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Committee on the Environment, Public Health and Food Safety

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2004/0217(COD)

10.3.2006

*****II**

DRAFT RECOMMENDATION FOR SECOND READING

on the Council common position for adopting a regulation of the European Parliament and of the Council on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004
(15763/3/2005 – C6-0000/2006 – 2004/0217(COD))

Committee on the Environment, Public Health and Food Safety

Rapporteur: Françoise Grossetête

Symbols for procedures

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

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

Amendments to a legislative text

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

CONTENTS

	Page
DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION	5
EXPLANATORY STATEMENT	13

DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

**on the Council common position for adopting a regulation of the European Parliament and of the Council on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004
(15763/3/2005 – C6-0000/2006 – 2004/0217(COD))**

(Codecision procedure: second reading)

The European Parliament,

- having regard to the Council common position (15763/3/2005 – C6-0000/2006),
 - having regard to its position at first reading¹ on the Commission proposal to Parliament and the Council (COM(2004)0599)²,
 - having regard to the amended Commission proposal (COM(2005)0577)³,
 - having regard to Article 251(2) of the EC Treaty,
 - having regard to Rule 62 of its Rules of Procedure,
 - having regard to the recommendation for second reading of the Committee on the Environment, Public Health and Food Safety (A6-0000/2006),
1. Approves the common position as amended;
 2. Instructs its President to forward its position to the Council and Commission.

Council common position

Amendments by Parliament

Amendment 1 RECITAL 5

(5) While taking into account the fact that the regulation of medicinal products must be fundamentally aimed at safeguarding public health, this aim must be achieved by means that do not impede the free movement of safe medicinal products within the Community. The differences between the national legislative, regulatory and administrative provisions on medicinal products tend to hinder intra-Community

(5) While taking into account the fact that the regulation of medicinal products must be fundamentally aimed at safeguarding public health, this aim must be achieved by means that do not impede the free movement of safe medicinal products within the Community. The differences between the national legislative, regulatory and administrative provisions on medicinal products tend to hinder intra-Community

¹ *Texts adopted*, 7.9.2005, P6_TA(2005)0331

² Not yet published in OJ.

³ Not yet published in OJ.

trade and therefore directly affect the operation of the internal market.

trade and therefore directly affect the operation of the internal market. ***Any action to promote the development and authorisation of medicinal products for paediatric use is therefore justified with a view to preventing or eliminating these obstacles. Article 95 of the Treaty is therefore the proper legal basis.***

Justification

Article 95 constitutes the basis for this Regulation and should therefore be specified.

Amendment 2

RECITAL 8

(8) It is appropriate to create a scientific committee, the Paediatric Committee, within the European Medicines Agency, hereinafter ‘the Agency’, with expertise and competence in the development and assessment of all aspects of medicinal products to treat paediatric populations. ***To this end, the Paediatric Committee should be independent from the pharmaceutical industry.*** The Paediatric Committee should be primarily responsible for the scientific assessment and agreement of paediatric investigation plans and for the system of waivers and deferrals thereof; it should also be central to various support measures contained in this Regulation. In its work, the Paediatric Committee should consider the potential significant therapeutic benefits for the paediatric patients involved in the studies or the paediatric population at large including the need to avoid unnecessary studies. The Paediatric Committee should follow existing Community requirements, including Directive 2001/20/EC, as well as International Conference on Harmonisation (ICH) guideline E11 on the development of medicinal products for the paediatric population, and it should avoid any delay in the authorisation of medicinal products for other populations deriving from the requirements for studies in the paediatric

(8) It is appropriate to create a scientific committee, the Paediatric Committee, within the European Medicines Agency, hereinafter ‘the Agency’, with expertise and competence in the development and assessment of all aspects of medicinal products to treat paediatric populations. ***The rules on scientific committees of the Agency, as laid down in Regulation (EC) No 726/2004, should apply to the Paediatric Committee. Members of the Paediatric Committee should therefore not have financial or other interests in the pharmaceutical industry which could affect their impartiality, should undertake to act in the public interest and in an independent manner, and should make an annual declaration of their financial interests.*** The Paediatric Committee should be primarily responsible for the scientific assessment and agreement of paediatric investigation plans and for the system of waivers and deferrals thereof; it should also be central to various support measures contained in this Regulation. In its work, the Paediatric Committee should consider the potential significant therapeutic benefits for the paediatric patients involved in the studies or the paediatric population at large including the need to avoid unnecessary studies. The Paediatric Committee should follow existing

population.

Community requirements, including Directive 2001/20/EC, as well as International Conference on Harmonisation (ICH) guideline E11 on the development of medicinal products for the paediatric population, and it should avoid any delay in the authorisation of medicinal products for other populations deriving from the requirements for studies in the paediatric population.

Justification

Within the 'better regulation' context, reference should be made to principles already adopted in other legislation which must apply under this Regulation, notably as regards the independence of members of the committee.

Amendment 3 RECITAL 10

(10) The introduction of the paediatric investigation plan in the legal framework concerning medicinal products for human use aims at ensuring that the development of medicinal products that are potentially to be used for the paediatric population becomes an integral part of the development of medicinal products, integrated into the development programme for adults. Thus, paediatric investigation plans should be submitted early during product development, in time for studies to be conducted in the paediatric population before marketing authorisation applications are submitted. It is appropriate to set a deadline for the submission of a paediatric investigation plan in order to ensure early dialogue between the sponsor and the Paediatric Committee. As the development of medicinal products is a dynamic process dependent on the result of ongoing studies, provision should be made for modifying an agreed plan where necessary.

(10) The introduction of the paediatric investigation plan in the legal framework concerning medicinal products for human use aims at ensuring that the development of medicinal products that are potentially to be used for the paediatric population becomes an integral part of the development of medicinal products, integrated into the development programme for adults. Thus, paediatric investigation plans should be submitted early during product development, in time for studies to be conducted in the paediatric population, ***where appropriate***, before marketing authorisation applications are submitted. It is appropriate to set a deadline for the submission of a paediatric investigation plan in order to ensure early dialogue between the sponsor and the Paediatric Committee. ***Furthermore, early submission of a paediatric investigation plan, combined with the submission of a deferral request as described below, will avoid delaying the authorisation for other populations.*** As the development of medicinal products is a dynamic process dependent on the result of ongoing studies, provision should be made for modifying an

agreed plan where necessary

Justification

The purpose of the amendment is to ensure that marketing authorisations for medicinal products for adults are not delayed while at the same time taking due account of the importance of the specific paediatric studies which applicants will be obliged to conduct.

Amendment 4 RECITAL 24

(24) It is essential to ensure that pharmacovigilance mechanisms are adapted to meet the specific challenges of collecting safety data in the paediatric population, including data on possible long-term effects. Efficacy in the paediatric population may also need additional study following authorisation. Therefore, an additional requirement for applying for a marketing authorisation that includes the results of studies conducted in compliance with an agreed paediatric investigation plan should be an obligation for the applicant to indicate how he proposes to ensure the long-term follow-up of possible adverse reactions to the use of the medicinal product and efficacy in the paediatric population. Additionally, where there is a particular cause for concern, ***provision should be made for the possibility of requiring*** the applicant ***to*** submit and implement a risk management system and/or perform specific post-marketing studies as a condition for the granting of the marketing authorisation.

(24) It is essential to ensure that pharmacovigilance mechanisms are adapted to meet the specific challenges of collecting safety data in the paediatric population, including data on possible long-term effects. Efficacy in the paediatric population may also need additional study following authorisation. Therefore, an additional requirement for applying for a marketing authorisation that includes the results of studies conducted in compliance with an agreed paediatric investigation plan should be an obligation for the applicant to indicate how he proposes to ensure the long-term follow-up of possible adverse reactions to the use of the medicinal product and efficacy in the paediatric population. Additionally, where there is a particular cause for concern, the applicant ***should*** submit and implement a risk management system and/or perform specific post-marketing studies as a condition for the granting of the marketing authorisation.

Justification

Where there are particular concerns, applicants must be required to submit an appropriate risk management plan.

Amendment 5
RECITAL 26

(26) For products falling within the scope of the requirement to submit paediatric data, if all the measures included in the agreed paediatric investigation plan are complied with, if the product **is authorised** in all Member States and if relevant information on the results of studies is included in product information, a reward should be granted in the form of a 6-month extension of the supplementary protection certificate created by Council Regulation (EEC) No 1768/92.

(26) For products falling within the scope of the requirement to submit paediatric data, if all the measures included in the agreed paediatric investigation plan are complied with, if the product **has received a marketing authorisation** in all Member States and if relevant information on the results of studies is included in product information, a reward should be granted in the form of a 6-month extension of the Supplementary Protection Certificate created by Council Regulation (EEC) No 1768/92. **Any decisions by Member States' authorities concerning the setting of prices for medicinal products or their inclusion in the scope of national health insurance schemes should have no bearing on the granting of this reward.**

Justification

It is important to encourage the availability of medicinal products for paediatric use throughout the territory of the EU. Moreover, applicants must not be penalised by administrative delays on the part of certain national authorities.

Amendment 6
ARTICLE 3, PARAGRAPH 2

2. Save where otherwise provided for in this Regulation, Regulation (EC) No 726/2004 shall apply to the Paediatric Committee.

2. Save where otherwise provided for in this Regulation, Regulation (EC) No 726/2004 shall apply to the Paediatric Committee, **including the provisions on the independence and impartiality of its members.**

Justification

Within the 'better regulation' context, reference should be made to principles already adopted in other legislation which must apply under this Regulation, notably as regards the independence of members of the committee.

Amendment 7
ARTICLE 16, PARAGRAPH 1

1. In the case of the applications referred to

1. In the case of the applications **for**

in Articles 7 and 8, the paediatric investigation plan shall be submitted with a request for agreement, ***unless otherwise*** justified, not later than upon completion of the human pharmaco-kinetic studies in adults specified in Section 5.2.3 of Part I of Annex I to Directive 2001/83/EC, so as to ensure that an opinion on use in the paediatric population of the medicinal product concerned can be given at the time of the assessment of the marketing authorisation or other application concerned.

marketing authorisation referred to in Articles 7 and 8 ***or the applications for waiver referred to in Articles 11 and 12***, the paediatric investigation plan ***or the application for waiver*** shall be submitted with a request for agreement, ***except in duly*** justified ***cases***, not later than upon completion of the human pharmaco-kinetic studies in adults specified in Section 5.2.3 of Part I of Annex I to Directive 2001/83/EC, so as to ensure that an opinion on use in the paediatric population of the medicinal product concerned can be given at the time of the assessment of the marketing authorisation or other application concerned.

Justification

The purpose of the amendment is to ensure that marketing authorisations for medicinal products for adults are not delayed while at the same time taking due account of the importance of the specific paediatric studies which applicants will be obliged to conduct.

Amendment 8

ARTICLE 34, PARAGRAPH 1, INTRODUCTORY PART

1. In the following cases, the applicant shall detail, ***in addition to the normal requirements for post marketing monitoring***, the measures to ensure the follow-up of efficacy and of possible adverse reactions to the paediatric use of the medicinal product:

1. In the following cases, the applicant shall detail the measures to ensure the follow-up of efficacy and of possible adverse reactions to the paediatric use of the medicinal product:

Justification

Within the 'better regulation' context, reference should be made to principles already adopted in other legislation which must apply under this Regulation, notably as regards pharmacovigilance.

Amendment 9

ARTICLE 34, PARAGRAPH 2 a (new)

2a. In addition to the provisions contained in paragraphs 1 and 2, the provisions on pharmacovigilance as laid

down in Regulation (EC) No 726/2004 and in Directive 2001/83/EC must apply to marketing authorisations for medicinal products which include a paediatric indication.

Justification

Within the 'better regulation' context, reference should be made to principles already adopted in other legislation which must apply under this Regulation, notably as regards pharmacovigilance.

Amendment 10
ARTICLE 36, PARAGRAPH 3

3. Where the procedures laid down in Directive 2001/83/EC have been used, the six-month extension of the period referred to in paragraph 1 shall be granted only if the product ***is authorised*** in all Member States.

3. Where the procedures laid down in Directive 2001/83/EC have been used, the six-month extension of the period referred to in paragraph 1 shall be granted only if the product ***has received a marketing authorisation*** in all Member States.

Justification

It is important to encourage the availability of medicinal products for paediatric use throughout the territory of the EU. Moreover, applicants must not be penalised by administrative delays on the part of certain national authorities.

Amendment 11
ARTICLE 43, PARAGRAPH 1, SUBPARAGRAPH 2

By, the*** Agency shall make the inventory public and shall update it regularly.

The Agency shall make the inventory public ***in the second year at the earliest and not later than****** and shall update it regularly.

Amendment 12
ARTICLE 45, PARAGRAPH 3 a (new)

3a. The Agency shall draw up scientific guidelines to establish assessment criteria for the significance of studies for the purposes of applying paragraph 3. These guidelines shall apply after receiving a favourable opinion from the Commission.

Justification

In this context, it is for the Agency, i.e. scientists, to decide which studies are considered necessary and/or relevant.

Amendment 13
ARTICLE 52, POINT 2)
Article 7, paragraph 4 a (new) (Regulation (EEC) No 1768/92)

4a. Notwithstanding paragraph 4, for five years following the entry into force of Regulation (EC) No .../... * [paediatric regulation], the application for an extension of the duration of a certificate already granted shall be lodged not later than six months before the expiry of the certificate.

**** Note to OJ: please insert number of this Regulation.***

Justification

The introduction of this transitional clause is important in so far as there are currently medicinal products whose certificate is due to expire but which may be important for the paediatric population.

EXPLANATORY STATEMENT

Thanks to this Regulation, medicinal products specifically intended for paediatric use will finally be able to be made available to children. In many cases, the medicines used for children are the same as those prescribed for adults. The only difference is that the doses are smaller. However, it is a well-known fact that children do not have the same metabolism as adults. This is why they need pharmaceutical forms different from those intended for adults, so as to ensure both that the medicinal products are better tolerated and that they are more effective.

We must therefore seek to ensure that this Community act is able to be implemented as soon as possible.

Your rapporteur welcomes, with some satisfaction, the common position, which both incorporates many of Parliament's amendments and accepts the introduction of specific incentives for European research.

However, your rapporteur wishes to make some adjustments to the common position to make the regulations more pragmatic.

In the area of pharmacovigilance and as regards the independence of members of the Paediatric Committee, reference should be made to directives and regulations already adopted in order to avoid overlapping of regulatory texts.

The development of medicinal products intended for children must not be allowed to hamper the development of medicinal products for adults. Your rapporteur is therefore proposing the introduction in certain cases of a duly justified derogation. This will make it possible, on scientific grounds, for the requirement for the results of the paediatric studies to be submitted at the same time as those of the studies in adults not to apply.

It is also necessary to introduce a transitional clause under Article 52. The introduction of such a clause is important in so far as there are currently medicinal products whose certificate is due to expire but which may be important for the paediatric population. Being too restrictive at this stage would risk blocking the development of new treatments. This transitional clause will not penalise the generics industry, which will be able to benefit from new medicinal products developed in this way.

Finally, this Regulation derives its legal basis from Article 95 of the EC Treaty, and it seems inconceivable that the Council should be proposing to delete this reference.

With the introduction of this Community act, the European Union will have effective means of promoting the development of medicinal products for paediatric use and closing this current major gap in the area of public health. That will mean that our children will no longer have to depend on the good will of the research sector in the USA or Asia.