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Committee on Industry, Research and Energy

2004/0217(COD)

26.5.2005

OPINION

of the Committee on Industry, Research and Energy

for the Committee on the Environment, Public Health and Food Safety

on the proposal for a Regulation of the European Parliament and the Council on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/83/EC and Regulation (EC) No 726/2004 (COM(2004)0599 – C6-0159/2004 – 2004/0217(COD))

Draftswoman: Patrizia Toia

PA_Leg

SHORT JUSTIFICATION

This regulation, once adopted and implemented, will represent a significant improvement in the rules relating to medicinal products for paediatric use, with the aim of guaranteeing safer and more effective pharmaceutical products for children. The proposal supports the development, and therefore an increase in supply, of medicinal products for children that are **specifically authorised and developed for paediatric use** on the basis of high-quality research.
The necessity and importance of the Regulation is immediately clear from one simple statistic: over 50% of the medicinal products used in Europe today to treat children are not subject to testing or authorised for paediatric use.
Your draftswoman, who agrees with the end goals and the main proposals of the Regulation and emphasises that there is **broad consensus among the players concerned** as regards these proposals, wishes to make the following remarks:

Paediatric Committee and Paediatric Investigation Plans (PIPs)

The creation of the body responsible for evaluating and approving the Paediatric Investigation Plans should be viewed as a positive development.
Your draftswoman considers that the tasks and criteria relating to evaluations and the further responsibilities of the Committee itself should be specified more clearly and in practical terms. However, it is also felt that these precise details should not be decided under this initial Regulation, but rather in the subsequent documents for which it provides.
It is therefore recommended that these further points be clearly defined in the 'guidelines'.

Incentives

Your draftswoman also agrees with the Commission's decision that the objective of the development of new pharmaceutical products (or of therapeutic indications, new pharmaceutical forms or new methods of administration), with a view to the placing on the market of products specifically developed and evaluated for use in children, should be attained **through a system of requirements and incentives** enabling the appropriate research and tests to be developed, without delaying the placing on the market of pharmaceutical products that are already ready for this.
It should nevertheless be emphasised that this system (which is based on a balancing of rules, requirements and incentives) can only function effectively if the rules are clear and controlled and, above all, incentives are geared selectively and proportionately to the efforts required. An excessively uniform incentive is liable to be too vague and thus ineffective.
In this connection, your draftswoman believes that the incentive concerning the 'six-month extension of the certificate' (i.e. for a fixed period which is the same for everyone) is only acceptable in that to date - i.e. on initial submission of the Regulation - a more selective and proportional procedure is not easily achievable in practical terms, owing both to the lack of significant statistics and to the difficulty of putting such a system into action.
Provision should therefore be made for the results obtained to be assessed, after an initial period of implementation of the Regulation, to check that the incentives are suitable and correspond to the objectives, and to schedule a possible review of the Regulation.

Dissemination of information and statistics

It is important that the studies and trials provided for and put into effect under the PIPs should not solely be notified to the entity responsible for authorising the placing on the market of pharmaceuticals (on the basis of those studies).
They should also be notified to the Paediatric Committee, which will have approved the proposal relating to them, and to all organisations operating in the field of research and clinical trials, in order to maximise the results of research, and of course to avoid duplications of effort, thereby enhancing the availability of information on the use of paediatric medicines in general.

Timing and procedures

Observations have been made by some of the parties concerned by the Regulation on the timing in the Commission proposal. It has been pointed out in particular that the Paediatric Committee is involved at too early a stage with respect to the development of the product. Your draftswoman does not believe it appropriate to bring forward amendments on this point at this stage in the consideration of the Regulation.
On the other hand, your draftswoman considers it necessary to speed up the PIP assessment phase and to shorten, with an eye to accelerating the process, the times laid down for the various stages involved.

Support for research

It is absolutely essential for there to be strong and widespread support for research in the field of child pharmacology.
Everyone is quite clear that child health is a primary objective both from a social standpoint and from that of protecting the rights of consumers - consumers who in this case are particularly susceptible and vulnerable and to whom extra attention should be awarded precisely because they cannot speak for themselves and only through their parents and family. Furthermore, this objective also coincides with that of supporting innovation in the pharmacological field, and dovetails with the major commitment the Commission will enter into in the field of research with the launch of the Seventh Framework Programme.
For these reasons, your draftswoman views the Commission's proposal relating to Medicines Investigation for the Children of Europe (MICE) as too vague (the proposal simply states that "the Commission intends to examine the possibility of setting up a paediatric study programme") and calls for that instrument to be laid down in this Regulation, or at least for a more precise and explicit commitment to be made and for procedures, timing and resources to be defined.

AMENDMENTS

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

Text proposed by the Commission[1]	Amendments by Parliament
Amendment 1 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. The Paediatric Committee should be primarily responsible for the assessment and agreement of paediatric investigation plans and for the system of waivers and deferrals thereof***, and it*** should also be central to various support measures contained in this Regulation. In all its work the Paediatric Committee should consider the potential significant therapeutic benefits of studies in children including the need to avoid unnecessary studies. It should follow existing Community requirements, including Directive 2001/20/EC, as well as International Conference on Harmonisation (ICH) guideline E11 on the development of medicines for children, and it should avoid any delay in the authorisation of medicines for other populations as a result of the requirements for studies in children.	(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 Paediatric Committee should be primarily responsible for the assessment and agreement of paediatric investigation plans and for the system of waivers and deferrals thereof***; to do this the Committee must be independent of the pharmaceutical industry and be composed of members with recognised and documented international-level experience and knowledge of that industry. It*** should also be central to various support measures contained in this Regulation. In all its work the Paediatric Committee should consider the potential significant therapeutic benefits of studies in children including the need to avoid unnecessary studies. It should follow existing Community requirements, including Directive 2001/20/EC, as well as International Conference on Harmonisation (ICH) guideline E11 on the development of medicines for children, and it should avoid any delay in the authorisation of medicines for other populations as a result of the requirements for studies in children.

[1] Not yet published in Official Journal.

Justification

The Paediatric Committee must perform its duties autonomously and in the interests of the paediatric population. It is therefore important to emphasise its independence from the pharmaceutical industry.

Amendment 2
RECITAL 10

(10) The introduction of the paediatric investigation plan in the legal framework concerning medicinal products for human use aims at ensuring that development of medicines for children 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 children before marketing authorisation applications are submitted.	(10) The introduction of the paediatric investigation plan in the legal framework concerning medicinal products for human use aims at ensuring that development of medicines for children 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 children***, and, wherever possible,*** before marketing authorisation applications are submitted.

Justification

The timing set to submit the paediatric investigation plan, i.e., at the completion of the human pharmaco-kinetic studies in adults, is too early and is too specific a milestone in the medicinal product development cycle. At this stage, it is premature for most products to require producing a detailed paediatric investigation plan. It would only be possible to develop a vague paediatric plan because of the lack of in-depth safety evaluation of a new molecule in adults generally required before considering the conduct of studies in children.

Amendment 3
RECITAL 11 a (new)

	(11a) In view of the fact that 50% of medicinal products for paediatric use have not been tested, provision should be made for funding for research on medicines for paediatric use which are not patent-protected or do not have supplementary protection certification to be financed under Community research programmes. It is necessary to establish the MICE (Medicines Investigation for the Children

of Europe).

Justification

It is essential to provide funding under Community research programmes to encourage research on and testing of medicinal products for paediatric use. Without a specific financial instrument the pharmaceutical industry would have no incentive to conduct studies into paediatric applications for pharmaceutical products not covered by a patent or a Supplementary Protection Certificate.

Amendment 4
RECITAL 21

(21) When an agreed paediatric investigation plan has led to the authorisation of a paediatric indication for a product already marketed for other indications, the marketing authorisation holder should be obliged to place the product on the market taking into account the paediatric information within two years following the date of approval of the indication. That requirement should relate only to products already authorised, but not to medicines authorised via a Paediatric Use Marketing Authorisation.	(21) When an agreed paediatric investigation plan has led to the authorisation of a paediatric indication for a product already marketed for other indications, the marketing authorisation holder should be obliged to place the product on the market taking into account the paediatric information within two years following the date of approval of the indication. ***The competent authorities should be able, in specific cases due to administrative delays, to grant derogations from this provision. Any such derogations should be justified on duly substantiated grounds.*** That requirement should relate only to products already authorised, but not to medicines authorised via a Paediatric Use Marketing Authorisation.

Justification

The placing of a product on the market may be delayed due to the time taken by the administrative procedures which determine the setting of prices and level of reimbursement. All this is beyond the control of the marketing authorisation holder who is, nevertheless, required to take all the necessary steps prior to marketing the product.

Amendment 5
RECITAL 22

(22) An optional procedure should be established to make it possible to obtain a single Community-wide opinion for a nationally authorised medicinal product	(22) An optional procedure should be established to make it possible to obtain a single Community-wide opinion for a nationally authorised medicinal product

when data on children following an agreed paediatric investigation plan form part of the marketing authorisation application. To achieve this, the procedure set out in Articles 32 to 34 of Directive 2001/83/EC may be used. This will allow the adoption of a Community harmonised Decision on use of the medicinal product in children and its introduction in all national product information.

when data on children following an agreed paediatric investigation plan form part of the marketing authorisation application. To achieve this, the procedure set out in Articles 32 to 34 of Directive 2001/83/EC may be used. This will allow the adoption of a Community harmonised Decision on use of the medicinal product in children and its introduction in all national product information.

In the meantime, it would be desirable for a European paediatric form to be drawn up to serve as a reference for the collection of all the data available in the various Member States on a pharmaceutical product desired to be marketed in the Union but at that moment placed on the market only at national level.

Justification

It would be useful to include a procedure that standardises the sets of forms in use in the Member States and paves the way for the introduction of the optional procedure referred to in the recital.

Amendment 6
RECITAL 23

(23) It is essential to ensure that pharmacovigilance mechanisms are adapted to meet the specific challenges of collecting safety data in children, including data on possible long-term effects. Efficacy in children 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 is made for the possibility of requiring*** the applicant to

(23) It is essential to ensure that pharmacovigilance mechanisms are adapted to meet the specific challenges of collecting safety data in children, including data on possible long-term effects. Efficacy in children 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, ***it is necessary, under the responsibility of the Committee, to require***

submit and implement a risk management system and/or perform specific post-marketing studies as a condition of the marketing authorisation.	the applicant to submit and implement a risk management system and/or perform specific post-marketing studies as a condition of the marketing authorisation.

Justification

In cases that give particular cause for concern, the applicant must be required to submit and implement a risk management system and/or perform specific post-marketing studies.

Amendment 7
RECITAL 28

(28) In order to increase the availability of information on the use of medicines in children, and to avoid the repetition of studies in children which do not add to the collective knowledge, the European database provided for in Article 11 of Directive 2001/20/EC should include ***an information resource of*** all ongoing, prematurely terminated, and completed paediatric studies conducted both in the Community and in third countries.	(28) In order to increase the availability of information on the use of medicines in children, and to avoid the repetition of studies in children which do not add to the collective knowledge, the European database provided for in Article 11 of Directive 2001/20/EC should include ***a European register of clinical trials of medicinal products for paediatric use comprising*** all ongoing, prematurely terminated, and completed paediatric studies conducted both in the Community and in third countries. ***Such studies should also be entered in the databases of clinical investigations currently in operation at national level.***

Justification

A European register covering all studies of medicinal products for paediatric use would be an efficient information resource which would make it possible to avoid duplicating paediatric trials and ensure that any information on the use of medicines to treat children could be found. That is why reference is also made to national data bases.

Amendment 8
ARTICLE 4 a (new)

	Article 4a
	The MICE (Medicines Investigation for the Children of Europe) paediatric study programme shall be established for the financing of studies on the paediatric use of medicinal products not covered by a

patent or a Supplementary Protection Certificate. It shall be proposed that adequate funding be allocated under Community research programmes to encourage studies and research on medicinal products for paediatric use.

Justification

This instrument ensures that research is carried out into pharmaceutical products that are not covered by a patent or a Supplementary Protection Certificate and would not therefore benefit from the incentives system under this Regulation, which has as its cornerstone the extension of the duration of patents and Supplementary Protections Certificates. It is essential to provide funding under Community research programmes to encourage research on and testing of medicinal products for paediatric use.

Amendment 9
ARTICLE 6, PARAGRAPH 2

All indirect interests that could relate to the pharmaceutical industry shall be entered in a register held by the Agency which the public may consult. The register shall be updated annually.	All ***direct and/or*** indirect interests that could relate to the pharmaceutical industry shall be entered in a register held by the Agency which the public may consult. The register shall be updated annually.

Justification

The aim is to ensure that relations between pharmaceutical companies and members of the committee are as transparent as possible.

Amendment 10
ARTICLE 7, PARAGRAPH 1, POINT (h a) (new)

(ha) to promote publicity campaigns on the role of the Committee and the arrangements available for the conducting of paediatric pharmaceuticals trials.

Justification

To date, the very low availability of children on whom tests on new pharmaceutical products for paediatric use can be conducted in compliance with the current safety rules provided for by the law has been one of the reasons for the scarce development of this type of product. This makes it all the more important for a publicity campaign to be conducted in relation to these issues.

Amendment 11
ARTICLE 7, PARAGRAPH 1, POINT (h b) (new)

hb) to assess the eligibility of a product for an eight-month supplementary protection certificate extension by carrying out a review of independently audited sales figures of the products concerned in accordance with Article 36(1).

Justification

A 6 month SPC extension may not be sufficient to encourage companies to invest in the development of paediatric indications for some relatively rare diseases. The 6-month SPC extension in the United States cannot be compared to the situation in the EU because prices are significantly lower in the EU. That's why in some cases a higher incentive seems to be necessary. On the other hand the 6 months are possibly an excessive incentive for drugs that are so-called blockbusters in the adult area.

Amendment 12
ARTICLE 14, PARAGRAPH 2

2. Within ***60*** days of receipt of the application, the Paediatric Committee shall adopt an opinion as to whether or not a product-specific waiver should be granted.	2. Within ***45*** days of receipt of the application, the Paediatric Committee shall adopt an opinion as to whether or not a product-specific waiver should be granted.
Either the applicant or the Paediatric Committee may request a meeting during that ***60***-day period.	Either the applicant or the Paediatric Committee may request a meeting during that ***45***-day period.
Whenever appropriate, the Paediatric Committee may request the applicant to supplement the particulars and documents submitted. Where the Paediatric Committee avails itself of this option, the ***60***-day time-limit shall be suspended until such time as the supplementary information requested has been provided.	Whenever appropriate, the Paediatric Committee may request the applicant to supplement the particulars and documents submitted. Where the Paediatric Committee avails itself of this option, the ***45***-day time-limit shall be suspended until such time as the supplementary information requested has been provided.

Justification

A time limit of 60 days seems too long, bearing in mind the aim of the proposal for a regulation; it is important that this time limit be reduced in order to ensure that the pharmaceutical products are available for paediatric use as soon as possible.

Amendment 13
ARTICLE 18, PARAGRAPH 1, SUBPARAGRAPH 1

1. Within ***60*** days of receiving a proposed paediatric investigation plan which is valid, the Paediatric Committee shall adopt an opinion as to whether or not the proposed studies will ensure the generation of the necessary data determining the conditions in which the medicinal product may be used to treat the paediatric population or subsets thereof, and as to whether or not the expected therapeutic benefits justify the studies proposed.	1. Within ***45*** days of receiving a proposed paediatric investigation plan which is valid, the Paediatric Committee shall adopt an opinion as to whether or not the proposed studies will ensure the generation of the necessary data determining the conditions in which the medicinal product may be used to treat the paediatric population or subsets thereof, and as to whether or not the expected therapeutic benefits justify the studies proposed.

Justification

A time limit of 60 days seems too long, bearing in mind the aim of the proposal for a regulation; it is important that this time limit be reduced in order to ensure that the pharmaceutical products are available for paediatric use as soon as possible.

Amendment 14
ARTICLE 18, PARAGRAPH 2

2. Within the ***60***-day period referred to in paragraph 1, the Paediatric Committee may request the applicant to propose modifications to the plan, in which case the time-limit referred to in paragraph 1 for the adoption of the final opinion shall be extended for a maximum of ***60*** days. In such cases, the applicant or the Paediatric Committee may request an additional meeting during this period. The time-limit shall be suspended until such time as the supplementary information requested has been provided.	2. Within the ***45***-day period referred to in paragraph 1, the Paediatric Committee may request the applicant to propose modifications to the plan, in which case the time-limit referred to in paragraph 1 for the adoption of the final opinion shall be extended for a maximum of ***45*** days. In such cases, the applicant or the Paediatric Committee may request an additional meeting during this period. The time-limit shall be suspended until such time as the supplementary information requested has been provided.

Justification

A time limit of 60 days seems too long, bearing in mind the aim of the proposal for a regulation; it is important that this time limit be reduced in order to ensure that the pharmaceutical products are available for paediatric use as soon as possible.

Amendment 15
ARTICLE 24, SUBPARAGRAPH 2

Member States shall take account of such an opinion. If the Paediatric Committee is asked to give an opinion under the first paragraph, it must do so within ***60*** days of receiving the request.	Member States shall take account of such an opinion. If the Paediatric Committee is asked to give an opinion under the first paragraph, it must do so within ***45*** days of receiving the request.

Justification

A time limit of 60 days seems too long, bearing in mind the aim of the proposal for a regulation; it is important that this time limit be reduced in order to ensure that the pharmaceutical products are available for paediatric use as soon as possible.

Amendment 16
ARTICLE 34

Where medicinal products are authorised for a paediatric indication following completion of an agreed paediatric investigation plan and those products have already been marketed with other indications, the marketing authorisation holder shall, within two years of the date on which the paediatric indication is authorised, place the product on the market taking into account the paediatric indication.	Where medicinal products are authorised for a paediatric indication following completion of an agreed paediatric investigation plan and those products have already been marketed with other indications, the marketing authorisation holder shall, within two years of the date on which the paediatric indication is authorised, place the product on the market taking into account the paediatric indication. ***The competent authorities may, in specific cases due to administrative delays, grant derogations from this provision. Any such derogations shall be justified on duly substantiated grounds.***

Justification

The placing of a product on the market may be delayed due to the time taken by the administrative procedures which determine the setting of prices and level of reimbursement. All this is beyond the control of the marketing authorisation holder who is, nevertheless, required to take all the necessary steps prior to marketing the product.

Amendment 17
ARTICLE 36, PARAGRAPH 1, SUBPARAGRAPH 1

1. Where an application under Articles 8 or 9 includes the results of all studies conducted in compliance with an agreed	1. Where an application under Articles 8 or 9 includes the results of all studies conducted in compliance with an agreed

paediatric investigation plan, the holder of the patent or supplementary protection certificate shall be entitled to a ***six-month*** extension of the period referred to in Articles 13(1) and 13(2) of Regulation (EEC) No 1768/92.	paediatric investigation plan, the holder of the patent or supplementary protection certificate shall be entitled to a ***four-month*** extension of the period referred to in Articles 13(1) and 13(2) of Regulation (EEC) No 1768/92. ***In addition, a further four-month extension shall be granted for products with combined annual sales in the European Union of less than EUR 100 million. Sales of the product must be determined three years prior to the expiry of the existing supplementary protection certificate on the basis of independently audited annual sales figures provided by the company concerned.***

Justification

A 6 month SPC extension may not be sufficient to encourage companies to invest in the development of paediatric indications for some relatively rare diseases. The 6-month SPC extension in the United States cannot be compared to the situation in the EU because prices are significantly lower in the EU. That's why in some cases a higher incentive seems to be necessary. On the other hand the 6 months are possibly an excessive incentive for drugs that are so-called blockbusters in the adult area.

Amendment 18
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 ***four or eight-month*** extension of the period referred to in paragraph 1 shall be granted only if the product is authorised in all Member States.

Justification

A 6 month SPC extension may not be sufficient to encourage companies to invest in the development of paediatric indications for some relatively rare diseases. The 6-month SPC extension in the United States cannot be compared to the situation in the EU because prices are significantly lower in the EU. That's why in some cases a higher incentive seems to be necessary. On the other hand the 6 months are possibly an excessive incentive for drugs that are so-called blockbusters in the adult area.

Amendment 19
ARTICLE 36, PARAGRAPH 4

4. Paragraphs 1, 2 and 3 shall apply to products that are protected by a supplementary protection certificate under Regulation (EEC) No 1768/92, or under a patent which qualifies for the granting of the supplementary protection certificate. They shall not apply to medicinal products designated as orphan medicinal products pursuant to Regulation (EC) No 141/2000.	4. Paragraphs 1, 2 and 3 shall apply to products that are protected by a supplementary protection certificate under Regulation (EEC) No 1768/92, or under a patent which qualifies for the granting of the supplementary protection certificate. They shall not apply to medicinal products designated as orphan medicinal products pursuant to Regulation (EC) No 141/2000 ***or products for which the active substance is already protected by a patent covering the paediatric use or formulation or has received any other form of data exclusivity or market exclusivity for a paediatric use.***
	Medical products granted an extension of the supplementary protection certificate may not obtain any other national or Community form of intellectual property protection, data exclusivity or market exclusivity for the paediatric use or form of the active substance.

Justification

1. The benefit (extension of patent period) should be proportional to the cost. There are strong indications that a 6 month benefit outnumbers the cost considerably for most products.. A reasonable return on investment should be given. For a big selling product one month will do, for limited selling products 6 months may be necessary. Most products will be in between. Commission Regulation 847/2000 following the orphan drugs regulation provides a good example of calculating cost and benefits.

2. The reward should be non-cumulative.

Amendment 20
ARTICLE 37, PARAGRAPH 2

The first paragraph shall also apply where completion of the agreed paediatric investigation plan fails to lead to the authorisation of a paediatric indication, but the results of the studies conducted are reflected in the summary of product characteristics, and if appropriate, in the	The first paragraph shall also apply where completion of the agreed paediatric investigation plan fails to lead to the authorisation of a paediatric indication, but the results of the studies conducted are reflected in the summary of product characteristics, and if appropriate, in the

package leaflet of the medicinal product concerned.	package leaflet of the medicinal product concerned. ***Where it is ascertained that, in a specific paediatric subpopulation identified in accordance with criteria and modalities defined by the Paediatric Committee, the conditions for recourse to the procedure laid down for orphan drugs are fulfilled, the authorisation holder may have recourse to whichever of the two procedures he chooses.***

Justification

The purpose of the amendment is to offer the applicant an additional possibility which would simplify the marketing authorisation procedure for orphan drugs.

Amendment 21
ARTICLE 42, PARAGRAPH 2, SUBPARAGRAPH 1

2. On the basis of the assessment under paragraph 1 and other information available, and following consultation with the Commission, the Member States and interested parties, the Paediatric Committee shall establish an inventory of therapeutic needs.	2. On the basis of the assessment under paragraph 1 and other information available, and following consultation with the Commission, the Member States and interested parties, the Paediatric Committee shall establish an inventory of therapeutic needs ***that awards due attention to the priorities of the moment in the paediatric medicines sector***.

Justification

A list of priorities in the paediatric pharmaceuticals field would enable pharmaceutical firms to streamline pharmacological research in those areas most in need of it at the time.

Amendment 22
ARTICLE 44, PARAGRAPH 2

2. All existing paediatric studies, as referred to in paragraph 1, shall be taken into consideration by the Paediatric Committee when assessing applications f***or paediatric investigation plans, waivers and deferrals and by competent authorities*** when assessing applications submitted pursuant to Articles 8, 9 or 31.	2. All existing paediatric studies, as referred to in paragraph 1, ***and all paediatric studies initiated prior to the entry into force of this Regulation, shall be eligible to be included in a paediatric investigation plan and*** shall be taken into consideration by the Paediatric Committee when assessing applications submitted pursuant to Articles 8, 9 or 31.

Justification

The Paediatric Committee may take account of the results of clinical studies on new pharmaceutical products for the paediatric population which were initiated before the entry into force of the Regulation.

Amendment 23
ARTICLE 48, PARAGRAPH 4

4. The Commission shall publish the names of the marketing authorisation holders involved and the amounts of and reasons for the financial penalties imposed.	4. The Commission shall publish the names of the marketing authorisation holders involved, ***and also of anyone infringing the provisions of this Regulation or of any regulations adopted in accordance with it,*** and the amounts of and reasons for the financial penalties imposed.

Justification

Provision should be made for penalties for infringements of the rules laid down in the regulation, in line with the provisions of Article 48 (1), (2) and (3).

Amendment 24
ARTICLE 49, PARAGRAPH 2

2. Within ***six*** years of entry into force of this Regulation, the Commission shall publish a general report on experience acquired as a result of its application, including in particular a detailed inventory of all medicinal products authorised for paediatric use since its entry into force.	2. Within ***four*** years of entry into force of this Regulation, the Commission shall publish a general report on experience acquired as a result of its application, including in particular a detailed inventory of all medicinal products authorised for paediatric use since its entry into force. ***In particular, the Commission shall produce an analysis of the rewards and incentives operations provided for in Articles 36 and 37, with a financial evaluation of the outlay on research and the profits realised thanks to the incentives. Should the analysis reveal any incongruity in the system laid down vis-à-vis the results that have or will be achieved, steps shall be taken to amend those Articles.***

Justification

A Commission review of the incentives system after 4 years will enable the actual equity of the

whole system of incentives for paediatric pharmacological research to be assessed and any necessary adjustments to be adopted.

PROCEDURE

Title	Proposal for a Regulation of the European Parliament and the Council on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/83/EC and Regulation (EC) No 726/2004
References	(COM(2004)0599 – C6-0159/2004 – 2004/0217(COD))
Committee responsible	ENVI
Committee asked for its opinion Date announced in plenary	ITRE 27.10.2004
Enhanced cooperation	No
Draftswoman Date appointed	Patrizia Toia 27.1.2005
Discussed in committee	16.3.2005 25.4.2005 24.5.2005
Date amendments adopted	24.5.2005
Result of final vote	for: 42 against: 0 abstentions: 4
Members present for the final vote	Ivo Belet, Jan Březina, Jerzy Buzek, Joan Calabuig Rull, Pilar del Castillo Vera, Jorgo Chatzimarkakis, Giles Chichester, Den Dover, Lena Ek, Adam Gierek, Umberto Guidoni, András Gyürk, Fiona Hall, David Hammerstein Mintz, Ján Hudacký, Romana Jordan Cizelj, Werner Langen, Anne Laperrouze, Nils Lundgren, Eluned Morgan, Angelika Niebler, Reino Paasilinna, Pier Antonio Panzeri, Miloslav Ransdorf, Teresa Riera Madurell, Mechtild Rothe, Paul Rübig, Andres Tarand, Britta Thomsen, Patrizia Toia, Catherine Trautmann, Claude Turmes, Nikolaos Vakalis, Alejo Vidal-Quadras Roca
Substitutes present for the final vote	María del Pilar Ayuso González, Zdzisław Kazimierz Chmielewski, Neena Gill, Norbert Glante, Françoise Grossetête, Edit Herczog, Peter Liese, Vittorio Prodi, John Purvis, Manuel António dos Santos, Esko Seppänen, Hannes Swoboda
Substitutes under Rule 178(2) present for the final vote	