long-standing support for the budgetisation of the EDF, which will provide for parliamentary supervision and democratic scrutiny of the EU's financial and technical cooperation with the ACP countries; gives the ACP countries an assurance that, through the exercise of its powers as one arm of the budgetary authority, it will prevent the diversion of funds from previous EDFs to other areas of the EU budget, by means of ringfencing and other appropriate measures;
24. Calls on the Commission to give a firm undertaking to draw up a detailed, comprehensive strategy designed to achieve the UN's millennium development objectives, in particular the elimination of poverty, and the objectives in the spheres of health and education;
25. Welcomes the Peace Facility set up by the European Union to finance peacekeeping operations by the African Union; calls on the Commission to take steps to ensure that prompt use is made of this instrument in the various conflict areas in Africa;
26. Encourages the Commission to implement the Action Plan on communicable diseases and reproductive health; insists that concrete action be taken in this area in order to mark the tenth anniversary of the International Conference on Population and Development (ICPD+10) in 2004;

27. Strongly recommends that the European policies aimed at progressing towards the establishment of an area of Freedom, Security and Justice (Tampere agenda) be implemented before the May 2004 deadline; points out that, following the Treaty of Nice, the next stage in the establishment of an area of freedom, security and justice provides for the application of the codecision procedure to most measures concerning asylum and immigration;
28. Recalls the need for major progress towards overall implementation of a European immigration policy; supports the Commission's proposals aimed at achieving a balance between measures to counteract illegal immigration and measures designed to ensure fair treatment and integration of legal immigrants;
29. Notes the Commission's determination to set up new cooperation programmes with third countries in the area of immigration, programmes which are part of the fight against clandestine immigration and trafficking in human beings;
30. Stresses the need to develop efficient management of the Member States' common borders in the framework of a coherent common policy in collaboration with the European Parliament; draws attention to the need to establish a Community operational structure, with a view to stepping up cooperation on the protection of external frontiers, in particular ahead of the 2004 enlargement;
31. Calls for the development of a new Schengen Information System (SIS) to be carried out in a transparent and democratic manner, which presupposes that Parliament should be consulted and that the provisions on data protection should be complied with;

Sustainable development and social policy

32. Agrees that sustainable development should be one of the major work priorities of the Commission; insists, however, that more focus must be given to concrete actions developing this policy towards employment, investment in human resources, prosperity and quality of life for European citizens;
33. Supports all additional efforts to enhance growth and sustainable development, including investment in European networks; stresses, however, that the beneficial effects of these measures will only be felt if the process of implementation is accelerated; insists that, alongside the TENs and R&D projects, investment in the human dimension and capital must be given the highest priority; recalls the importance of the Commission's role in this process and declares its own readiness to contribute to speedy decision-making where necessary;
34. Takes the view that the establishment of an integrated electricity market in an enlarged Europe will improve security of supply, but that further efforts should be made to achieve a satisfactory level of electrical interconnectivity; calls for a new proposal on closer coordination in the sector with a view to preventing blackouts similar to those recently suffered by Italy, Sweden, Denmark and the United Kingdom;
35. Welcomes the support for innovation, research and development, which are fundamental to European growth and the European Union's Lisbon strategy, in particular the action plan which aims to increase investment in research and development in line with the

target of 3% of GDP and to attract more and more human resources to the research sector; points out that specific measures must be taken to meet the needs of innovative SMUs active in Europe;

36. Acknowledges that consideration should be given to the idea of establishing a European Research Council, endowed with adequate resources, with a view to strengthening fundamental research in Europe; takes the view that such a body should give priority to bottom-up approaches, cover all scientific areas and be based on scientific criteria;
37. Underlines the importance of smoothly functioning services of general interest; deplores in this context the fact that the Commission again does not intend to propose a framework directive on services of general interest, as requested by Parliament on several occasions and by the European Council meeting in Laeken;
38. Notes that the extension of the 'Lamfalussy' approach to the banking, insurance and UCITS sectors is not included in the Commission's priorities for 2004; supports this extension in principle but reminds the Commission firmly that this support is conditional upon a guarantee of a call-back for the European Parliament on the implementing measures to be adopted in these areas;
39. Underlines again the importance of an effective and dynamic follow-up and implementation of the Lisbon strategy in 2004; considers that the Lisbon structural reform agenda has to result in better, and sustainable, jobs, in order to create a knowledge-based economy; insists that economic, environmental and social reforms must be mutually supportive and must be achieved in close cooperation with all actors concerned; looks to the Commission to step up cooperation with the social partners with a view to drawing up joint strategies and measures to achieve the employment objectives laid down in Lisbon, in particular greater involvement for the elderly and women on the labour market;
40. Deplores the absence of any reference to the European economic and social model; is of the opinion that one consequence of the specificity of the European economic and social model should be that the Commission considers more carefully possible social and environmental consequences of its proposals, in particular when putting forward initiatives to liberalise economic activities further;
41. Calls on the Commission to regard as a priority measures to remedy the serious socio-economic effects of the various plans to reconstitute fish stocks on communities that are highly dependent on fishing;
42. Welcomes the thematic strategies incorporated into the legislative programme, such as those outlined in the sixth action programme on the environment; stresses the importance a Commission initiative aimed at drawing up a thematic strategy on the urban environment;
43. Calls on the Commission to take practical steps to follow up the conclusions of the Thessaloniki European Council of 19 and 20 June 2003, which called for the establishment of 'a European diplomacy on environment and sustainable development', and urges the Commission to put forward a specific political strategy in this area; asks to be kept regularly informed, between now and June 2005, about the progress made

towards establishing a network of experts, in keeping with the strategy, adopted in Barcelona, on integrating the environment into external policies;

44. Notes the new measures presented by the Commission with a view to completing the internal market, liberalising the various transport sectors and guaranteeing passengers using all modes of transport increased safety; in that connection, points out that the onus is now on the Council to speed up its efforts to adopt common positions on extremely important matters, such as social provisions in the sphere of road transport, the introduction of a system imposing certain restrictions on the use of heavy good vehicles, public service requirements and the award of public service contracts in the sphere of the transport of passengers by rail, road and inland waterway, and EU-OPSs in civil aviation;
45. Emphasises that the Commission must implement all the measures required to take account of the increase in life expectancy, a major challenge which the European Union will be required to meet in the near future, and to implement a large-scale information campaign on health and eating habits;
46. Points out that, in Council Decision 2003/578/EC of 22 July 2003 on guidelines for the employment policies of the Member States¹, the need for an adequate labour supply and the promotion of active ageing is emphasised, with a view to encouraging enterprises to hire or retain older employees, strengthening access to training and changing employer attitudes;
47. Calls on the Commission to put forward practical proposals to build on the momentum established by the European Year of People with Disabilities;
48. Urges that the new generation of Community programmes in the areas of education, culture, youth and audiovisual policy for the post-2006 period should be programmed in good time in order to ensure continuity in terms of both policy and implementation;

Eurostat

49. Calls on the Commission to address the Eurostat case and all its aspects with the utmost seriousness; deplores the fact that the action plan provides no proper explanation for the Commission's failure to react for so long to the crisis in Eurostat, despite the evidence which mounted up over the years;
50. Draws the Commission's attention to the deficiencies within its internal communication system, in particular to the need to improve the flow of information at all levels within the Commission in order to ensure that it is in a position to exercise its tasks properly; in this context, however, warns against establishing new bureaucratic structures; is disappointed at the fact that, despite commitments to improve European governance, the Commission is not planning to come forward with a proposal for a code of good administrative behaviour or a regulation on administrative law;
51. Welcomes the commitment expressed by the President of the Commission to strengthening OLAF's operational independence and capability, including internal investigations; expects the Commission to come up with concrete proposals with a view

¹ OJ L 197, 5.8.2003, p. 13.

to having them adopted before the enlargement, i.e. by this Parliament; calls on OLAF to complete all its outstanding investigations concerning Eurostat and to submit its final reports to Parliament as soon as possible, and by 15 January 2004 at the latest;

52. Demands that the Commission urgently take all necessary measures to change the culture of secrecy and complacency regarding financial control instruments, so that any wrongdoing can in future be quickly detected and dealt with, and that it take steps to address immediately the need for effective communication between Commissioners and their Directorates-General; calls for existing rules (such as the Commissioners' Code of Conduct and the rules governing the Commission's relationship with OLAF) to be implemented in full, and for the outstanding cases concerning whistle-blowers to be resolved as soon as possible and procedures developed for their protection;
53. Calls on its committees responsible to hold hearings or similar meetings to scrutinise closely developments concerning the Commission's accounting system and calls for that step to be accompanied by an assessment of the overall stage reached in implementing the financial control instruments which form part of the reform package, in the light of the Eurostat affair;

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54. Instructs its President to forward this resolution to the Council, the Commission and the governments and parliaments of the Member States and the future Member States that will join the European Union in May 2004.

Role of the Union in conflict prevention in Africa and in particular in the implementation of the Linas-Marcoussis Agreement in the Côte d'Ivoire

European Parliament resolution on the European Union's role in conflict prevention in Africa and particularly in the implementation of the Linas-Marcoussis Agreement in Côte d'Ivoire

The European Parliament,

- having regard to its previous resolutions on Côte d'Ivoire,
 - having regard to the Linas-Marcoussis Agreement, negotiated under the auspices of France with the participation of the UN, the Economic Community of West African States (ECOWAS) and the EU, and signed by all parties to the Côte d'Ivoire civil conflict on 24 January 2003,
 - having regard to the fact that the EU is represented by both the Commission and the Council on the Monitoring Committee on the Linas-Marcoussis Agreement,
 - having regard to the efforts made by ECOWAS to re-establish peace and security, thereby safeguarding the national integrity of Côte d'Ivoire,
 - having regard to the declarations by the Presidency, on behalf of the European Union, of 22 September and 27 October 2003,
 - having regard to the declaration by the President of the UN Security Council of 13 November 2003,
 - having regard to its resolution of 15 March 2001 on developing the Union's capabilities in conflict prevention and civil crisis management¹,
 - having regard to the Council's decision of 22 January 2001 setting up the permanent bodies of the Common European Security and Defence Policy (CESDP),
 - having regard to the Italian Presidency's declaration of 9 December 2003 on behalf of the European Union,
 - having regard to Rule 37(4) of its Rules of Procedure,
- A. whereas this conflict, which cannot be attributed to the ethnic factor alone, has complex and multidimensional origins, including in particular poverty, unequal distribution of wealth, social injustice, human rights violations, the oppression of minorities, religious discrimination and the dysfunctional State,

¹ OJ C 343, 5.12.2001, p. 261.

- B. concerned at the failure to secure a peaceful resolution to the conflict in Côte d'Ivoire and at the suspension by rebel ministers of their participation in the government of national reconciliation, precipitating the inability to implement the Linas-Marcoussis Agreement and the freeze on disarmament plans and the commitment of European funds,
- C. whereas the mandate and role of the Monitoring Committee on the Linas-Marcoussis Agreement and the various actors engaged in the process have met with some criticism,
- D. mindful of the political, economic and humanitarian risks that a resumption of hostilities in Côte d'Ivoire poses to the whole subregion, and that conflict prevention mechanisms have clearly failed in the current crisis,
- E. whereas the Ivorian 'rebel forces' have so far opposed the demilitarisation of non-governmental armed groups, which was due to begin on 1 August 2003 under international supervision; and whereas all the military commanders of both government and rebel forces agreed on 10 December 2003, in the presence of the peace-keeping forces, that before Christmas they would withdraw all heavy artillery pieces from the frontline, gather in their weapons, confine their men to barracks and clear all roadblocks,
- F. whereas on 24 November 2003 Kofi Annan, speaking to the United Nations Security Council, expressed his fear of a resumption of the conflict between rebel and government forces in Côte d'Ivoire,
- G. whereas the Commission has decided to grant Côte d'Ivoire EUR 6 million in aid for victims of the conflict and EUR 30 million over three years for a rehabilitation programme additional to the programmes adopted in the framework of the 7th and 8th EDFs and the national indicative programme under the 9th EDF,
- H. alarmed at the Commission's position in favour of extending by one year the current fisheries agreement with Côte d'Ivoire despite the fact that the implementation of development cooperation under the Cotonou Agreement in fact remains suspended owing to the conflict,
- I. whereas the European Union Council decided on 17 November 2003 to allocate EUR 250 million from the European Development Fund to a Peace Facility for Africa which is intended to provide the African Union with the financial muscle to ensure stability and peace in Africa,
- J. whereas the implementation of the reforms envisaged by the various agreements concluded by the political and military forces must lead a unified and cohesive Côte d'Ivoire to credible, transparent and open elections in 2005,
- 1. Deplores the lack of political goodwill and the slow progress of the implementation of the Linas-Marcoussis Agreement; nevertheless welcomes the consideration given by the Ivorian Council of Ministers to the texts deriving from the Linas-Marcoussis Agreement on the nationality code and naturalisation requirements, the electoral code, eligibility requirements, in particular concerning eligibility to seek election as President of the Republic, and the land ownership code, and hopes that these will be adopted by the

parliament and, in the case of those texts requiring a referendum amending the constitution, by a majority of the electorate;

2. Calls on all parties to ensure the scrupulous application of the Linas-Marcoussis Agreement and calls for a stronger commitment from the EU and other international actors in the peace process;
3. Calls on the ministers from the rebel forces to take up their seats again in the government in order to work towards appeasement and national reconciliation in the spirit of the Linas-Marcoussis Agreement;
4. Condemns the human rights violations that have occurred, and calls for an international committee of inquiry to be set up to investigate the abuses committed by the government and the rebels;
5. Calls on the UN Security Council to consider the possibility of increasing the strength of the ECOWAS mission in Côte d'Ivoire, within the context of the African Union Peace Facility, and of transforming it into a UN peace-keeping force;
6. Calls for the ECOWAS peace-keeping force to be given an extended mandate and to be reinforced, and for the costs to be borne by the international community;
7. Calls for a rapid start to the programme of disarmament, demobilisation and reintegration of non-governmental armed forces; welcomes the fact that prisoners of war have started to be released;
8. Calls for the authority of the State (administration and public services) to be restored throughout the country and welcomes the reinstatement of prefects and sub-prefects in the western part of the country;
9. Welcomes the European Union's confirmation, via the Presidency of the Council, of its willingness to support the reunification and reconstruction of Côte d'Ivoire by all possible means;
10. Strongly condemns the concept of 'ivoirité', which serves to exclude part of the population from playing any democratic part in political activity in the country, and calls on President Gbagbo to urge his government and the Ivorian military to guarantee the protection of civilians, whatever their ethnic origin or nationality; deplores the recent arbitrary arrests and detention without trial of politicians mainly from political parties other than the President's ruling party;
11. Strongly condemns any attempt to make direct or indirect use of violence in the political process in Côte d'Ivoire, as well as any threats to law and order and stability in the country; strongly condemns, in this context, the attacks on UN personnel in Bouaké and Man on 24 and 25 October 2003;
12. Condemns the murder of the journalist Jean Hélène, who worked as correspondent for Radio France International in Côte d'Ivoire, and calls on the Ivorian authorities to continue their action to fully investigate this crime;

13. Regrets the lack of visibility and transparency with regard to the operations of the Monitoring Committee on the Linas-Marcoussis Agreement, and calls on France, which hosted the formal peace negotiations, to make, in due course, a provisional assessment of the implementation of the Agreement;
14. Urges the Commission to evaluate systematically the impact of EC actions targeted at the prevention of conflict in specific regions of tension;
15. Calls for conflict prevention and structural stability to be key objectives of EU development policy; considers that EU conflict-prevention policy must address the structural causes of conflicts linked to poverty, including unequal distribution of wealth, social injustice, human rights violations, the oppression of minorities and religious discrimination;
16. Instructs its President to forward this resolution to the Council, the Commission, the ACP-EU Council, the African Union secretariat and the Government of Côte d'Ivoire.