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***I
REPORT

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

By letter of 26 November 2001 the Commission submitted to Parliament, pursuant to Article 251(2), Article 152(4)(b) and Article 95 of the EC Treaty, the proposal for a regulation of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products (COM(2001) 404 - 2001/0252 (COD)).

At the sitting of 13 December 2001 the President of Parliament announced that she had referred this proposal to the Committee on the Environment, Public Health and Consumer Policy as the committee responsible and the Committee on Budgets, the Committee on Budgetary Control, the Committee on Legal Affairs and the Internal Market, the Committee on Industry, External Trade, Research and Energy and the Committee on Agriculture and Rural Development for their opinions (C5-0591/2001).

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

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

At the last meeting it adopted the draft legislative resolution by 37 to 16 with 1 abstention.

The following were present for the vote: Caroline Jackson, chairman; Mauro Nobilia, Alexander de Roo, vice-chairmen; Rosemarie Müller, rapporteur; Per-Arne Arvidsson, María del Pilar Ayuso González, Emmanouil Bakopoulos (for Mihail Papayannakis), Hans Blokland, Armonia Bordes (for Laura González Álvarez), John Bowis, Philip Bushill-Matthews (for Martin Callanan), Dorette Corbey, Chris Davies, Véronique De Keyser (for Anne Ferreira), Avril Doyle, Karl-Heinz Florenz, Pernille Frahm, Robert Goodwill, Françoise Grossetête, Marie Anne Isler Béguin, Piia-Noora Kauppi (for Cristina Gutiérrez Cortines), Christa Klaß, Bernd Lange, Peter Liese, Giorgio Lisi (for Raffaele Costa), Torben Lund, Jules Maaten, Minerva Melpomeni Malliori, Patricia McKenna, Eryl Margaret McNally (for Catherine Stihler), Jorge Moreira da Silva, Emilia Franziska Müller, Antonio Mussa (for Jim Fitzsimons), 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, Karin Scheele, Horst Schnellhardt, Inger Schörling, Jonas Sjöstedt, Renate Sommer (for Marialiese Flemming), María Sornosa Martínez, Ioannis Souladakis (for Kathleen Van Brempt), Charles Tannock (for Eija-Riitta Anneli Korhola), Nicole Thomas-Mauro, Astrid Thors, Antonios Trakatellis, Phillip Whitehead.

The opinions of the Committee on Budgets, the Committee on Budgetary Control, the Committee on Industry, External Trade, Research and Energy and the Committee on Agriculture and Rural Development are attached; the Committee on Legal Affairs and the Internal Market decided on 24 January 2002 not to deliver an opinion.

The report was tabled on 7 October 2002.

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

DRAFT LEGISLATIVE RESOLUTION

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

(Codecision procedure: first reading)

The European Parliament,

– having regard to the Commission proposal to the European Parliament and the Council (COM(2001) 404)[1],

– having regard to Article 251(2), Article 152(4)(b) and Article 95 of the EC Treaty, pursuant to which the Commission submitted the proposal to Parliament (C5-0591/2001),

– having regard to Rule 67 of its Rules of Procedure,

– having regard to the report of the Committee on the Environment, Public Health and Consumer Policy and the opinions of the Committee on Budgets, the Committee on Budgetary Control, the Committee on Industry, External Trade, Research and Energy and the Committee on Agriculture and Rural Development (A5-0330/2002),

1. Approves the Commission proposal as amended;

2. Asks to be consulted again should the Commission intend to amend the proposal substantially or replace it with another text;

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

Text proposed by the Commission	Amendments by Parliament
Amendment 1 Recital 8	
(8) With a view to harmonising the internal market for new medicinal products, this procedure should also be made compulsory for any medicinal product which is intended to be administered to humans or animals and contains an entirely new active substance, that is, one that has not yet been authorised in the Community.	(8) With a view to harmonising the internal market for new medicinal products, this procedure should also be made compulsory for any medicinal product which is intended to be administered to humans or animals and contains an entirely new active substance, that is, one that has not yet been authorised in the Community. ***Provision should be made in this context for a derogation for small and medium-sized enterprises so that***

[1] OJ C 75 E, 26.3.2002, p. 189.

	the cost of marketing the medicinal products developed by these enterprises can be kept within reasonable bounds.

Justification

SMEs need this derogation because they require greater flexibility. Centralised and decentralised procedures are both needed to meet public health requirements. This provision is required particularly in view of the cost of translations and the high level of charges involved in the centralised procedure. This would also take account of practical requirements if the enterprise intends to market in a certain number of Member States only. Without such a derogation, some enterprises might refrain from marketing new medicinal products entirely or be compelled to sell their new developments.

Amendment 2
Recital 9

(9) As regards medicinal products for human use, optional access to the centralised procedure should also be provided for in cases where use of a single procedure produces added value for the patient. This procedure should remain optional for medicinal products which, although not belonging to the abovementioned categories, are nevertheless a therapeutic innovation. It is also appropriate to allow access to this procedure for medicinal products which, although not innovative, may be of benefit to society or to patients if they are authorised from the outset at Community level, such as certain medicinal products which cannot be supplied without a medical prescription. This option may be extended to generic medicinal products authorised by the Community, provided that this in no way undermines either the harmonisation achieved when the reference medicinal products were evaluated or the results of that evaluation.	(9) As regards medicinal products for human use, optional access to the centralised procedure should also be provided for in cases where use of a single procedure produces added value for the patient. This procedure should remain optional for medicinal products which, although not belonging to the abovementioned categories, are nevertheless a therapeutic innovation. It is also appropriate to allow access to this procedure for medicinal products which, although not innovative, may be of benefit to society or to patients if they are authorised from the outset at Community level, such as ***herbal medicinal products and*** certain medicinal products which cannot be supplied without a medical prescription. This option may be extended to generic medicinal products authorised by the Community, provided that this in no way undermines either the harmonisation achieved when the reference medicinal products were evaluated or the results of that evaluation.

Justification

The use of herbal medicines is advantageous for society, and the access of all patients in the EU to such medicines must be facilitated. Voluntary central authorisation will improve market access for herbal medicines in the Member States.

Amendment 3
Recital 10

(10) In the field of veterinary medicinal products, administrative measures should be provided for in order to take account of the specific features of this field, particularly those due to the regional distribution of certain diseases. The field of application of the centralised procedure should also include medicinal products used within the framework of Community provisions regarding prophylactic measures for epizootic diseases.	(10) In the field of veterinary medicinal products, administrative measures should be provided for in order to take account of the specific features of this field, particularly those due to the regional distribution of certain diseases. ***The Commission should draw up, as a matter of urgency, a specific regulation aimed at resolving the problems concerning the availability of medicinal products for veterinary use and should in particular introduce a policy for 'orphan' medicinal products for veterinary use analogous to that established for human medicinal products by Regulation (EC) No 141/2000, implemented through Regulation (EC) No 847/2000. This regulation should create the necessary mechanisms to ensure that all needs are covered by at least two therapeutic alternatives in the European Union, with the objective of guaranteeing both competition and the diversity of available protection options and thereby preventing the emergence of resistance. The Commission should submit a proposal within six months after the adoption of the present Regulation.*** The field of application of the centralised procedure should also include medicinal products used within the framework of Community provisions regarding prophylactic measures for epizootic diseases.

Justification

Provision needs to be made for a Community policy in favour of 'orphan' veterinary medicines in order to put an end to the current scarcity as soon as possible, taking an approach similar to that followed for 'orphan' medicinal products for human use.

Amendment 4
Recital 11

(11) In the interest of public health, it is necessary that authorisation decisions under the centralised procedure be taken on the basis of the objective scientific criteria of quality, safety and efficacy of the medicinal product concerned, to the exclusion of economic and other considerations. However, Member States should be able exceptionally to prohibit the use on their territory of medicinal products for human use which infringe objectively defined concepts of public policy and public morality. Moreover, a veterinary medicinal product may not be authorised by the Community if its use would contravene the rules laid down by the Community within the framework of the *C*ommon *A*gricultural *P*olicy.	(11) In the interest of public health, it is necessary that authorisation decisions under the centralised procedure be taken on the basis of the objective scientific criteria of quality, safety and efficacy ***and added therapeutic value (as referred to by the Council in its conclusions of 29 June 2000),*** of the medicinal product concerned, to the exclusion of economic and other considerations. However, ***only those medicinal products may be authorised in respect of which the underlying clinical trials correspond to the ethical requirements of Directive 2001/20/EC of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use, and the*** Member States should be able exceptionally to prohibit the use on their territory of medicinal products for human use which infringe ***further*** objectively defined concepts of public policy and public morality. Moreover, a veterinary medicinal product may not be authorised by the Community if its use would contravene the rules laid down by the Community within the framework of the *c*ommon *a*gricultural *p*olicy.

Justification

It should not be possible to have clinical trials carried out in developing countries with respect to products primarily geared to Western markets.
Non comparative evaluation of new drugs has become unacceptable because of the large number of therapeutic alternatives for most diseases and the artificially high price of new drugs. The interest of public health requires comparison favouring the best choices for patients in all Member States.

Amendment 5
Recital 12

(12) Provision should be made whereby the quality, safety and efficacy criteria provided for by Directives 2001/83/EC and 2001/82/EC apply to medicinal products authorised by the Community.	(12) Provision should be made whereby the quality, safety and efficacy criteria provided for by Directives 2001/83/EC and 2001/82/EC apply to medicinal products authorised by the Community. ***The same criteria should also apply to medicinal products intended for paediatric use. It is essential for such medicinal products to have been evaluated in children before being authorised. Medicinal products which have already been authorised and are intended for children must be subject to subsequent evaluation.***

Justification

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

Amendment 6
Recital 12 a (new)

	(12 a) 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 the directive for clinical trials (2001/20/EC, 04.04.2001) 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

The metabolism of a child differs from that of an adult and often requires medicinal products in different dosages and with different means of administration. To date, very few medicinal products have been tested as to their suitability for administration to children because of the cost involved. It has, therefore, become customary for doctors to treat a large number of children using medicinal products which are actually authorised solely for adults ("off-label use"). In order to ensure maximum safety and efficacy with respect to children as well, medicinal products for their use therefore have to be tested especially. Nevertheless, the approach of the rapporteur goes too far. A lot of drugs (for example Viagra) are not intended for use in children. It would be absurd and -even more -unethical to carry out tests in children for such medicinal products. To restrict the clinical trials in children to the extent which is absolutely necessary, and to avoid misuse the criteria of the directive for clinical trials (2001/20/EC) must be respected.
The provision of medicinal products, especially for children, must be improved. Children have a different metabolism from adults and normally require a different dosage and method of administering medicines. However, very few medicinal products are tested for their suitability for children. The practice has thus developed that many children are treated with drugs which are actually only authorised for adults ('off-label' use). In order to ensure the safest and most efficacious use of medicinal products for children, there must be products specially authorised for children.

Amendment 7
Recital 12a (new)

(12a) 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

Self-explanatory.

Amendment 8
Recital 12a (new)

(12a) The 'orphan drugs' regulation provides good incentives for the development of medicinal products against rare diseases which occur in the EU since it provides for an exclusive marketing period for such medicinal products. It cannot, however, offer an incentive for developing tropical medicinal products since they can almost only be used outside the EU and it is therefore of no significance how long a firm may market such a product exclusively within the EU. The Commission should consider whether transferring the patent or data protection from a tropical medicinal product to another medicinal product marketed in the EU is an appropriate means of creating financial compensation for expenditure on research into the development of medicines to treat tropical diseases.

Justification

The market has clearly failed to research and develop medicinal products against diseases caused by poverty. Of a total of 1 450 new medicinal products which came on to the market between 1972 and 1997, only 13 were specially designed for the treatment of tropical diseases and designated essential drugs (Tropical Medicine and International Health, Volume 4, Issue 6, p. 412).

Special incentives should therefore be devised for the development of medicinal products against tropical diseases. The Commission has already pointed to a precedent for transferring data protection between various indications in the form of its '10 plus 1' proposal for the directive on medicinal products for human and veterinary use. Consideration should be given to whether transferability can also be introduced between different active substances.

In addition, there are other sources of support for tropical medicinal products such as the Global Fund for combating HIV/AIDS, tuberculosis and malaria, or INCO under the EU's research framework programme. Mr Khanbai's report (A5-0263/2001) contains further ideas. However, most publicly financed research programmes have the great drawback that, although money is allocated, there is no guarantee that medicinal products will be developed through to authorisation. The main failing in the case of tropical medicinal products is that the bridge between the discovery of the active substance and fully developed, clinically tested medicinal products is only rarely completed owing to the cost involved. Transferable data

protection might be beneficial in this context as the 'reward' is only forthcoming if a firm has submitted a preparation capable of obtaining authorisation.

Amendment 9
Recital 14 a (new)

(14 a) The legislation on medicinal products involves aspects related to public health, industrial policy and single market. A good balance of these aspects should be reached whenever legislation on medicinal products is prepared.

Justification

Parliament bears no responsibility for the internal organisation of the Commission. However, the need of a balanced approach should be incorporated in the regulation.

Amendment 10
Recital 16a (new)

(16a) The Agency should test a pilot project for prior certification of the test protocol for clinical trials. For this purpose, enterprises submit their test plans before the start of the trials and receive confirmation from the Agency that they are methodically sound and will not be rejected by the Agency when subsequently submitted in an application for authorisation.

Justification

This procedure should improve the methodical quality of clinical test protocols and minimise costs for all concerned. Such a system of prior certification of test plans is successfully used in material testing. The Helsinki Declaration requires that all test plans should be subject to commentary by a scientifically competent body before trials begin.

Amendment 11
Recital 19a (new)

Whereas the Agency's budget is composed of fees paid by the private sector and

contributions paid out of the Community budget to implement Community policies.

Justification

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

Amendment 12
Recital 19b (new)

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

Justification

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

Amendment 13
Recital 20

(20) The field of activity of the Scientific Committees should be enlarged and their operating methods and composition modernised. Scientific advice for future applicants seeking marketing authorisation should be provided more generally and in greater depth. Similarly, structures allowing the development of advice for companies should be put in place. The Committees should be able to delegate some of their evaluation duties to standing working parties open to experts from the scientific world appointed for this purpose, whilst retaining total responsibility for the scientific opinions issued. The appeal procedures should be amended to provide a better guarantee for	(20) The field of activity of the Scientific Committees should be enlarged and their operating methods and composition modernised. Scientific advice for future applicants seeking marketing authorisation should be provided more generally and in greater depth. Similarly, structures allowing ***for*** the development of advice for companies ***– especially small and medium-sized undertakings -*** should be put in place. The Committees should be able to delegate some of their evaluation duties to standing working parties open to experts from the scientific world appointed for this purpose, whilst retaining total responsibility for the scientific opinions issued. The appeal procedures should be

applicants' rights.	amended to provide a better guarantee for applicants' rights.

Justification

Compulsory central authorisation for new active substances and for medicinal products resulting from biotechnical processes poses major demands on SMUs. Accordingly, advice structures specifically geared to SMUs should be set up in the EMEA.

Amendment 14
Recital 24

(24) It is also necessary to take measures for the supervision of medicinal products authorised by the Community, and in particular for the intensive supervision of undesirable effects of these medicinal products within the framework of Community pharmacovigilance activities, so as to ensure the rapid withdrawal from the market of any medicinal product presenting ***an unacceptable level of*** risk under normal conditions of use.	(24) It is also necessary to take measures for the supervision of medicinal products authorised by the Community, and in particular for the intensive supervision of undesirable effects of these medicinal products within the framework of Community pharmacovigilance activities, so as to ensure the rapid withdrawal from the market of any medicinal product presenting ***a negative benefit/ risk balance*** under normal conditions of use.

Justification

Adverse drug reactions have no meaning per se. They have to be weighed up against the benefits provided by a given drug.

Amendment 15
Recital 30a (new)

	(30a) The transparency directive (89/105/EC) provides for rapid patient access to new medicinal products, fixing the maximum duration of negotiations on prices and reimbursement at 180 days. In practice, these rules are not always observed. The Commission should submit as soon as possible a report on the

	transposition, and proposals for the revision and implementation of this Directive.

Justification

The transparency directive (89/105/EC) provides for rapid patient access to new medicinal products, fixing the maximum duration of negotiations on prices and reimbursement at 180 days. In practice, these rules are not always observed. It is not acceptable, however, that patients do not gain access to new medicinal products until a very late stage because of protracted negotiations when the applicable EU law prescribes shorter deadlines. Moreover, all the authorities' efforts to speed up the processing of applications for authorisation would be undermined by later delays.

Amendment 16
Article 1, first paragraph

The purpose of this Regulation is to lay down Community procedures for the authorisation, supervision and pharmacovigilance of medicinal products for human and veterinary use, and to establish a European ***Agency for the Evaluation of*** Medicinal Products (hereinafter referred to as 'the Agency').	The purpose of this Regulation is to lay down Community procedures for the authorisation, supervision and pharmacovigilance of medicinal products for human and veterinary use, and to establish a European Medicinal Products ***Agency*** (hereinafter referred to as 'the Agency').

Justification

The name should be simplified and, at the same time, constitute a general description of its tasks, since the Agency carries out a number of tasks in addition to the assessment of medicinal products (pharmacovigilance, etc.).

Amendment 17
Article 1, paragraph 2a (new)

	Within 30 days following the granting of the marketing authorisation, and following consultation with the undertaking which holds that authorisation, the Commission and the Member States shall consider the scope for agreeing, on the basis of pharmacoeconomic principles, a European

price for the new medicinal products, a price which individual Member States may adjust in accordance with parameters reflecting the cost of living. Should no such agreement be reached, the Member States shall take whatever decisions are required. Once the procedure has been completed, the medicinal products concerned shall immediately be placed on the market in those Member States which have given their authorisation on the basis of the said agreement.

Justification

The EU has no powers to stipulate that national sickness insurance or social security schemes should cover particular medicinal products. However, in the case of medicinal products for which authorisation is granted by the centralised authorities it would be advisable for negotiations to be held between the Commission and the Member States on the basis of pharmacoeconomic principles, with a view to laying down the price of the medicinal products concerned, leaving the Member States the task of drawing up arrangements to govern the reimbursement of the cost of the various classes of medicinal products.

Under such a scheme, the laborious negotiations carried out at national level could be substantially speeded up, with the result that the new medicinal products would be placed on the market promptly, thereby offering major benefits to patients.

Amendment 18
Article 1 a (new)

Article 1 a

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

Justification

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

Amendment 19
Article 2, subparagraph 2

The holder of a marketing authorisation for the medicinal products covered by this Regulation should be established in the Community. The holder ***shall be responsible for placing those medicinal products on the market.***	The holder of a marketing authorisation for the medicinal products covered by this Regulation should be established in the Community. The holder ***is responsible for ensuring that the placing on the market of those medicinal products, whether by himself or by his/her representative, is done in compliance with the provisions of this Regulation.***

Justification

In certain cases the holder of a marketing authorisation delegates some or all of his activities to a third party, and certain tasks are indeed frequently carried out by local companies or affiliated agents (product withdrawal, the provision of supplies to local distributors, advertising, the provision of information to patients and prescribers, dealings with the Member States' central authorities, etc.).

Being able to delegate certain activities to a third party will enable the holder of the marketing authorisation to exercise his responsibility in greater accordance with the way in which companies are organised on a practical basis and will enable qualified individuals (as defined in the various EU texts) to make more effective use of their skills.

Amendment 20
Article 2, subparagraph 2 a (new)

	An evaluation of the positive effects of the product should be undertaken in relation to the risk of negative effects of the product on the user's health, on public health, or on the environment.

Justification

An environmental risk assessment should accompany all applications for marketing, to allow the evaluation of such risks in relation to the positive effects of the drug for the patient or treated animal.

Amendment 21
Article 3.3, letter (b)

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

Reference to parts of the summary of characteristics covered by patent would ensure that generics are not forced to include uses and formulations that are covered by a patent - which would either open generic companies to litigation or prevent generics from using the centralised procedure.

Amendment 22
Article 3.3, letter (c)

(c) the generic medicinal product is authorised under the same name in all the Member States where the application has been made.	(c) the generic medicinal product is authorised under the same name in all the Member States where the application has been made. ***For the purpose of this Regulation and Directives 2001/83/EC and 2001/82/EC all the linguistic versions of the INN are deemed to be the same.***

Justification

The Scientific Names (INN) of compounds can differ between countries (i.e. they are not written in Latin). The INN names are often used as the only name or part of the name of the generic product. Therefore, it is critically important that all linguistic versions of the INN are deemed the same otherwise the Centralised would be unworkable for generics.

Amendment 23
Article 5, paragraph 3

3. At the request of the Executive Director of the Agency or the Commission representative, the Committee for Human Medicinal Products shall also draw up an opinion on any scientific matter concerning the evaluation of medicinal products for	3. At the request of the Executive Director of the Agency or the Commission representative, the Committee for Human Medicinal Products shall also draw up an opinion on any scientific matter concerning the evaluation of medicinal products for

human use.	human use. ***The Committee shall also formulate an opinion whenever there is disagreement in the assessment of medicinal product through the mutual recognition procedure. Opinions shall be accessible on the Internet, in accordance with EU Regulation 1049/2001 on access to documents.***

Justification

The Agency has failed to ensure transparency of its decision towards the public and the health professionals. To be consistent with the Charter of Fundamental Rights of the European Union and its Article 41, and with Regulation 1049/2001 on access to EU documents. This new Regulation should provide for access of the public to diverging opinions among Committee members on condition that anonymity is observed.

Amendment 24
Article 6, paragraph 1, subparagraph 1

1. Each application for authorisation for a medicinal product for human use shall specifically include all the information and documents referred to in Articles 8(3), 10a and 11 of Directive 2001/83/EC, and Annex I thereto. The information and documents are to take account of the unique, Community nature of the authorisation requested, and particularly of the use of a single name for the medicinal product.	1. Each application for authorisation for a medicinal product for human use shall specifically include all the information and documents referred to in Articles 8(3), 10a and 11 of Directive 2001/83/EC, and Annex I thereto. ***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 of the European Parliament and of the Council on good clinical practice. As a rule, that will exclude the recognition of clinical trials carried out in the developing countries, unless the medicinal product concerned is primarily geared to the domestic market in that country.*** The information and documents are to take account of the Community nature of the authorisation requested, and ***except in justified cases*** of the use of a single name for the medicinal product.

Justification

It should not be possible to have clinical trials carried out in developing countries with respect to products primarily geared to Western markets

Amendment 25
Article 6, paragraph 1, subparagraph 2

The application shall be accompanied by the fee payable to the Agency for the examination of the application.	The application shall be accompanied by the fee payable to the Agency for the examination of the application. ***Where appropriate, the application may include in the expert report a comparison of the new medicinal product with previously authorised medicinal products for the same indications with regard to its efficacy, adverse reactions and simplicity of administration.***
	If the new medicinal product submitted for authorisation is intended for paediatric use, the application should state that it has been tested for suitability for children by being subjected to the necessary clinical trials to verify its quality, safety and efficacy.

Justification

In the case of a newly authorised medicinal product, a comparison with existing medicinal products, may be a useful part of an application. Accordingly, manufacturers should have the possibility to submit a review of the therapeutic progress in the documentation submitted with the application for authorisation.

Amendment 26
Article 6, paragraph 1a (new)

	1a. The application must show that the medicinal product has also been screened for its suitability for the treatment of

	tropical diseases, as well as the result of the screening.

Justification

This proposal is to ensure that new active substances are in future routinely tested for their efficacy on the most important tropical diseases. Hitherto, only a few producers carrying out research into medicinal products have automatically tested their new active substances destined for the European market for their effectiveness against tropical diseases. Computer-aided screening would make this possible at low cost.

Amendment 27
Article 7, letter (b)

(b) may ask for a State laboratory or a laboratory designated for this purpose to test the medicinal product for human use, its starting materials and, if need be, its intermediate products or other constituent materials in order to ensure that the control methods employed by the manufacturer and described in the application documents are satisfactory;	(b) may ask for a State laboratory or a laboratory designated for this purpose ***which has no interest in the granting of authorisation for the medicinal product*** to test the medicinal product for human use, its starting materials and, if need be, its intermediate products or other constituent materials in order to ensure that the control methods employed by the manufacturer and described in the application documents are satisfactory;

Justification

The guarantee of independence is essential. For that reason, the laboratory should not be linked in any way with the product being tested.

Amendment 28
Article 8, paragraph 2, subparagraph 1

2. Where it considers it necessary in order to complete its examination of an application, the Committee for Human Medicinal Products may require the applicant to submit to a specific inspection of the manufacturing site of the medicinal product concerned.	2. Where it considers it necessary in order to complete its examination of an application, the Committee for Human Medicinal Products may require the applicant to submit to a specific inspection of the manufacturing site of the medicinal product concerned.

Such inspections may be carried out unannounced.

Justification

Self-explanatory.

Amendment 29
Article 8, paragraph 2, subparagraph 2

The inspection shall be carried out within the time-limit laid down in the first subparagraph of Article 6(3), by inspectors from the Member State holding the appropriate qualifications, who ***may*** be accompanied by a rapporteur or an expert appointed by the Committee.	The inspection shall be carried out within the time-limit laid down in the first subparagraph of Article 6(3), by inspectors from the Member State holding the appropriate qualifications, who ***must*** be accompanied by a rapporteur or an expert appointed by the Committee.

Justification

Since the Committee for Human Medicinal Products may insist on carrying out a specific inspection of a site, an expert appointed by the Committee should be present at the inspection.

Amendment 30
Article 9, paragraph 3

3. Within ***30*** days of its adoption, the Agency shall send the final opinion of the Committee for Human Medicinal Products to the Commission, to the Member States and to the applicant, together with a report describing the assessment of the medicinal product by the Committee and stating the reasons for its conclusions.	3. Within ***15*** days of its adoption, the Agency shall send the final opinion of the Committee for Human Medicinal Products to the Commission, to the Member States and to the applicant, together with a report describing the assessment of the medicinal product by the Committee and stating the reasons for its conclusions.

Justification

This amendment aims at reducing the decision making timelines which have been heavily

criticised during the audit (cf. Evaluation of the Operation of Community Procedures for the Authorisation of Medicinal Products; section 5.1.14, Page 110). The European Commission has proposed a modest reduction in one part of the process by shortening the duration of the consultation periods of Member States from 28 days down to 15 days. However, even after this improvement the process could still take more than 75 days, and reduction of other administrative steps is necessary and possible.

Amendment 31
Article 9, paragraph 4, letter (ba) (new)

	(ba) Details of any other conditions or restrictions which should where necessary be imposed on the medicinal product concerned as a means of securing its safe and effective use, in particular mechanisms for controlling and monitoring its use and administration once authorised.

Justification

There are especially dangerous medicinal products on the market, whose use and administration should be thoroughly monitored for the sake of patients. This amendment provides necessary tools under Community law for improving the safety of medicines.

Amendment 32
Article 10, paragraph 1, subparagraph 1

1. Within ***30*** days of receipt of the opinion referred to in Article 5.2, the Commission shall prepare a draft of the decision to be taken in respect of the application.	1. Within ***15*** days of receipt of the opinion referred to in Article 5.2, the Commission shall prepare a draft of the decision to be taken in respect of the application.

Justification

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

Amendment 33
Article 10, paragraph 2, subparagraph 2 a (new)

The final Commission decision shall be taken within 15 days after the end of the procedures referred to in Articles 77.3 and 77.4.

Justification

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

Amendment 34
Article 10, paragraph 6a (new)

6a. In the case of innovative medicinal products which can be used to treat incurable diseases, the Agency shall lay down a streamlined procedure with a view to making such medicinal products available as quickly as possible.

Justification

Self-explanatory.

Amendment 35
Article 10 a (new)

Article 10 a

If a manufacturer withdraws an application for authorisation submitted to the Agency before a decision on authorisation is taken, the Agency shall

notify the competent authorities of the Member States.

Justification

A number of applications for authorisation are withdrawn by the manufacturers during the assessment period. There must be a guarantee that information acquired during an interrupted authorisation procedure at the EMEA is known to the competent authorities of the Member States.

Amendment 36
Article 11, paragraph 2 a (new)

2 a. Information about all refusals and the reasons for them shall be made publicly accessible.

Justification

Negative decisions and the reasons for them are important information that shall be made publicly accessible.

Amendment 37
Article 12, paragraph 2

2. Notification of marketing authorisation shall be published in the Official Journal of the European Communities, quoting in particular the date of authorisation ***and*** the registration number in the Community Register.	2. Notification of marketing authorisation shall be published in the Official Journal of the European Communities, quoting in particular the date of authorisation***,*** the registration number in the Community Register***, the INN (international non-proprietary name) of the active component of the medicinal product, the pharmaceutical form and the ACT code.***

Justification

At present, only the proprietary name, the name of the authorisation holder, the registration number in the Community Register and data relating to the decision and the notification are published, far too little in the light of EU information policy. The aim of the Official Journal

of the European Communities is to provide information, but in the case of authorisations granted for medicinal products European doctors, pharmacists, dentists and citizens receive too little information: the INN of the active component, the pharmaceutical form and the ATC code are not disclosed.

Amendment 38
Article 12, paragraph 3

3. The Agency shall publish the assessment report on the medicinal product for human use drawn up by the Committee for Human Medicinal Products and the reasons for its opinion in favour of granting authorisation, after deletion of any information of a commercially confidential nature.	3. The Agency shall ***immediately*** publish ***and make publicly accessible in a Register*** the assessment report on the medicinal product for human use drawn up by the Committee for Human Medicinal Products and the reasons for its opinion in favour of granting authorisation, after deletion of any information of a commercially confidential nature. ***The reasons for each indication covered by the application shall be stated separately.***

Justification

Industry should have no say in the scientific part of the final edition of assessment reports, and article 12 has to be technically consistent with Article 9.
In the event that one or more indications applied for are not authorised, this is important information for doctors and patients enabling them to make a better assessment of the risks of 'off-label' use.

Amendment 39
Article 12, paragraph 4, subparagraph 3

Upon request by the Agency, particularly in the context of pharmacovigilance, the marketing authorisation holder shall provide the Agency with all data relating to the volume of sales of ***or*** prescriptions for the medical product concerned at Community level.	Upon request by the Agency, particularly in the context of pharmacovigilance, the marketing authorisation holder shall provide the Agency with all data relating to the volume of sales of, prescriptions for ***and reactions to*** the medical product concerned at Community level.

Justification

For consumer safety, the information provided should also include reactions.

Amendment 40
Article 13, paragraph 2

2. Any authorisation which is not followed by the actual placing of the medicinal product for human use authorised on the Community market within ***two*** years of authorisation shall cease to be valid.	2. Any authorisation which is not followed by the actual placing of the medicinal product for human use authorised on the Community market within ***three*** years of authorisation shall cease to be valid.

Justification

It would appear that a two-year period is not sufficient for the system to operate properly, particularly on account of the different arrangements in force in the various Member States for allowing medicinal products to enter the market.

Amendment 41
Article 13, paragraph 2a (new)

	2 a. Under exceptional circumstances and on public-health grounds the competent authority may grant a derogation from the provision laid down in the preceding paragraph. Such a derogation must be duly justified.

Justification

Self-explanatory.

Amendment 42
Article 13, paragraph 3a (new)

	In the first five years after being placed on the market, the package leaflet of every medicinal product must bear the phrase: 'Newly authorised medicinal product. Please notify any adverse reactions'.

Justification

Particularly in the case of new medicinal products, patients should be encouraged to notify

any adverse reactions so that the scale of any problems arising in practice may be rapidly investigated.

Amendment 43
Article 13, paragraph 4

4. Following consultation with the applicant, an authorisation may be granted subject to certain specific obligations, to be reviewed annually by the Agency. By way of derogation from paragraph 1, the authorisation shall be valid for one year, on a renewable basis.	4. 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 together with deadlines and date of fulfilment, shall be made publicly accessible in a Register, in accordance with EU Regulation 1049/2001 on access to documents***. By way of derogation from paragraph 1, the authorisation shall be valid for one year, on a renewable basis.

Justification

Accountability of all interested parties must be ensured yet industry often fails to provide post marketing studies that were requested. The specific obligations mentioned fall within the definition of Public document in Regulation 1049/2001 on access to EU documents.

Amendment 44
Article 13, paragraph 5

5. In exceptional circumstances, ***when one of the grounds referred to in Annex I to Directive 2001/83/EC applies to an application***, and following consultation with the applicant, authorisation may be granted only under specific conditions. Continuation of the authorisation shall be linked to the annual reassessment of these conditions.	5. In exceptional circumstances, and following consultation with the applicant, authorisation may be granted ***subject to the obligation to introduce specific procedures for assessing product safety, for notifying the relevant authorities of any incident and for taking any necessary action immediately.***
	Such authorisation may be granted only for objective, verifiable reasons and must be based on one of the grounds listed in Annex I to Directive 2001/83/EC.

Justification

The purpose of this amendment is to define more clearly the risk-management plan and the criteria for granting this kind of special authorisation.

Amendment 45
Article 13, paragraph 6, subparagraph 2a and 2b (new)

On the basis of a duly reasoned request the Committee for Human Medicinal Products may call for the duration of the scientific and clinical trials to be extended. That request must stipulate the additional length of time needed for the scientific and clinical trials to be carried out successfully.

The request must be drawn up at least 15 days before the end of the period of scientific and clinical trial. It shall be submitted to the board of the Agency, which shall take a decision on the request as soon as possible and before the end of the trial period. The Agency shall notify the applicant as soon as possible of the request for an extension and of the action taken on that request by the board of the Agency.

Justification

Under the accelerated procedure there must be a minimum duration for scientific and clinical trial so as to ensure that a medicinal product is safe and that patients are not put at risk. Furthermore, it must be possible for the duration of the trials to be extended where analysis of the product concerned proves to be complex.

Amendment 46
Article 13, paragraph 8

8. Medicinal products for human use which have been authorized in accordance with the provisions of this Regulation shall benefit from the ***ten-year*** period of protection referred to in Article 10(1) of Directive 2001/83/EC.	8. Medicinal products for human use which have been authorized in accordance with the provisions of this Regulation shall benefit from the period of protection referred to in Article 10(1) of Directive 2001/83/EC.

Justification

Technical amendment in order to maintain consistency between the Regulation and the Directives. A similar provision is not needed for veterinary products since article 35 already refers to Directive 2001/82/EC without mentioning any period length.

Amendment 47
Article 13a (new)

The Commission shall carry out an in-depth study of the actual application in practical terms of the directive on transparency (EC 1989/105) in all the EU Member States and in the applicant countries. Depending on the results obtained, Parliament shall reserve the right to ask the Commission to reconsider the principles of that directive and, if necessary, to consider re-opening it.

Justification

Under the directive on transparency (EC 1989/105) the Member States are required to initiate price/reimbursement procedures within 180 days of the date of a marketing authorisation – which never occurs in the case of certain Member States, some of which take an average of two years to grant a reimbursement. There are even cases in which it has taken four years for a product to be placed on the market.

The Transparency Committee which was set up to monitor the implementation of the directive has never succeeded in genuinely shortening the relevant time periods in the case of certain Member States, whilst the Commission itself has on a number of occasions expressed the wish to have the bases and the principles of the directive reconsidered.

The main problem is, naturally enough, the de facto inequality of patients in the EU as regards access to treatment, since a given medicinal product may not be placed on certain markets on account of the slowness of the administrative processes in certain Member States, even though it is fully authorised within the European Union.

Infringement procedures are rare, since companies whose products are affected fear retaliation within their Member State in respect of their other products if they bring an action before the Commission.

Amendment 48
Article 15, paragraph 1

1. After an authorisation has been issued in accordance with this Regulation, the holder of the marketing authorisation for a medicinal product for human use shall, in respect of the methods of manufacture and control provided for in points (d) and (h) of Article 8(3) of Directive 2001/83/EC, take account of technical and scientific progress and make any amendments that may be required to enable the medicinal products to be manufactured and checked by means of generally accepted scientific methods. He/she shall apply for approval for these amendments in accordance with this Regulation.	1. After an authorisation has been issued in accordance with this Regulation, the holder of the marketing authorisation for a medicinal product for human use shall, in respect of the methods of manufacture and control provided for in points (d) and (h) of Article 8(3) of Directive 2001/83/EC, take account of technical and scientific progress and make any amendments that may be required to enable the medicinal products to be manufactured and checked by means of generally accepted scientific methods ***and with due regard to Community law***. He/she shall apply for approval for these amendments in accordance with this Regulation.

Justification

Self-explanatory.

Amendment 49
Article 15a (new)

	The applicant and/or holder of the marketing authorisation shall be responsible for the accuracy of the documents and data submitted. Should the Agency find that the data submitted is incorrect, it shall require the applicant to carry out the necessary corrections forthwith 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 has been falsified, it shall immediately inform the law enforcement authorities in the Member States.

Justification

Most applications for authorisation contain correct data. A framework for action must be created to cope with any instances where incorrect data is submitted.

Amendment 50
Article 18, paragraph 4a (new)

	4a. When it does so the Member State shall also ensure that health professionals are rapidly informed of the action and its reasons. The network provided by the professional associations should be fully used to this purpose. The Member States should inform the Commission and the Agency of the procedures put in place to this purpose.

Justification

The Regulation and Directive 2001/83/EEC put emphasis on the communication of information from the healthcare professional to the marketing authorisation and subsequently to Competent Authorities. It is equally important that the results of these reports are communicated back. Experience has shown that health care professionals such as doctors and pharmacists who are in direct contact with the patients about medicines, are not rapidly informed about decisions taken by Competent Authorities after pharmacovigilance evaluation. This procedure is detrimental to the efficiency of the pharmacovigilance system, therefore it is essential that authorities guarantee timely feedback to health professionals.

Amendment 51
Article 18, paragraph 6

6. The Agency shall, ***upon request, inform any person concerned of the final decision***.	6. The Agency shall ***make the decision publicly accessible, immediately after it has been taken, in an ad hoc Register in accordance with EU regulation 1049/2001 on access to documents***.

Justification

It is essential that the Agency provides online information to the public and professionals whenever emergency measures are taken and vital interests of the population are at stake.

Amendment 52
Article 19, subparagraph 1a (new)

In order to ensure that the competent authorities are fully independent, at least the activities relating to pharmocovigilance, the operation of communications networks and market surveillance should receive public funding commensurate with the tasks conferred upon those authorities.

Justification

The monitoring activities conferred upon the competent authorities will increase in volume on account of the new tasks with which those authorities have been entrusted. In order to ensure that those tasks are performed successfully, the public funding which is essential to the smooth running of the system should be made available as of now.

Amendment 53
Article 20, subparagraph 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 about suspected adverse reactions to medicinal products for human use which have been authorised by the Community in accordance with this Regulation. If necessary, the Committee for Human Medicinal Products may, in accordance with Article 5 of this Regulation, formulate 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 about 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 through an ad hoc Register in accordance with EU regulation 1049/2001 on access to documents***. If necessary, the Committee for Human Medicinal Products may, in accordance with Article 5 of this Regulation, formulate opinions on the measures necessary. ***These opinions and measures shall be made***

publicly accessible.

Justification

The Agency should stop its paternalistic communication policy when it comes to adverse drug reactions, be they suspected or confirmed. Instead, the Agency should strive to ensure collaboration of all interested parties. It should encourage the public and professionals to notify adverse events, and keep them informed on a routine and user-friendly basis.

Amendment 54
Article 20, subparagraph 3

The holder of the marketing authorisation and the competent authorities of the Member States shall ensure that all relevant information about suspected adverse reactions to the medicinal products authorised under this Regulation are brought to the attention of the Agency in accordance with the provisions of this Regulation.	The holder of the marketing authorisation and the competent authorities of the Member States shall ensure that all relevant information about suspected adverse reactions to the medicinal products authorised under this Regulation are brought to the attention of the Agency in accordance with the provisions of this Regulation. ***Patients shall be encouraged to communicate any adverse reaction to their health professionals or directly to the holder of the marketing authorisation.***

Justification

European legislation requires that healthcare professionals notify adverse reactions to the authorities. The advantage of that system is that medically uniform terminology is used and data are easily comparable. However, patients should be encouraged to communicate any adverse reaction to their health professionals or to the marketing authorisation holder.

Amendment 55
Article 21a (new)

The holder of the marketing authorisation shall ensure that the competent authorities are the first to be informed of an imminent suspension of sales and the withdrawal

	from the market of a medicinal product, followed by the public or shareholders.

Justification

This clarification is necessary as the authorities were informed far too late in the Lipobay case.

Amendment 56
Article 22, paragraph 1, subparagraph 1

1. The holder of an authorisation to place a medicinal product for human use on the market shall ensure that all suspected serious adverse reactions occurring within the Community to a medicinal product authorised in accordance with the provisions of this Regulation which are brought to his/her attention by a health-care professional, are recorded and reported immediately to the Member States in whose territory the incident occurred, and ***in no case*** later than 15 days following the receipt of the information.	1. The holder of an authorisation to place a medicinal product for human use on the market shall ensure that all suspected serious adverse reactions occurring within the Community to a medicinal product authorised in accordance with the provisions of this Regulation which are brought to his/her attention by a health-care professional ***or by a patient*** are recorded and reported immediately to the Member States in whose territory the incident occurred, and ***under no circumstances*** later than 15 days following the receipt of the information.

Justification

The holder of an authorisation to place a medicinal product on the market must be required to keep detailed records of any adverse reactions notified to him by patients.

Amendment 57
Article 22, paragraph 2, subparagraph 2

Save in exceptional circumstances, these reactions shall be communicated in the form of a report transmitted electronically and in accordance with the guidelines referred to in Article 24.	***T***hese reactions shall be communicated in the form of a report transmitted electronically and in accordance with the guidelines referred to in Article 24.

Justification

The processing and, where appropriate, dissemination of this information on reactions is greatly accelerated in electronic form, which is important in emergencies.

Amendment 58
Article 22, paragraph 3, subparagraph 1

3. The holder of the authorisation to place the medicinal product for human use on the market shall be required to maintain detailed records of all suspected adverse reactions within or outside the Community which are reported to him/her by a health-care professional.	3. The holder of the authorisation to place the medicinal product for human use on the market shall be required to maintain detailed records of all suspected adverse reactions within or outside the Community which are reported to him/her by a health-care professional ***or by a patient***.

Justification

The holder of an authorisation to place a medicinal product on the market must be required to keep detailed records of any adverse reactions notified to him by patients.

Amendment 59
Article 22, paragraph 3, subparagraph 2

Unless other requirements have been laid down as a condition of the granting of the marketing authorisation by the Community, these records shall be submitted, in the form of a updated periodical report on safety, 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 records shall be submitted at three-yearly intervals, or immediately upon request.	Unless other requirements have been laid down as a condition of the granting of the marketing authorisation by the Community, these records shall be submitted, in the form of a updated periodical report on safety, 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 market*** and once a year for the following two years. Thereafter, the records shall be submitted at three-yearly intervals, or immediately upon request.

Justification

This addition is for clarification. The initial placing on the market is the appropriate point of

reference since it is only at that point that pharmacovigilance actually begins. If the issuing of the authorisation were to be regarded as the reference point, it might be that owing to the protracted negotiations over price and reimbursement, a firm would not have to deliver the first periodic report until some three years after the product has been placed on the market, which is not desirable.

Amendment 60
Article 22, paragraph 3

3. The holder of the authorisation to place the medicinal product for human use on the market shall be required to maintain detailed records of all suspected adverse reactions within or outside the Community which are reported to him/her by a health-care professional. Unless other requirements have been laid down as a condition of the granting of the marketing authorisation by the Community, these records shall be submitted, in the form of a updated periodical report on safety, 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 records shall be submitted at three-yearly intervals, or immediately upon request. These records shall be accompanied by a scientific evaluation.	3. The holder of the authorisation to place the medicinal product for human use on the market shall be required to maintain detailed records of all suspected adverse reactions within or outside the Community which are reported to him/her by a health-care professional. Unless other requirements have been laid down as a condition of the granting of the marketing authorisation by the Community, these records shall be submitted, in the form of a updated periodical report on safety, 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 records shall be submitted at three-yearly intervals, or immediately upon request. These records shall be accompanied by a scientific evaluation ***of the benefits and the risks of the medicinal product.***

Justification

Adverse drug reactions (suspected or confirmed) must be weighed up against proven benefits, otherwise the evaluation has no clinical relevance.

Amendment 61
Article 22, paragraph 3a (new)

	3a. The holder of a marketing authorisation shall not be authorised to communicate information concerning

pharmacovigilance issues to the general public without the consent of the Agency.

Justification

The purpose of this amendment is to allow communication between the relevant authorities and the holder of the marketing authorisation in the event of a problem.

Amendment 62
Article 24, paragraph 1

The Commission in consultation with the Agency, Member States, and interested parties, shall draw up guidance on the collection, verification and presentation of adverse reaction reports.	The Commission in consultation with the Agency, Member States, and interested parties, shall draw up guidance on the collection, verification and presentation of adverse reaction reports. ***Such guidance shall lay down rules of conduct for health-care professionals concerning the targeted dissemination of information about adverse reactions which have occurred in practice.***

Justification

Serious shortcomings have been observed in the dissemination by health-care professionals of information about adverse reactions. Accordingly, health-care professionals must be made aware of the problem so that, on the one hand, adverse reactions are recognised more systematically and reported to the competent authorities and, on the other, that patients are informed more accurately about any probable adverse reactions to medicinal products.

Amendment 63
Article 24, paragraph 3

The Agency, in consultation with the Member States and the Commission, shall set up a data-processing network for the rapid transmission of data between 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	The Agency, in consultation with the Member States and the Commission, shall set up a data-processing network for the rapid transmission of data between 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.	2001/83/EC. ***Furthermore, such data shall be held in public databases and made accessible, in an appropriate form and at no charge, to any interested parties.***

Justification

Warnings about faulty manufacture or serious adverse reactions should be made accessible to all interested parties.

Amendment 64
Article 24, subparagraph 3 a (new)

	For a period of two years following marketing authorisation, specific pharmacovigilance data shall be collected by means of increased surveillance by doctors of targeted small groups of patients. This data shall be collated and evaluated by the Agency.

Justification

This additionally proposed procedure will ensure that in the beginning there will be a systematic follow-up of new medicinal products by doctors. Doctors are the competent persons nearest to the patients. They know whether a reaction is due to an administered drug or not.

Amendment 65
Article 24a (new)

	Article 24a
	The Agency shall publish an annual report on the recorded reactions and point out further research requirements.

Justification

A report on reactions should be published each year to identify trends, to record undetermined effects for independent scientists and other interested parties in a clear way and to encourage research.

Amendment 66
Article 26 a (new)

The Agency and national public pharmacovigilance systems should also be organised and operate as an interactive pharmacovigilance system under which monitoring of the area in which adverse reactions appear is carried out on a continuous basis by specialists in clinical pharmocology working for universities and/or suitably equipped hospitals. These specialists shall take active steps to compile information concerning the onset of adverse reactions to the new medicinal products, interacting continuously with all the actors involved (undertakings, pharmacists, doctors, specialists) and with patients' associations. The operational interactive pharmacovigilance units shall be distributed on a rational basis throughout the area to be covered, linked by an IT network and coordinated by the national pharmacovigilance service, which in turn shall be linked to the Agency. The Agency shall coordinate the national pharmacovigilance systems, which shall operate in accordance with criteria of competence, transparency and objectivity, and shall compile a database to which access shall be granted to undertakings in connection with the products in respect of which they hold authorisations.

Justification

A system organised in this way would be able to play a very effective and timely role in preventing the spread of adverse reactions and would prove highly beneficial not only in the area of public health but also for the undertakings involved. Moreover, it would be possible to establish, under the aegis of national health authorities and the EMEA, a database containing information on adverse reactions to medicinal products following their placing on the market.

Amendment 67
Article 26 b (new)

During the first five years the holder of the marketing authorisation shall contribute,

	in the individual Member States, to the costs of the interactive public pharmacovigilance system as defined in the previous article. The level of the contribution in the individual EU Member States shall be determined on the basis of the net annual profits generated by the sale of the new medicinal product in question and shall then be laid down by the Commission. The pharmacovigilance systems in the individual Member States and at EMEA level shall operate in an independent, transparent manner.

Justification

A pharmacovigilance system managed by public bodies in a transparent and objective manner with a view to ensuring its effectiveness must be 'interactive', i.e. managed by specialists capable of fostering the continuous compilation of data in the area concerned and linked to all the actors in the pharmaceuticals sector (producers, those who sell medicinal products and those who prescribe medicinal products) and representatives of patients' associations. The resources funding such a system must be public, but in part also private, in accordance with the precautionary principle, given that the period immediately following the placement of a medicinal product on the market in fact represents a further, long-term test period, broader in scope than the clinical trials which precede the registration of the product in question.

In addition, a pharmacovigilance system works to the benefit of consumers and the industry itself, which can forestall in good time the onset and spread of dangerous toxic effects which invariably give rise to serious economic losses for the undertakings involved.

Amendment 68
Article 27, paragraph 3

3. At the request of the Executive Director of the Agency or the Commission representative, the Committee for Veterinary Medicinal Products shall also draw up an opinion on any scientific matter concerning the evaluation of medicinal products for veterinary use.	3. At the request of the Executive Director of the Agency or the Commission representative, the Committee for Veterinary Medicinal Products shall also draw up an opinion on any scientific matter concerning the evaluation of medicinal products for veterinary use. ***The Committee shall also formulate an opinion whenever there is disagreement in the assessment of a veterinary medicinal product through the mutual recognition procedure. Opinions shall be accessible on the Internet, in accordance with EU Regulation 1049/2001 on access to documents.***

Justification

The Agency has failed to ensure transparency of its decision towards the public and the health professionals. To be consistent with Regulation 1049/2001 on access to EU documents. This new Regulation should provide for access of the public to diverging opinions among Committee members on condition that anonymity is observed.

Amendment 69
Article 30, paragraph 2, subparagraph 1

Where it considers it necessary in order to complete its examination of the application, the Committee for Veterinary Medicinal Products may require the applicant to submit to a specific inspection of the manufacturing site of the veterinary medicinal product concerned.	Where it considers it necessary in order to complete its examination of the application, the Committee for Veterinary Medicinal Products may require the applicant to submit to a specific inspection of the manufacturing site of the veterinary medicinal product concerned. ***Such inspections may be made unannounced.***

Justification

Self-explanatory.

Amendment 70
Article 30, paragraph 2, subparagraph 2

The inspection, which shall be completed within the time-limit referred to in the first subparagraph of Article 28(3), shall be undertaken by inspectors from the Member State who possess the appropriate qualifications and who ***may*** be accompanied by a rapporteur or expert appointed by the Committee.	The inspection, which shall be completed within the time-limit referred to in the first subparagraph of Article 28(3), shall be undertaken by inspectors from the Member State who possess the appropriate qualifications and who ***must*** be accompanied by a rapporteur or expert appointed by the Committee.

Justification

Since the Committee for Human Medicinal Products may insist on carrying out a specific inspection of a site, an expert appointed by the Committee should be present at the inspection.

Amendment 71
Article 31, paragraph 2, subparagraph 2

Within 60 days of receipt of the grounds for appeal, the Committee for Veterinary Medicinal Products shall re-examine its opinion in accordance with the conditions laid down in the second subparagraph of Article 55(1). The conclusions reached on the appeal shall be annexed to the final opinion.	Within 60 days of receipt of the grounds for appeal, the Committee for Veterinary Medicinal Products shall re-examine its opinion in accordance with the conditions laid down in the second subparagraph of Article 55(1). ***If the grounds for appeal include new data, not available at the time of the original submission, then this period will be extended by 30 days.*** The conclusions reached on the appeal shall be annexed to the final opinion.

Justification

If new data has become available since the submission, and could help solve the issue, then there should be an appeal procedure with extra time granted to assess the new data. See also Article 55(1).

Amendment 72
Article 31, paragraph 3

3. Within ***30*** days of its adoption, the Agency shall forward the final opinion of the Committee for Veterinary Medicinal Products to the Commission, to the Member States and to the applicant, together with a report describing the assessment of the veterinary medicinal product by the Committee and stating the reasons for its conclusions.	3. Within ***15*** days of its adoption, the Agency shall forward the final opinion of the Committee for Veterinary Medicinal Products to the Commission, to the Member States and to the applicant, together with a report describing the assessment of the veterinary medicinal product by the Committee and stating the reasons for its conclusions.

Justification

The length of the administrative stages should be shortened.

Amendment 73
Article 31, paragraph 4, letter (ca) (new)

(ca) Details of any other conditions or restrictions which should where necessary be imposed on the veterinary medicinal product concerned as a means of securing its safe and effective use, in particular mechanisms for controlling and monitoring its use and administration once authorised.

Justification

There are especially dangerous medicinal products on the market, whose use and administration should be thoroughly monitored for the sake of human and animal health patients. This amendment provides necessary tools under Community law for improving the safety of medicines.

Amendment 74
Article 32 a (new)

Article 32 a

If a manufacturer withdraws an application for authorisation submitted to the Agency before a decision on authorisation is taken, the Agency shall notify the competent authorities of the Member States.

Justification

A number of applications for authorisation are withdrawn by the manufacturers during the assessment period. Information acquired during an interrupted authorisation procedure at the EMEA should be shared with the competent authorities of the Member States.

Amendment 75
Article 33, paragraph 2 a (new)

2 a. Information about all refusals and the reasons for them shall be made publicly accessible.

Justification

Negative decisions and the reasons for them are important information that shall be made publicly accessible.

Amendment 76
Article 34, paragraph 3

3. The Agency shall publish the assessment report on the veterinary medicinal product for drawn up by the Committee for Veterinary Medicinal Products and the reasons for its opinion in favour of granting authorisation, after deletion of any information of a commercially confidential nature.	3. The Agency shall publish ***and make publicly accessible in a Register*** the assessment report on the veterinary medicinal product drawn up by the Committee for Veterinary Medicinal Products and the reasons for its opinion in favour of granting authorisation, after deletion of any information of a commercially confidential nature.

Justification

Industry should have no say in the scientific part of the final edition of assessment reports, and article 12 has to be technically consistent with Article 9.

Amendment 77
Article 35, paragraph 2

Any authorisation which is not followed by the actual placing of the medicinal product for human use authorised on the Community market within ***two*** years of authorisation shall cease to be valid.	Any authorisation which is not followed by the actual placing of the medicinal product for human use authorised on the Community market within ***three*** years of authorisation shall cease to be valid.

Justification

A two-year period is not sufficient to allow for the various factors which may cause actual placing on the market to be deferred. For example, a product intended to treat a sporadic disease will not be sold until that disease breaks out. Furthermore, small and medium-sized businesses may need to find a partner for the purpose of marketing a new product.

Amendment 78
Article 35, paragraph 2a (new)

	2a. Under exceptional circumstances and on public-health grounds the competent authority may grant a derogation from the provisions laid down in the preceding paragraph. Such a derogation must be duly justified.

Justification

A derogation on public-health grounds (risk of epidemic, etc.) may usefully be granted in respect of a given medicinal product.

Amendment 79
Article 40, paragraph 6

6. The Agency shall***, upon request, inform any person concerned of the final decision***.	6. The Agency shall ***make the decision publicly accessible, immediately after it has been taken, in an ad hoc Register in accordance with EU regulation 1049/2001 on access to documents***.

Justification

It is essential that the Agency provides online information to the public and professionals.

Amendment 80
Article 41, paragraph 1a (new)

	1a. In order to ensure that the competent authorities are fully independent, at least the activities relating to pharmocovigilance, the operation of communications networks and market surveillance should receive public funding commensurate with the tasks conferred upon those authorities.

Justification

The monitoring activities conferred upon the competent authorities will increase in volume on account of the new tasks with which those authorities have been entrusted. In order to ensure

that those tasks are performed successfully, the public funding which is essential to the smooth running of the system should be made available as of now.

Amendment 81
Article 42, subparagraph 1

The Agency, acting in close cooperation with the national pharmacovigilance systems established in accordance with Article 102 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. If necessary, the Committee for Veterinary Medicinal Products may, in accordance with Article 5 of this Regulation, formulate opinions on the measures necessary.	The Agency, acting in close cooperation with the national pharmacovigilance systems established in accordance with Article 102 of Directive 2001/82/EC, shall receive all relevant information about suspected adverse reactions to veterinary medicinal products for which have been authorised by the Community in accordance with this Regulation ***This information shall be made publicly accessible through an ad hoc Register in accordance with EU regulation 1049/2001 on access to documents***. If necessary, the Committee for Veterinary Medicinal may, in accordance with Article 5 of this Regulation, formulate opinions on the measures necessary. ***These opinions and measures shall be made publicly accessible.***

Justification

The Agency should stop its paternalistic communication policy when it comes to adverse drug reactions, be they suspected or confirmed. Instead, the Agency should strive to ensure collaboration of all interested parties. It should encourage the public and professionals to notify adverse events, and keep them informed on a routine and user-friendly basis.

Amendment 82
Article 43, letter (d)

(d) providing the competent authorities with any other information relevant to the evaluation of the risks and benefits of a veterinary medicinal product, particularly information concerning post-marketing safety studies.	(d) providing the competent authorities with any other information relevant to the evaluation of the risks and benefits of a veterinary medicinal product, particularly information concerning post-marketing safety studies***, with particular reference to the presence of any residues of medicinal products in animal-based foodstuffs***.

Justification

Self-explanatory.

Amendment 83
Article 50, paragraph 1, letter (da) (new)

	(da) the Committee for Human Medicinal Products shall consult paediatric specialists in connection with all problems relating to the assessment of medicinal products for use by children.

Justification

Self-explanatory.

Amendment 84
Article 50, paragraph 2

2. The Committees referred to in points (a) to (d) of paragraph 1 may each establish working parties ***and expert groups. For this purpose they shall adopt, in accordance with their rules of procedure, precise arrangements for delegating certain tasks to these working parties and groups.***	2. The Committees referred to in points (a) to (d) of paragraph 1 may each establish ***standing and temporary*** working parties***.***
	The committees referred to paragraph 1(a) and (b) shall set up panels in order to secure the benefit, in connection with the evaluation of medicinal products, of expertise focused in particular on a specific type of medicinal product or treatment.
	The committees referred to paragraph 1(a) to (d) shall lay down in their rules of procedures the precise arrangements for consulting the panels and delegating certain tasks to them. They shall also determine the arrangements for nominating members of the working parties and the panels on the basis of the lists of experts referred to in the second subparagraph of Article 55(2).

Justification

The Commission has not taken sufficient account of developments in new treatments, research into which calls for specific expertise. This consideration (which is of major significance to product safety) should therefore be taken into account when members of the working parties and the panels are selected.

Amendment 85
Article 50, paragraph 2 a (new)

2a. The Committee for herbal medicinal products takes over the tasks of the Committee for human medicinal products with regard to the evaluation of herbal medicinal products.

Justification

Self-explanatory.

Amendment 86
Article 50, paragraph 4 a (new)

4a. The opinion of all committees shall contain minority views if such have been expressed.

Justification

It is important that dissenting minority views are reflected in the opinion.

Amendment 87
Article 51, paragraph 1, letter (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) ***Making publicly available in an ad hoc Register in accordance with EU Regulation 1049/2001,*** 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, periodically checking the effectiveness of the medicinal products in cooperation with undertakings, patients' associations and health-care professionals (doctors and pharmacists);

Justification

Following the Charter of Fundamental Rights of the EU and EU Regulation 1049/2001 on public access to documents, the Agency has the obligation to set up online Registers of its public documents as of June 2002.

Amendment 88
Article 51, paragraph 1(d)

(d) assuring the dissemination of information on adverse reactions to medicinal products authorised in the Community, by means of a database permanently accessible to all Member States;	(d) assuring the dissemination of information on adverse reactions to medicinal products authorised in the Community, by means of a database permanently accessible to all Member States; ***health-care professionals, manufacturers and the general public shall have appropriate levels of access to that database, with business secrecy protection and of personal data being guaranteed***;

Justification

The authorities should have access to all data. Manufacturers should be entitled to access to data concerning their own products. Health-care professionals should have access to information expressed in expert terminology while patients require easily comprehensible information in layman's terms. Accordingly, access to the database should be graduated according to need.

Amendment 89
Article 51, paragraph 1, letter (d a) (new)

(a) Assisting the Commission and Members States in the rapid communication of information relevant to

	pharmacovigilance to the associations of health professionals;

Justification

The Regulation and Directive 2001/83/EEC put emphasis on the communication of information from the healthcare professional to the marketing authorisation and subsequently to Competent Authorities. It is equally important that the results of these reports are communicated back. Experience has shown that health care professionals such as doctors and pharmacists who are in direct contact with the patients about medicines, are not rapidly informed about decision taken by Competent Authorities after pharmacovigilance evaluation. This procedure is detrimental to the efficiency of the pharmacovigilance system, therefore it is essential that authorities guarantee timely feedback to health professionals.

Amendment 90
Article 51, paragraph 1, letter (g)

(g) coordinating the verification of compliance with the principles of good manufacturing practice, good laboratory practice and good clinical practice;	(g) coordinating the verification of compliance with the principles of good manufacturing practice, good laboratory practice, good clinical practice ***and the verification of compliance with pharmacovigilance obligations;***

Justification

This is intended to establish an explicit legal basis for pharmacovigilance inspections in order to reinforce compliance with requirements set out under pharmaceutical legislation.

Amendment 91
Article 51, paragraph 1, letter (j)

(j) creating a database on medicinal products, to be accessible to the general public, and ***giving technical assistance for its maintenance***;	(j) 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 as to their efficacy, reactions and contraindications 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

The database on medicinal products should serve the public and professionals as a priority. Maintenance supported by EC funding is essential for ensuring independence of the Agency and guaranteeing its public health mission.
The database will be most useful for patients if it enables comparisons to be made between different medicinal products. As a first step, therefore, the aim should be to facilitate a comparison of efficacy, reactions and contraindications on the basis of the information already authorised for the package leaflet. This is both technically and legally simple as the information is already authorised for publication and firms cannot therefore characterise it and challenge it as unfair.
The database should also include information about which medicinal products are specifically authorised for administration to children.
The information provided for the general public should be expressed in terms comprehensible to the layman.

Amendment 92
Article 51, paragraph 1(n)

(n) drawing up, at the ***Commission's*** request, any other scientific opinion concerning the evaluation of medicinal products or the starting materials used in the manufacture of medicinal products.	(n) drawing up, at the request ***of the Commission or of the European Parliament***, any other scientific opinion concerning the evaluation of medicinal products or the starting materials used in the manufacture of medicinal products.

Justification

The same rules should apply as were agreed with respect to the European Food Safety Authority (see Article 29(1) of Regulation (EC) No 178/2002).

Amendment 93
Article 51, paragraph 1(na) (new)

(na) compilation of scientific information concerning pathogenic agents which might be used in biological warfare and an assessment of the stock of vaccines and medicinal products currently available to combat such agents; the assessment

should include a survey of any shortcomings in research and in strategies to combat biological warfare;

Justification

Pathogenic agents might be used in biological warfare. The EU should, therefore, develop strategies to be implemented in an emergency

Amendment 94
Article 51, paragraph 1, letter (na) (new)

(na) 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

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 95
Article 51, paragraph 2

2. The database provided for in point (j) of paragraph 1 shall 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	2. The database provided for in point (j) of paragraph 1 shall 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

Chapters IV (Title III) of Directive 2001/83/EC and Directive 2001/82/EC Respectively. The database shall subsequently be extended to include other medicinal products.	Chapters IV (Title III) of Directive 2001/83/EC and Directive 2001/82/EC respectively. The database shall subsequently be extended to include ***any*** medicinal products ***marketed in the European Union.***

Justification

The degree of transparency and information to the public and health professionals has to be harmonised for all medicines released on the EU market.

Amendment 96
Article 51, 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.

Justification

In order to ensure appropriate information, the database may also include information about clinical trials.

Amendment 97
Article 52

The Agency may give a scientific opinion, in the context of cooperation with the World Health Organisation, for the assessment of certain medicinal products for human use intended exclusively for the markets of non-member countries. For this purpose, on the recommendation of the World Health Organisation, a request shall be submitted to the Agency, in accordance with the provisions of Article 6. The Committee for Human Medicinal Products shall be responsible for drawing up the Agency's opinion, in accordance with the provisions of Articles 6 to 9. The provisions of Article 10 shall not apply.	The Agency may give a scientific opinion, in the context of cooperation with the World Health Organisation, for the assessment of certain medicinal products for human use intended exclusively for the markets of non-member countries. For this purpose, on the recommendation of the World Health Organisation, a request shall be submitted to the Agency, in accordance with the provisions of Article 6. The Committee for Human Medicinal Products shall be responsible for drawing up the Agency's opinion, in accordance with the provisions of Articles 6 to 9. ***The Agency may give a scientific opinion in the context of***

cooperation with the Office International des Epizooties, for the assessment of certain medicinal products for veterinary use intended exclusively for the markets of third countries. For this purpose a request shall be submitted to the Agency, in accordance with the provisions of Article 28. The Committee for Veterinary Medicinal Products shall be responsible for drawing up the Agency's opinion, in accordance with the provisions of Articles 28, 29, 30 and 31. The provisions of Article 10 ***or Article 32*** shall not apply.

Justification

This is proposed for the human pharmaceuticals but is equally needed by the veterinary sector. It removes the requirement to obtain a full marketing authorisation just for the purpose of facilitating registration in Third Countries with no intention of marketing in the EU.

Amendment 98
Article 53, Paragraph 3

3. Where there is a fundamental conflict over scientific points and the body concerned is a Community agency or a scientific committee, the Agency and the body concerned shall work together either to solve the conflict or to submit a joint document to the Commission clarifying the scientific points of conflict.	3. Where there is a fundamental conflict over scientific points and the body concerned is a Community agency or a scientific committee, the Agency and the body concerned shall work together either to solve the conflict or to submit a joint document to the Commission clarifying the scientific points of conflict. ***That document shall be published immediately after its adoption.***

Justification

The same rules should apply as were agreed with respect to the European Food Safety Authority (see Article 30(1) and (2) of Regulation (EC) No 178/2002).

Amendment 99
Article 53, paragraph 4

4. Save as otherwise provided for in this Regulation, in Directive 2001/83/EC or in Directive 2001/82/EC, where there is a fundamental conflict over scientific points and the body concerned is a body in a Member State, the agency and the national body concerned shall work together either to solve the conflict or to prepare a joint document clarifying the scientific points of conflict.	4. Save as otherwise provided for in this Regulation, in Directive 2001/83/EC or in Directive 2001/82/EC, where there is a fundamental conflict over scientific points and the body concerned is a body in a Member State, the agency and the national body concerned shall work together either to solve the conflict or to prepare a joint document clarifying the scientific points of conflict. ***That document shall be published immediately after its adoption.***

Justification

The same rules should apply as were agreed with respect to the European Food Safety Authority (see Article 30(1) and (2) of Regulation (EC) No 178/2002).

Amendment 100
Article 53a (new)

	Article 53a
	The Agency shall collect information on the methodology used by the Member States' authorities to ascertain the added therapeutic value to be achieved by a new medicinal product. To promote scientific exchange and avert potential conflict, the Agency shall draw up discussion papers which compare these approaches and formulate open questions.

Justification

Scientific debate over the term 'added therapeutic value' is complex and should be monitored by a Community body. This proposal is based on a recommendation of the G-10 group on medicinal products (see Recommendation No. VIIb in the G-10 final report of April 2002). A working group of the Commission's High Level Committee on Health has drawn a similar conclusion (see point 7 of the report by the 'Pharmaceuticals and Public Health' working group of March 2000).

Amendment 101
Article 54, paragraph 1, subparagraph 1

1. Each Member State shall appoint, for a three-year term which shall be renewable, one member to the Committee for Human Medicinal Products and one member to the Committee for Veterinary Medicinal Products. Members shall be chosen for their role and experience in the evaluation of medicinal products for human and veterinary use as appropriate and shall maintain relevant contacts with the competent national authorities.	***1. With a view to the appointment of the members of the Committee for Human Medicinal Products, the Committee on Herbal Medicinal Products and the Committee for Veterinary Medicinal Products, each Member State shall propose, for each committee, five persons selected on the basis of their role and their experience in the evaluation of human or veterinary medicinal products.***

Justification

The Commission has not taken sufficient account of developments in new treatments, research into which calls for particular expertise. This consideration (which is of major significance to product safety) and the quality of the experts based on recognised experience should therefore be taken into account when members are selected. Geographic distribution is a further factor which must be taken into account in the selection of members.

Amendment 102
Article 54, paragraph 1, subparagraph 2

The committees may coopt a maximum of five additional members chosen on the basis of their specific scientific competence. These members shall be appointed for a term of three years which shall be renewable.	***On the basis of those proposals the Executive Director shall appoint one member per Member State, taking into account the need for the committee to be multidisciplinary in nature. Those members shall maintain relevant contacts with the competent national authorities.*** ***The members appointed on a proposal from the Member States shall propose to the Executive Director (with a view to securing their appointment) five additional members for each committee, chosen on the basis of their specific scientific competence.***

	The members of each committee shall be appointed for a three-year period which shall be renewable.
	Wherever possible, the committees shall seek to establish contacts, on an advisory basis, with associations of people affected, patients, people working in the sector, etc.

Justification

The Commission has not taken sufficient account of developments in new treatments, research into which calls for particular expertise. This consideration (which is of major significance to product safety) and the quality of the experts based on recognised experience should therefore be taken into account when members are selected. Geographic distribution is a further factor which must be taken into account in the selection of members.

Amendment 103
Article 54, paragraph 1, subparagraph 4

The Executive Director of the Agency or his/her representative and representatives of the Commission shall be entitled to attend all the meetings of the Committees and ***working parties*** convened by the Agency or its committees.	The Executive Director of the Agency or his/her representative and representatives of the Commission shall be entitled to attend all the meetings of the Committees and ***all the meetings*** convened by the Agency or its committees.

Justification

The Commission has not taken sufficient account of developments in new treatments, research into which calls for particular expertise. This consideration (which is of major significance to product safety) and the quality of the experts based on recognised experience should therefore be taken into account when members are selected. Geographic distribution is a further factor which must be taken into account in the selection of members.

Amendment 104
Article 54, paragraph 5

5. Each Committee shall establish its own rules of procedure.	5. Each Committee shall establish its own rules of procedure.
These rules shall in particular lay down the procedures for appointing and replacing the Chairman, the procedures for delegating certain tasks to working parties ***and*** the establishment of a procedure for the urgent adoption of opinions, particularly in relation	These rules shall in particular lay down:
	(a) the procedures for appointing and replacing the Chairman,
	(b) the procedures for ***consulting and*** delegating certain tasks to working parties,

to the provisions on market surveillance and pharmacovigilance laid down in this Regulation.	***(c) the procedures for the organisation of public hearings,***
	(d) consultation, in connection with the medicinal-product evaluation procedures, of the panels referred to in the second subparagraph of Article 50(2),
	(e) the establishment of a procedure for the urgent adoption of opinions, particularly in relation to the provisions on market surveillance and pharmacovigilance laid down in this Regulation.
They shall enter into force after receiving a favourable opinion from the Commission and the Management Board.	They shall enter into force after receiving a favourable opinion from the Commission and the Management Board.

Justification

The same rules should apply as were agreed with respect to the European Food Safety Authority (see Article 28(1) and (9)(g) of Regulation (EC) No 178/2002)
The opportunity to consult panels must be included in the provisions covering each committee.

Amendment 105
Article 55, paragraph 1, subparagraph 1

1. Where, in accordance with the provisions of this Regulation, the Committee for Human Medicinal Products or the Committee for Veterinary Medicinal Products is required to evaluate a medicinal product, it shall appoint one of its members to act as rapporteur for the coordination of the evaluation. The Committee concerned may appoint a second member to act as co-rapporteur.	1. Where, in accordance with the provisions of this Regulation, the Committee for Human Medicinal Products***, the Committee on Herbal Medicinal Products*** or the Committee for Veterinary Medicinal Products is required to evaluate a medicinal product, it shall appoint one of its members to act as rapporteur for the coordination of the evaluation. The Committee concerned may appoint a second member to act as co-rapporteur. ***The rapporteur shall establish contact with patients' representatives in order to take into account the experience that they have acquired in the indication field of the relevant medicinal product.***

Justification

This addition is required because of the establishment of a specialist committes for the assessment of herbal medicinal products.
Patients, and particularly those who have suffered from chronic illnesses, have acquired personal experience which might provide the rapporteur with useful information for the assessment of the new medicinal product.

Amendment 106
Article 55, paragraph 1, subparagraph 1a (new)

When the panels referred to in the second subparagraph of Article 50(2) are consulted, the Committee shall forward to them the evaluation report(s) drawn up by the rapporteur or the co-rapporteur. An opinion issued by a panel shall be forwarded to the chairman of the relevant committee in such a way as to ensure that the deadlines laid down in Article 6(3) and Article 28(3) are met.

The substance of that opinion shall be included in the final evaluation report published pursuant to Article 12(3) and Article 34(3).

Justification

The procedure needs to be clarified. The amendment is self-explanatory.

Amendment 107
Article 55, paragraph 1, subparagraph 2

If there is an appeal against one of its opinions, the Committee concerned shall appoint a different rapporteur and, where necessary, a different co-rapporteur from those appointed for the initial opinion. This appeal procedure may deal only with the points of the opinion initially identified by the applicant and may be based ***only*** on ***the*** scientific data available at the time the Committee adopted the initial opinion.	If there is an appeal against one of its opinions, the Committee concerned shall appoint a different rapporteur and, where necessary, a different co-rapporteur from those appointed for the initial opinion. This appeal procedure may deal only with the points of the opinion initially identified by the applicant and may be based on scientific data ***not*** available at the time the Committee adopted the initial opinion.

	Consultation of a panel may be requested in connection with such an appeal.

Justification

If new data has become available since the submission, and could help solve the issue, then there should be an appeal procedure with extra time granted to assess the new data. See also Article 31.

Amendment 108
Article 55, paragraph 2, subparagraph 1

2. Member States shall transmit to the Agency the names of national experts with proven experience in the assessment of medicinal products who would be available to serve on working parties or expert groups of the Committee for Human Medicinal Products or the Committee for Veterinary Medicinal Products, together with an indication of their qualifications and specific areas of expertise.	2. Member States shall transmit to the Agency the names of national experts with proven experience in the assessment of medicinal products who would be available to serve on working parties or expert groups of the Committee for Human Medicinal Products ***the Committee on Herbal Medicinal Products*** or the Committee for Veterinary Medicinal Products, ***and also on panels,*** together with an indication of their qualifications and specific areas of expertise.

Justification

This addition is required because of the establishment of a specialist committes for the assessment of herbal medicinal products.

Amendment 109
Article 55, paragraph 2, subparagraph 2 a (new)

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

	be declared in an ad hoc Register in accordance with EU Regulation 1049/2001 accessible at the Agency and on the Internet.

Justification

One of the main problems with the Agency is the lack of democratic control and the fact that it is attached to DG Enterprise instead of DG Health and Consumer Protection. This new Regulation should solve this problem, taking into account the enlargement of the EU.

Amendment 110
Article 56, paragraph 2, subparagraph 1

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

Justification

It is clear that officials of the EAEMP should be subject to the requirement to act in an independent manner and to declare their financial interests.

The annually updated declaration of financial interests corresponds to the rules which apply to the European Food Safety Authority (see Article 37(1) of Regulation (EC) No 178/2002).

Amendment 111
Article 56, paragraph 2, subparagraph 1a (new)

	The Agency´s code of conduct shall provide for implementation of this article with

	particular reference to the acceptance of gifts.

Justification

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

Amendment 112
Article 56, paragraph 2, subparagraph 2

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

Justification

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

Amendment 113
Article 57, paragraph 1

1. The Executive Director shall be appointed by the Management Board, on ***a proposal from the Commission, for a period of five years, which shall be renewable***.	1. The Executive Director shall be appointed by the Management Board, on ***the basis of a list of candidates, for a period of five years. The list of candidates shall be proposed by the Commission following an Open Competition held subsequent to a call for expressions of interest published in the Official Journal of the European Communities and elsewhere. The appointment shall be renewable. Before appointment, the candidate nominated by the Management***

	Board shall be required forthwith to make a statement to the European Parliament and to answer any questions put by its Members. The person appointed may be removed from the post by a majority of the Management Board.

Justification

The same rules should apply as were agreed with respect to the European Food Safety Authority (see Article 26(1) of Regulation (EC) No 178/2002).

Amendment 114
Article 57, paragraph 2, introduction

2. The Executive Director shall be the legal representative of the Agency. He/she shall be responsible:	2. The Executive Director shall be the legal representative of the Agency. He/she shall be responsible ***for appointing the members of the scientific committees, pursuant to Article 54(1) or other provisions of Community law and***:

Justification

Consistency with earlier amendments.

Amendment 115
Article 57, paragraph 3, first subparagraph

3. Each year, the Executive Director shall submit the following to the Management Board for approval, while 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 the following to the Management Board for approval, while making a distinction between the Agency's activities concerning medicinal products for human use***, herbal medicinal products*** and those concerning veterinary medicinal products:

Justification

This addition is required because of the establishment of a specialist committees for the

assessment of herbal medicinal products.

Amendment 116
Article 58, paragraph 1, first subparagraph

1. The Management Board shall consist of ***four representatives of the Member States, four representatives of the European Parliament, four representatives of the Commission, and four representatives of patients and industry, appointed by the Commission.***	1. The Management Board shall consist of ***15 members 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, together with one representative of the Commission. Two of the members shall come from industrial associations, one from patients' organisations, one from doctors' organisations, and one shall represent social security schemes. The list drawn up by the Commission shall be forwarded to the European Parliament, together with the relevant documentation. As soon 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. Appointment of the members of the Management Board shall be carried out in such a way as to guarantee the highest expert qualifications, a broad spectrum of relevant expert knowledge and the widest possible geographical spread in the Union.***

Justification

The same rules should apply as were agreed with respect to the European Food Safety Authority (see Article 25(1) of Regulation (EC) No 178/2002). In addition, a representative of the various social security schemes should also be included, since they play an important role in the medicinal products sector, although not in the foodstuffs sector.

Amendment 117
Article 58, paragraph 2

2. The term of office of the representatives shall be three years. It shall be renewable.	2. The term of office of the representatives shall be three years. It shall be renewable ***once***.

Justification

Self-explanatory.

Amendment 118
Article 58, paragraph 3

3. The Management Board shall elect its Chairman for a term of three years and shall adopt its rules of procedure. Decisions of the Management Board shall be adopted by a majority of two-thirds of its members.	3. The Management Board shall elect its Chairman for a term of three years and shall adopt its rules of procedure. Decisions of the Management Board shall be adopted by a majority of two-thirds of its members. ***The Management Board shall invite the chairmen of the scientific committees to attend its meetings, but they shall not have the right to vote.***

Justification

The chairmen of the scientific committees should be kept informed about the development and the work programme of the Agency.

Amendment 119
Article 59, first paragraph

The Advisory Board shall consist of one representative from each of the national authorities competent in the authorisation of human and veterinary medicinal products. The Executive Director or his representative and the representatives of the Commission shall have the right to attend the meetings of the Advisory Board.	The Advisory Board shall consist of one representative from each of the national authorities competent in the authorisation of human and veterinary medicinal products. ***In addition, it shall include a representative of the European Pharmacology Society, a representative of the pharmaceuticals industry, a representative of the patients' associations and a representative of each category of health-care professionals (doctors and pharmacists).*** The Executive Director or his representative and the representatives of the Commission shall

	have the right to attend the meetings of the Advisory Board.

Justification

The Advisory Board should be expanded to include all actors in the pharmaceuticals sector, starting with representatives of the industry, academics, doctors and pharmacists and consumers' associations.

Amendment 120
Article 60, paragraph 1

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

Justification

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

Amendment 121
Article 60, paragraph 1a (new)

	In order to ensure full independence, activities relating to pharmacovigilance, at least the operation of communications networks and market surveillance should receive public funding commensurate with the tasks conferred.

Justification

The monitoring activities conferred upon the competent authorities will increase in volume on

account of the new tasks which those authorities have been entrusted. In order to ensure that those tasks are performed successfully, the public funding which is essential to the smooth running of the system should be made available as of now.

Amendment 122
Article 60, paragraph 2

2. The expenditure of the Agency shall include the staff, administrative, infrastructure and operational expenses and expenses resulting from contracts entered into with third parties.	2. 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

The funding of new tasks must be clarified from the outset.

Amendment 123
Article 60, paragraph 3

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

Justification

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

Amendment 124
Article 60, paragraph 6

6. The Management Board shall adopt the Agency's final budget before the beginning of the financial year, adjusting it where necessary to the Community subsidy and the Agency's other resources.	6. The Management Board shall adopt the Agency's final ***work programme and final*** budget before the beginning of the financial year, adjusting it where necessary to the Community subsidy and the Agency's other resources. ***Any modification of the establishment plan and of the budget shall be notified to the budgetary authority under the form of a rectifying budget.***

Justification

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

Amendment 125
Article 60, paragraph 9

9. By 31 March of each year at the latest, the Director shall forward to the Commission, the Management Board and the Court of Auditors the accounts for all the Agency's revenue and expenditure in respect of the preceding financial year. The Court of Auditors shall examine them in accordance with Article 248 of the Treaty.	9. By 31 March of each year at the latest, the Director shall forward to the Commission, the Management Board and the Court of Auditors the accounts for all the Agency's revenue and expenditure in respect of the preceding financial year. The Court of Auditors shall examine them in accordance with Article 248 of the Treaty ***and shall publish an annual report on the Agency's activities.***

Justification

The same rules should apply as were agreed with respect to the European Food Safety Authority (see Article 38(1)(f) of Regulation (EC) No 178/2002).

Amendment 126
Article 60 (10)

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

Justification

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

Amendment 127
Article 60a (new)

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

Justification

The EMEA has already taken a decision with the agreement of its management board (dated 1

June 1999) concerning the terms and conditions for internal investigations in relation to the prevention of fraud, corruption and any illegal activity detrimental to the Communities' interests. This decision lays down the procedures governing cooperation with OLAF.

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

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

Amendment 128
Article 61

Article 61	Article 61
The structure and the ***amount*** of the fees referred to in Article 60(1) shall be established by the Council acting under the conditions provided for by the Treaty on a proposal from the Commission, following the latter's consultation of organisations representing the interests of the pharmaceutical industry at Community level.	The structure and the ***level*** of the fees referred to in Article 60(1) shall be established by the Council acting under the conditions provided for by the Treaty on a proposal from the Commission, following the latter's consultation of organisations representing the interests of the pharmaceutical industry at Community level. ***The Management Board shall adjust the level of the fees each year in accordance with the EU inflation rate established by Eurostat.***

Justification

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

Amendment 129
Article 61, subparagraph 1a (new)

	Applications related to medicinal products presented by small and medium size companies, established in the Community, shall benefit from a fee reduction and/or a delayed payment of the fee, as for orphan drugs, according to provisions which will be adopted by the Commission.

Justification

In order to stimulate the development of small and medium size enterprises in the European Community, it seems appropriate to introduce a provision for lower fees to allow these companies to better allocate resources in research, development and placing on the market of their products.

Amendment 130
Article 69

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

Justification

Above all, the Agency should give vigorous support to small and medium-sized undertakings which will, henceforth, be obliged to use the central authorisation procedure for all new active substances.

Amendment 131
Article 70

To ensure an appropriate level of transparency, the Management Board, on the basis of a proposal by the Executive Director, in agreement with the Commission, shall adopt rules to ensure the availability to the public of regulatory, scientific or technical information concerning the authorisation or supervision of medicinal products ***which is not of a confidential nature***.	To ensure ***the highest*** level of transparency, the Management Board, on the basis of a proposal by the Executive Director, in agreement with the Commission, shall adopt rules ***and set up an ad hoc Register*** to ensure the availability to the public of regulatory, scientific or technical information concerning the authorisation or supervision of medicinal products, ***in accordance with the EU Regulation 1049/2001 on access to documents.***

Internal rules and procedures of the Agency, its Committees and its working groups shall be made available to the public at the Agency and on the Internet.

A copy of all scientific information, except for confidential data of a commercial nature, shall be made available to interested parties, in response to a written request and on payment of a fee which covers the material costs involved. Regulatory information on applications for authorisation submitted, the stage reached in the procedure, interim decisions, authorisations and any conditions imposed shall be published on the Internet in an easily comprehensible format. Regulation 1049/2001 on public access to documents of the EU institutions shall also apply to the Agency.

An easily comprehensible format and language understandable by a layman shall be used for the drafting of European Public Assessment Reports (EPARs). EPARs shall include a section on the conditions imposed before the medicinal product was authorised.

Probabilities of successful treatment and reactions shall be expressed as natural frequencies (number needed to treat/number needed to harm).

Justification

This article shall comply with provisions of EU Regulation 1049/2001 to create real transparency of the Agency activities.
In order to inspire confidence in the independence and competence of the Agency, it must work in as transparent a fashion as possible. That will also facilitate the discussion by external scientists about the efficacy and safety of medicinal products. In turn, patients are entitled to easily comprehensible and comprehensive information about the properties of the medicinal product which is being administered to them.
It has proved to be the case that biostatistical information is more realistically assessed by

the layman if it is not expressed in percentages but in cases per treatment group (Source: Science, Vol. 290, 22 December 2000, pages 2261-2262; viewable at http://www.sciencemag.org/cgi/content/full/290/5500/2261).

Amendment 132
Article 73, paragraph 4

4. The Agency shall keep an up-to-date list of the medicinal products referred to in paragraph 1 made available for compassionate use. ***Article 22(1) and Article 23*** shall apply *mutatis mutandis*.	4. The Agency shall keep an up-to-date list of the medicinal products referred to in paragraph 1 made available for compassionate use. ***Title II Chapter 3 on pharmacovigilance*** shall apply *mutatis mutandis*.

Justification

All the rules on pharmacovigilance should apply mutatis mutandis.

Amendment 133
Article 73, paragraph 6

6. ***No medicinal product*** administered for compassionate reasons may be the subject of a paid transaction, except in special cases determined beforehand in national legislation.	6. ***Medicinal products*** administered for compassionate reasons ***shall be financed by the manufacturer and*** may ***not*** be the subject of a paid transaction, except in special cases determined beforehand in national legislation.

Justification

The dispensing of unauthorised medicinal products against payment to groups of patients suffering from serious and, in most cases, fatal pathologies is not acceptable.

Amendment 134
Article 73, paragraph 7a (new)

	7a. Where a compassionate use programme is set up, the manufacturer shall ensure that the patients taking part also have

	access to the new medicinal product during the period between authorisation and placing on the market.

Justification

The compassionate use programme normally ends with authorisation. Usually, however, it is years before the price and reimbursement negotiations are concluded and the new medicinal product is actually available on the market. This period should be covered.

Amendment 135
Article 74, paragraph 3

3. At the Agency's request, the Commission may impose financial penalties on the holders of marketing authorisations granted under this Regulation if they fail to observe certain obligations laid down in connection with the authorisations. The maximum amounts as well as the conditions and methods for collection of these penalties shall be laid down by the Commission in accordance with the procedure ***foreseen*** in Article 77(2).	3. At the Agency's request, the Commission may impose financial penalties on the holders of marketing authorisations granted under this Regulation if they fail to observe certain obligations laid down in connection with the authorisations. The maximum amounts as well as the conditions and methods for collection of these penalties shall be laid down by the Commission in accordance with the procedure ***provided for*** in Article 77(2). ***The Commission shall publish the names of the holders of marketing authorisations involved and the amount and the reasons of the financial penalties imposed.***

Justification

The public should be informed of the names of holders of marketing authorisations who do not fulfil their obligations and on whom financial penalties are imposed.
The public should be informed of the names of holders of marketing authorisations who do not fulfil their obligations and on whom financial penalties are imposed.

Amendment 136
Annex I, paragraph 3

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

Justification

Competition increases quality; monopolies lead to encrustation. This principle also holds for regulatory authorities. For that reason competing responsibilities of European and national regulatory authorities should be maintained, in contrast to the Commission's proposal.

Since 1995 it has been possible to have new, non-biotechnologically produced substances licensed either through the centralised procedure at the European regulatory authority EMEA in London or through the mutual recognition procedure. Both of these licensing procedures are performed using equally high standards, guaranteeing drugs of equally high quality for the patients. The choice between the competing processes has resulted in increased efficiency of the processes. 40% of the new active ingredients are registered using the mutual recognition procedure, 60% in the central process. This efficiency-promoting competition should be maintained.

Furthermore it is essential for small and medium enterprises to have the optionality between these 2 procedures.

EXPLANATORY STATEMENT

The challenges involved in new legislation on medicinal products are immense: such legislation is required to deliver to patients new, safe and effective medicinal products, to strengthen the competitiveness of the European pharmaceuticals industry and to prepare the authorisation and pharmacovigilance structures for enlargement.

This proposal for a regulation constitutes one of a package of measures which the European Commission has proposed with a view to reforming EU legislation on medicinal products and also includes two directives, one on medicinal products for human use and one on veterinary medicinal products.

The proposal for a regulation regulates the structures and working methods of the EAEMP (European Agency for the Evaluation of Medicinal Products) and the authorisation procedure for medicinal products. A report submitted by the Commission in 2001 undertook an assessment of the authorisation procedure and of the entire body of legislation on medicinal products. The findings of an investigation conducted by an external adviser and the experience acquired by those involved in the procedure in the period 1995-2000 constituted the basis for the report. Those findings have been incorporated into this Commission proposal for a regulation.

1. Authorisation procedure / scope of the regulation

The establishment of the EAEMP in 1995 provided an opportunity to introduce central authorisation for medicinal products throughout the EU. To that end, the EAEMP draws up a scientific opinion, on the basis of which the Commission issues a centralised authorisation. In a very short space of time, that procedure proved that it was appropriate and efficient. However, to date, it has been compulsory only in the case of medicinal products resulting from biotechnical processes and voluntary in the case of a few other medicinal products.

In addition to the **centralised authorisation procedure**, a **decentralised procedure** also exists whereby a medicinal product authorised on a national basis and geared to a limited sector of the European market may also be authorised for use in one or more other Member States on the basis of the **mutual recognition procedure**.

Pursuant to the proposal for a regulation, both authorisation procedures would continue to exist side-by-side. The innovatory aspect of the proposal is that, in future, all medicinal products with new active substances would have to be authorised centrally. Your rapporteur supports this proposed extension of the scope of the regulation. This will ensure that the scientific resources of the Member States, on which the EAEMP may call, will be used to the full. A high level of expert knowledge in the expert opinion is an essential precondition for the safety and efficacy of new 'high-value' medicinal products. What is more, safe and effective medicinal products with new active substances would be more rapidly available to all patients throughout the EU. Finally, manufacturers would have more rapid market access if medicinal products were authorised centrally, and that would result in a gradual improvement of the domestic market for medicinal products. However, an amendment seeking to suppress this extention was adopted by the Environment Committee.

1.1. Exceptional procedures

The Commission is proposing three new exceptional procedures. They should enable the patients concerned to have more rapid access to innovative therapies.

In the **accelerated assessment and decision-making procedure for medicinal products for human use** which is of major interest for public health, medicinal products to be administered to fight cancer, HIV infection and many other diseases may be made available to patients more rapidly by means of a shortened authorisation procedure. However, a guarantee must be given that the safety, efficacy and quality thereof are not adversely affected by the shortness of the procedure.

In the case of medicinal products in respect of which the risk-benefit balance for patients with serious illnesses is likely to be favourable, **provisional authorisation** may be given for one year, subject to strict conditions. Compliance with those conditions and an annual reassessment must ensure that the patients concerned do derive genuine benefit therefrom.

Medicinal products still at the clinical trials stage may be made available, subject to compliance with detailed conditions, to seriously ill patients before authorisation (known as 'compassionate use'). In so doing, however, account must be taken of the patient's quality of life and an improved prognosis of the course of the pathology. In addition, the medicinal products should, as a rule, be provided free of charge.

Your rapporteur welcomes these three exceptional procedures which are vitally important for the patients involved.

1.2. Pilot project involving price negotiations

In order to speed up market access for medicinal products even more, your rapporteur proposes that the Commission should consider a project whereby the prices of centrally authorised medicinal products would be established. Under a project of that nature, pharmaceuticals manufacturers and representatives of the Member States might – on a voluntary basis - negotiate centrally on prices and eligibility for reimbursement under social security schemes. That would result in a shortening of the sometimes excessively ongoing negotiations in several Member States.

2. Data exclusivity

The proposal provides for data exclusivity for periods of 10 years or 10 years plus one year if, within the first eight years of the ten-year period, a new indication of significant clinical use is demonstrated. Your rapporteur supports that proposal, since it would provide an incentive for research and ensure data exclusivity periods of equal duration throughout the EU.

3. EAEMP (European Agency for the Assessment of Medicinal Products)

3.1. Funding

One essential task of the new legislation on medicinal products is to prepare the EAEMP's bodies for future challenges and to establish procedures which will ensure a high level of health protection in connection with the authorisation of medicinal products. By coordinating scientific resources in the EU and delivering expert opinions of the quality, safety and efficacy of medicinal products for human use and for veterinary use, the EAEMP will assume a central role in cooperation with the national licensing authorities. However, if the Agency is to be allotted new tasks under this legislation, appropriate funding must also be secured.

3.2. Management Board and Executive Director

The Management Board, the EAEMP's central decision-making body, authorises the work programme and approves the budget, thereby setting the course for the Agency's success. The Commission proposal arbitrarily establishes the composition of the body, laying down specific numbers of seats on the Board to be allocated to various groups: the Member States, the European Parliament, the Commission and Industry and Patients. That is not the way to go about it. Your rapporteur proposes that the same rules should apply to the EAEMP Management Board as to the European Food Safety Authority. Accordingly, the membership of the Management Board would be determined jointly by the Council and the European Parliament.

Contrary to the Commission proposal, too, the post of Executive Director should also be filled in accordance with the procedure applying to the European Food Safety Authority, i.e. from a short list established after an Open Competition. Your rapporteur proposes, further, that a representative of the various social security schemes should also have a seat on the Board.

3.3. EAEMP scientific committees

Your rapporteur originally proposed that a **Committee on Paediatric Medicinal Products** be added to the current list of committees and that the proposed **Committee on Herbal Medicinal Products** be upgraded. Both committees should enjoy the same status as the Committee for Human Medicinal Products and should be authorised to draw up expert opinions on issues relating to the assessment of, respectively, herbal and paediatric medicinal products. However, the amendments on the establishment of the Committee on Paediatric Medicinal Products were rejected by the Environment Committee.

3.3.1. Committee on Herbal Medicinal Products

The task of this new committee would be to draw up Community plant monographs for herbal medicinal products and, on request, to deliver expert opinions. Such expert opinions delivered by this committee should constitute the basis for central authorisation by the Commission or by the Member State authorities. This procedure would enable the Member States for the first time ever to consult centrally compiled plant monographs. That would considerably simplify patients' access to herbal medicinal products in Europe.

3.3.2. Committee on Paediatric Medicinal Products

More than half of the medicinal products administered to children in the EU have never been tested as to their suitability for administration to children. In other words, children are having administered to them medicinal products which are designed for adults, although the metabolism of a child is different from that of an adult. Accordingly, children require different doses of medicinal products. In order to improve this situation, all new medicinal products should be thoroughly tested as to their suitability for administration to children, with responsibility for their assessment being transferred to the new Committee on Paediatric Medicinal Products. Extending the period of data exclusivity may create an incentive for medicinal products already authorised for administration to adults to be subsequently tested as to their suitability for administration to children. That would improve the supply of paediatric medicinal products and ensure the safety, efficacy and quality thereof.

3.4. Transparency

Members of the scientific committees and of all the other bodies of the EAEMP must be independent and carry out their duties solely in the public interest. They should also be required to submit an annual declaration of their financial interests.

With regard to public access to EAEMP information and decisions, the transparency of the measures proposed by the Commission should be enhanced even further.

4. Pharmacovigilance

The Commission proposal notes that problems exist in the field of pharmacovigilance, in other words of the recording of adverse reactions of authorised medicinal products. It proposes measures to strengthen pharmacovigilance procedure. Safety must be a central criterion as early as the authorisation process, with due account being taken of the risk-benefit ratio. Effective monitoring and control by the competent authority are essential pillars of a properly functioning system of pharmacovigilance, as is a stricter obligation on manufacturers to report on the safety of a product. Your rapporteur proposes that, in the future, it should be possible for adverse reactions to be reported not only by health-care professionals but also directly by patients themselves. To that end, each package containing a medicinal product should also include a report form to be returned to the manufacturer.

The compilation of an EAEMP database with varying levels of access for the Member States, health-care professionals, industry and patients will create transparency and improve access to information. In the event of a crisis situation arising, it would also facilitate the taking of emergency measures. The EMEAP has a key role to play in an efficient pharmacovigilance system in the EU as the coordinating and supervisory body.

5. Conclusion

The patient must occupy centre stage in any consideration concerning the recasting of legislation on medicinal products. Safe and effective medicinal products to restore patients to health or to improve the quality of life of the chronically sick is a basic requirement of the health-care systems in the Member States and of European policy on medicinal products. Legislation which provides maximum health protection and simultaneously creates optimum framework conditions for a competitive and innovative pharmaceutical industry offers the best prospects for an effective supply of medicinal products in the EU. Although it will not be easy to create a trouble-free internal market for a sector within which 15 – and soon to be many more – differing health-care systems operate; the opportunity should be seized to accelerate a reform which will benefit patients.

20 June 2002

OPINION OF THE COMMITTEE ON AGRICULTURE AND RURAL DEVELOPMENT

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

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

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

the proposal for a Directive of the European Parliament and of the Council amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products (COM(2001) 404 – C5-0593/2001 – 2001/0254(COD))

Draftsman: Robert William Sturdy

PROCEDURE

The Committee on Agriculture and Rural Development appointed Robert William Sturdy draftsman at its meeting of 8 January 2002.

The committee considered the draft opinion at its meetings of 19 March 2002, 28 May 2002 and 19 June 2002.

At the last meeting it adopted the following conclusions unanimously.

The following were present for the vote: Joseph Daul, chairman; Albert Jan Maat, vice-chairman; Robert William Sturdy, rapporteur; Gordon J. Adam, Carlos Bautista Ojeda, Arlindo Cunha, Christel Fiebiger, Francesco Fiori, Christos Folias, Jean-Claude Fruteau, Georges Garot, Lutz Goepel, Willi Görlach, Liam Hyland, María Izquierdo Rojo, Elisabeth Jeggle, Salvador Jové Peres, Hedwig Keppelhoff-Wiechert, Heinz Kindermann, Dimitrios Koulourianos, Astrid Lulling (for Neil Parish), Véronique Mathieu, Hans-Peter Mayer (for Michl Ebner), Xaver Mayer, Karl Erik Olsson, Mikko Pesälä, Encarnación Redondo Jiménez, and Agnes Schierhuber.

SHORT JUSTIFICATION

The Commission's proposals for amending the regulatory framework for the approval of veterinary medicinal products in the EU acknowledge the lack of availability of veterinary medicines and are a positive step forward in addressing this problem.

The proposals recognise the need for veterinary medicinal products in ensuring the health and welfare of animals. They take into account animal health and welfare as well as public health, whereas previously the system has focussed exclusively on public health with little regard for the health and welfare of animals. A licensing system that takes into account both these requirements will bring back the much-needed balance, to the benefit of people and animals.

In recognising the lack of availability of veterinary medicines, the proposals give some welcome suggestions for improving the system of registration, allowing medicines to be approved efficiently while at the same time ensuring that only safe, efficacious and high-quality medicines reach the marketplace. An improved system would achieve this without an overly burdensome procedure – what the Commission has called "cutting red tape."

The Commission's proposals offer special provisions to increase medicines availability for horses not intended for the human food-chain as well as other animals such as rabbits and ferrets.

The Commission's proposals offer extended data protection to increase the incentives for companies to invest in producing new medicines for animals. They offer special protection for medicines developed for fish and bees, which currently face the worst medicines availability crisis.

The proposals remove the administrative requirement to re-license products every five years, instead proposing a strengthening of the existing in-use monitoring and reporting system. This is coupled with proposals for extended record-keeping for treatment of animals destined for the food-chain, aimed at supporting full traceability throughout the EU.

Overall, the Commission's proposals will achieve the following:

- They will support the welfare and safety of humans. Consumers expect that animals, whose produce they eat, are free of disease; the public should be protected from diseases that can be passed on to humans; and farmers should be able to have access to registered and approved safe, efficacious and high-quality medicines should their animals fall ill.

- They will support the welfare of animals. By encouraging innovation they will encourage new treatments, enabling animals to have access to the medicines they need to stay healthy or be treated if they become sick.

- They will encourage and enable companies to continue to invest in research and development in order to bring new treatments to the market, and stay ahead of the spread or emergence of new diseases. Keeping research and development facilities in Europe will safeguard jobs and keep Europe as a centre of innovation.

The Commission's proposals aim at making practical improvements to the system for

scrutinising, evaluating and approving veterinary medicinal products based on 20 years of experience of the current system. In general, they propose welcome measures to increase transparency and ease of use of the system, making it less burdensome, less cumbersome and less time-consuming while at the same time protecting the interests of members of society and animals.

However, the Commission's proposals have some major weaknesses that could undermine the practical effectiveness of the solutions proposed.

They do not reflect an understanding of the length of time it takes to obtain registration and to develop the data required for the extension of a marketing authorisation to different species and to different sicknesses, whether for a food-producing animal or not.

They do not fully recognise that the number-one focus must be solving the medicines availability crisis by getting products to the market at the same time as ensuring no lapse in existing provisions for human and animal safety.

They do take into account the fundamental nature of the animal-health markets. Due to the species-specific, regional and often sporadic nature of animal diseases, the markets are, in practice, tiny when compared to those for human pharmaceuticals.

Animal medicines must be licensed to similar standards of quality, safety and efficacy as human pharmaceutical products, yet the economic realities of the potential marketplaces mean that it may not be economically feasible to bring them to market. A great many veterinary medicinal products are "orphan drugs" when the criteria for human pharmaceutical products are applied in the same manner.

Therefore the draftsman would propose a series of amendments that would address these problems without compromising human health or animal health and welfare.

AMENDMENTS

The Committee on Agriculture and Rural Development calls on the Committee on the Environment, Public Health and Consumer Policy, as the committee responsible, to incorporate the following amendments into its report:

Text proposed by the Commission[1]	Amendments by Parliament

Amendment 1

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

Recital 10

(10) In the field of veterinary medicinal products, administrative measures should be provided for in order to take account of the specific features of this field, particularly those due to the regional distribution of certain diseases. The field of application of the centralised procedure should also include medicinal products used within the framework of Community provisions regarding prophylactic measures for epizootic diseases.	(10) In the field of veterinary medicinal products, administrative measures should be provided for in order to take account of the specific features of this field, particularly those due to the regional distribution of certain diseases. ***The Commission should develop, as a matter of urgency, a specific legal instrument to set out a policy for veterinary 'orphan' medicinal products, analogous to that developed for human medicines by Regulation (EC) No. 141/2000, and implemented by Regulation (EC) No 847/2000.*** The field of application of the centralised procedure should also include medicinal products used within the framework of Community provisions regarding prophylactic measures for epizootic diseases.

Justification

There is a declining availability of veterinary medicinal products, particularly for minor species or minor diseases. This policy was one of the medium-term proposals for solutions published in the Communication from the Commission to the Council and European Parliament ("Availability of veterinary medicinal products"), 05.12.2000, COM(2000) 806. It is further supported by the statements contained within the "Whereas" clauses (9) and (10)

[1] OJ C 75, 26.03.2002.

of the proposal for a Directive amending Directive 2001/82/EC (2001/0254 (COD).

Amendment 2
Article 28 (1)

1. Each application for authorisation for a medicinal product for veterinary use shall specifically include all the information and documents referred to in Articles 12(3), 13a and 14 of Directive 2001/82/EC, and Annex I thereto. ***The information and documents are to take account of the unique, Community nature of the authorisation requested, and particularly of the use of a single name of the medicinal product***.	1. Each application for authorisation for a medicinal product for veterinary use shall specifically include all the information and documents referred to in Articles 12(3), 13a and 14 of Directive 2001/82/EC, and Annex I thereto.
The application shall be accompanied by the fee payable to the Agency for the examination of the application.	The application shall be accompanied by the fee payable to the Agency for the examination of the application.

Justification

There should be more flexibility in the requirement for one trademark for all of Europe. This is becoming increasingly difficult to achieve, diverts time and resources and may delay product coming to market and after Enlargement may become impossible.

Amendment 3
Article 31 (2)

2. Within 15 days of receipt of the opinion referred to in paragraph 1, the applicant may provide written notice to the Agency that he/she wishes to appeal. In that case the applicant shall forward the detailed grounds for his/her appeal to the Agency within 60 days of receipt of the opinion.	2. Within 15 days of receipt of the opinion referred to in paragraph 1, the applicant may provide written notice to the Agency that he/she wishes to appeal. In that case the applicant shall forward the detailed grounds for his/her appeal to the Agency within 60 days of receipt of the opinion.

Within 60 days of receipt of the grounds for appeal, the Committee for Veterinary Medicinal Products shall re-examine its opinion in accordance with the conditions laid down in the second subparagraph of Article 55(1). The conclusions reached on the appeal shall be annexed to the final opinion.	Within 60 days of receipt of the grounds for appeal, the Committee for Veterinary Medicinal Products shall re-examine its opinion in accordance with the conditions laid down in the second subparagraph of Article 55(1). ***If the grounds for appeal include new data, not available at the time of the original submission, then this period will be extended by 30 days.*** The conclusions reached on the appeal shall be annexed to the final opinion.

Justification

If new data has become available since the submission, and could help solve the issue, then there should be an appeal procedure with extra time granted to assess the new data. See also Article 55(1).

Amendment 4
Article 33, paragraph 1, point b

(b) in the case of zootechnical veterinary medicinal products and growth promoters, when the safety and welfare of the animals and/or consumer safety ***and benefits in terms of health*** have not been sufficiently taken into account;	(b) in the case of zootechnical veterinary medicinal products and growth promoters, when the safety and welfare of the animals and/or consumer safety have not been sufficiently taken into account;

Justification

It is unreasonable to assume that veterinary medicinal products administered to animals might directly benefit human health. A more reasonable approach is to require veterinary medicinal products not to damage human health. Reference to benefits in terms of health should therefore be deleted.

Amendment 5
Article 35 (2) and (3)

2. ***Any*** authorisation ***which is not followed by the actual placing on the market of*** the veterinary medicinal product authorised on the Community market ***within two years of authorisation shall cease to be valid***.	2. ***The marketing*** authorisation ***holder shall state in each periodic safety update report submitted in accordance with Article 44 whether*** the veterinary medicinal product authorised ***is actually*** on the Community market.

3. When an authorised veterinary medicinal product previously placed on the market is no longer actually present on the market for two consecutive years, the authorisation for the product shall cease to be valid.	***Delete***

Justification

Requiring the marketing authorisation holder to include information in the reports required under Article 44(3) will achieve the same objective without forcing products off the market if they are not required, or cannot be marketed or manufactured for a 2-year period.

Amendment 6
Article 35, paragraph 5

5. When an application is lodged for a marketing authorisation in respect of veterinary medicinal products of major interest, ***particularly*** from the point of view of animal health ***and from the viewpoint of therapeutic innovation***, the applicant may request an accelerated assessment procedure. Due reasons are to be given for the request.	5. When an application is lodged for a marketing authorisation in respect of veterinary medicinal products of major interest from the point of view of animal health, the applicant may request an accelerated assessment procedure. Due reasons are to be given for the request. ***The Veterinary Committee shall consider in particular the application of this procedure in respect of medicinal products which meet the specific needs of smaller species or minor uses, and also of laying hens. In such cases the Agency, pursuant to the provisions of Regulation (EC) No 297/95, shall apply a reduction in the fees relating to authorisation.***
If the Committee for Veterinary Medicinal Products accepts the application, the time-limits laid down in the first subparagraph of Article 28(3) shall be reduced to 150 days.	If the Committee for Veterinary Medicinal Products accepts the application, the time-limits laid down in the first subparagraph of Article 28(3) shall be reduced to 150 days.

Justification

The value of the procedure concerned in the case of smaller species or minor uses should be more clearly stated.

Amendment 7
Article 52

The Agency may give a scientific opinion, in the context of cooperation with the World Health Organisation, for the	The Agency may give a scientific opinion, in the context of cooperation with the World Health Organisation, for the

assessment of certain medicinal products for human use intended exclusively for the markets of non-member countries. For this purpose, on the recommendation of the World Health Organisation, a request shall be submitted to the Agency, in accordance with the provisions of Article 6. The Committee for Human Medicinal Products shall be responsible for drawing up the Agency's opinion, in accordance with the provisions of Articles 6 to 9. The provisions of Article 10 shall not apply.	assessment of certain medicinal products for human use intended exclusively for the markets of non-member countries. For this purpose, on the recommendation of the World Health Organisation, a request shall be submitted to the Agency, in accordance with the provisions of Article 6. The Committee for Human Medicinal Products shall be responsible for drawing up the Agency's opinion, in accordance with the provisions of Articles 6 to 9. ***The Agency may give a scientific opinion in the context of cooperation with the Office International des Epizooties, for the assessment of certain medicinal products for veterinary use intended exclusively for the markets of third countries. For this purpose a request shall be submitted to the Agency, in accordance with the provisions of Article 28. The Committee for Veterinary Medicinal Products shall be responsible for drawing up the Agency's opinion, in accordance with the provisions of Articles 28, 29, 30 and 31.*** The provisions of Article 10 ***or Article 32*** shall not apply.

Justification

This is proposed for the human pharmaceuticals but is equally needed by the veterinary sector. It removes the requirement to obtain a full marketing authorisation just for the purpose of facilitating registration in Third Countries with no intention of marketing in the EU.

Amendment 8
Article 55 (1)

1. Where, in accordance with the provisions of this Regulation, the Committee for Human Medicinal Products or the Committee for Veterinary Medicinal Products is required to evaluate a medicinal product, it shall appoint one of its members to act as rapporteur for the coordination of the evaluation. The Committee concerned may appoint a	1. Where, in accordance with the provisions of this Regulation, the Committee for Human Medicinal Products or the Committee for Veterinary Medicinal Products is required to evaluate a medicinal product, it shall appoint one of its members to act as rapporteur for the coordination of the evaluation ***taking into consideration any proposal from the applicant for the***

second member to act as co-rapporteur.	***choice of rapporteur***. The Committee concerned may appoint a second member to act as co-rapporteur.
If there is an appeal against one of its opinions, the Committee concerned shall appoint a different rapporteur and, where necessary, a different co-rapporteur from those appointed for the initial opinion. This appeal procedure may deal only with the points of the opinion initially identified by the applicant and may be based ***only*** on ***the*** scientific data available at the time the Committee adopted the initial opinion.	If there is an appeal against one of its opinions, the Committee concerned shall appoint a different rapporteur and, where necessary, a different co-rapporteur from those appointed for the initial opinion. This appeal procedure may deal only with the points of the opinion initially identified by the applicant and may be based on scientific data ***not*** available at the time the Committee adopted the initial opinion.

Justification

If new data has become available since the submission, and could help solve the issue, then there should be an appeal procedure with extra time granted to assess the new data. See also Article 31.

Amendment 9
Article 70

To ensure an appropriate level of transparency, the Management Board, on the basis of a proposal by the Executive Director, in agreement with the Commission, shall adopt rules to ensure the availability to the public of regulatory, scientific or technical information concerning the authorisation or supervision of medicinal products which is not of a confidential nature.	To ensure an appropriate level of transparency, the Management Board, on the basis of a proposal by the Executive Director, in agreement with the Commission, ***and after consultation with interested parties,*** shall adopt rules to ensure the availability to the public of regulatory, scientific or technical information concerning the authorisation or supervision of medicinal products which is not of a confidential nature.

Justification

The applicant / marketing authorisation holder should be involved in the decisions.

Amendment 10
Article 72 (1)

1. Only one authorisation may be granted	***Delete***

to a particular applicant for a specific medicinal product.

However, for objective verifiable reasons relating to public health or the availability of medicinal products to health professionals and/or patients, the Commission may authorise the same applicant to submit more than one application to the Agency for that medicinal product.

1. For objective verifiable reasons relating to public health or the availability of medicinal products to health professionals and/or patients, the Commission may authorise the same applicant to submit more than one application to the Agency for that medicinal product.

Justification

The wording is too restrictive and makes it at the sole discretion of the Commission to grant or withhold permission for a copycat licence.

Amendment 11
ANNEX I (4)

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

Delete

Justification

The flexibility to register in the markets where the disease and / or species occurs will ensure that the medicines are registered in those markets. Compelling registration via the centralised procedure may mean the product is not registered at all.

Amendment 12
Directive of the European Parliament and of the Council amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products
ARTICLE 1 (5)
"Article 5 (Directive 2001/82/EC)

1. No veterinary medicinal product may be placed on the market of a Member State unless a marketing authorisation has been issued by the competent authorities of that Member State in accordance with

1. No veterinary medicinal product may be placed on the market of a Member State unless a marketing authorisation has been issued by the competent authorities of that Member State in accordance with

this Directive or a marketing authorisation has been granted in accordance with Regulation (EEC) No 2309/93.	this Directive or a marketing authorisation has been granted in accordance with Regulation (EEC) No 2309/93.
The various strengths***, pharmaceutical forms, administration routes,*** presentations and any amendment under Article 39 must be authorised under the first subparagraph and shall be considered part of the same authorisation.	The various strengths ***and*** presentations ***of a single pharmaceutical formulation*** and any amendment under Article 39 must be authorised under the first sub-paragraph and shall be considered part of the same authorisation.

Justification

A marketing authorisation should only be defined down to the level of different formulations. Making a single marketing authorisation cover all presentations and products containing one particular active substance will undermine data protection provisions.

Amendment 13
ARTICLE 1 (7)
Article 10, paragraph 1 (Directive 2001/82/EC)

1. If there is no authorised medicinal product in a Member State for a condition affecting a species of pet animal or animals kept in zoos or circuses, the veterinarian may, particularly in order to avoid causing unacceptable suffering to the animal concerned, under his/her personal responsibility, treat the animal(s) with:	1. If there is no authorised medicinal product in a Member State for a condition affecting a species of pet animal or animals kept in zoos or circuses ***or on fur farms***, the veterinarian may, particularly in order to avoid causing unacceptable suffering to the animal concerned, under his/her personal responsibility, treat the animal(s) with:

Justification

These articles lay down 'cascade' provisions, which in the proposal are divided between two articles, with Article 10 applying to pets, zoo and circus animals and horses, while Article 11 applies to food-producing animals. However, animals also exist and receive medication which do not fall into any of these categories. Among them are animals on fur farms, which should also be mentioned in Article 10. Alternatively, Article 10 could simply refer to 'non-food-producing animals'.

Amendment 14

ARTICLE 1 (7)

Article 13, paragraph 1 (Directive 2001/82/EC)

1. By way of derogation from point (j) of the first subparagraph of Article 12(3), and without prejudice to the law relating to the protection of industrial and commercial property, the applicant shall not be required to provide the results of the safety and residue tests or of the pre-clinical and clinical trials if he/she can demonstrate that the medicinal product is a generic of a reference medicinal product authorised within the meaning of Article 5 for not less than ten years in a Member State or the Community.	1. By way of derogation from point (j) of the first subparagraph of Article 12(3), and without prejudice to the law relating to the protection of industrial and commercial property, the applicant shall not be required to provide the results of the safety and residue tests or of the pre-clinical and clinical trials if he/she can demonstrate that the medicinal product is a generic of a reference medicinal product authorised within the meaning of Article 5 for not less than ten years in a Member State or the Community.
However, the ten-year period provided for in the first subparagraph is extended to ***13*** years in the case of veterinary medicinal products for ***fish or bees***.	However, the ten-year period provided for in the first subparagraph is extended to ***15*** years in the case of veterinary medicinal products for ***smaller species and laying hens, provided that the applicant places the medicinal product on the market in the course of the first two years following authorisation.***

Justification

The duration of the industrial-property protection period for medicinal products should be extended to a minimum of 15 years in order to enable the industry to derive full benefit from such products.

Amendment 15

ARTICLE 1 (7)

Article 13 (4) (Directive 2001/82/EC)

4. In the case of veterinary medicinal products intended for one or more ***food-producing*** species and containing a new active substance that has not been authorised in the Community by [date] the ten-year period provided for in the first subparagraph of paragraph 1 shall be extended by one year for each extension of the marketing authorisation to another ***food-producing*** species, if it is authorised within the ***three*** years following the granting of the initial	4. In the case of veterinary medicinal products intended for one or morespecies and containing a new active substance that has not been authorised in the Community by [date] the ten-year period provided for in the first subparagraph of paragraph 1 shall be extended by one year for each extension of the marketing authorisation to another species ***or other significant new therapeutic indication,*** if it is authorised within the ***eight*** years following the granting of the initial

marketing authorisation.	marketing authorisation. ***Significant new therapeutic indications are those which, during the scientific evaluation prior to their authorisation, are held to bring a significant clinical benefit in comparison with existing therapies.***
The extension of one, two or three years of further data protection also applies to any initial marketing authorisation relative to two, three or four food-producing species, respectively.	The extension of one, two or three years of further data protection also applies to any initial marketing authorisation relative to two, three or four food-producing species, respectively.
This period cannot, however, exceed a total of 13 years***, for a marketing authorisation for four or more food-producing species***.	This period cannot, however, exceed a total of 13 years.
The extension of the ten-year period to 11, 12, or 13 years shall be granted only if the marketing authorisation holder had also been at the origin of the maximum residue limits established for the species covered by the authorisation.	The extension of the ten-year period to 11, 12, or 13 years ***in relation to a food-producing species*** shall be granted only if the marketing authorisation holder had also been at the origin of the maximum residue limits established for the species covered by the authorisation.

Justification

New data is also needed for extending products to companion animals or to new diseases in the same food-producing animal and should also be protected. Developing this data and registration may take more than three years.

Amendment 16 ARTICLE 1 (8)
Article 13c (Directive 2001/82/EC)

After marketing authorisation has been granted, the marketing authorisation holder may allow use to be made of the pharmaceutical, safety and residues, preclinical and clinical documentation contained in the file with a view to examining a subsequent application for a veterinary medicinal product having the same qualitative and quantitative composition in active substances and the same pharmaceutical form.	***The*** marketing authorisation holder may allow use to be made of the pharmaceutical, safety and residues, preclinical and clinical documentation contained in the file with a view to examining a subsequent ***or parallel*** application for a veterinary medicinal product having the same qualitative and quantitative composition in active substances and the same pharmaceutical form.

Justification

Companies increasingly need to cooperate to develop animal medicines, or to bring them to market in all Member States. Penalising one partner with a delayed marketing authorisation will not encourage this. Being able to co-launch is important

Amendment 17
ARTICLE 1 (9)
Article 14 (1) (Directive 2001/82/EC)

(1) Name of the veterinary medicinal product followed by the strength and the pharmaceutical form;	(1) Name of the veterinary medicinal product followed by the strength and ***optionally*** the pharmaceutical form;

Justification

If the name of the product becomes too long then it will be impossible to fit it onto labels of small packs. The 'pharmaceutical form' is not always necessary in the name.

Amendment 18
ARTICLE 1 (17)
Article 27 (3) (Directive 2001/82/EC)

3. In order to allow the continuous evaluation of the relationship between the benefits and the risks, the marketing authorisation holder shall also forthwith forward to the competent authorities any new information which might entail the amendment of the contents of the file or of the approved summary of the product characteristics. In particular, he/she shall forthwith inform the competent authorities of any prohibition or restriction imposed by the competent authorities of any country in which the veterinary medicinal product is marketed or of any rejection of an application for authorisation submitted in a third country.	***Delete***

Justification

Non-EU countries may use different criteria to accept or reject products that bear no relation to the authorisation process in the EU, unless 'equivalence' has been demonstrated with the EU through the establishment of a mutual recognition agreement.

Amendment 19
ARTICLE 1 (18)
Article 28 (2) and (3) (Directive 2001/82/EC)

2. ***Any authorisation that is not followed within two years of its issue by the*** actual marketing of the authorised veterinary medicinal product in the authorising Member State ***shall cease to be valid***.	2. ***The marketing authorisation holder shall state in each periodic safety update report submitted in accordance with article 75(5) whether there is*** *a*ctual marketing of the authorised veterinary medicinal product in the authorising Member State ***during the period covered by the report***.
3. When an authorised veterinary medicinal product previously placed on the market in the authorising Member State, is no longer actually present on the market in that Member State for a period of two consecutive years, the authorisation shall cease to be valid.	***Delete***

Justification

Requiring the marketing authorisation holder to include information in the reports required under Article 75(5) will achieve the same objective without forcing products off the market if they are not required, or cannot be marketed or manufactured for a 2-year period.

Amendment 20
ARTICLE 1 (21)
Article 34 (2) (Directive 2001/82/EC)

2. With a view to promote the harmonisation of veterinary medicinal products authorised for not less than ten years in the Community, and to strengthen the efficiency of the provisions of Article 11, the Member States shall send to the coordination group, no later than [date], a list of	2. With a view to promote the harmonisation of veterinary medicinal products authorised for not less than ten years in the Community, and to strengthen the efficiency of the provisions of Article 11, the Member States shall send to the coordination group, no later than [date], a list of

veterinary medicinal products for which a harmonised summary of product characteristics should be prepared.	veterinary medicinal products for which ***the relevant marketing authorisation holders have agreed that*** a harmonised summary of product characteristics should be prepared.
The coordination group shall agree on a list of medicinal products, on the basis of proposals sent by the Member States, and shall forward this list to the Commission.	The coordination group shall agree on a list of medicinal products, on the basis of proposals sent by the Member States, and shall forward this list to the Commission.
The medicinal products in this list are subject to the provisions in Paragraph 1 following a timetable established in cooperation with the Agency.	The medicinal products in this list are subject to the provisions in Paragraph 1 following a timetable established in cooperation with the Agency ***and the interested parties.***
The Commission, acting in collaboration with the Agency, and taking into consideration the views of interested parties, shall agree the final list.	The Commission, acting in collaboration with the Agency, and taking into consideration the views of interested parties, shall agree the final list ***and timetable.***

Justification

Harmonisation should be sought, but not at the expense of indications lost from the product label, especially given the current medicines availability crisis. Harmonisation will be resource-intensive; a practical timetable is necessary

Amendment 21
ARTICLE 1 (44)
Article 67 (a), (ii) (a) (Directive 2001/82/EC)

(a) veterinary medicinal products for food-producing animals;	***Delete***

Justification

Existing national product distribution systems and food-residue monitoring programmes in the Member States are all shown to be safe and effective. Due to different interpretations of the term "medicine" and the different professional rules existing in each Member State for "prescribing," this proposal will not create a harmonised European situation. It will over-ride national sovereignty and will be very damaging to the interests of animal welfare, farmers and thousands of rural businesses which are registered to supply certain categories of animal medicines in some Member States.

The existing law provides for protection for the consumer of foodstuffs from the treated animal – this clause should be reinstated (the Commission's proposal calls for a deletion!)

Extending the existing timeframe from 5 to 7 years will restrict access to medicines without corresponding benefits. The four-year period represents the end of the intense in-use monitoring (pharmacovigilance) period for a new product (Article 75.5). The "unless" clause should be reinstated, as it allows individual cases to be assessed on their merits.

Amendment 22
ARTICLE 1 (44)
Article 67 (b) (Directive 2001/82/EC)

(b) "In addition, a prescription shall be required for new veterinary medicinal products containing an active substance which has been authorised for use in a veterinary medicinal product for less than ***seven years.***"	(b) "In addition, a prescription shall be required for new veterinary medicinal products containing an active substance which has been authorised for use in a veterinary medicinal product for less than ***four years unless, having regard to the information and particulars provided by the applicant, or experience acquired in the practical use of the veterinary medicinal product, the competent authorities are satisfied that none of the criteria referred to in (a) to (d) of the first paragraph apply.***"

Justification

Extending the existing timeframe from 5 to 7 years will restrict access to medicines without corresponding benefits. The four-year period represents the end of the intense in-use monitoring (pharmacovigilance) period for a new product (Article 75.5). The "unless" clause should be reinstated, as it allows individual cases to be assessed on their merits.

Amendment 23
ARTICLE 1 (44)
Article 67 (c) (Directive 2001/82/EC)

(c) those products in respect of which special precautions must be taken by the veterinarian in order to avoid any unnecessary risk to: - the target species, - the person administering the products to the animal, ***- the consumer of foodstuffs obtained from the treated animal,*** - the environment;	(c) those products in respect of which special precautions must be taken by the veterinarian in order to avoid any unnecessary risk to: - the target species, - the person administering the products to the animal, ***delete*** - the environment;

Justification

See Amendment 21.

Amendment 24
ARTICLE 1 (44)
Article 67 (e) (Directive 2001/82/EC)

(e) magistral or officinal formulae intended for animals. In addition, a prescription shall be required for new veterinary medicinal product containing an active substance which has been authorised for use in a veterinary medicinal product for less than ***seven years.***	(e) magistral or officinal formulae intended for animals. In addition, a prescription shall be required for new veterinary medicinal product containing an active substance which has been authorised for use in a veterinary medicinal product for less than ***four years, unless, having regard to the information and particulars provided by the applicant, or experience acquired in the practical use of the veterinary medicinal product, the competent authorities are satisfied that none of the criteria referred to in (a) to (d) of the first paragraph apply.***

Justification

See amendment 21.

Amendment 25
ARTICLE 1 (45)
Article 69 (Directive 2001/82/EC)

Member States shall ensure that the owners or keepers of food-producing animals can provide proof of purchase, possession and administration of veterinary medicinal products to such animals for a period of five years after ***slaughter***.	Member States shall ensure that the owners or keepers of food-producing animals can provide proof of purchase, possession and administration of veterinary medicinal products to such animals for a period of five years after ***medication***.

Justification

Keeping records for five years after medication will ensure perfectly well that an animal's medical history can be traced, for example if medicine residues are found in the animal or in food products derived from it. In practice, residues ought not to be found once the withdrawal period for the medicine has elapsed.

21 June 2002

OPINION OF THE COMMITTEE ON BUDGETS

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

on

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

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

3) the proposal for a European Parliament and Council directive on amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products (COM(2001) 404 – C5-0593/2001 – 2001/0254(COD))

Draftsman: Wilfried Kuckelkorn

PROCEDURE

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

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

At the last meeting it adopted the following amendments unanimously.

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

SHORT JUSTIFICATION

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

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

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

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

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

AMENDMENTS

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

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

Text proposed by the Commission[1]	Amendments by Parliament

Amendment 1
Recital 19a (new)

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

Justification

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

Amendment 2
Recital 19b (new)

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

Justification

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

[1] OJ C 75E, 26.03.02 p. 189.

Amendment 3
Article 60, paragraph 1

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

Justification

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

Amendment 4
Article 60, paragraph 3

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

Justification

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

Amendment 5
Article 60, paragraph 6

The Management Board shall adopt the	The Management Board shall adopt the

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

Justification

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

Amendment 6
Article 61

Article 61	Article 61
The structure and the ***amount*** of the fees referred to in Article 60(1) shall be established by the Council acting under the conditions provided for by the Treaty on a proposal from the Commission, following the latter's consultation of organisations representing the interests of the pharmaceutical industry at Community level.	The structure and the ***level*** of the fees referred to in Article 60(1) shall be established by the Council acting under the conditions provided for by the Treaty on a proposal from the Commission, following the latter's consultation of organisations representing the interests of the pharmaceutical industry at Community level. ***The Management Board shall adjust the level of the fees each year in accordance with the EU inflation rate established by Eurostat.***

Justification

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

Amendment 7
Article 69

Article 69	Article 69
The Management Board shall, in the case	***Administrative measures for*** veterinary

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

Justification

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

20 June 2002

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

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

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

Draftsman: Umberto Scapagnini

PROCEDURE

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

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

At the last meeting it adopted the following amendments by 36 votes to 4, with 1 abstention.

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

SHORT JUSTIFICATION

This new Regulation is not a fundamental change from the one entered into force seven years ago, and the review envisaged is a pragmatic one, which takes account of the experience in implementing the current framework.

As the lead Committee, the Committee on the Environment, Public Health and Consumer Policy will certainly take care of the aspects directly linked to the safety and to the preservation of human and animal health, as well as to the general objectives of public health systems.

As the Committee responsible for Industry and External Trade, we would like to focus on a limited number of points, so as to support pharmaceutical industries' efforts to remain competitive in a world of increasing globalisation.

In order to meet more effectively patient demand for innovative medicines, the European pharmaceutical industry needs to work in the right business environment while protecting entrepreneurship so as to enhace its ability to generate a constant flow of innovative therapeutic aids to the benefit of patients, as well as attempting to reduce the technological gap between themselves and the U.S. and Japanese industries. Competitiveness of the EU industry must be maintained.

Other points to take into consideration with the report are the following:

- Protect SME's in the sector from being totaly overcome by the exploitation of research, to protect their access to results and guard them from being compressed extensively by the commercialization period.
- In the interest of patients and in part of the national "health systems", it is important to ensure a reasonable time frame in which the double registration approach is still monitored.
- With regard to the safety of patients, by balancing control with economical aspects only a limited number of "generic medicines" can be allowed with generic names but with the original trademark specified in order to guarantee the quality of production.

The draftsman has therefore limited himself to a few procedural suggestions which might have an immediate impact in reducing the cost and complexity of procedures for the involved companies avoiding redundant testing for both innovators and generic manufacturers and greatly increase their flexibility and ability to act swiftly on the market.

Besides the amendments contained in this opinion, the draftsman intends, in co-operation with his colleague in charge, to table amendments to the Directives, which aim at the same objective and follow the same lines.

AMENDMENTS

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

Text proposed by the Commission[1]	Amendments by Parliament
Amendment 1 Article 2, second paragraph	
The holder of a marketing authorisation for the medicinal products covered by this Regulation should be established in the Community. The holder shall be responsible for placing those medicinal products on the market.	The holder of a marketing authorisation for the medicinal products covered by this Regulation should be established in the Community. The holder shall be responsible for placing those medicinal products on the market. ***The holder is responsible for ensuring that the placing on the market of those medicinal products, whether by himself, or by a third party, is done in compliance with the provisions of this Regulation.***
Justification	
This amendment takes account of the variety of channels and commercial agreements for the distribution of pharmaceuticals, and avoids legal uncertainty both for the consumers and the business partners by ensuring that these marketing schemes do not interfere with the responsibility related to certification processes.	
Amendment 2 Article 3, point 3, header	
3. ***A*** generic form of a medicinal product authorised by the Community may be authorised by the competent authorities of ***the*** Member State***s*** in accordance with Directive 2001/83/EC and Directive 2001/82/EC under the following conditions:	3. ***The same medicinal product or a*** generic form of a medicinal product authorised by the Community may be authorised by the competent authorities of ***a*** Member State in accordance with Directive 2001/83/EC and Directive 2001/82/EC under the following conditions:
Justification	
The Commission proposals allow generic applications relating to marketing authorisations granted by the Community (i.e. using the Centralised Procedure) to be filed either via the	

[1] OJ C 75E, 26.3.2002, p.189-.

Centralised Procedure (as it was the case so far), or using one of the other procedures involving the national Member States authorities. This amendment proposes that the companies having obtained the initial marketing authorisation (or their contracted licensees), should also be allowed to file abridged (reduced applications based on the reference to the originator file) applications, to obtain duplicate authorisations in one or more Member States. This is consistent with Article 10c of the proposed modifications to the Directive.

Amendment 3
Article 3.3, letter (b)

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

Reference to parts of the summary of characteristics covered by patent would ensure that generics are not forced to include uses and formulations that are covered by a patent - which would either open generic companies to litigation or prevent generics from using the centralised procedure.

Amendment 4
Article 3.3, letter (c)

(c) the generic medicinal product is authorised under the same name in all the Member States where the application has been made.	(c) the generic medicinal product is authorised under the same name in all the Member States where the application has been made. ***For the purpose of this Regulation and Directives 2001/83/EC and 2001/82/EC all the linguistic versions of the INN are deemed to be the same.***

Justification

The Scientific Names (INN) of compounds can differ between countries (i.e. they are not written in Latin). The INN names are often used as the only name or part of the name of the generic product. Therefore, it is critically important that all linguistic versions of the INN are deemed the same otherwise the Centralised would be unworkable for generics.

Amendment 5
Article 9, paragraph 3

3. Within ***30*** days of its adoption, the Agency shall send the final opinion of the Committee for Human Medicinal Products to the Commission, to the Member States and to the applicant, together with a report describing the assessment of the medicinal product by the Committee and stating the reasons for its conclusions.	3. Within ***five calendar*** days of its adoption, the Agency shall send the final opinion of the Committee for Human Medicinal Products to the Commission, to the Member States and to the applicant, together with a report describing the assessment of the medicinal product by the Committee and stating the reasons for its conclusions.

Justification

The purpose of this amendment is to reduce the length of the decision-making process (which was heavily criticised during the audit).

Amendment 6
Article 10, paragraph 1, subparagraph 1

1. Within ***30*** days of receipt of the opinion referred to in Article 5(2), the Commission shall prepare a draft of the decision to be taken in respect of the application.	1. Within ***ten*** days of receipt of the opinion referred to in Article 5(2), the Commission shall prepare a draft of the decision to be taken in respect of the application.

Justification

The purpose of this amendment is to reduce the length of the decision-making process and to clarify the substance of the draft decision.

Amendment 7
Article 10, paragraph 1, subparagraph 2

In the event of a draft decision granting marketing authorisation, the draft shall ***include or*** make reference to the documents mentioned in points (a), (b) and (c) of the first subparagraph of Article 9(4).	In the event of a draft decision granting marketing authorisation, the draft shall make reference to the documents mentioned in points (a), (b) and (c) of the first subparagraph of Article 9(4).

Justification

The purpose of this amendment is to reduce the length of the decision-making process and to clarify the substance of the draft decision.

Amendment 8
Article 10, paragraph 2

2. The Commission shall take a final decision in accordance with the procedure referred to in Article 77(3) if the draft decision accords with the Agency's opinion.	2. The Commission shall take a final decision in accordance with the procedure referred to in Article 77(3) if the draft decision accords with the Agency's opinion.
The Commission shall take a final decision in accordance with the procedure referred to in Article 77(4) if the draft decision does not accord with the Agency's opinion.	The Commission shall take a final decision in accordance with the procedure referred to in Article 77(4) if the draft decision does not accord with the Agency's opinion.
	The final Commission decision shall be taken within three days of the end of the procedures referred to in Article 77(3) and (4).

Justification

This is to ensure speedy implementation.

Amendment 9
Article 13, paragraph 1

1. ***Without prejudice to paragraphs 2 and 3,*** authorisation shall be valid for an unlimited period.	1. Authorisation shall be valid for an unlimited period.

Justification

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

Amendment 10
Article 13, paragraph 2

2. Any authorisation which is not followed by the actual placing of the medicinal product for human use authorised on the	***deleted***

Community market within two years of authorisation shall cease to be valid.

Justification

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

Amendment 11
Article 13, paragraph 3

3. When an authorised medicinal product previously placed on the market is no longer actually present on the market for two consecutive years, the authorisation shall cease to be valid.	***deleted***

Justification

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

Amendment 12
Article 35, paragraph 1

1. ***Without prejudice to paragraphs 2 and 3,*** authorisation shall be valid for an unlimited period.	1. Authorisation shall be valid for an unlimited period.

Justification

A pharmaceutical company is unlikely to make the significant investment required to obtain a marketing authorisation if it does not intend to market the product. However, there are legitimate reasons why a product may not be on the market for a particular period of time. For example, if it is a drug to treat a sporadic disease, it may only occasionally be required.

Amendment 13
Article 35, paragraph 2

2. Any authorisation which is not followed by the actual placing of the veterinary medicinal product authorised on the Community market within two years of authorisation shall cease to be valid.	***deleted***

Justification

A pharmaceutical company is unlikely to make the significant investment required to obtain a marketing authorisation if it does not intend to market the product. However, there are legitimate reasons why a product may not be on the market for a particular period of time. For example, if it is a drug to treat a sporadic disease, it may only occasionally be required.

Amendment 14
Article 35, paragraph 3

3. When an authorised veterinary medicinal product previously placed on the market is no longer actually present on the market for two consecutive years, the authorisation for the product shall cease to be valid.	***deleted***

Justification

A pharmaceutical company is unlikely to make the significant investment required to obtain a marketing authorisation if it does not intend to market the product. However, there are legitimate reasons why a product may not be on the market for a particular period of time. For example, if it is a drug to treat a sporadic disease, it may only occasionally be required.

Amendment 15
Article 72, point 1

Only one authorisation may be granted to a particular applicant for a specific medicinal product.	
However for objective verifiable reasons relating to public health or the availability	

of medicinal products to health professionals and/or patients, the Commission may authorise the same applicant to submit more than one application to the Agency for that medicinal product.

Justification

The fact that the same product can have several indications should not impede its marketing for only part of its possible purposes. Splitting the certification process by authorising separate applications is a means to accelerate the availability of a drug for the consumer, while a single application would cause delays to cover all possible uses, even marginal. As long as public health protection is not lowered, the choice of a single or several applications should be left to the applicant.

Amendment 16
Annex I, point 3

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

Justification

Mandatory recourse to the centralised procedure for all new substances would be too rigid in many cases, notably for drugs developed by SMEs that cannot envisage a simultaneous marketing in the EU as a whole.

Amendment 17
Annex I, paragraph 4

4. Medicinal products intended for veterinary use, containing a new active substance which was not included in the composition of any medicinal product for veterinary use authorised in the

deleted

Community prior to the date of entry into force of this Regulation.

Justification

The flexibility to register in those particular geographical markets where the disease and/or species occurs will ensure that the medicines are registered in those markets. Compelling unnecessarily costly registration via the centralised procedure may mean the product is not registered at all.

21 June 2002

OPINION OF THE COMMITTEE ON BUDGETARY CONTROL

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

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

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

- on a proposal for a Directive of the European Parliament and of the Council amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products
(COM(2001) 404 – C5-0593/2001 – 2001/0254 (COD))

Draftsman: Jan Mulder

PROCEDURE

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

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

At the last meeting it adopted the following amendments unanimously.

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

SHORT JUSTIFICATION

The European Parliament is the discharge authority for only four of the agencies currently in existence[1].

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

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

AMENDMENTS

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

Text proposed by the Commission[2]	Amendments by Parliament
Amendment 1 Article 56 (2)	
2. Members of the Management Board, members of the Advisory Board, members of the Committees, rapporteurs and experts shall not have financial or other interests in the pharmaceutical industry which could affect their impartiality They shall undertake to act in the public interest and in an independent manner. All indirect interests which could relate to this industry shall be entered in a register held by the Agency which the public may consult.	2. Members of the Management Board, members of the Advisory Board, members of the Committees, rapporteurs and experts shall not have financial or other interests in the pharmaceutical industry which could affect their impartiality. They shall undertake to act in the public interest and in an independent manner. All indirect interests which could relate to this industry shall be entered in a register held by the Agency which the public may consult ***on request, at the Agency's offices.***

[1] Centre for Development of Vocational Training, Thessaloniki.
Foundation for Improvement of Living and Working Conditions, Dublin.
Reconstruction Agency for Kosovo, Thessaloniki
European Food Safety Authority
[2] OJ C not yet available.

	The Agency´s code of conduct shall provide for implementation of this article with particular reference to the acceptance of gifts.
Members of the Management Board, members of the Advisory Board, members of the Committees, rapporteurs and experts who participate in meetings or working groups of the Agency shall declare, at each meeting, any specific interests which could be considered to be prejudicial to their independence with respect to the points on the agenda.	Members of the Management Board, members of the Advisory Board, members of the Committees, rapporteurs and experts who participate in meetings or working groups of the Agency shall declare, at each meeting, any specific interests which could be considered to be prejudicial to their independence with respect to the points on the agenda. ***These declarations shall be available to the public.***

Justification

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

Amendment 2
Article 58(1)

1. The Management Board shall ***consist of four representatives of the Member States, four representatives of the European Parliament, four representatives of the Commission, and four representatives of patients and industry, appointed by the Commission.***	1. The Management Board shall ***be composed of 14 members appointed by the Council in consultation with the European Parliament from a list drawn up by the Commission which includes a number of candidates substantially higher than the number of members to be appointed, plus a representative of the Commission. Four of the members shall have their background in organisations representing patients and industry.*** ***The list drawn up by the Commission, accompanied by the relevant documentation, shall be forwarded to the European Parliament. As soon as possible and within three months of such communication, the European Parliament may make its views available for consideration by the Council, which will then appoint the Management Board.*** ***The members of the Board shall be***

	appointed in such a way to secure the highest standards of competence, a broad range of relevant expertise and, consistent with these, the broadest possible geographic distribution within the Union.
The full members of the Management Board may arrange to be replaced by alternates.	

Justification

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

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

Amendment 3
Article 60 (10)

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

Justification

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

Amendment 4
Article 60a (new)

Combating fraud

1. ***In order to combat fraud, corruption and other unlawful activities the provisions of Regulation (EC) No 1073/1999 of the European Parliament and of the Council of 25 May 1999[1] concerning investigations conducted by the European Anti-Fraud Office (OLAF) shall apply without restriction.***

2. The Agency shall accede to the Interinstitutional Agreement of 25 May 1999 concerning internal investigations by the European Anti-Fraud Office (OLAF)[2] and shall issue, without delay, the appropriate provisions applicable to all the employees of the Agency.

Justification

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

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

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

Amendment 5
Article 70

To ensure ***an appropriate*** level of transparency, the Management Board, on the basis of a proposal by the Executive Director, in agreement with the Commission, shall adopt rules to ensure the availability to the public of regulatory,

To ensure ***a high*** level of transparency, the Management Board, on the basis of a proposal by the Executive Director, in agreement with the Commission, shall adopt rules to ensure the availability to the public of regulatory, scientific or technical

[1] OJ L 136, 31 May 1999.
[2] OJ L 136, 31 May 1999.

scientific or technical information concerning the authorisation or supervision of medicinal products which is not of a confidential nature.	information concerning the authorisation or supervision of medicinal products which is not of a confidential nature. ***The internal rules of procedure of the Agency and its committees and working groups shall be made available to the public and published on the internet.***

Justification

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

ANNEX 1

AGENCY	DISCHARGE AUTHORITY	GIVEN TO
Centre for Development of Vocational Training[1] Thessaloniki (formerly Berlin) [1975] Foundation for Improvement of Living and Working Conditions[2] Dublin [1975]	European Parliament (on recommendation by Council)	Management Board
Reconstruction Agency for Kosovo (OBNOVA)[3] Thessaloniki [1999] European Food Safety Authority (EFSA)[4] Provisional seat: Brussels [2002]	European Parliament (on recommendation by Council)	Director
Environment Agency[5] Copenhagen [1990] European Training Foundation[6] Turin [1990] Monitoring Centre for Drugs and Drug Addiction[7] Lisbon [1993] Agency for the Evaluation of Medicinal Products[8] London [1993] Office for Harmonisation in the Internal Market[9] Alicante [1994] Community Plant Variety Office[10] Angers [1994] Translation Centre for Bodies of the EU[11] Luxembourg [1994] Agency for Safety and Health at Work[12] Bilbao [1995] Monitoring Centre for Racism and Xenophobia[13] Vienna [1997]	Management Board	Director

[1] Council Regulation 337/75 of 10.2.1975
[2] Council Regulation 1365/75 of 26.5.1975
[3] Council Regulation 2454/99 of 15.11.1999
[4] Regulation 178/92 of the European Parliament and the Council of 28.1.2002
[5] Council Regulation 1210/90 of 7.5.1990
[6] Council Regulation 1360/90 of 7.5.1990
[7] Council Regulation 302/93 of 8.2.1993
[8] Council Regulation 2309/93 of 23.7.1993
[9] Council Regulation 40/94 of 20.12.1993
[10] Council Regulation 2100/94 of 27.7.1994
[11] Council Regulation of 2965/94 of 28.11.1994
[12] Council Regulation 2062/94 of 18.7.1994
[13] Council Regulation 1035/97 of 2.6.1997