Decision in Respect of an Application by E.I. Du Pont De Nemours & Company for the Grant of an Extension of Duration of the SPC No. 1996/028 for COZAAR

1. This decision relates to an application by E.I. Du Pont De Nemours and Company (hereinafter 'Du Pont') for the grant of an extension of the duration of the SPC No. 1996/028 which was lodged with the Patents Office on 23 February 2009. The SPC had been granted to Du Pont on 25 June 1997 (with an expiry date of 2 September 2009) in respect of the medicinal product "COZAAR which contains Losartan potassium" (hereinafter COZAAR). The active ingredient, Losartan potassium, is used to treat high blood pressure in humans and was protected by Irish patent No. 69984 (granted on 16 October 1996). Merck Sharp & Dohme Limited (hereinafter 'Merck') holds a licence from Du Pont under both the patent and the SPC and it also has a Marketing Authorisation (MA) for COZAAR in Ireland.

2. In support of the application on 23 February 2009, the Applicant submitted a number of additional documents and these may be identified as follows:-

D1 – a copy of SPC No. 1996/028 for COZAAR.

D2 – a copy of a Commission Decision of 22 January 2009 for a new oral formulation of COZAAR suitable for paediatric use.

D3 – supporting assertions made by the Merck, the Marketing Authorisation holder. These were to the effect that (i) the active ingredient "Losartan potassium" was marketed as "COZAAR and/or associated names" in all the Member States of the EU; (ii) applications for authorisation of a paediatric indication for "COZAAR and/or associated names" and a new oral paediatric formulation of "COZAAR and/or associated names" had been made in all Member States under Article 8 of the Paediatric Regulation; and (iii) a confirmation that "COZAAR and/or associated names" was authorised to be placed on the market in all Member States and the details of these authorisations were to be found in Annex I of document D2.

D4 – a Preliminary Variation Assessment Report (PVAR) issued by the College ter

Beoordeling van Geneesmiddelen (CBG - Medicines Evaluations Board of The Netherlands) on 28 January 2008. This relates to a "Type II Variation" application to the Marketing Authorisation for COZAAR.

D5 – an email issued by the CBG to the Concerned Member States (CMS) on 13 February 2009 with the subject "Type II Variation application – email from RMS confirming clock off".

D6 - a certified copy of the positive Opinion on compliance with an agreed paediatric investigation plan (PIP) for COZAAR issued by the Paediatric Committee (PDCO) of the European Medicines Agency (EMEA) on 6 February 2009.

D7 – copies of the Irish Marketing Authorisations for 50 and 100 mg tablet forms of COZAAR and for an 'Initiation Pack" containing both 12.5 and 50mg tablets.

As there are a number of abbreviated expressions used throughout this decision I have listed them in an attached Annex – Glossary of Terms'

3. On 2 March 2009 the Applicant submitted a copy of the Irish Marketing Authorisation for the oral paediatric formulation of COZAAR that had been issued by the Irish Medicines Board on 27 February 2009 arising out of the Commission Decision of 22 January 2009 (document D8). On 7 July 2009 the Applicant submitted the following supporting documentation: lists of national MAs which had issued by that date for both the new paediatric formulation and a Type II variation of COZAAR (accompanied by an disk containing copies of all the authorisations), plus a copy of the "end of procedure" email sent by the CBG to all CMS in relation to the Type II variation application which included a statement of compliance with the PIP (document D9). The Applicant also submitted further written arguments in support of its case and confirmed that only Greece remained to issue both MAs. On 9 July 2009 the Applicant submitted copies of both the oral paediatric formulation and the Type II variation MAs issued by Greece. On 17 July 2009 the Applicant submitted further written submissions for the Examiner in support of its application. On 22 July the Applicant submitted documentation from the Lithuanian Medicines Agency confirming the issue of the updated MA for the paediatric indication of COZAAR on 1 July 2009.

4. Having considered all the information supplied by the Applicant, the Examiner replied on 24 July 2009 and concluded that the application did not comply with the requirements of the SPC Regulation. In particular, she stated that it did not meet the requirements laid down in either Article 8(1)(d)(i) or 8(1)(d)(ii) on the date of filing i.e. 23 February 2009 or before the limit (cut-off) date for filing provided for under Article 7 i.e. 2 March 2009. She also expressed the opinion that she did not see how the application could be rectified under the Article 10(3) provision and stated her intention to reject the application.

5. In normal circumstances the Applicant would have been allowed a period of up to 4 months to attempt to address these deficiencies. However, as the SPC for COZAAR was due to expire on 2 September, the Applicant was offered the option of requesting a hearing at the earliest opportunity. On 29 July 2009 the Applicant formally requested a hearing and that hearing took place before me, acting on behalf of the Controller, on 21 August 2009. At the hearing the Applicant was represented by Ms. Sinéad Dunne of Tomkins & Co. and Ms. Deeba Hussain of Merck.

6. In considering this application I shall make reference to the following EU legislation:-

(i) Directive 2001/83/EC relating to *"medicinal products for human use"* – hereinafter the 'Mutual Recognition Procedure Directive'.

(ii) Council Regulation (EEC) No. 1768/92 concerning *"the supplementary protection certificate for medicinal products"* and as subsequently amended by the Paediatric Regulation to provide for an SPC extension and codified as Regulation (EC) 469/2009 – hereinafter the 'SPC Regulation'.

(iii) Regulation (EC) No. 1901/2006 on *"medicinal products for paediatric use"* – hereinafter the 'Paediatric Regulation'

(iv) Regulation (EC) No. 726/2004 on *"Community procedures for the authorisation and supervision of medicinal products for human and veterinary use …"*– hereinafter the 'Centralised Procedure Regulation'.

7. The European system for the authorisation of medicinal products for human and animal use was introduced with the objective of ensuring the availability of safe, effective and high quality medicines to citizens throughout the European Union in as short a time as possible. This led to the creation of the European Agency for the Evaluation of Medicinal Products (later the European Medicines Agency or EMEA) together with a legislative framework providing that no medicinal product could be placed on the market of an EU Member State unless the competent authority of that state or the EMEA had issued an appropriate Marketing Authorisation.

8. Today, this system offers three routes for the authorisation of medicinal products; the so-called "centralised procedure" (under the Community Procedures Regulation) using the EMEA; and two procedures based on the so-called "mutual recognition" of national authorisation procedures (under the Mutual Recognition Procedure Directive). The "decentralised procedure" (DCP) applies to medicinal products that have not been authorised before in any Member State. If the medicinal product has already been granted an MA in one of the Member States, then the "mutual recognition" procedure (MRP) is used. This is based on the principle of recognition by one or more Member States of an already existing national MA. One Member State acts as the reference member state (RMS) and coordinates the subsequent procedure so that, at the end of the prescribed period, national MAs may be granted in all the Member States involved. Since 1 January 1998 the MRP procedure is compulsory for all medicinal products to be marketed in a Member State other than in the one they were first authorised.

9. The SPC Regulation provides the circumstances and means by which an applicant can obtain up to five years additional protection for a medicinal product (marketed for use in humans) to compensate for the time taken to obtain regulatory approval to put this product on the market. The additional term of protection provided by the SPC relates to the active ingredient within the medicinal product and the actual scope of protection is defined by the basic patent for the active ingredient upon which the SPC application is based.

10. The Paediatric Regulation prescribes the system for promoting and authorising paediatric testing of medicinal products in the EU. Its basic aim is to improve the knowledge on the use of such products in the paediatric population (i.e. between birth

and 18 years) throughout the EU. In order to attain its objective to reward companies for carrying out paediatric testing of their products, this regulation has amended the original SPC Regulation to provide in Article 36 the means by which a reward in the form of an additional 6-month extension to the term of protection provided by the SPC may be obtained:-

> *Article 36(1) "Where an application under Article 7 or 8 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.*
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> *The first subparagraph 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.*
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> *(2) The inclusion in a marketing authorisation of the statement referred to in Article 28(3) shall be used for the purposes of applying paragraph 1 of this Article.*
>
> *(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.*
>
> *(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.*
>
> *(5) ....*

11. A “paediatric investigation plan” or PIP is defined in Article 2(2) of the Paediatric Regulation as: *“a research and development programme aimed at ensuring that the necessary data are generated determining the conditions in which a medicinal product may be authorised to treat the paediatric population.”*

12. Articles 7 to 10 of the Paediatric Regulation provide for the MA requirements to be applied to medicinal products. Article 7 applies to an MA application for any new medicinal product, not just paediatric products. Article 8, which deals with those authorised products that are protected by an SPC or by a patent that qualifies for the granting of an SPC, applies to applications for extensions or variations to these authorisations of *‘new indications, including paediatric indications, new pharmaceutical forms and new routes of administration’*. Article 8 continues:- *“For the purposes of the first subparagraph, the documents referred to in Article 7(1) shall cover both the existing and new indications, pharmaceutical forms and routes of administration.”* In the present case it is Article 7(1)(a) that is relevant:

> *Article 7(1). An application for marketing authorisation under Article 6 of Directive 2001/83/EC in respect of a medicinal product for human use which is not authorised in the Community at the time of entry into force of this Regulation shall be regarded as valid only if it includes, in addition to the particulars and documents referred to in Article 8(3) of Directive 2001/83/EC, one of the following:*
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> > *(a) the results of all studies performed and details of all information collected in compliance with an agreed paediatric investigation plan.*

In other words, to proceed in this manner with an application for an extension or a variation to an existing authorisation, an applicant must supply all the results of studies and details of all information collected in compliance with the agreed PIP.

13. Articles 23 and 24 of the Paediatric Regulation specifically address the issue of compliance with the PIP and require that the appropriate competent authority in each Member State must verify this compliance:

> Article 23*(1). The competent authority responsible for granting marketing*

authorisation shall verify whether an application for marketing authorisation or variation complies with the requirements laid down in Articles 7 and 8 and whether an application submitted pursuant to Article 30 complies with the agreed paediatric investigation plan.

Where the application is submitted in accordance with the procedure set out in Articles 27 to 39 of Directive 2001/83/EC, the verification of compliance, including, as appropriate, requesting an opinion of the Paediatric Committee in accordance with paragraph 2(b) and (c) of this Article, shall be conducted by the reference Member State.

(2). The Paediatric Committee may, in the following cases, be requested to give its opinion as to whether studies conducted by the applicant are in compliance with the agreed paediatric investigation plan:

(a) by the applicant, prior to submitting an application for marketing authorisation or variation as referred to in Articles 7, 8 and 30, respectively;

(b) by the Agency, or the national competent authority, when validating an application, as referred to in point (a), which does not include an opinion concerning compliance adopted following a request under point (a);

(c) by the Committee for Medicinal Products for Human Use, or the national competent authority, when assessing an application, as referred to in point (a), where there is doubt concerning compliance and an opinion has not been already given following a request under points (a) or (b).

In the case of point (a), the applicant shall not submit its application until the Paediatric Committee has adopted its opinion, and a copy thereof shall be annexed to the application.

(3). If the Paediatric Committee is requested to give an opinion under paragraph 2, it shall do so within 60 days of receiving the request.

Member States shall take account of such an opinion.

Article 24. If, when conducting the scientific assessment of a valid application for Marketing Authorisation, the competent authority concludes that the studies are not in conformity with the agreed paediatric investigation plan, the product shall not be eligible for the rewards and incentives provided for in Articles 36, 37 and 38.

14. Recital 26 of the Paediatric Regulation effectively sets out the essential conditions that must be met in order for the reward of the 6-month extension of the SPC to be granted:- "… *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 …*".

15. Before considering in detail the Examiner's objections regarding the requirements of Article 8(1)(d)(i) and 8(1)(d)(ii), I will briefly summarise the relevant facts of the case.

16. Merck made an application to the EMEA to agree a paediatric investigation plan (PIP) on 16 May 2007. This was shortly before the Paediatric Committee (PDCO) of the EMEA come into being on 26 June 2007. This PIP was agreed on 26 February 2008 and required three different studies to be carried out on COZAAR by Merck:-

(i) To investigate a liquid formulation of COZAAR for children i.e. a new form of COZAAR as an oral suspension.

(ii) To investigate whether COZAAR would be a good treatment for proteinurea in children i.e. a new use for COZAAR.

(iii) To investigate whether COZAAR would be suitable for its normal purpose, the treatment of hypertension in very young children (aged from 0.5 to 6 years) i.e. a new paediatric indication for COZAAR.

17. I shall deal initially with the first part of the PIP, namely the oral suspension. The

PDCO issued a compliance report on 8 May 2008 regarding the first part of the PIP, as a result of which Merck submitted an application for an extension to its original MA for COZAAR to cover a 2.5mg/ml powder and solvent for oral suspension. The procedures for updating the MA for an application made under Article 8 of the SPC Regulation are given in Articles 28 and 29 of the Paediatric Regulation. In this case, COZAAR came within Article 29 because it had been previously authorised under the MRP (for treating hypertension in adults). This article provides for an application to be submitted in accordance with the procedure laid down in Articles 32 - 34 of the MRP Directive.

18. The Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh) was set up under Directive 2004/27/EC (amending the MRP Directive) and in February 2009 it issued a document "Recommendations for implementing Commission Decisions following an Article 29 application under the Paediatric Regulation". To be eligible for this procedure the medicinal product must be:- (i) authorised in the Community through national, mutual recognition or decentralized procedure, and (ii) protected by either a SPC or by a patent that qualifies for an SPC. Such an application must concern the authorisation of:- (i) new indications, including paediatric indications or (ii) a new pharmaceutical form, or (iii) a new route of administration. The application must be accompanied by results of studies and information in compliance with an agreed PIP. The procedure is limited to the evaluation of the paediatric data including, if relevant, supportive adult data. Accordingly, applications can be either extensions to existing authorisations leading to the grant of a new marketing authorisation (MA) or a variation to an existing MA in the case of new indications.

19. Following an opinion issued by the Committee for Medicinal Products for Human Use (CHMP) on 23 October 2008, the EC Commission issued its decision on 22 January 2009 (document D2) authorising the Member states to amend the national MAs to provide for the oral formulation of COZAAR under the Article 29 procedure. This decision required the amended MAs to be based on the summary of product characteristics (SmPC), the labelling and the package leaflet as set out in Annex III of the document. Lastly, Member States were reminded that they were expected to issue the amended MA within 30 days from publication of the decision. The corresponding amended MA in Ireland was issued by the Irish Medicines Board on 27 February 2009.

20. I shall now turn to examine in detail the Examiner's observations and objections as detailed in her letter of 24 July 2009.

21. In relation to the timing of the application, the Examiner noted that Articles 7(4) and 7(5) were relevant as they provided for the filing of an application for the extension of an already granted SPC. Article 7(4) states: - *"The application for an extension of the duration of a certificate already granted shall be lodged not later than two years before the expiry of the certificate."* However, Article 7(5) contains the following transitional provision (due to expire on 26 January 2012):- *"Notwithstanding paragraph 4, for five years following the entry into force of Regulation (EC) No 1901/2006, 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."* In the present case, given that SPC No. 1996/028 was due to expire on 2 September 2009, the cut-off date for filing the application for the extension was 2 March 2009 as mentioned previously. The Examiner duly noted that the application for the extension was filed on 23 February 2009, i.e. before the cut-off date.

22. The Examiner went on to consider the content of the application for a certificate as provided for in Article 8, with Article 8(3) referring specifically to an application for the extension of the duration of a certificate already granted (as in the present case) and requiring the particulars as set out in Article 8.1(d)(i) and 8.1(d)(ii) to be provided:-

> *8(1). The application for a certificate shall contain:*
>
> > *(d) where the application for a certificate includes a request for an extension of the duration:*
> >
> > *(i) a copy of the statement indicating compliance with an agreed completed paediatric investigation plan as referred to in Article 36(1) of Regulation (EC) No 1901/2006;*
> >
> > *(ii) where necessary, in addition to the copy of the authorisation to place the product on the market as referred to in point (b), proof of possession of authorisations to place the product on the market of all other Member States, as referred to in Article 36(3) of Regulation (EC) No 1901/2006.*

8(2). Where an application for a certificate is pending, an application for an extended duration in accordance with Article 7(3) shall include the particulars referred to in paragraph 1(d) of this Article and a reference to the application for a certificate already filed.

8(3). The application for an extension of the duration of a certificate already granted shall contain the particulars referred to in paragraph 1(d) and a copy of the certificate already granted.

23. The Examiner concluded as follows: *"In summary, a valid application for an extension must be filed at least 6 months prior to the expiry of the SPC and the applicant must, at that date, have a copy of the statement indicating compliance with an agreed completed paediatric investigation plan and an updated marketing authorisation in all Member States."*

24. In support of the requirement under Article 8(1)(d)(i), the Applicant submitted a copy of the Commission Decision of 22 January 2009 relating to the oral suspension form of COZAAR (document D2). The Applicant made particular reference to the statement in preamble (3) of the this decision: *"... it has been verified that the application includes the results of all studies performed and details of all information collected in compliance with the agreed paediatric investigation plan."*

25. Having examined this decision, I agree with the opinion of the Examiner that the statement in preamble (3) specifically refers only to the studies performed in respect of the *"new pharmaceutical form associated with a new strength"* for COZAAR, namely the 2.5mg/ml powder and solvent for oral suspension. In other words, it relates to only one part of the agreed PIP – this view would appear to be supported by the fact that neither the resulting Irish MA (issued on 27 February 2009) nor any of the MAs issued by other Member States contain any statement of compliance.

26. I shall now turn to the two remaining parts of the PIP, namely the new use of COZAAR in treating proteinurea in children up to 18 years of age, and the paediatric indication for COZAAR for treating hypertension in very young children as outlined respectively in parts (ii) and (iii) of the PIP in paragraph 17. On 19 November 2008

Merck submitted a request to the PDCO for an opinion as to whether the studies conducted under (ii) the new use for COZAAR, and (iii) the paediatric indication (as outlined in paragraph 17) were in compliance with the agreed PIP - this request was made under Article 23(2)(a) of the Paediatric Regulation. This resulted in the Paediatric Committee issuing a positive Opinion on compliance on 6 February – document D3. This opinion also contains a footnote in this document stating *"This Opinion does not entitle to the rewards and incentives referred to in Title V of Regulation (EC) No. 1901/2006, as amended."*

27. Subsequently Merck also submitted an application for a Type II variation of the MA for COZAAR to update the results from the studies linked to parts (ii) and (iii) of the PIP in the product information for COZAAR. On 28 January 2009 The Netherlands CBG, in its role as RMS, issued a Preliminary Variation Assessment Report (PVAR) concerning this application. On 13 February 2009 the RMS sent an email with the subject "Type II Variation application – email from RMS confirming clock off" (document D5) to the CMS informing them that Merck was being given until 14 March 2009 to address all comments relating to the PVAR by the CMS. The Applicant made particular reference to the following extract from this email in the letter accompanying the application:- *"The Netherlands Agency has acknowledged that the Applicant should be entitled to the rewards and incentives provided for in Articles 36, 37 and 38. … It is submitted that whilst the MA variation procedure for COZAAR will continue, the assessment of compliance with the agreed PIP is now complete. Therefore the statement of compliance specified in the email of the Netherlands Agency is not subject to change and is the actual statement which will be included in all the national varied MAs."*

29. In disagreeing with this interpretation, the Examiner quoted from a procedural advice document issued by the EMEA:- "Validation of new marketing authorisation application - extension/variation application and compliance check with an agreed PIP" as follows:- "*If during the scientific assessment of the application by the National Competent Authority (Reference Member State in general) it is concluded that in fact the studies have not been conducted in compliance with an agreed PIP, and consequently the initial positive outcome on compliance is not confirmed, this should be substantiated in detail, and the EMEA/PDCO should be informed."* The Examiner concluded by

remarking that in her opinion the RMS could not issue a definitive statement on compliance until all aspects of the variation procedure had been completed.

30. The Examiner went on to consider the "end of procedure" email (document D9) issued by the CBG of The Netherlands to all CMS on 6 April 2009 informing them that the MA variation procedure had been positively concluded. The email also provided the wording of a PIP compliance statement that was to be included in the updated MAs for the COZAAR 12.5, 50 and 100mg tablets together with the updated product information. This email reminded the Member States of their duty to implement these changes to the national MAs within 30 days of receipt of the translations from Merck. On 20 April 2009 the Irish Medicines Board issued MAs for the 12.5, 50 and 100mg film-coated tablets for the paediatric indication *"treatment of essential hypertension in adults and in children and adolescents 6 – 16 years of age."* and included the statement of compliance as required by the CBG under "Part I – Product Specific Details of the product information. Although the Examiner accepted that this email clearly provided a statement of compliance, she concluded that, since it was not issued until after the limit date of 2 March, it was not admissible and the extension application was not compliant with Article 8(1)(d)(i).

31. The Examiner then considered the requirements under Article 8.1(d)(ii) and noted the reference in this provision to Article 36(3) of the Paediatric Regulation which states:- *"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."*

32. In her interpretation of Article 36(3) the Examiner referred to Recital 26 of the Paediatric Regulation:- "… *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*". Furthermore, she noted that on the EMEA website, the term 'product information' refers to the Summary of Product Characteristics, labelling and package leaflet. On this basis she reasoned that the Article 36(3) provision required the MA to have been updated in all Member States before the applicant would be entitled to

receive the 6-month extension. In this case, given that the required updated MA for COZAAR was not available in any Member State before the 2 March limit date, she concluded that the application did not comply with Article 8.1(d)(ii). I believe the Examiner is correct in her interpretation of this point, particularly when Article 36 is considered as a whole. I do not accept the arguments of the Applicant that either the MA issued for the oral formulation or the original MAs issued for the adult indication of COZAAR may be used in regard to this Article. While the first paragraph of Article 36(1) provides for the reward, the second paragraph clearly underlines the importance of reflecting the results of the completed paediatric studies in the summary of product characteristics and, where appropriate, the package leaflet of the medicinal product concerned even in the case where completion of the PIP fails to lead to the authorisation in the paediatric population (e.g. the use of COZAAR in the treatment of paediatric proteinurea).

33. To ascertain whether the defects outlined above might have been remedied, the Examiner considered the provisions of Articles 7(3) and 10(3). Article 7 provides for the timing for filing both an SPC application and an extension application. In particular, Article 7(3) states that an application for an extension may be made when *"… the appropriate requirements of Article 8(1)(d) or Article 8(2), respectively, are fulfilled."* The Examiner went on to remark that, despite the fact that Article 7(3) did not explicitly provide for the filing an extension application based on an already granted SPC, she did not believe that the basic requirements applying to such an application should be any different in such a situation. Hence, she concluded that the applicant must be in possession of the statement of compliance and the updated MAs at the date of filing of the extension application.

34. The Examiner also considered whether the Applicant might have been able to rectify the defects using the provision in Article 10(3):- *"Where the application for a certificate does not meet the conditions laid down in Article 8, the authority referred to in Article 9(1) shall ask the applicant to rectify the irregularity, or to settle the fee, within a stated time."* However, she interpreted this provision as affording the applicant an opportunity to remedy only formal defects, e.g. to correct obvious errors or supply missing pages, etc. She did not believe it allowed the Applicant to supplement the application with documents that did not exist at the date of filing. She remarked that:- *"A*

more liberal interpretation of this article would render Article 7(5) meaningless i.e. an applicant could simply file an application for an extension citing nothing more that his name and address and SPC number."

35. At the hearing Ms. Hussain explained that the Applicant did not agree with the Examiner's interpretation of Article 7. In particular, she argued that, as the application came under the transitional provision of Article 7(5), the requirements of Article 7(3) did not necessarily apply as at the actual date of filing of the application. She suggested that, as long as the minimum requirements for filing were satisfied prior to or at the limit date, it would be permissible for the Applicant to rectify any irregularities as provided for in Article 10(3) after that date.

36. Given that Article 7(5) clearly is a transitional provision to allow for extension applications to certificates already granted and, given the typical lengths of time needed to satisfy the legislative requirements such as agreeing the PIP, conducting the paediatric studies, applying for MA extensions, etc, it would appear unduly burdensome and disproportionate to demand that all the these requirements be met at the filing date. In this particular case all the available documentary evidence does appear to indicate that the Applicant has been prompt at all times in pursuing this application, from their initial request to agree the original PIP shortly after the Paediatric Regulation entered into force, to their dealings subsequently with all the various regulatory authorities.

37. I believe the Examiner raised an important issue when she mused on whether it might be possible for an applicant to merely file an extension application by supplying nothing more that a name, address and SPC number. This does beg the question as to what might constitute the minimum requirements for filing a valid application in the case of an application coming under the Article 7(5) provision.

38. It is Articles 9(2) and 9(3) of the SPC Regulation that provide for what is required to be published by an industrial property office after receipt of an application for an extension to an SPC :-

> *9(2). Notification of the application for a certificate shall be published by the authority referred to in paragraph 1. The notification shall contain at least the*

following information:

(a) the name and address of the applicant;

(b) the number of the basic patent;

(c) the title of the invention;

(d) the number and date of the authorisation to place the product on the market, referred to in Article 3(b), and the product identified in that authorisation;

(e) where relevant, the number and date of the first authorisation to place the product on the market in the Community;

(f) where applicable, an indication that the application includes an application for an extension of the duration.

9.3. Paragraph 2 shall apply to the notification of the application for an extension of the duration of a certificate already granted or where an application for a certificate is pending. The notification shall additionally contain an indication of the application for an extended duration of the certificate.

39. In my view this is instructive in coming to a conclusion as to what the minimum requirements might be in relation to lodging a valid application in such a case. In other words, the requirements of Article 8 (1)(a), (b) and (c) become sufficient for a valid application under the Article 7(5) transitional provision and I note that that the documents supplied by the Applicant on the filing date and listed in paragraph 2 satisfy these requirements.

40. On this basis the Applicant does appear to be entitled to use the provision in Article 10(3) to supplement the application with the necessary documentation so as to satisfy the outstanding requirements of Articles 8(1)(d)(i) and 8(1)(d)(ii); namely a copy of the statement indicating compliance with the PIP, a copy of the updated MA from the Irish Medicines Board and proof of possession of updated MAs in all the other Member States. The statement of PIP compliance that was sent to the Applicant by the CBG on 6 April 2009 had been submitted to the Examiner on 7 July as mentioned in paragraph 3. As indicated in paragraph 30, the Irish Medicines Board had issued the updated MA for the paediatric indication of COZAAR on 20 April 2009 and a copy was supplied to the Examiner on 7 July 2009. With the submission of the approval letter (plus translation)

from the Lithuanian Medicines Agency on 22 July 2009, this completed the set of updated MAs from the Member States has now been submitted and this means that the Applicant had finally complied with all the requirements of Article 8(1)(d)(ii) as of that date.

41. In conclusion, therefore, the application by Du Pont for the grant of an extension of the duration of the SPC No. 1996/028 is allowed. The SPC will now expire on 2 March 2010.

Dr. Michael Lydon
Hearing Officer
23 September 2009

ANNEX

GLOSSARY OF TERMS

CBG - College ter Beoordeling van Geneesmiddelen of The Netherlands

CHMP - Committee for Medicinal Products for Human Use

CMDh - Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human

CMS – Concerned Member states

DCP – Decentralised procedure

EMEA – European Medicines Agency

IMB – Irish Medicines Board

MA – Marketing Authorisation

MS – Member State (of European Union)

MRP – Mutual recognition procedure

PDCO – Paediatric Committee

PIP – Paediatric investigation plan

PVAR – Preliminary Variation Assessment Report

RMS – Reference Member State

SPC – Supplementary Protection Certificate

SmPC – Summary of product characteristics