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***II
RECOMMENDATION FOR SECOND READING

on the Council common position 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))

Committee on the Environment, Public Health and Consumer Policy

Rapporteur: Rosemarie Müller

Symbols for procedures

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

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

Amendments to a legislative text

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

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PROCEDURAL PAGE

At the sitting of 23 October 2002 Parliament adopted its position at first reading on the proposal for 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 Agency for the Evaluation of Medicinal Products (COM(2001) 404 – 2001/0252(COD)).

At the sitting of 9 October 2003 the President of Parliament announced that the common position had been received and referred to the Committee on the Environment, Public Health and Consumer Policy (10949/2/2003 – C5-0463/2003).

The committee had appointed Rosemarie Müller rapporteur at its meeting of 13 September 2001.

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

At the latter meeting it adopted the draft legislative resolution by 55 votes to 1, with 0 abstentions.

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

The recommendation for second reading was tabled on 28 November 2003.

DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

on the Council common position 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),

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

– having regard to the amended proposal (COM(2002) 735)[3],

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

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

– having regard to the recommendation for second reading of the Committee on the Environment, Public Health and Consumer Policy (A5-0425/2003),

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

[1] Texts Adopted, 23.10.2002, P5_TA(2002)0504.
[2] OJ C 75 E, 26.3.2002, p. 189.
[3] Not yet published in OJ.

Justification

The amendment reinstates the call made by Parliament in Amendment 130 from the first reading, albeit it in a different part of the proposal.

Amendment 2
Recital 14 a (new)

(14a) In order to ensure maximum safety and efficacy with respect to the administration of medicinal products for children as well, in future all medicinal products which might be useful for children must be tested with regard to their administration to children respecting the criteria laid down in Directive 2001/20/EC and particular incentives should be created for research into special paediatric medicinal products. In addition, an incentive should be created to test medicinal products already long established for adult use for their subsequent use by children.

Justification

Identical with Amendment 6 from first reading. Neither the Council nor the Commission accepted this amendment. Since the first reading, the Commission has made progress with the work of preparing its legislative proposals, but the submission of these proposals has once again been postponed beyond the date announced to Parliament, a date which had already been put back several times. For that reason, Parliament should demonstrate its increasing impatience and table this amendment once again.

Amendment 3
Recital 14 b (new)

(14b) The Community is required, pursuant to Article 178 of the EC 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 ensure that only efficacious, safe and top quality medicinal products are exported, and create further incentives to carry out research into medicinal

products against widespread tropical diseases.

Justification

Identical with Amendment 7 from first reading.

Amendment 4
Recital 16 a (new)

(16a) The entire body of legislation relating to medicinal products involves matters relating to public health.

Justification

Identical with the first part of Amendment 173 from first reading.
This amendment emphasises Parliament's wish that, once the new College of Commissioners has taken up its duties in August 2004, and following a corresponding reorganisation, the Commission's Directorate-General for Health should be responsible for issues relating to the approval of medicinal products.

Amendment 5
Recital 19 a (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. The core tasks of the Agency should be entirely covered by the Community budget.

Justification

Partial reinstatement of Amendment 152 from first reading.
Core financing should be provided from the EU budget to ensure independence.

Amendment 6
Article 3, paragraph 3, point (b)

(b) the summary of the product characteristics is in all relevant respects	(b) the summary of the product characteristics is in all relevant respects

consistent with that of the medicinal product authorised by the Community; and	consistent with that of the medicinal product authorised by the Community ***except where those parts of the summary of characteristics would still be covered by patent law at the time the generic medicine was marketed***; and

Justification

Retabling of Amendment 21 from first reading as adopted on 23 October 2002.

Amendment 7
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.*** **** Four years after the entry into force of this Regulation.***	5. ***Four years after the entry into force of this Regulation, the list in Annex 3(a) shall be replaced by that in Annex 3(b).***

Justification

At first reading, Parliament supported the Commission proposal laying down a compulsory centralised authorisation procedure for all new active substances with a view to ensuring that patients throughout Europe enjoy the quickest possible access to new medicinal products. The Council rejected that proposal, agreeing instead to a compulsory centralised authorisation procedure for new active substances for only four indications. In your rapporteur's view, Parliament should restate its position from first reading in modified form. Accordingly, the list of indications in the annex should be extended and, in a few years' time, a clear mechanism laid down for the automatic extension of the centralised authorisation procedure. This proposal is most consistent with the close outcome of the vote at first reading in Parliament.

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	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.	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.***

Justification

Partial reinstatement of Amendment 23 from first reading.
Like all other European institutions, the Agency should be as transparent as possible in its decision-making. In the case of the Agency, transparency is particularly important to ensure that patients can trust in the high standards of the evaluation. It is also important to foster scientific discussion and progress by enabling independent scientists to scrutinise the data and arguments which formed the basis of authorisation decisions. This call is in line with Article 41 of the Charter of Fundamental Rights of the European Union and Regulation 1049/2001 on access to documents of the EU institutions.

Amendment 9
Article 6, paragraph 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 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.	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 confirmation that the clinical trials conducted with regard to the medicinal product comply with the ethical requirements of Directive 2001/20/EC. As a rule, this will exclude the recognition of clinical trials carried out in developing countries, unless the medicinal product concerned is primarily geared to the domestic market in that country.*** 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.

Justification

Partial retabling of Amendment 24 from first reading. Trials conducted outside the EU must also comply with the principles of clinical good practice and ethical requirements.

Amendment 10
Article 6, paragraph 3, subparagraph 1 a, 1 b and 1 c (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. That request must stipulate the additional length of time needed for the analysis of the scientific data in the file concerning the application for marketing authorisation to be carried out successfully.

The request must be drawn up at least 15 days before the end of the period laid down for analysis of the scientific data in the file concerning the application for marketing authorisation. It shall be submitted to the Management Board of the Agency, which shall take a decision on the request as soon as possible and before the end of the assessment period.

Justification

Retabling of Amendment 175 from first reading.

Amendment 11
Article 14, paragraph 7

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.***

Justification

Reinstatement of Amendment 43 from first reading in modified form.

Like all other European institutions, the Agency should be as transparent as possible in its decision-making. In the case of the Agency, transparency is particularly important to ensure that patients can trust in the high standards of the evaluation. It is also important to foster scientific discussion and progress by enabling independent scientists to scrutinise the data and arguments which formed the basis of authorisation decisions. This call is in line with Article 41 of the Charter of Fundamental Rights of the European Union and Regulation 1049/2001 on access to documents of the EU institutions.

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 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.	11. ***Without prejudice to the law on the protection of trade 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 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.

Justification

Although the Council's position, guaranteeing a longer period of protection for new active substances approved under the centralised procedure, offers a strong incentive to pharmaceuticals undertakings to step up their research activities, at first reading some 90% of Members supported the '8 + 2 + 1' compromise on this issue. Accordingly, your rapporteur is restating Parliament's position.

Amendment 13
Article 17

The applicant or the holder of a marketing authorisation shall be responsible for the accuracy of the documents and of the data submitted.	The applicant or the holder of a marketing authorisation shall be responsible for the accuracy of the documents and of the data submitted. ***Should the Agency find that the data submitted are incorrect, it shall forthwith require the applicant to carry out the necessary corrections and to complete them within a period of two months. Should that deadline not be respected, the Agency shall reject the application. Should the Agency find that data have been falsified, it shall immediately inform the law enforcement authorities in the Member States.***

Justification

Reinstatement of Amendment 49 from first reading. Most applications for authorisation contain correct data. However, a framework for action must be created to cope with instances where incorrect data are submitted.

Amendment 14
Article 20, paragraph 7

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

Justification

Reinstatement of Amendment 51 from first reading in modified form.

Like all other European institutions, the Agency should be as transparent as possible in its decision-making. In the case of the Agency, transparency is particularly important to ensure that patients can trust in the high standards of the evaluation. It is also important to foster scientific discussion and progress by enabling independent scientists to scrutinise the data and arguments which formed the basis of authorisation decisions. This call is in line with article 41 of the Charter of Fundamental Rights of the European Union and Regulation 1049/2001 on access to documents of the EU institutions.

Amendment 15

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 Human Medicinal Products 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. ***This information shall be made publicly accessible.*** Where appropriate, the Committee for Human Medicinal Products shall, in accordance with Article 5 of this Regulation, draw up opinions on the measures necessary. ***These opinions shall be made publicly accessible.***

Justification

Reinstatement of Amendment 53 from first reading in modified form.

Like all other European institutions, the Agency should be as transparent as possible in its decision-making. In the case of the Agency, transparency is particularly important to ensure that patients can trust in the high standards of the evaluation. It is also important to foster scientific discussion and progress by enabling independent scientists to scrutinise the data and arguments which formed the basis of authorisation decisions. This call is in line with Article 41 of the Charter of Fundamental Rights of the European Union and Regulation 1049/2001 on access to documents of the EU institutions.

Amendment 16
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 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.	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 ***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.

Justification

In its amended proposal, the Commission chose this wording with a view to improving Parliament's Amendment 59 from first reading. A single time-frame is thus laid down for the Community as a whole, even if the marketing of a medicinal product authorised under the centralised procedure may start at different times in individual Member States as a result of negotiations on prices and refunds. Unfortunately, the Council rejected that wording. However, it should be reinstated with a view to ensuring that the actual date on which a product is placed on the market triggers the regular, six-monthly submission of pharmacovigilance reports during the first two years.

Amendment 17
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.***

Justification

Reinstatement of Amendment 63 from first reading in modified form.

Like all other European institutions, the Agency should be as transparent as possible in its decision-making. In the case of the Agency, transparency is particularly important to ensure that patients can trust in the high standards of the evaluation. It is also important to foster scientific discussion and progress by enabling independent scientists to scrutinise the data and arguments which formed the basis of authorisation decisions. This call is in line with Article 41 of the Charter of Fundamental Rights of the European Union and Regulation 1049/2001 on access to documents of the EU institutions.

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	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.	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.***

Justification

Reinstatement of Amendment 68 from first reading in modified form.

Like all other European institutions, the Agency should be as transparent as possible in its decision-making. In the case of the Agency, transparency is particularly important to ensure that patients can trust in the high standards of the evaluation. It is also important to foster scientific discussion and progress by enabling independent scientists to scrutinise the data and arguments which formed the basis of authorisation decisions. This call is in line with Article 41 of the Charter of Fundamental Rights of the European Union and Regulation 1049/2001 on access to documents of the EU institutions. The mutual recognition procedure could become much more transparent than it is today.

Amendment 19
Article 39, paragraph 2, subparagraph 2

To this end, the marketing authorisation holder shall submit 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.

Justification

The purpose of minimising renewals is to reduce unnecessary bureaucracy. Re-formatting and re-submitting the entire dossier merely increases bureaucracy and adds nothing to patient safety. The additional costs imposed by this would be significant for low-turnover products or minor uses or minor species, and could lead to products being withdrawn.

Amendment 20
Article 45, paragraph 7

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

Justification

Reinstatement of Amendment 79 from first reading in modified form.

Like all other European institutions, the Agency should be as transparent as possible in its decision-making. In the case of the Agency, transparency is particularly important to ensure that patients can trust in the high standards of the evaluation. It is also important to foster scientific discussion and progress by enabling independent scientists to scrutinise the data and arguments which formed the basis of authorisation decisions. This call is in line with Article 41 of the Charter of Fundamental Rights of the European Union and Regulation 1049/2001 on access to documents of the EU institutions.

Amendment 21
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. ***This information shall be made publicly accessible.*** 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.***

Justification

Reinstatement of Amendment 80 from first reading in modified form.

Like all other European institutions, the Agency should be as transparent as possible in its decision-making. In the case of the Agency, transparency is particularly important to ensure that patients can trust in the high standards of the evaluation. It is also important to foster

scientific discussion and progress by enabling independent scientists to scrutinise the data and arguments which formed the basis of authorisation decisions. This call is in line with Article 41 of the Charter of Fundamental Rights of the European Union and Regulation 1049/2001 on access to documents of the EU institutions.

Amendment 22
Article 56, paragraph 1 a (new)

1a. The Committee for Herbal Medicinal Products shall take over the tasks of the Committee for Human Medicinal Products with regard to the evaluation of herbal medicinal products.

Justification

Reinstatement of Amendment 85 from first reading. This amendment emphasises once again that there should be a specialised scientific committee for herbal medicinal products.

Amendment 23
Article 56, paragraph 2

2. The committees referred to in paragraph 1(a) to (d) may each establish standing and temporary working parties. The committees referred to in paragraph 1(a) ***and*** (b) may establish scientific advisory groups in connection with the evaluation of specific types of medicinal products or treatments, to which the committee concerned may delegate certain tasks associated with drawing up the scientific opinions referred to in Articles 5 and 30.	2. The committees referred to in paragraph 1(a) to (d) may each establish standing and temporary working parties. The committees referred to in paragraph 1(a)***,*** (b) ***and (d)*** may establish scientific advisory groups in connection with the evaluation of specific types of medicinal products or treatments, to which the committee concerned may delegate certain tasks associated with drawing up the scientific opinions referred to in Articles 5 and 30.

Justification

New amendment to react to the new clause inserted by the Council as letter (d) which sets up a specialised scientific Committee for Herbal Medicinal Products. This new committee should have the same opportunity to establish scientific advisory groups as the existing committees.

Amendment 24
Article 57, paragraph 1, subparagraph 2, point (b)

(b) transmitting on request and making	(b) transmitting on request and making

available**,** assessment reports, summaries of product characteristics, labels and package leaflets or inserts for these medicinal products;	***publicly*** available**,** assessment reports, summaries of product characteristics, labels and package leaflets or inserts for these medicinal products; ***establishing that the labels and package leaflets or inserts are written in simple, clear language comprehensible to the public and that they are scientifically accurate, and periodically checking the effectiveness of the medicinal products in cooperation with undertakings, patients' associations and health-care professionals (doctors and pharmacists);***

Justification

Reinstatement of Amendment 87 from first reading in modified form. The list of tasks should state explicitly that the Agency is responsible for ensuring that patient leaflets are easily readable.

Amendment 25
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*** its maintenance ***independently from pharmaceutical companies; the database should enable a comparison to be made between various medicinal products in terms of efficacy, adverse reactions and contra-indications on the basis of the information already authorised for the package leaflet; the database shall include a section on medicinal products which may be administered to children;*** the information provided shall be worded in an appropriate and comprehensible manner;

Justification

Reinstatement of Amendment 91 from first reading.

Amendment 26
Article 57, paragraph 1, letter (p a) (new)

(pa) taking part in and implementing capacity-building measures in developing countries, particularly through initial and further training courses for employees of the authorisation and inspection authorities in such countries;

Justification

Identical with Amendment 94 from first reading.

To ensure the safety of medicinal products worldwide, the Agency should make a contribution towards the formation of independent structures in developing countries with particular reference to inspection, quality control, identification of counterfeit products and observance of ethical criteria in clinical trials. These encounters also promote scientific exchange worldwide and impart knowledge which may in turn be important for the evaluation of medicinal products in Europe.

Amendment 27
Article 57, paragraph 2

(2) The database provided for in paragraph 1(k) should include the summaries of product characteristics, the patient or user package leaflet and the information shown on the labelling. The database shall be developed in stages, priority being given to medicinal products authorised under this Regulation and those authorised under Chapter 4 of Title III of Directive 2001/83/EC and of Directive 2001/82/EC respectively. The database shall subsequently be extended to include any medicinal product placed on the market within the Community.	(2) The database provided for in paragraph 1(k) should include the summaries of product characteristics, the patient or user package leaflet and the information shown on the labelling ***and anonymised pharmacovigilance data***. The database shall be developed in stages, priority being given to medicinal products authorised under this Regulation and those authorised under Chapter 4 of Title III of Directive 2001/83/EC and of Directive 2001/82/EC respectively. The database shall subsequently be extended to include any medicinal product placed on the market within the Community.

Justification

Partial reinstatement of Amendments 95 and 157 from first reading. The Agency's remit should also cover the running of a publicly accessible database containing pharmacovigilance information. Transparency in the sphere of pharmacovigilance is particularly important in order to encourage members of the healthcare professions to notify side effects themselves. Doctors would then be able, for example, to check in the database for other, similar notifications and thereby establish whether they had discovered a previously unknown side effect. They would also be able to see that it makes a difference whether they themselves notify side effects or not. However, the reservations expressed by the Commission

and Council, namely that private data must be protected, should be taken seriously, The wording should therefore make clear that only anonymised pharmacovigilance data may be made available to the public.

Amendment 28
Article 57, paragraph 2, subparagraph 1 a (new)

Where appropriate, the database shall also include information about clinical trials either currently being carried out or already completed. The Commission shall issue guidelines on the data fields which may be made accessible to the public, taking as its basis the best practice employed by independent scientific organisations.

Justification

The Council rejected Parliament's Amendment 96 from first reading. In its amended proposal, the Commission notes that Directive 2001/20 on clinical trials already provides for a database on such trials. However, it is not accessible to the public under any circumstances, as Article 11 (1) of the directive in question makes clear. If research is to be both effective and transparent, an additional, public database on clinical trials should be set up. It should contain only details of the research methods employed, but not confidential or personal data such as that incorporated in the database set up under Directive 2001/20, to which the public quite rightly has no access. This amendment is intended to take account of the reservations expressed by the Commission and Council.

On ethical grounds, a public database is very important: on the one hand, ethically dubious duplications of trials can be prevented, and, on the other, patients who are seriously ill can obtain information about clinical trials involving the treatment of their diseases more quickly. they can discover whether they meet the criteria for inclusion in the trial and the name of the person or body they must contact. The database is thus a valuable adjunct to compassionate use programmes. For these reasons, since the mid-1990s US law has stipulated that all clinical trials concerning serious or potentially fatal diseases must be registered in a public database ((http://www.nlm.nih.gov/pubs/factsheets/clintrial.html).

The publicly accessible data fields should be administered in a manner consistent with the best practice employed by independent scientific organisations. One example of such good practice is provided by the organisation Controlled Trials (www.controlled-trials.com/isrctn/), which runs an Internet database in which researchers and firms can voluntarily register their ongoing or completed clinical trials. Given the success of the site, these data fields should not pose problems as regards the protection of personal data and commercial confidentiality. It is important, however, that only late Phase II or III trials should be included, so that the large number of participants makes the traceability of individuals' personal data impossible.

Amendment 29
Article 60

At the request of the Commission, the Agency shall, in respect of authorised medicinal products, collect any available information on methods that Member States' competent authorities use to determine the added therapeutic value that any new medicinal product provides.	***T***he Agency shall, in respect of authorised medicinal products, collect any available information on methods that Member States' competent authorities use to determine the added therapeutic value that any new medicinal product provides. ***To promote scientific exchange and avert potential conflict, the Agency shall draw up discussion papers which compare these approaches and formulate open questions.***

Justification

Reinstatement of Amendment 100 from first reading. The scientific discussion about the concept of 'therapeutic added value' is complex but very important for long-term developments of national budgets for medicinal expenses. The agency should therefore not only collect data but rather play an active role in facilitating the debate.

Amendment 30
Article 61, paragraph 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. ***With a view to the appointment of the members of*** the Committee for Medicinal Products for Human Use and the Committee for Medicinal Products for Veterinary Use***, each Member State shall propose, for each committee, five members and five alternates***. ***On the basis of those proposals, the Executive Director shall appoint one member and one alternate per Member State for a three-year term which may be renewed. When doing so, he shall take account of the objective of maintaining the interdisciplinary nature of each committee.***
The alternates shall represent and vote for the members in their absence and may act as rapporteurs in accordance with Article 62.	The alternates shall represent and vote for the members in their absence and may act as rapporteurs in accordance with Article 62.
Members and alternates shall be chosen for their role and experience in the evaluation of medicinal products for human and	Members and alternates shall be chosen for their role and experience in the evaluation of medicinal products for human and

veterinary use as appropriate and shall ***represent the competent*** national authorities.	veterinary use as appropriate and shall ***maintain appropriate relations with*** national authorities.

Justification

Members of the scientific committees should act as independent experts, i.e. competence should be a more important criterion than nationality. In addition, the committees should cover a broad range of areas of expertise so that they can properly carry out the interdisciplinary task of providing the best possible scientific assessments of medicinal products.

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.

Justification

Reinstatement of Amendment 105 from first reading. The role of the specialised Committee on Herbal Medicinal Products should be mentioned.

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 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	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, ***the Committee on Herbal Medicinal Products*** or the Committee for Medicinal Products for Veterinary Use, together with an

expertise.	indication of their qualifications and specific areas of expertise.

Justification

Reinstatement of Amendment 108 from first reading. The role of the specialised Committee on Herbal Medicinal Products should be mentioned.

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 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.***

Justification

Reinstatement of Amendment 115 from first reading and of the original Commission proposal.

Amendment 34
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***, two representatives of the European Parliament, two representatives of***

patients' organisations and two representatives of doctors' organisations.

They shall be appointed by the Council in consultation with the European Parliament on the basis of a list drawn up by the Commission and 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, in a manner consistent with these criteria, the broadest possible geographic spread within the Union.

Justification

At first reading Parliament voted for the management board model employed for the European Food Safety Authority (EFSA) (Amendment 116). The Council rejected that model and instead decided to remove Parliament's existing representatives on the Management Board. Your rapporteur takes the view that Parliament should modify its position at first reading and approve the principle that each Member State should be entitled to one representative on the Management Board. However, this arrangement is acceptable only if Parliament continues to be represented on the Board, along with representatives of various civil society organisations.

On the basis of the model outlined above, the Management Board would have 33 seats and would thus still be smaller than the Board appointed under the existing arrangement, which has 34 seats (two representatives from each of the 15 Member States, plus two from the Commission and two from Parliament).

Amendment 35
Article 67, paragraph 4

4. Activities relating to pharmacovigilance,	4. ***In order to ensure full independence,***

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

Justification

Retabling of Amendment 121 from first reading.

Amendment 36
Article 67, paragraph 5

5. The expenditure of the Agency shall include staff remuneration, administrative and infrastructure costs, and operating expenses; and expenses resulting from contracts entered into with third parties.	5. The expenditure of the Agency shall include the staff, administrative, infrastructure and operational expenses and expenses resulting from contracts entered into with third parties. ***In the event of additional tasks being transferred to the Agency, the Commission shall provide the Agency with the appropriate resources. In the event of a dispute, the Agency shall refer the matter to the budgetary authority.***

Justification

Retabling of Amendment 122 from first reading.

Amendment 37
Article 73, subparagraph 1 a (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.

Justification

Partial retabling of Amendment 131 from first reading in a different place to take account of the new Article 73.

Amendment 38
Article 78, paragraph 2

2. The committees referred to in Article 56(1) and any working parties and scientific advisory groups established in accordance with that Article shall in general matters establish contacts, on an advisory basis, with parties concerned with the use of medicinal products, in particular patient organisations and health-care professionals' associations. Rapporteurs appointed by these committees ***may***, on an advisory basis, ***establish*** contacts with representatives of patient organisations and health-care professionals' associations relevant to the indication of the medicinal product concerned.	2. The committees referred to in Article 56(1) and any working parties and scientific advisory groups established in accordance with that Article shall in general matters establish contacts, on an advisory basis, with parties concerned with the use of medicinal products, in particular patient organisations and health-care professionals' associations. Rapporteurs appointed by these committees ***shall***, on an advisory basis, ***establish*** contacts with representatives of patient organisations and health-care professionals' associations relevant to the indication of the medicinal product concerned.

Justification

Partial reinstatement of Amendment 102 from first reading

Amendment 39
Annex, paragraph 3

3. Medicinal products for human use ***containing*** a new active substance which, on the date of entry into force of this Regulation, was not authorised in the Community***, for which the therapeutic indication is the treatment of any of the following diseases***:	3. ***(a)*** Medicinal products for human use ***which fall into one of the following categories and which contain*** a new active substance which, on the date of entry into force of this Regulation, was not authorised in the Community:
– acquired immune deficiency syndrome,	***- General anti-infectives for systemic use (ATC Code J)***
– cancer,	***- Medicinal products for diseases of the alimentary tract and metabolic disorders (ATC Code A)***
– neurodegenerative disorder,	***- Antineoplastic and immunomodulating agents (ATC Code L)***
– diabetes.	***- Medicinal products for the treatment of the nervous system (ATC Code N)***
	- Orphan medicinal products pursuant to Regulation (EC) No 141/2000 of the

European Parliament and of the Council of 16 December 1999.

3.(b) Four years following the entry into force of this Regulation, the following provision shall apply:

Medicinal products intended for human use which contain a new active substance which was not authorised in the Community prior to the date of entry into force of this Regulation.

Justification

At first reading, Parliament supported the Commission proposal laying down a compulsory centralised authorisation procedure for all new active substances with a view to ensuring that patients throughout Europe enjoy the quickest possible access to new medicinal products. The Council rejected that proposal, agreeing instead to a compulsory centralised authorisation procedure for new active substances for only four indications. In your rapporteur's view, Parliament should modify its position at first reading, in order to signal to the Council that it is prepared to be flexible, on the one hand, and to establish the medium-term objective of compulsory authorisation procedures for all new active substances, on the other. At this stage, the list of indications should be extended and agreement reached on a clear mechanism for the automatic extension of the centralised authorisation procedure in a few years' time. A provision concerning that automatic extension should therefore be incorporated into Article 3.

Amendment 40
Annex, paragraph 3 a (new)

3a. Medicinal products intended for veterinary use, containing a new active substance which was not included in the composition of any medicinal product for veterinary use authorised in the Community prior to the date of entry into force of this Regulation.

Justification

This amendment reinstates the wording of the Commission proposal confirmed by Parliament at first reading.

The three most important arguments in favour of compulsory centralised authorisation procedures for all new active substances in medicinal products for veterinary use can be summarised as follows:

Firstly, on animal welfare grounds new medicinal products for veterinary use should be made

available throughout Europe as quickly as possible.

Secondly, disparities in access to medicinal products for veterinary use in the Member States should be avoided. The compulsory centralised authorisation procedure will ensure equality of access in all Member States. Manufacturers will not then be able to choose only attractive markets, and animal owners in Member States with less attractive markets will not be prevented from obtaining the medicinal products vital to the health of their animals.

Thirdly, the procedures for setting waiting periods following the use of medicinal products on animals kept for foodstuffs production should, if at all possible, be the same throughout Europe in order to protect consumers against the dangers posed by residues of such products. It would make sense for the authorisation procedures for medicinal products to be carried out at the same level as the procedures for fixing the waiting periods, i.e. at European level. Centralised procedures for the authorisation of medicinal products for veterinary use can therefore make an important contribution to food safety in Europe.

EXPLANATORY STATEMENT

Background

On 23 October 2002 Parliament adopted at first reading, by a large majority, with its amendments, the proposal for a regulation laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency. On 29 September 2003 the Council of Health Ministers adopted a common position.

What follows is a brief appraisal of the Council's common position in terms of its bearing on the issues of most importance to Parliament.

Protection

The protection period proposed by the Commission, i.e. 10 years plus one year for any new indication for medicinal products authorised under the compulsory procedure or the decentralised procedure, was reduced by Parliament to eight years. Parliament also stipulated that 10 years must elapse between the initial authorisation of a medicinal product and the placing of that product on the market. In connection with any new indication, one additional year of protection was to be granted under both the centralised and the decentralised procedure.

The Council's common position lays down differing periods for the centralised and decentralised procedures. Thus, a protection period of 10 years, plus one year for any new indication, is laid down for medicinal products authorised under the centralised procedure. In the case of medicinal products authorised under the decentralised procedure, however, the corresponding period is only eight years and the generic medicinal product may only be placed on the market once two years have elapsed.

Your rapporteur sees the Council's decisions on protection in connection with the centralised authorisation procedure as an attempt to create incentives which will encourage pharmaceuticals undertakings to push ahead with research designed to develop new, innovative medicinal products in the interests of patients. However, under the decentralised authorisation procedure no additional one-year period of protection is granted in connection with any new indication. An opportunity has thus been lost to encourage research into proven active substances which may offer scope for the development of new treatments.

For the reasons outlined above, your rapporteur takes the view that amendments should be tabled restating Parliament's position at first reading, which was adopted by a large majority.

The following table gives an overview of the decisions concerning protection:

	Compulsory centralised authorisation procedure	**Voluntary centralised authorisation procedure/decentralised authorisation procedure**
Original Commission proposal	10 years' protection + 1 year for any new indication; placing on the market possible after 10 or 11 years, as appropriate.	ditto

Parliament first reading	8 years' protection + 1 year for any new indication; placing on the market possible after 10 or 11 years as appropriate.	ditto
Council common position	10 years' protection + 1 year for any new indication; placing on the market possible after 10 or 11 years as appropriate.	8 years' protection; placing on the market possible after 10 years.

Centralised authorisation procedure - Annex

At first reading, Parliament endorsed the Commission proposal stipulating that, in future, in addition to medicinal products manufactured using biotechnological procedures, all new active substances should be subject to the compulsory centralised authorisation procedure. In contrast, the Council's common position stipulates that only medicinal products for human use which contain a new active substance for which the therapeutic indication is the treatment of acquired immune deficiency syndrome, cancer, neurodegenerative disorders or diabetes will be subject to that procedure. It stipulates, further, that four years after the entry into force of the regulation, and after consulting the Agency, the Commission may submit proposals to amend the annex, proposals which may be adopted by the Council acting by a qualified majority. As regards medicinal products for veterinary use, the Council has stipulated that the centralised authorisation procedure will be compulsory only if the medicinal product is intended for use as a performance enhancer in order to promote the growth of or to increase yields from treated animals.

Your rapporteur takes the view that the key issue for patients is the prompt availability throughout Europe of innovative, safe medicinal products. For that reason, she has tabled an amendment incorporating a new category of diseases (rare diseases within the meaning of Regulation (EC) No 141/2000) into the list in the annex which covers medicinal products for human use and expanding the range of indications to include the corresponding ATC codes. In the case of medicinal products for veterinary use, she has retabled the amendment adopted at first reading stipulating that all new active substances should be subject to the compulsory centralised authorisation procedure.

Management Board

Parliament amended the Commission proposal, stipulating that the Management Board should be structured along the lines of the similar body in the European Food Safety Authority (EFSA). The Council's common position departs substantially from that standpoint laying down that, alongside one representative of each Member State, the Board should include only four representatives of the Commission. Parliament cannot accept this proposal, and your rapporteur has therefore retabled the relevant amendment from first reading in modified form.

Scientific committees

In contrast to Parliament's standpoint, the Council's common position does not provide for the appointment of the members of the scientific committees by the Executive Director. Your rapporteur takes the view that the selection procedure proposed by Parliament is that best suited to guaranteeing the interdisciplinary nature of the committees, hence the decision to retable the amendment from first reading.

Database

Parliament attaches great importance to the setting-up of a database which makes available to the public key information concerning medicinal products which is not subject to the rules governing data protection. In keeping with that standpoint, your rapporteur has tabled an amendment reiterating in more succinct form the calls made at first reading.

Final assessment

Pleasingly, the Council has incorporated many of Parliament's first reading amendments into its common position: for example, it accepted the proposal concerning a fresh authorisation procedure after five years combined with a risk-benefit study and a three-year waiting period which must elapse before authorised medicinal products may be placed on the market. The common position also reflects further Parliament calls concerning the compilation of information on side effects and the transparency of the authorisation procedures. High standards have thus been set for the safety, efficacy and quality of medicinal products and progress has been made with the development of an effective pharmacovigilance system in Europe. Accordingly, only minor changes have been proposed to the provisions governing pharmacovigilance.

In overall terms, your rapporteur welcomes many aspects of the Council's common position, although the Council's decisions concerning the authorisation procedures, protection and the composition of the Agency's Management Board are unsatisfactory and require improvements. The amendments tabled make the requisite changes to the common position.

Your rapporteur takes the view that the next few months should see intensive discussions designed to ensure that the legislative process can be completed by the end of the current parliamentary term.