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STATEMENT OF THE COUNCIL'S REASONS

Subject : Common Position adopted by the Council on 10 March 2006 with a view to the adoption of 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

STATEMENT OF THE COUNCIL'S REASONS

I. INTRODUCTION

1. On 29 September 2004 the Commission adopted a proposal for a Regulation of the European Parliament and of the Council on Medicinal Products for Paediatric Use and amending Regulation (EEC) No 1768/92, Directive 2001/83/EC and Regulation (EC) No 726/2004[1].

2. The Economic and Social Committee adopted its opinion at its 417th plenary session on 11/12 May 2005[2].

3. The European Parliament adopted its first-reading Opinion on 7 September 2005[3].

4. The Commission adopted an amended proposal on 10 November 2005[4].

5. On 9 December 2005, the Council reached a political agreement with a view to adopting a common position in accordance with Article 251 of the Treaty.

6. On 10 March 2006, the Council adopted its common position on the proposal as set out in doc. 15763/05.

II. OBJECTIVES

7. The general objectives of the Commission proposal are to:
   - increase the development of medicines for use in children,
   - ensure that medicines used to treat children are subject to high quality research,
   - ensure that medicines used to treat children are appropriately authorised for use in children,

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1 OJ C 321, 28.12.2004, p.12, text in doc. 13880/04 ECO 168 SAN 157 CODEC 1166.
2 OJ C 267, 27.10.2005, p.1
3 11956/05 CODEC 705 ECO 94 SAN 134.
4 14487/05 ECO 138 SAN 175 CODEC 1019.

- improve the information available on the use of medicines in children,
- achieve these objectives without subjecting children to unnecessary clinical trials and in full compliance with Directive 2001/20/EC (the Clinical Trials Directive)[5].

III. COMMON POSITION

General

8. The Council, which agrees with the objectives of the proposal, has nevertheless endeavoured to improve some of the provisions and to add further features, notably as regards research into paediatric use of off-patent medicines (Article 40), safeguarding measures aiming at keeping paediatric products on the market (Article 35) and as concerns transparency (Articles 25 and 41). During the detailed reading of the proposal (November 2004-November 2005) a number of drafting changes have been introduced to clarify the text, address legal/linguistic issues and to ensure the overall coherence of the Regulation. Amendments that are of a pure legal/linguistic nature are normally not mentioned below.

9. In its Plenary vote on 7 September 2005, the European Parliament adopted 69 amendments to the proposal.

   (a) 42 of these have been incorporated, either in full, in part or in principle into the Council's common position corresponding to around two thirds of the proposed amendments,
   (b) 27 amendments have not been accepted.

10. When preparing its common position, the Council examined closely the Commission's amended proposal. With the exception of redrafts (notably to Articles 32 and 49) the common position incorporates most of the amendments proposed by the European Parliament accepted or accepted in principle by the Commission in its amended proposal.

[5] OJ L 121, 01.05.2001, p. 34.

11. In the legal-linguistic finalisation of the text of the common position certain recitals and articles have been renumbered. This document follows the numbering used in the common position and therefore the numbering sometimes differs from that of the texts of the Parliament's Opinion and the amended proposal.

Recitals

12. In Recital (3), the European Parliament proposed additional wording on types of formulation and the route of administration (Amendment 1), which has been accepted with minor redrafting to improve clarity.

13. The European Parliament also proposed some clarifications to Recital (4) (Amendment 2), Recital (5) (Amendment 4)and Recital (7) (Amendment 5), which were all included in the Common Position, although the words "where indicated" in Recital (4) were considered to be redundant and were not included.

14. The European Parliament proposed to insert a new Recital (4a) concerning an inventory of paediatric medicinal products (Amendment 3), which the Council decided not to include, since it prefers the structure of the Commission proposal. The provision regarding the inventory should remain in Article 42 in Title VI (communication and coordination).

15. As concerns Recital (8) on the Paediatric Committee, the first and third parts of Amendment 6 were accepted with minor redrafting, although the Council did not consider the Paediatric Committee to be primarily responsible for the ethical assessment of the Paediatric Investigation Plan. Ethical assessment of proposals for clinical trials is the primary responsibility of the Ethics Committees. The Council does not support the second part of the amendment as it does not consider that members of the Paediatric Committee must have international-level experience and knowledge of the pharmaceutical industry.

16. In Recital (10) the Council agrees with part of Amendment 7. As for the second part of this Amendment, the Council has deemed it more appropriate to clarify that the reason for the legal provisions in Article 16 (1) is to ensure an early dialogue between the physical or legal person developing a new medicinal product and the Paediatric Committee.

17. In Recital (11) the Council agreed in principle to Amendment 8, but made a minor redrafting, pointing to the use of waivers and deferrals, in order to maintain coherence within the Regulation.

18. The Council shares the view of the European Parliament that research into the paediatric use of medicinal products, which are not protected by a patent or supplementary protection certificate, is important and to this aim proposes a new Article 40 as well as a new Recital (12) that contains the ideas behind Amendment 9, but with minor redrafting to maintain coherence with the new article to which it refers.

19. Amendment 10 to Recital (16) has been included in the common position.

20. The Council has amended Recital (18) to correspond to the amendments of Article 32.

21. The European Parliament in Amendment 11 proposed to amend Recital (22). The Council, for reasons set out in relation to Article 33, cannot support this amendment.

22. Amendment 12 proposes to introduce in Recital (23) reference to "a European paediatric form" aimed at facilitating Community wide marketing of paediatric medicines placed on the market only at national level. The Council cannot support this amendment since it does not correspond to any existing provisions in the Proposal or any proposed amendments to the existing provisions.

23. The Council is also unable to support Amendment 13 to Recital (24) since the competent authorities that grant the marketing authorisations monitor the fulfilment of the terms and conditions of the marketing authorisation and the post-authorisation obligations; this is not the responsibility of the Paediatric Committee.

24. The common position also contains a new Recital (25), which refers to the new article 35.

25. The Council does not support Amendment 14 to Recital (26), for reasons that are outlined in the text regarding Article 36 below.

26. In order to give an explanation for certain provisions in Article 52 (amendments to the SPC Regulation), relating to the reward mechanisms foreseen under Title V, the Council inserted a new Recital (27).

27. As regards Recital (31), the Council has decided to stress that unnecessary repetition of studies should be avoided and to include the first part of Amendment 15 proposed by the Parliament concerning a European register of paediatric clinical trials. The second and third parts of this amendment have not been accepted as the former repeats text already in place and the latter does not correspond to any existing provisions or proposed amendments of existing provisions. An additional sentence was added at the end of the paragraph to echo the amendment to Article 41 which provides that parts of the paediatric clinical trials database shall be publicly accessible.

28. The Council supports the structure of the Commission proposal, and, consequently, holds that the provisions on the inventory of therapeutic needs should be maintained in Title VI (communication and coordination). It can therefore not support Amendment 16, which proposes that Recital (32) should be deleted.

29. The Council supports the proposal in Amendment 17 to stress the importance of using also data from third countries, but made some minor redrafting of this amendment to Recital (33) to improve clarity.

30. The Council has included a new Recital (38) that explains why the proposed Regulation is in accordance with the principles of subsidiarity and proportionality required in Article 5 of the Treaty.

Title I - Introductory provisions

31. Like the European Parliament, the Council considers it necessary to clarify that the paediatric population should not be subject to any kind of unnecessary trials and has therefore included the first part of amendment 18 into Article 1. However, the Council cannot support the second part of the Amendment as the Regulation applies to the entire paediatric population without exception.

32. The Council considers it appropriate to move the definition of *paediatric use marketing authorisation* to Article 2, which contains other definitions.

33. The Council shares the position of the European Parliament that it is important that the Paediatric Committee be established within 6 months after the entry into force of the Regulation and has therefore included Amendment 20 in the first subparagraph of Article 3(1), together with a redrafting to ensure that the other deadlines of the Regulation can still be met. For legal/linguistic reasons, a minor redrafting was also made in the second subparagraph of this paragraph.

34. Article 4 of the Proposal deals with the composition of the Paediatric Committee. Here, the Council, in analogy to what is the case for the Committee for Human Medicinal Products, has decided to introduce alternates for the members and to specify the procedure for their appointment.

The Council has also accepted in principle in subparagraphs (c) and (d) of Article 4(1) Amendment 21 proposed by the European Parliament but with redrafting. The Council accepted the part of the amendment that concerns consultation of the European Parliament. In view of the introduction of alternates, the Council considers that six members are sufficient to represent the interests of healthcare professionals and patient associations. However, the Council considers that it should be made clear that three members should represent healthcare professionals and three members should represent patient associations. The list of disciplines represented on the Committee applies to the Committee as a whole and should be incorporated in the list of disciplines set out at the end of the paragraph.

35. Article 5(1) sets out the procedure for agreeing an opinion in the Paediatric Committee. Here, the Council has integrated in principle Amendment 22. The first part has been accepted with minor redrafting to improve clarity. The Council supports the transparency intended in the second part, but considers that the provision should be included in Article 25, which deals with procedural issues, including transparency.

As for Amendment 23 to Article 5(3), the Council considers it unnecessary to define the respective numbers of representatives of the Commission or Executive Director of the Agency that could attend the meetings of the Paediatric Committee.

36. The Council has decided to delete Article 6 of the Proposal on independence and impartiality of the members of the Paediatric Committee, since detailed provisions on such requirements are already set out in Regulation (EC) No 726/2004, to which explicit reference is made in Article 3(2). For this reason, the Council cannot support Amendment 24.

37. Article 6 of the common position sets out the tasks of the Paediatric Committee. Here, the Council supports the objective of Amendment 25 to paragraph (1)(g), but notes that the Regulation already provides for free scientific advice in Article 27. Also, Article 47(3) provides that assessments by the Committee will be free of charge. If this amendment were to be included it would, for reasons of consistency, be necessary to specify "free of charge" for all other tasks listed in Article 6(1), and therefore the Council cannot support it.

The Council agrees in principle to Amendments 26 and 29 by the European Parliament to form a new subparagraph (i) of Article 6(1) on establishment of an inventory of paediatric medicinal products needs. But the Council noted that this requires amendment of subparagraph (e) of Article 6(1) in order to avoid unnecessary repetition.

The Council supports the principle that the Committee should advise on communication about the conduct of clinical trials in children (Amendment 27) and therefore agrees to introduce a new subparagraph (j) of Article 6(1), but does not consider it appropriate for the Paediatric Committee to have a self-promoting function.

Further, the Council has added a new subparagraph (k) of Article 6(1) concerning the selection of the symbol for paediatric medicines (see Article 32).

Finally, the Council has included Amendment 28 on advice available from third countries in Article 6(2) with minor redrafting to improve clarity.

Title II - Marketing authorisation requirements

38. Article 7 deals with General authorisation requirements. The Council considers that Amendment 30, which opens a possibility to provide information on ongoing paediatric studies, is not necessary. The Commission Proposal does not require the completion of all paediatric studies at the time of application for marketing authorisation. The "deferral" provision allows for delay in the initiation of paediatric clinical studies so as to ensure that the studies are only done when it is safe and ethical to do so. The Commission Proposal also provides for the deferral decision to contain a timetable to complete the studies. The Council agrees with the Commission proposal in these respects.

39. Article 8 also deals with General authorisation requirements. This Article has been slightly redrafted to clarify the scope.

The Council agrees in principle with the ideas behind Amendment 31 to Article 8, but considers this amendment to be redundant. Article 27 already refers to the application of Regulation (EC) No 726/2004 and Directive 2001/83/EC, which by association includes their implementing measures such as the variation regulations, in particular Commission Regulation (EC) No 1085/2003, to which the amendment introduces a reference.

The Council also considers that Amendment 32 is not necessary, since Article 28(1) of the proposed Regulation already opens the centralised procedure to marketing authorisation applications which include one or more paediatric indications selected on the basis of studies conducted in compliance with an agreed paediatric investigation plan. In addition, Article 29 provides that applications referred to in Article 8 relating to products authorised through the mutual recognition procedure may obtain an opinion from the Committee on Human Medicinal Products of the European Medicines Agency. This in turn will lead to a Commission Decision which will be binding on Member States.

40. The provisions in Article 10 on compliance checks of paediatric investigation plans have been adjusted to clarify the responsibilities of various actors.

41. The Council agrees to Amendment 33, which states that the Paediatric Committee should appoint a rapporteur as part of the preparation of decisions on product specific waivers (first subparagraph of Article 13(2)).

The Council also agrees in principle to Amendment 34 in Article 13(3). But the reference to informing the applicant has been moved to Article 25 to improve coherence in the text. The deadline has been changed to "ten days" as it is not the practice to use the term "working days" in the Community legislation relating to medicinal products.

42. In Article 14(1), the Council agrees to Amendment 35 on updating and public availability of the list of waivers.

43. Article 16 sets out provisions for the timing of the submission of the Paediatric Investigation Plan. The European Parliament had proposed three amendments (36, 37 and 38) to this Article. The Council cannot support these for the following reasons:

The Council agrees with the Commission proposal that provides for the summary report to be prepared by the Agency. This is consistent with the operating methods of the Committee on Orphan Medicinal Products. Ten days are inadequate for the preparation of the summary report by the Agency.

The introduction of the paediatric investigation plan into the legal framework concerning medicinal products for human use aims at ensuring that the development of medicines for children becomes integrated into the overall development programme for medicinal products. The Council agrees that it is appropriate, therefore, 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 on whether studies are required and, if so, the type of studies and their timing compared to studies in adults.

The deadline provided for in Article 16(1) of the proposed Regulation is a dead-line to submit a draft plan and not a dead-line for the initiation of studies. In addition, the plan may contain a request for a deferral of the initiation or completion of studies.

The Commission proposal provides a mechanism for the modification of the paediatric investigation plan. This will ensures continuing dialogue between the applicant and the Paediatric Committee during the product development.

The Council considers that the proposed amendment would result in little, if any, investigation of the use of a product in children early in the product's development. This would impede innovation in paediatric therapeutics and have negative consequences for public health.

44. In Article 17(1) on handling of a proposal for a paediatric investigation plan, the Council has included Amendment 39 with a minor addition to improve clarity, and also clarified the scope.

45. Article 22 deals with the modification of a paediatric investigation plan. Here, the Council agrees to the first two parts of Amendment 40. The last part has not been accepted since the Proposal provides that the applicant has to request modifications to an agreed plan. As this request is the modified plan, it is unnecessary for the opinion on the modified plan to contain a dead-line for the submission of the modified plan.

46. The provisions in Article 23 on compliance checks of paediatric investigation plans have been adjusted to clarify the responsibilities of various actors.

47. The Council has inserted a number of amendments to Article 25 in order to clarify the procedure and support transparency. The second part of Amendment 22 from the European Parliament (compare Article 5) has been included, as has Amendment 42 to Article 25(5), with minor redrafting. The Council considers that ten days should be sufficient time for the Agency to adopt a decision. The Council is however not able to support Amendment 41, since details on the interaction between the rapporteurs and the applicants should be set out in the rules of procedure of the Paediatric Committee.

Title III - Marketing authorisation procedures

48. Article 28 deals with marketing authorisation procedures for applications falling within the scope of Articles 7 and 8. Parts one and two of Amendment 43 are adopted in principle in the second subparagraph of Article 28(1), but the Council suggests some minor redrafting. The third part has not been accepted as there are detailed scientific Community guidelines on the presentation of information on indications that have been approved, not approved and contra-indicated. The aims of this amendment are achieved through the application of these guidelines, which are amended regularly to take account of technical progress. The Council has also introduced changes to paragraph 3 in order to meet concerns on double rewards similar to those raised by the European Parliament in Amendment 52 (see Article 36 below).

49. The definition of a *paediatric use marketing authorisation* was moved from Article 30 to Article 2 for reasons of clarity.

50. Article 32 deals with the identification of medicinal products for paediatric use. Here, the Council introduced a number of changes, notably to clarify that all medicinal product granted a marketing authorisation for a paediatric indication should display a specific symbol on their labels, and to clarify the procedure for selecting this symbol.

The European Parliament had proposed two amendments to this Article. The Council agrees in principle to the first part of Amendment 44, but with a suggested redraft. The second part cannot be accepted as the Council considers that it is preferable to make use of available expertise and adopt the symbol with the minimum delay. The Council agrees, therefore, that the Commission should adopt the symbol based on a recommendation from the Paediatric Committee.

The Council accepts in principle Amendment 45 and has therefore introduced a new subparagraph in Article 32. The Council, however considers that it would be confusing for the patient and carer if some, but not all, products authorised for paediatric use were identified by a Community symbol on the label. The symbol, therefore, should apply to all medicinal products with a paediatric indication. In addition, the meaning of the symbol should be explained in the patient information leaflet and a deadline should be introduced for the application of the symbol.

Title IV - Post-authorisation requirements

51. Article 33 deals with the deadline for placing products authorised for a paediatric indication on the market. The second part of Amendment 46 has been included in Article 33, with a slight redrafting. The Council considers that the register should be coordinated by the European Medicines Agency. In order to maintain flexibility, no reference to the competent authorities is made, since it may be possible to use existing databases for the register. The Council does not accept the first part; since it considers it inappropriate to include a provision that does not create any legal obligation. The Council supports the text of the Commission Proposal which makes it clear that the legal obligation is to market within two years. In addition, the Council does not agree to the third part of the amendment (which corresponds to Amendment 11). Existing EC pharmaceutical legislation sets out clear deadlines both for the granting of a marketing authorisation and for national decisions concerning the pricing and reimbursement for medicinal products. The Council considers that it is inappropriate, therefore, to provide for derogations in the application of this provision in cases where competent authorities are unable to meet such deadlines.

52. Article 34(2) deals with risk management systems when the Competent Authority has cause for concern. The European Parliament, in Amendment 47, proposed to make such a system compulsory. The Council recalls that the EC pharmaceutical legislation has recently been amended and now contains strengthened and new pharmacovigilance measures, including risk management systems. The proposed Regulation contains a provision for the competent authority, whenever it has cause for concern, to require a risk management system to be put in place. The Council does not find it appropriate to make this provision compulsory, as there may be occasions when such a requirement would add an unnecessary burden and may present a barrier to access to appropriate medicines.

Although the Council supports the objective of Amendments 48, 49 and 83 that introduce new provisions on pharmacovigilance, they are not considered to be necessary; since provisions relating to the communication of information on pharmacovigilance matters already exist in EC pharmaceutical legislation and apply to all medicinal products authorised in the Community (Article 24(5) of Regulation (EC) No 726/2004 and Article 104(9) of Directive 2001/83/EC).

53. The Council has decided to insert a new Article 35 to ensure that products with a paediatric indication for which the market authorisation holder has benefited from the rewards in this Regulation stay on the market. This new article is very similar to Amendment 50 of the European Parliament, with some redrafting. The Council supports the principle behind this amendment, but considers that there is a need for a corresponding recital and has introduced some redrafting to clarify both the scope and that any third party should have expressed an intention to continue marketing the product. Also the Council considers that there should be a dead-line for informing the Agency of the intention to discontinue placing a product on the market.

Title V - Rewards and incentives

54. Article 36 deals with the requirements that must be met in order for a Supplementary Protection Certificate (SPC) to be prolonged six months.

One objective of the proposed Regulation is to ensure that safe and effective authorised medicines are available for children. Therefore, one of the criteria for granting an extension of the period set out in the SPC should be that the product must be authorised in all Member States. The same principle applies to the reward of market exclusivity provided for in the Regulation on orphan medicinal products. For this reason, the Council cannot agree to Amendment 51. In addition, the proposed Regulation requires that the information from the completed paediatric investigation plan must be included in the summary of product characteristics before SPC extension can be granted. Marketing authorisation procedures, therefore, must be completed before the SPC extension can be granted. For the same reasons, the associated Amendment 14 to Recital (26) has also been rejected.

Article 36(4) states which products are entitled to a six month prolongation of the SPC. Here, the second part of Amendment 52 has been accepted in principle. The Council supports the principle of avoiding double rewards gained on the basis of the same research in the following particular situation. The new Article 10(1) of Directive 2001/83/EC as amended by Directive 2004/27/EC, provides that the period of market protection shall be extended by one year if the marketing authorisation holder obtains an authorisation for a new indication which is judged to bring significant clinical benefit in comparison with existing therapies. In the case of a new paediatric indication, this additional year of market protection should not be granted together with the six-month extension when based on the same research. To avoid this cumulative reward, the Council has introduced a new paragraph in Article 36.

The Council cannot agree to the first part of the amendment, which relates to patents. A basic patent (protecting the molecule) covers all medicinal uses of the substance, hence it covers also any paediatric medicinal use. A specific paediatric patent only exists in the case of a so-called 'usage patent'. The Commission proposal prolongs the basic patent; in such circumstances it would be difficult to operate the "non-cumulative" test set out in the first part of the amendment and it would go against the objective of stimulating innovation and research. However, consistent with the spirit of the amendment, the Council considers that there is a need to clarify that the rewards and incentives which resulted from completion of an agreed paediatric investigation plan should only be available if at least some significant research was completed after the entry into force of the Regulation. Amendments have therefore been introduced into Articles 28(3) and 45(3).

Amendment 53 proposes to introduce a new paragraph stating that the prolongation should only be admissible once per medicinal product. The Council does not consider that this amendment is necessary since this provision is already provided for in Article 52, indent 7, which amends Article 13 of Regulation (EEC) No 1768/92 (the "SPC Regulation").

55. The Council is unable to support Amendment 54 proposed to Article 37 since orphan medicinal products are subject to the same authorisation procedures as other medicinal products. There are already provisions in EC pharmaceutical legislation to allow, where necessary, the early authorisation of orphan medicinal products, such as the provisions for accelerated assessment or conditional marketing authorisation set out in Regulation (EC) No 726/2004 (Article 14).

56. Article 39(3) deals with an inventory of incentives provided by the Community and Member States to support research into, and the development and availability of, medicinal products for paediatric use. In Amendment 55, the European Parliament proposes to make this publicly available. The Council agrees to this and has included the amendment with some minor redrafting to improve clarity.

57. Like the European Parliament, the Council strongly supports the inclusion of a specific reference to the funding of studies on the paediatric use of off-patent medicinal products, in form of a new Article 40, but suggests redrafting compared to Amendments 56, 63 and 64. The Council considers that the specific name of the programme should not be given in the Regulation. Also the funding should be delivered through the Community Framework Programmes or any other Community initiatives for the funding of research. Furthermore, the Council considers that the reference to the study programme should be included only in Article 40, and not in Article 48.

Title VI - Communication and coordination

58. Article 41(1) deals with a European database on clinical trials. Like the European Parliament, the Council supports the introduction of transparency into the paediatric clinical trials database, but agrees that clarification is needed regarding what is to be included and how the details would be entered into the database. Amendment 57 has therefore been included in paragraph 1 and a new paragraph 2, with some redrafting, as has Amendment 58 on guidance.

59. The Council has introduced deadlines in Article 42 on collection of existing data on use of medicinal products in the paediatric population.

60. Article 43 deals with the inventory of paediatric needs. The Council agrees with the ideas behind the amendments to the text as set out in the first and second parts of the new Article 2b proposed in Amendment 19 by the European Parliament, and has redrafted Articles 43(2) and 43(3). The deadline has been extended to three years to ensure that there is sufficient time to complete all phases of the work involved. The Council cannot agree to the amendments to the text set out in the other new articles of Amendment 19 because they either involve duplication of work or are incomplete. The Council does not support the proposal to change the structure of the Regulation, since it considers the structure of the Commission proposal to be more coherent.

61. Article 45 deals with paediatric studies completed prior to the entry into force of the Regulation on Paediatric Medicines. The Council has clarified the scope of this Article. Here and in Article 46, the wording has been changed to make it clear that the Competent Authority has the discretion to decide whether or not to vary a marketing authorisation. It should be noted that the Competent Authority, when deciding on the action to take, is subject to pharmacovigilance provisions in Community law. The Council shares the intentions behind Amendments 62 and 69, but considers that both amendments should be included in Article 45(2) and not in Article 56. In response to parts of Amendment 52, the Council decided to modify Article 45(3) (compare Article 36 above).

Title VII - General and final provisions

62. Article 48 deals with the Community contribution to the European Medicines Agency. The Council agrees in principle to Amendment 63. The first part has been included in Article 48 with minor redrafting. For the second part, the Council considers that the reference to the study programme should be included in Article 40, and not in Article 48.

63. Article 49 deals with penalties for infringements of the Regulation. The Council supports the intentions behind Amendment 66, and has included it, with some minor redrafting. The Council considers that the harmonisation of national measures proposed in Amendment 65 would require the adoption of Community legislation to this aim, and can therefore not support this amendment.

64. Article 50 of the common position deals with reports to be prepared by the European Commission. The Council discussed in detail the necessary analysis of the impact of the reward mechanisms. It agrees, in principle, to Amendment 67 and has included it in Article 50(3) with some redrafting. The Council fully supports a provision for the Commission to carry out detailed analyses of the economic impact resulting from the application of the Regulation. However, the Council wishes to ensure that there are sufficient data available to make robust analyses. Since this might not be the case already after six years, the analysis of economic impact could take place later, but within ten years. In addition the Council decided that there should be an analysis of the estimated consequences for public health.

65. The Council decided to delete Article 50 of the Proposal, since it considers that the provisions in Article 6 of the common position are sufficient as a basis for rules of procedure for the Paediatric Committee, which should be decided within EMEA in order guarantee flexibility.

66. Article 51 on comitology has been adapted to correspond to standard wording.

67. Article 52 contains amendments necessary to Regulation (EEC)1768/92 "the SPC Regulation". In particular, a new paragraph 4 is inserted into Article 7 of Regulation (EEC)1768/92, stating that the application for an SPC prolongation shall be lodged no later than two years before the expiration of the SPC. The Council considers that the two-year deadline in the Proposal is necessary to ensure transparency for generic competition. The Council can therefore not support Amendment 68, which shortens the deadline to six months.

Following detailed "technical" examination of the proposed amendments to the SPC Regulation, the Council has decided to change some of the provisions of the Proposal and has also introduced some new amendments to this Regulation.

68. The Council has inserted a new Article 53 in order to introduce an amendment to Directive 2001/20/EC aiming at making public part of the information on paediatric clinical trials entered in the European database on clinical trials.

69. Article 57 deals with the entry into force of the provisions of the proposed regulation. Since there is no legal basis in current legislation nor any sufficiently empowered existing committee to agree paediatric investigation plans in advance of the entry into force of the Regulation, applications submitted before that date cannot include findings from studies which are part of an agreed paediatric investigation plan. Therefore, the Council cannot support Amendment 70. But research in advance of the entry into force of the Regulation is not discouraged. In accordance with Article 45(2) (Amendment 62), existing and on-going studies at the time of entry into force of the Regulation shall be eligible to be included in a paediatric investigation plan once the Regulation is adopted.

The Council also considers that the suggested time-limits in Amendment 71 would not allow sufficient time for the necessary prior steps to be taken e.g. establishment of the Paediatric Committee or agreement of paediatric investigation plans, and can therefore not support this amendment.

IV. CONCLUSION

70. The Council has incorporated a considerable number of the European Parliament's amendments in its common position, which is fully in line with the objectives of the Commission proposal.

The common position of the Council has the special health care needs of children as its main objective and strives to strike a balance between different considerations. The Commission has acknowledged the overall balance of the Council's common position and welcomed the Political Agreement at the Council (EPSCO) on 9 December 2005.