

P5_TA-PROV(2002)0504

European Agency for the Evaluation of Medicinal Products *I**

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

¹ OJ C 75 E, 26.3.2002, p. 189.

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

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.

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 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products⁽¹⁾, implemented through Commission Regulation (EC) No 847/2000⁽²⁾. Such a 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.

⁽¹⁾ OJ L 18, 22.1.2000, p. 1.

⁽²⁾ OJ L 103, 28.4.2000, p. 5.

Amendment 4

Recital 11

(11) In the interest of public health, it is necessary that authorisation decisions under the centralised procedure be taken on

(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 Common Agricultural Policy.

the basis of the objective scientific criteria of quality, safety, 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 of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use⁽¹⁾, 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 common agricultural policy.

⁽¹⁾ OJ L 121, 1.5.2001, p. 34.

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.

Amendment 6
Recital 12 a (new)

(12a) In order to ensure maximum safety and efficacy with respect to the administration of medicinal products for children, as well, in future, all medicinal products which might be useful for children must be tested with regard to their administration to children respecting the criteria laid down in Directive 2001/20/EC and particular incentives should be created for research into special paediatric medicinal products. In addition, an incentive should be created to test medicinal products already long-established for adult use for their subsequent use by children.

Amendment 7
Recital 12 b (new)

(12b) The Community is required, pursuant to Article 178 of the Treaty, to take account of the development policy aspects of any measure and to promote the creation of conditions fit for human beings worldwide. Pharmaceutical law should 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.

Amendment 8
Recital 12 c (new)

(12c) Regulation (EC) No 414/2000 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.

Amendment 147
Recital 12 d (new)

(12d) Article 3(2) of the Treaty obliges the Community to recognise and integrate gender aspects in all policy areas. For pharmaceutical legislation, this means that differences between the sexes in terms of the efficacy and safety of medicinal products should be evaluated in clinical trials and patients informed of the results. The Commission should adapt the technical guidelines for applicants and holders of marketing authorisation accordingly.

Amendment 173
Recital 13 a (new)

(13a) The entire body of legislation relating to medicinal products involves matters relating to public health.

Amendment 10
Recital 16 a (new)

(16a) The Agency should test a pilot project for prior certification of the test protocol for clinical trials. For this purpose, enterprises should 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.

Amendment 152
Recital 17 a (new)

(17a) The Agency's budget should be composed of fees paid by the private sector and contributions paid out of the Community budget to implement Community policies. The core tasks of the Agency should be entirely covered by the Community budget.

Amendment 12
Recital 17 b (new)

(17b) Paragraph 25 of the Interinstitutional Agreement of 6 May 1999 between the European Parliament, the Council and the Commission on budgetary discipline and improvement of the budgetary procedure⁽¹⁾ provides that the Financial Perspective will be adjusted in order to cover the new needs resulting from enlargement.

⁽¹⁾ OJ C 172, 18.6.1999, p. 1.

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

(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

scientific opinions issued. The appeal procedures should be amended to provide a better guarantee for applicants' rights.

purpose, whilst retaining total responsibility for the scientific opinions issued. The appeal procedures should be amended to provide a better guarantee for applicants' rights.

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.

Amendment 163/rev
Recital 29

(29) In line with the current provisions of Directives 2001/83/EC and 2001/82/EC, the term of validity of a Community marketing authorisation should be ***unlimited***. Furthermore, any authorisation not used for two consecutive years, that is to say, one which has not led to the placing on the market of a medicinal product in the Community during that period, should be considered invalid, in order, in particular, to avoid the administrative burden linked to maintaining such authorisations.

(29) In line with the current provisions of Directives 2001/83/EC and 2001/82/EC, the term of validity of a Community marketing authorisation ***for new medicinal products*** should be ***limited initially to five years***. Furthermore, any authorisation not used for two consecutive years, that is to say, one which has not led to the placing on the market of a medicinal product in the Community during that period, should be considered invalid, in order, in particular, to avoid the administrative burden linked to maintaining such authorisations.

Amendment 15
Recital 30 a (new)

(30a) Council Directive 89/105/EC of 21 December 1988 relating to the transparency of measures regulating the prices of medicinal products for human use

and their inclusion in the scope of national health insurance systems⁽¹⁾ 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 implementation of that Directive, and proposals for its revision and enforcement.

⁽¹⁾ OJ L 40, 11.2.1989, p. 8.

Amendment 18
Article 1 a (new)

Article 1a

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.

Amendment 140
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 shall be responsible for placing those medicinal products on the market. *He may use a local representative as defined in Directive 2001/83/EC.*

Amendment 20
Article 2, paragraph 2 a (new)

An evaluation of the positive effects of the product must 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.

Amendment 21

Article 3, paragraph 3, point (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

Amendment 22

Article 3, paragraph 3, point (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 (international non-proprietary name) are deemed to be the same.***

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 human use.

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. ***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 Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents⁽¹⁾.***

⁽¹⁾ OJ L 145, 31.5.2001, p. 43.

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. As a rule, that will exclude the recognition of clinical trials carried out in developing countries, unless the medicinal product concerned is primarily geared to the domestic market in that country.*** 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.

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. ***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 must 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.

Amendment 26

Article 6, paragraph 1 a (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.

Amendment 175

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

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

On the basis of a duly reasoned request the Committee for Human Medicinal Products may call for the duration of the analysis of the scientific data in the file concerning the application for marketing authorisation to be extended. That request must stipulate the additional length of time needed for the analysis of the scientific data in the file concerning the application for marketing authorisation to be carried out successfully.

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

Amendment 27

Article 7, point (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;

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 made unannounced.

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.

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.

Amendment 31

Article 9, paragraph 4, point (b a) (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.

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.

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 Article 77(3) and (4).

Amendment 34

Article 10, paragraph 6 a (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.

Amendment 153

Article 10 a (new)

Article 10a

If a manufacturer withdraws an application for authorisation submitted to the Agency before a decision on authorisation is taken, the manufacturer shall communicate its reasons for doing so to the Agency. The Agency shall immediately notify the competent

authorities of the Member State concerned.

Amendment 36
Article 11, paragraph 2 a (new)

2a. Information about all refusals and the reasons for them 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 ATC (Agreed Therapeutic Categories) code.***

Amendments 38 and 174
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, ***provided that such information is not vital in respect of human health or the environment.***

The reasons for each therapeutic indication covered by the application shall be stated separately.

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 adverse reactions to*** the *medicinal* product concerned at Community level.

Amendment 165/rev
Article 13, paragraph 1

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

1. Without prejudice to paragraphs 2 and 3, ***marketing*** authorisation ***for new medicinal products*** shall be valid for ***five years***.

The authorisation must be renewed after five years on the market, on the basis of a comparative reassessment by the competent authority of the updated risk/benefit balance. Following that renewal the marketing authorisation shall be valid for an unlimited period. At the time of the renewal of the marketing authorisation, Annexes I-III to that authorisation shall also be updated.

The reassessment procedure must be completed at least 30 days before the expiry of the original marketing authorisation. The competent authority shall as soon as possible notify the authorisation holder of the results of the reassessment.

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.

Amendments 41 and 146
Article 13, paragraph 2 a (new)

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

Amendment 42
Article 13, paragraph 3 a (new)

3a. 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’.

Amendment 43
Article 13, paragraph 4, subparagraph 1

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

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 Regulation (EC) No 1049/2001.***

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 a requirement 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.

Amendment 45

Article 13, paragraph 6, subparagraphs 2 a and 2 b (new)

On the basis of a duly reasoned request the Committee for Human Medicinal Products may require the duration of the scientific and clinical trials to be extended. The 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 Management 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 Management Board.

Amendment 46

Article 13, paragraph 8

8. Medicinal products for human use which have been authorised 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 authorised 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.

Amendment 47

Article 13 a (new)

Article 13a

The Commission shall carry out an in-depth study of the actual application in practical terms of Directive 89/105/EEC in all the EU Member States and in the applicant countries. Depending on the results obtained, the European Parliament

shall have the option of calling on the Commission to review the principles of that Directive and, if necessary, to consider revising it.

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.

Amendment 49
Article 15 a (new)

Article 15a

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

Amendment 50
Article 18, paragraph 4, subparagraph 2 a (new)

The Member State shall also ensure that health professionals are rapidly informed of the action and the reasons therefor. The network provided by the professional associations should be fully utilised to this end. Member States shall inform the Commission and the Agency of the procedures put in place for this purpose.

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 a Register in accordance with Regulation (EC) No 1049/2001.*

Amendment 52
Article 19, paragraph 1 a (new)

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

Amendment 53
Article 20, paragraph 1

The Agency, acting in close cooperation with the national pharmacovigilance systems established in accordance with Article 102 of Directive 2001/83/EC, shall receive all relevant information 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,

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 a Register in accordance with Regulation (EC) No*

formulate opinions on the measures necessary.

1049/2001. 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.***

Amendment 54
Article 20, paragraph 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.***

Amendment 141
Article 21 a (new)

Article 21a

The holder of a marketing authorisation shall inform the competent authorities first of all before any imminent withdrawal of a medicinal product from the market.

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,

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

and *in no case* later than 15 days following the receipt of the information.

incident occurred, and *under no circumstances* later than 15 days following the receipt of the information.

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.

These reactions shall be communicated in the form of a report transmitted electronically and in accordance with the guidelines referred to in Article 24.

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*.

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.

Amendments 60 and 148

Article 22, paragraph 3, subparagraph 3

These records shall be accompanied by a

These records shall be accompanied by a

scientific evaluation.

scientific evaluation *of the benefits and the risks of the medicinal product, which classifies effects according to sex and age group of patients.*

Amendment 61
Article 22, paragraph 3 a (new)

3a. The holder of a marketing authorisation may not communicate information concerning pharmacovigilance issues to the general public without the consent of the Agency.

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.***

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 2001/83/EC.

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. ***Furthermore, such data shall be held in public databases and made accessible, in an appropriate form and free of charge, to any interested parties.***

Amendment 64
Article 24, paragraph 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.

Amendment 65
Article 24a (new)

Article 24a

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

Amendment 66
Article 25 a (new)

Article 25a

The Agency and national public pharmacovigilance systems shall 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 pharmacology 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 undertakings shall be granted access in connection with the products for which they hold authorisations.

Amendment 67
Article 25 b (new)

Article 25b

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 Article 25a. The level of the contribution in the individual 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 Agency level shall operate in an independent, transparent manner.

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 Regulation (EC) No 1049/2001.***

Amendment 69
Article 30, paragraph 2, subparagraph 1

2. 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.

2. 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.***

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.

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, this period will be extended by 30 days.*** The conclusions reached on the appeal shall be annexed to the final opinion.

Amendment 72
Article 31, paragraph 3

3. Within ***30*** days of its adoption, the Agency shall forward the final opinion of

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.

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.

Amendment 73

Article 31, paragraph 4, point (c a) (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.

Amendment 155

Article 32 a (new)

Article 32a

If a manufacturer withdraws an application for authorisation submitted to the Agency before a decision on authorisation is taken, the manufacturer shall communicate its reasons for doing so to the Agency. The Agency shall immediately notify the competent authorities of the Member State concerned.

Amendment 75

Article 33, paragraph 2 a (new)

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

Amendment 76

Article 34, paragraph 3

3. The Agency shall publish the assessment report on the veterinary medicinal product

3. The Agency shall publish *and make publicly accessible in a Register* the

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.

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.

Amendment 166/rev
Article 35, paragraph 1

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

1. Without prejudice to paragraphs 2 and 3, *marketing* authorisation *for new medicinal products* shall be valid for *five years*.

The authorisation must be renewed after five years on the market, on the basis of a comparative reassessment by the competent authority of the updated risk/benefit balance. Following that renewal the marketing authorisation shall be valid for an unlimited period. At the time of the renewal of the marketing authorisation, Annexes I-III to that authorisation shall also be updated.

The reassessment procedure must be completed at least 30 days before the expiry of the original marketing authorisation. The competent authority shall as soon as possible notify the authorisation holder of the results of the reassessment.

Amendment 77
Article 35, 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.

Amendment 78
Article 35, paragraph 2 a (new)

2a. In exceptional circumstances and on

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

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 a Register in accordance with Regulation (EC) No 1049/2001.*

Amendment 80
Article 41, paragraph 1 a (new)

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

Amendment 81
Article 42, paragraph 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 a Register in accordance with Regulation (EC) No 1049/2001.* 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.*

Amendment 82
Article 43, paragraph 2, point (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.***

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 in points (a) and (b) of paragraph 1 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 in points (a) to (d) of paragraph 1 shall lay down in their rules of procedure precise arrangements for consulting the working parties and panels and delegating certain tasks to them. They shall also determine the arrangements for appointing 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).

Amendment 85
Article 50, paragraph 2 a (new)

2a. The Committee for Herbal Medicinal Products shall take over the tasks of the

***Committee for Human Medicinal Products
with regard to the evaluation of herbal
medicinal products.***

Amendment 83
Article 50, paragraph 2 b (new)

2b. 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.

Amendment 86
Article 50, paragraph 4 a (new)

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

Amendment 87
Article 51, paragraph 1, subparagraph 2, point (b)

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

(b) making ***publicly*** available ***in an ad hoc Register in accordance with Regulation (EC) No 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, and periodically checking the effectiveness of the medicinal products in cooperation with undertakings, patients' associations and health-care professionals (doctors and pharmacists);***

Amendment 88
Article 51, paragraph 1, subparagraph 2, point (d)

(d) ***assuring*** the dissemination of information on adverse reactions to medicinal products authorised in the Community, by means of a database

(d) ***ensuring*** 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;

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 and personal data protection being guaranteed;***

Amendment 89

Article 51, paragraph 1, subparagraph 2, point (d a) (new)

(da) assisting the Commission and Member States in the rapid communication of information concerning pharmacovigilance to the associations of healthcare professionals;

Amendment 90

Article 51, paragraph 1, subparagraph 2, point (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 and good clinical practice ***and the verification of compliance with pharmacovigilance obligations;***

Amendment 91

Article 51, paragraph 1, subparagraph 2, point (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 in terms of efficacy, adverse reactions and contra-indications on the basis of the information already authorised for the package leaflet; the database shall include a section on medicinal products which may be administered to children; the information provided shall be worded in an appropriate***

and comprehensible manner;

Amendment 92

Article 51, paragraph 1, subparagraph 2, point (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.

Amendment 93

Article 51, paragraph 1, subparagraph 2, point (n a) (new)

(na) compilation of scientific information concerning pathogenic agents which might be used in biological warfare, and 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;

Amendment 94

Article 51, paragraph 1, subparagraph 2, point (n b) (new)

(nb) 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;

Amendments 95 and 157

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

2. The database provided for in point (j) of paragraph 1 shall include the summaries of product characteristics, the patient or user package leaflet, the information shown on the labelling, **as well as pharmacovigilance data**. The database shall be developed in stages, priority being given to medicinal

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.

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 *all* medicinal products *marketed in the European Union*.

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.

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.

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.***

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.***

Amendment 100

Article 53 a (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.

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.

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 thus appointed shall propose to the Executive Director 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 term of three years which shall be renewable.

Wherever possible, the committees shall seek to establish contacts, on an advisory basis, with associations of people affected, such as patients, health-care professionals, etc.

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

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.

all the meetings of the Committees and **all the meetings** convened by the Agency or its committees.

Amendment 104

Article 54, paragraph 5, subparagraph 2

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 to the provisions on market surveillance and pharmacovigilance laid down in this Regulation.

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,

(c) **the procedures for the organisation of public hearings,**

(d) **the 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.

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 as regards the therapeutic indications for the product.**

Amendment 106
Article 55, paragraph 1, subparagraphs 1 a and 1 b (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).

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.

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.

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. A list of conflicts of interests shall be published in a Register in accordance with Regulation (EC) No 1049/2001. The register shall be accessible at the Agency and on the Internet.

Amendment 110

Article 56, paragraph 2, subparagraph 1

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. ***Officials of the Agency***, 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, ***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***.

Amendment 111

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

The Agency's code of conduct shall provide for implementation of this Article with particular reference to the acceptance of

gifts.

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.***

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.***

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:

Amendment 115

Article 57, paragraph 3, introduction

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, ***those concerning herbal medicinal products*** and those concerning veterinary medicinal products:

Amendment 116

Article 58, paragraph 1, subparagraph 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 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.***

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**.

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.**

Amendment 119
Article 59, paragraph 1

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.

Amendment 120
Article 60, paragraph 1

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

1. 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 shall re-**

Agency.

examine when necessary the level of the contributions on the basis of an evaluation of needs and the level of fees.

Amendment 121
Article 60, paragraph 1 a (new)

1a. In order to ensure full independence, at least the activities relating to pharmacovigilance, the operation of communications networks and market surveillance should receive public funding commensurate with the tasks conferred.

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.*

Amendment 123
Article 60, paragraph 3

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.

3. 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.

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 in the form of an amending budget.***

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.***

Amendment 126

Article 60, paragraph 10

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.

10. 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.

Amendment 127

Article 60 a (new)

Article 60a

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)⁽¹⁾ shall apply without restriction.

2. The Agency shall accede to the

Interinstitutional Agreement of 25 May 1999 between the European Parliament, the Council and the Commission 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.

⁽¹⁾ OJ L 136, 31.5.1999, p. 1.

⁽²⁾ OJ L 136, 31.5.1999, p. 15.

Amendment 128

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 as established by Eurostat.***

Amendment 129

Article 61, paragraph 1a (new)

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

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 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

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.

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 responsibility for translations *being taken over* by the Agency.

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 a 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 Regulation (EC) No 1049/2001*.

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.

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 (EC) No 1049/2001 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).

Amendment 145
Article 72, paragraph 1

1. Only one authorisation may be granted to a particular applicant for a specific medicinal product. Deleted

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.

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.

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.

Amendment 134
Article 73, paragraph 7 a (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.

Amendment 135

Article 74, paragraph 3, subparagraph 1 a (new)

The Commission shall publish the names of the holders of marketing authorisations involved and the amount of, and reasons for, the financial penalties imposed.

Amendment 162

Article 74 a (new)

Article 74a

A European patient group shall mean a group:

- representing patients from more than five Member States,*
- representing specific categories of disease or umbrella groups working in the area of long-term chronic diseases,*
- working on a non-profit basis.*

A European patient group shall have a secretariat responsible for relations with the EU institutions and shall work in the interest of patients to promote information about new medical developments and research and development opportunities, and shall also provide information about the impact of European legislation on its membership. The group shall submit its workplan and all sources of funding in an annual statement to the Commission and the European Parliament.