Intellectual Property Office

BL O/098/15

04 March 2015

COUNCIL REGULATION (EC) 469/2009 CONCERNING THE CREATION OF A SUPPLEMENTARY PROTECTION CERTIFICATE FOR MEDICINAL PRODUCTS

and

COUNCIL REGULATION (EC) 1901/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON MEDICINAL PRODUCTS FOR PAEDIATRIC USE

APPLICANT	Otsuka Pharmaceuticals Company Limited
ISSUE	Whether the application for an extension to SPC/GB/04/039 may be granted
HEARING OFFICER	Dr L Cullen

DECISION

Introduction

1 This decision relates to an application, dated 12 October 2012, filed by Otsuka Pharmaceutical Co., Ltd ("the applicant") for a six month extension to the period of protection provided by a supplementary protection certificate (SPC) granted to the applicant and accorded the number SPC/GB04/039.

2 The SPC was granted on 14 April 2005 and, subject to the payment of the correct fee, entered into force on 27 October 2009. The expiry date of the SPC (if not extended) is 26 October 2014. The product for which this SPC was granted is '*Aripiprazole or a salt thereof'*. This is the active ingredient in the medicinal product marketed by the applicant under the name Abilify (RTM). This medicinal product is

used to treat schizophrenia and bipolar type I disorder (also referred to as bipolar affective disorder).

3 The basic patent on which the SPC relies is EP(UK) 0367141 B1, filed on 27 October 1989 with a priority date of 31 October 1988, which was granted by the European Patent Office (EPO) on 10 January 1996.

4 The marketing authorization EU/1/04/276/001-020 supplied in support of this SPC application was granted on 4 June 2004 by a decision of the European Commission on a recommendation from the European Medicines Agency (EMEA).

5 In the covering letter, dated 12 October 2012, submitted with their application for a six-month extension the applicant stated that "*significant studies contained in the agreed paediatric investigation plan ... have been completed. At this time however EMEA has not issued a varied marketing authorisation containing an Article 28(3) statement*."

6 The examiner in his first official response, dated 26 April 2013, noted that *"...the application does not comply with Article 8(1)(d)(i), in other words the application is deficient in that there is no statement indicating compliance with an agreed completed paediatric investigation plan in accordance with Article 28(3) of Regulation (EC) 1901/2006.*" In addition, the examiner reported that *"I have checked the public record for the marketing authorisation and can find no indication as yet of a statement of compliance on any of the recent variations. Indeed it would appear that the paediatric investigation plan is not as yet completed and may not be until January 2016 (see page 9 of the EMEA decision on P/99/2011)."* He then asked the applicant to provide an estimate of when they expected the agreed Paediatric Implementation Plan (PIP) to be completed, validated and the marketing authorisation (MA) updated to reflect the statement of compliance with Article 28(3) of the paediatric regulation and to provide an explanation of why they thought this.

7 In further correspondence, dated 2 September 2013, the applicant sought, as a main request, to persuade the examiner that a paediatric extension should be granted based on the application as filed which included details of all the studies in the paediatric population that had been completed up to that time. As an auxiliary request, the applicant requested that they be allowed more time to complete the remaining paediatric studies and to provide the updated MA as provided for in the ruling of the Patents Court in *EI du Pont de Nemours & Co v UK Intellectual Property Office* [2009] EWCA Civ 966 (hereafter *DuPont*)[1].

8 The Examiner, in his official examination report dated 16 June 2014, acknowledged the relevance of the case law cited by the applicant to deciding if more time should be given to cure the irregularity identified with the application, i.e. lack of an Article 28(3) statement to meet the requirement of Article 8(1)(d) of the SPC regulation. However, he noted that this case law also made clear that providing more time to cure the irregularity in this application did not only relate to the reasonable conduct of

[1] This was an appeal from the Patents Court (see *EI du Pont de Nemours & Co v UK Intellectual Property Office* [2009] EWHC 1112 (Ch)) which in turn was an appeal from the decision of the hearing Officer at the IPO (BL O/096/09, *DuPont). For full text of decision see IPO website at https://www.ipo.gov.uk/p-challenge-decision-results/p-challenge-decision-results-bl?BL_Number=O/096/09*.

the applicant. The proximity of the expiry date of the SPC was also a consideration. In particular, the examiner noted that, *"given that the SPC is due to expire in a little over 4 months time I am guided to take into account how close to the expiry of the SPC full compliance with Article 8(1) is expected".* The examiners view was that the irregularity in the application could not be cured after the SPC has expired because of the uncertainty this created for third parties. Thus the application for an extension should be refused unless there was a credible prospect that the necessary compliance statement would be issued and the MA updated before expiry of the SPC. The examiner gave the applicant until 17 July 2014, i.e. just over 3 months before expiry of the SPC on 26 October 2014, to supply the compliance statement or request the matter be decided.

9 Having requested an as-of-right extension of two months to the date for response, the applicant replied on 17 September 2014, providing details of some further studies that had been completed in the period since their previous letter dated 2 September 2013. They referred to some updates to the SmPC of the MA regarding the use of the medicinal product Abilify in the paediatric population. The applicant maintained their main request and their auxiliary request, as stated in their letter of 2 September 2013.

10 In his official examination report, dated 30 September 2014, the examiner maintained his view that the application for an extension to the granted SPC did not meet the requirements of Article 8(1)(d)(i) and that the request for an extension to the SPC should be refused.

11 The applicant, in their letter dated 17 September 2014, had initially requested an oral hearing but withdrew this request in writing on 5 November 2014 and asked to have a decision prepared based on the papers already on file. My decision is outlined in the following paragraphs.

Issues to be decided

12 Both the examiner and applicant are in agreement that this application for an extension to a granted SPC does not include an updated MA from the EMEA including a statement of compliance. As the examiner has stated in his official examination report dated 16 June 2014, in the absence an updated MA from the EMEA including a statement of compliance from the applicant, the issues to be decided are:

i) Can the application be granted under Article 10(1) as it stands based on the paediatric studies already completed?

ii) If the answer to (i) is in the negative can further time be given for an Article 8(1) statement to issue?

iii) If a compliance statement is not expected to issue before the SPC expires can the extension application be refused under Article 10(2)?

13 I agree with this summary save in one regard. If in answer to (iii) above, I find that the application should be rejected, this is on the basis of the applicant failing to rectify the irregularity under Article 10(4) to address the conditions laid down in

Article 8 and not a failure of the application to meet the conditions laid down in the Regulation under Article 10(2).

The Relevant Law

14 The relevant legislation concerning the grant of a six-month extension to the duration of an SPC is Regulation (EC) No 1901/2006 (hereafter "the paediatric regulation") [2,3].

15 The paediatric regulation is referred to specifically in Council Regulation (EC) 469/2009 ("the SPC regulation"), which lays down the regime for granting SPCs in general and also refers to the requirements for obtaining an extension to a granted SPC[4].

Council Regulation (EC) 1901/2006 - the paediatric regulation

16 The paediatric regulation establishes a system for promoting the testing of medicines in the paediatric population and authorising medicines for use in that population. The objective of this regulation is to provide suitable incentives and rewards to companies that produce medicinal products so that they will carry out clinical tests to find out the effectiveness of these drugs when used in children but also ensuring that no unnecessary clinical or other trials take place involving children. It is well established that medicinal products can have different effects when used in adults and when used in children and that tests should be carried out in children to determine if and what these different effects are. This is made clear in the recitals to the paediatric regulation; see for example recitals 4-6. The rewards and incentives provided to companies to carry out this work are laid down in Article 36 of the paediatric regulation, which reads:

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

[2] Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 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.

[3] (i) Regulation (EEC) No 1768/92 of the European Parliament and of the Council of 18 June 1992 concerning the creation of a supplementary protection certificate for Medicinal products; (ii) Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the member states relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use; (iii) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the community code relating to medicinal products for human use, as amended; (iv) Regulation (EEC) 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.

[4] Council Regulation (EC) 469/2009 concerning the creation of a supplementary protection certificate for medicinal products is a codification of Council Regulation (EEC) 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products which had been substantially amended several times. Regulation (EC) 469/2009 superceded Regulation (EEC) 1768/92. Annex II to Regulation 469/2009 indicates the correlation between the recitals and Articles in Regulation 1768/92 and those in 469/2009

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.

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*.*

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.*

17 As is clear from Article 36(1), one of these rewards is a six-month extension to the term of an SPC.

18 Articles 7, 8, 24 and 28(3) from the paediatric regulation are also relevant to the determination of whether or not this reward can be granted

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:

(a) the results of all studies performed and details of all information collected in compliance with an agreed paediatric investigation plan;

(b) a decision of the Agency granting a product-specific waiver;

(c) a decision of the Agency granting a class waiver pursuant to Article 11;

(d) a decision of the Agency granting a deferral.

For the purposes of point (a), the decision of the Agency agreeing the paediatric investigation plan concerned shall also be included in the application.

2. The documents submitted pursuant to paragraph 1 shall, cumulatively, cover all subsets of the paediatric population.

Article 8

In the case of authorised medicinal products which are protected either by a supplementary protection certificate under Regulation (EEC) No 1768/92, or by a patent which qualifies for the granting of the supplementary protection certificate, Article 7 of this Regulation shall apply to applications for authorisation of new indications, including paediatric indications, new pharmaceutical forms and new routes of administration. For the purposes of the first subparagraph, the documents referred to in Article 7(1) shall cover both the existing and the new indications, pharmaceutical forms and routes of administration.

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.*

Article 28

.....

*3. **If the application complies with all the measures contained in the agreed completed paediatric investigation plan and if the summary of product characteristics reflects the results of studies conducted in compliance with that agreed paediatric investigation plan, the competent authority shall include within the marketing authorisation a statement indicating compliance of the application with the agreed completed paediatric investigation plan.** For the purpose of the application of Article 45(3), this statement shall also indicate whether significant studies contained in the agreed Paediatric Investigation Plan have been completed after the entry into force of this Regulation.*

Council Regulation (EC) 469/2009 - the SPC regulation

19 Article 1 entitled “Definitions” in parts 1(e) and 1(d) defines a ‘certificate’ and an ‘application for an extensions of the duration’ as follows:

(d) ‘certificate’ means the supplementary protection certificate

(e) ‘application for an extension of the duration’ means an application for an extension of the duration of the certificate pursuant to Article 13(3) of this Regulation and Article 36 of Regulation (EC) No 1901/2006 ....

20 Article 13 entitled “Duration of the certificate” explains, in part (3) that the duration of a certificate may be extended for only one period of six-months to provide for the reward under Article 36 of the paediatric regulation

3. The periods laid down in paragraphs 1 and 2 shall be extended by six months in the case where Article 36 of Regulation (EC) No 1901/2006 applies. In that case, the duration of the period laid down in paragraph 1 of this Article may be extended only once.

21 Article 7, entitled “Application for a certificate”, outlines in sections (3)-(5) when the application for an extension to a certificate must be made:

Article 7

.....

3. The application for an extension of the duration may be made when lodging the application for a certificate or when the application for the certificate is pending and the appropriate requirements of Article 8(1)(d) or Article 8(2), respectively, are fulfilled.

4. 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.

5. 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.

Article 7(4) applies to the current application.

22 Article 8, entitled "Content of the application for a certificate", sets down the criteria to be fulfilled in order to qualify for the reward of a six month extension to the duration of a SPC:

Article 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.

23 Article 10, entitled "Grant of the certificate or rejection of the application for a certificate", refers to steps that must be taken to grant or reject an application for an extension to an SPC:

Article 10

1. Where the application for a certificate and the product to which it relates meet the conditions laid down in this Regulation, the authority referred to in Article 9(1) shall grant the certificate.

2. The authority referred to in Article 9(1) shall, subject to paragraph 3, reject the application for a certificate if the application or the product to which it relates does not meet the conditions laid down in this Regulation.

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.

4. If the irregularity is not rectified or the fee is not settled under paragraph 3 within the stated time, the authority shall reject the application.

5. Member States may provide that the authority referred to in Article 9(1) is to grant certificates without verifying that the conditions laid down in Article 3(c) and (d) are met.

6. Paragraphs 1 to 4 shall apply mutatis mutandis to the application for an extension of the duration.

Relevant case law

UK Courts

24 The Court of Appeal in *DuPont*[1] considered what is required in an application for an extension to an SPC to meet the requirements of Article 8(1)(d)(i) and 8(1)(d)(ii) of the SPC regulation. It also considered the circumstances under which rectification under Article 10(3) could be used to address the deficiencies identified

25 This case has been referred to by both the examiner and the applicant in support of their arguments. It concerns whether or not it is possible for an applicant for an extension to an SPC to provide outstanding documents, in this case copies of national MAs which had been updated to show the results of the paediatric studies and included the relevant compliance statement under Article 28(3) of the Paediatric Regulation. These were not available when the deadline for the application for the extension passed but subsequently became available before the expiry date of the SPC. Under the Mutual Recognition Procedure (MRP) for updating the MA, once the competent body from the reference member state confirms that all the steps have been completed and that the MA has been updated with the results of studies in children and a statement of compliance, then the relevant competent body in each member state in the EU is responsible for issuing the updated national MA incorporating the results of the paediatric studies and including a statement of compliance with the agreed PIP for their territory[5]. A requirement for the reward under Art 36(1) of the Paediatric Regulation is that the applicant provides proof that the MAs in all EU member states have been updated with the results of the paediatric studies and include a compliance statement to confirm this – see Articles 8(1)(d)(i) and (ii) of the SPC regulation. If the competent body in one member state was slow to carry out its task, this could have a significant effect on the ability of the applicant to show that they have met this requirement. The court found that it was

[5] For an explanation of the authorisation procedures for medicinal products in the UK market via the national route under Directive 2001/83/EC or centralised route under EC regulation 726/2004, see the explanation and discussion in the original IPO decision concerning *DuPont* and the subsequent appeal hearings on this case – see footnote 1 above – and see also the explanation and discussion in IPO decision BL O/035/09 *Merck* – see footnote 6 below

appropriate for the applicant to be able to provide various documents to confirm that the medicinal product was the subject of an updated MA in all the EU member states after the deadline for the application for the extension had passed.

IPO Decision

26 The conditions for the grant of a paediatric extension where the medicinal product was the subject of a centralised authorisation procedure under the EMEA, as is the case with the application in suit, were considered by this hearing officer in IPO decision *BL O/035/09, Merck*[6]. An application for an extension to the duration of granted SPC number SPC/GB/02/002 for the active ingredient, caspofungin, was made under Article 7 of Regulation (EC) 1768/92 (which is superceded by Article 7 of the SPC regulation)[4] to obtain the reward provided under Article 36(1) of the paediatric regulation. This active ingredient is authorised for human use as the medicinal product Cancidas, an anti-fungal agent, and as noted already, was the subject of a central MA from the EMEA.

27 The application for an extension to the duration of the granted SPC was found not to meet the requirements of Article 8(1)(d)(i) of Regulation (EC) 1768/92 (which is superceded by Article 8 of the SPC regulation)[4]. A statement of compliance with an agreed completed paediatric investigation plan as referred to in Article 36(1) of the Paediatric Regulation was not included in the centralised MA from the EMEA filed with the application. Also the centralised MA did not reflect the results from the studies conducted in the paediatric population in its summary of product characteristics (SmPC). The applicant argued that correspondence from the Paediatric Committee of the EMEA which stated that it was the opinion of the Paediatric Committee that the studies carried out by the applicant were in compliance with the agreed completed paediatric investigation plan was sufficient as evidence to fulfil the requirement under Article 36(1) and Art 28(3) of the Paediatric Regulation for a statement of compliance with an agreed completed paediatric investigation plan.

28 However, based on an analysis of Articles 8, 23, 28 and 36 of the Paediatric Regulation, the Hearing Officer found that this opinion of the Paediatric Committee of the EMEA on compliance with an agreed completed paediatric investigation plan was not sufficient on its own as a statement of compliance with an agreed completed paediatric investigation plan because it was not a decision from the competent authority for granting MAs as required by Article 23(1) of the paediatric regulation (see paragraph 41 of the *Merck* decision). Also, after the Paediatric Committee issued its opinion on compliance with the agreed PIP, there were still some additional steps that had to be completed before the application for the varied market authorisation to show the new paediatric indication could be granted. The essential step was the necessity to complete an update to the SmPC to reflect the outcomes of the completed agreed PIP as referred to in Article 28(3) of the Paediatric Regulation. The decision of the European Commission, which is the competent body for granting a centralised MA, and the associated SmPC filed by the applicant with their application for an extension to the granted SPC for caspofungin in 2008, was identical to the centralised MA filed by the applicant with his original SPC

[6] For full text of decision see https://www.ipo.gov.uk/p-challenge-decision-results/p-challenge-decision-results-bl?BL_Number=O/035/09.

application for caspofungin in 2001. Thus, the SmPC had not been altered in any way to indicate the outcome of the agreed completed PIP.

29 While I accept that IPO decisions are not binding on me, those decisions, such as this one which relate to very similar situations provide a useful comparison and support for the conclusions reached.

Analysis

30 In the paragraphs below, I consider, first, what is the status of the application for an extension to the duration of granted SPC number SPC/GB04/039 at the filing date for the extension. I will, then, consider the situation regarding the status of the application between the deadline for filing the application for the extension and the expiry date of the granted SPC. In each case, I will consider if they meet or do not meet the requirements for the grant of an extension to an SPC under the SPC regulation. I will also consider what the situation is regarding the application at the expiry date of the SPC.

Situation on Date of Application for Extension to SPC

31 The application for the extension to SPC/GB/04/039 was made on 12 October 2012. The expiry date for the granted SPC is 26 October 2014. According to Article 7(4) of the SPC regulation, such an application has to be "*lodged not later than two years before expiry of the certificate*". Thus, as the examiner and the applicant both indicate, the application meets this requirement.

32 This application relates to a centralised MA granted by the European Commission based on a recommendation from the EMEA. As such, the approval process for the MA and, more importantly, any update to the MA to show compliance with an agreed PIP are dealt with centrally by the EMEA. The centralised approval process for MAs by the EMEA and the MRP process, mentioned above and used by national competent bodies for approving medicinal products, such as the Medicines and Healthcare Products Regulatory Authority (MHRA)[7] in the UK, were discussed in some detail in the IPO decisions on *Merck* (see BL O/035/09) and *DuPont* (BL O/096/09) respectively and I do not propose to repeat these explanations here, please refer to these decisions for further detail.

33 At the time of the application, i.e. 12 October 2012, the EMEA had not completed all the steps necessary to issue a compliance statement under Article 28(3) of the paediatric regulation. The applicant acknowledges this in the cover letter they sent with their application for the extension.

34 This is a substantive point because if all the studies have not been completed by the applicant, then the results of these studies cannot be submitted by the applicant to the Paediatric Committee of the EMEA for review and assessment and agreement on how to update the MA. The EMEA has to satisfy itself that the draft MA proposed by the applicant which will include the results from these studies is a fair and appropriate reflection of the results. Once this process has been completed, then

[7] See https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency/services-information

the EMEA will provide the necessary statement of compliance under Article 28(3) of the paediatric regulation, approve the updated MA and recommend to the European Commission to issue a decision granting the updated MA. It is only at that point that the applicant is in a position to provide an updated MA in support of their application for an extension to the granted SPC.

Situation between Date of Application for Extension to SPC and Date of Expiry of the SPC

35 Having reviewed all the correspondence between the applicant and the examiner in the period after the date of application on 12 October 2014 and the final official examination report from the examiner dated 30 September 2014, it is clear that the applicant and the EMEA still have not completed all the steps necessary to issue a compliance statement under Article 28(3). Although, studies in the paediatric population have continued and the MA has been updated (i.e. varied) as the results from these studies have become available, i.e., Commission decisions C(2014) 2588 of 10.04.2014; C(2013) 490 of 24.01.2013; and C(2012) 3209 of 10.05.2012 amending the MA granted by decision C(2004) 2063 of 07.06.2004 for "*Abilify – aripiprazole*". However, all the studies necessary to cover all the paediatric population, i.e. age range from 0-18 years, for both indications have not been completed. Completion of all these studies is necessary to achieve conformity with the agreed PIP have not been completed. This is clear from the correspondence from the applicant dated 17 September 2014.

36 In *Dupont*, the Court of Appeal found that an applicant for an extension to an SPC should be allowed to supplement their application to correct any irregularity identified at the time of application under Article 10(3) of the SPC regulation. The subsequent inclusion of documents necessary to support an application for an extension to an SPC was considered by the court to be an appropriate response to correcting such an irregularity.

37 Jacob LJ posed the question whether the deficiencies identified in the application for the extension to an SPC at the time of the application fell within the meaning of an "irregularity" under Article 10(3). In answering this question he stated the following (emphasis added):

> *46. Thus far I have deliberately used the word "deficiency" to cover the defects in the original application by du Pont, namely the lack of an Article 28(3) statement and the lack of proof of MAs in all Member States updated to include the PIP information. Do these deficiencies amount to an "irregularity"? If so they can be cured by rectification by the applicant. As I have said the deficiencies have in fact now been cured and the Office, quite properly as one would expect, has indicated that it will extend the appropriate time for rectification accordingly, if it has power to do that.*
>
> *47. It will be seen that Article 10(3) is mandatory – the Office "shall ask the applicant to rectify." The Hearing Officer's decision took a faintly absurd position. It accepted that Article 10(3) required it to state a time for du Pont to cure the irregularity and set a date of 6th July. At the same time it held that the irregularity cannot be cured at all. So the date set was pointless.*

48. With respect that cannot be right on any view. Time only has to be given to cure "an irregularity." If the deficiencies cannot be so regarded then there is no obligation to give any time. ***The real question therefore is how widely the word "irregularity" is to be read. Does it cover anything required by Art. 8(1) of the SPC Regulation which is missing or incomplete, or does it have some more limited meaning?***

49. Miss May contends for the latter. She suggested "irregularity" means only something missing from the application which could have been contained within it at the time. Or, if not that, something which could have been produced by the last moment an application could be made. Something missing which could not have been produced by at least then was not an "irregularity" – it was a fundamental incurable defect. ***So in this case, the Article 28(3) statement and the necessary MAs from all Member States had not come into existence by either the date of application or the last possible date for an application****. So although du Pont have now got "all their ducks in a row" and have done so before the basic SPC has expired it is too late to cure the position.*

50. Further, she submits, there is no point in providing for the time limits of Article 7 (2 years save for the transitional period when it is 6 months) if the applicant can supplement its application with post-application material.

*51****. I see no reason for giving "irregularity" such a restrictive meaning – and every reason to give it a wide enough meaning to encompass cases such as the present where the defect is cured after the date of application****.*

52. Firstly and most tellingly, all the Recitals and the Explanatory Memorandum which Miss May deployed so effectively in persuading me on the first two points turn against her argument on this point For they are all about ***the reward of an extension being made available if the applicant complies with its PIP and gets the necessary MAs. The reward is for that, not for doing all that before the application is made.***

53. Most tellingly there is no Recital or other material indicating everything must be in the application or capable of being in the application by the date it must be made.

54. ***Moreover if she were right, then the problem of the laggard Member State would be significant – and it would be unrealistic to think that the Community legislator was so innocent as to think that all Member States would be certain to get it right within the 90 days provided for. There is no indication of any intention that the reward should be contingent upon all Member States doing the right thing in time.*** *And no indication that the legislator intended to draw a distinction between what might be called a "mere irregularity" and something more fundamental.*

38 Thus, I find that I need to consider what if any materials the applicant has provided in support of their application for an extension after the latest date for an application for an extension to the SPC had passed, i.e., 26 October 2012 and if any of these can be considered to cure the identified irregularity. If they do, then it is appropriate for them to be taken into account in deciding whether or not an extension to the SPC can be granted.

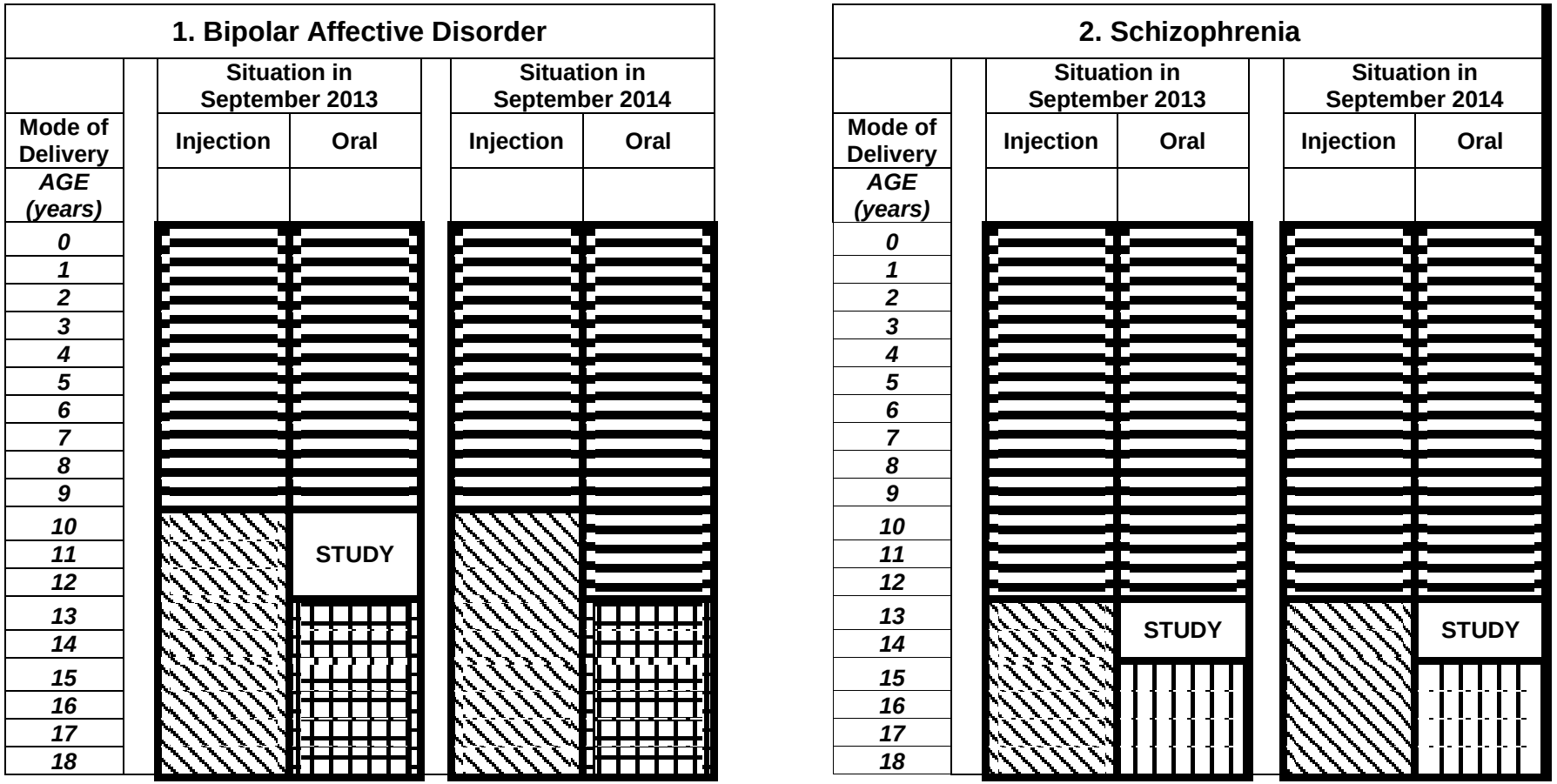
39 The correspondence provided by the applicant after the date of application for the extension to the SPC had expired, i.e. the applicant's letter dated 2 September 2013 and 17 September 2014 does not include an updated MA with an appropriate compliance statement under Article 28(3) of the paediatric regulation. However, this correspondence does provide an update on the progress of the paediatric studies being conducted in accordance with the agreed PIP. I have summarised this graphically in Figure 1.

40 Taking account of Figure 1 and having reviewed the correspondence, I consider that while the applicant has provided an update on the progress of the various studies to determine how effective Abilify is in the treatment of subsets of the paediatric population, all the studies necessary to cover the whole paediatric population for both indications have not yet been completed. As Figure 1 illustrates and, as outlined by the applicant in their letter dated 17 September 2014 (i.e., one month before expiry of the SPC), a study in 13 and 14 year olds in relation to schizophrenia was still in progress and had not been completed or analysed or submitted to the EMEA . All the studies in relation to bipolar type 1 disorder had been completed and from the correspondence provided by the applicant, it appears that the MA has been updated, i.e. varied, to include the results from this study – see Commission decision C(2014) 2588 of 10.04.2014 amending the MA for "Abilify –aripiprazole".

41 Although only one study remains, completing the studies in the paediatric population is only part of the work that has to be carried out to determine how the medicinal product will work in the paediatric population and to obtain the reward under the paediatric regulation. It is necessary for all the various studies to be completed by the applicant in conformity with the agreed Paediatric investigation Plan (PIP) and for all the results of these studies to be reviewed and validated by the EMEA. The EMEA has to confirm that all work has been completed, the results of all these studies have been included in the SmPC of the relevant MA and that the updated MA is available for all member states. For a centralised MA such as in this case, the confirmation from the EMEA that the MA have been updated to include all the relevant results will also meet the requirement to ensure that the updated MA applies in each member state of the European Union.

42 I note that, in his examination report dated 26 April 2013, the examiner sought further information from the applicant about when they considered that all the necessary studies would be completed and when the other steps necessary to provide the updated MA would be likely to take place. The examiner stated "*I have checked the public record for the marketing authorisation and can find no indication as yet of a statement of compliance on any of the recent variations. Indeed it would appear that the paediatric investigation plan is not as yet completed and may not be until January 2016 (see page 9 of the EMEA decision on P/99/2011)*[8]*. You are asked to provide an estimate of when you expect the PIP to be completed, validated and the marketing authorisation updated to reflect the statement of compliance and the*

[8] *EMEA decision P/99/2011 agreeing the PIP and granting a waiver. See also the entry for Abilify on the EMEA website at* *http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000471/human_med_000619.j&mid=WC0b01ac058001d124*



KEY for Table

WAIVER – Condition does not occur	*APPROVED 2013 (after date of application)*
WAIVER – no significant therapeutic benefit	*APPROVED 2009 (before date of application)*
STUDY *ONGOING STUDY*	

Figure 1: Effectiveness of Ability to treat (1) **Bipolar Affective Disorder** and (2) **Schizophrenia** in children – progress of paediatric studies as part of agreed paediatric implementation plan (PIP) carried out after date of application for extension (October 2012).

reasons you think this. In light of this I will take a view as to how I should apply the teaching of E I du Pont de Nemours & Co v UK Intellectual Property Office."

43 I note also that, in their subsequent correspondence, the applicant did not address this request from the examiner for an estimate of when matters would be complete. Thus, the best estimate of when the agreed PIP is likely to be completed is January 2016 which the examiner deduced from his consideration of the PIP decision, supplied by the applicant with their application and is also part of the public record for Abilify on the EMEA website[8]. This, taken with the situation reported in the applicant's correspondence of 17 September 2014, i.e. 5 weeks before expiry of the SPC, would suggest that it is quite possible that all the necessary steps will not be completed before expiry of the SPC.

44 In deciding whether or not to grant an extension to the SPC in this case, I accept that I can consider what steps have been taken after the deadline for application for the extension had passed, given the view expressed by the Court of Appeal in *DuPont*. However, I note that in *DuPont,* all of the steps necessary to meet the requirements for an extension to the SPC were completed after the date of application had expired but before the date of expiry of the SPC. The court in *DuPont* took the view that in this situation, it was appropriate for the applicant to be allowed to provide this updated information to the IPO in support of the application for an extension after the deadline for making the application had passed. I note that in doing so the court in *DuPont* considered that matters needed to be resolved before expiry of the SPC and, indeed, conducted an expedited appeal and delivered an oral decision on the day in order to allow matters to be resolved before expiry of the SPC at issue in that case. The court considered (see para 11 of the judgement) that it was best to deal with matters as expeditiously as possible because "*It is not clear whether an SPC can be extended after it has expired. And in any event third parties would be in a position to enter the market when the SPC expired.* "

45 The applicant has argued, for example, in their agent's letter of 17 September 2014, that: "*The purposes of the Paediatric Regulation would be frustrated if no reward was available to parties carrying clinical investigations into the use of paediatric medicines."* They consider that this is especially true in their case because they have already carried out "*significant investigations into Abilify"* and "*several pivotal clinical trials have already been completed in this regard".* Indeed as I note above and in Figure 1, most of the necessary studies have been completed. In their letter dated 2 September 2013, the applicant states that they have "*been investigating paediatric uses for Abilify for almost a decade, and pivotal clinical trials have already been completed in this regard*." They then go on to summarise the studies that took place between 2004 and 2007 in the USA and Europe to first investigate the use of Abilify in children; the interactions between the applicant and the EMEA in 2008-2011 in order to obtain an agreed PIP and the studies carried out since then to meet this agreed PIP.

Table 1: Summary of events concerning the use of “Abilify – aripiprazole” to treat paediatric population

Date	Type	Status	Reference	Indication	Age	Note
04.06.2004	Marketing Authorisation	granted	C(2004) 2063	schizophrenia		Original authorisation for ABILIFY - aripiprazole
21.03.2008	Type II variation	application		schizophrenia	13-17	Based on data from first paediatric studies in 2004-2007;
21.08.2009	Type II variation	granted	EMEA/H/C/ 000471/II/0048	schizophrenia	15-17	Not enough data to cover 13-14 age group; EMEA suggested conduct additional investigations; modify to PIP-01 already in progress?
31.03.2008	PIP-01	application		bipolar type 1 disorders	all	
22.12.2009	PIP-01	withdrawn		bipolar type 1 disorders	all	Applicant withdraws PIP application – variation to PIP-01 from EMEA requested after day 60 of procedure
20.03.2010	PIP-02	application		bipolar type 1 disorders & schizophrenia	all	
20.12.2010	PIP-02	modification		bipolar type 1 disorders & schizophrenia	all	Questions from Paediatric Committee lead to modification of PIP-02 application
14.04.2011	PIP-02	agreed	EMEA P/99/2011	bipolar type 1 disorders & schizophrenia		Included waiver for certain age ranges; deferral for some and agreed PIP for certain age ranges for both indications – 2 studies identified
24.01.2013	Type II variation	granted	C(2013) 490	Bipolar type 1 disorders	13-18	Amendments to C(2004) 2063
10.04.2014	Type II variation	granted	C(2014) 2588			Amendments to C(2004) 2063

46 The applicant considers (see agents letter dated 2 September 2013) that the *"the delay in obtaining a Marketing Authorisation containing an Article 28(3) statement is due in large part to the withdrawal and resubmission of the original PIP application at the request of the EMEA."* They expand this argument further by stating (my emphasis added) that "*had the EMEA not requested a variation in the PIP application after day 60 and the original PIP application of March 31, 2008 been further pursued,* ***it seems likely that the PIP could have been agreed and completed much earlier****, and likely early enough for the Commission to issue an Article 28(3) statement before the expiry of the Abilify SPC (October 27, 2014).* ***A delay of around sixteen months occurred between withdrawal of the initial PIP application and EMEA approval of the subsequent PIP application*****.**

47 While I recognise that the IPO is the body responsible for granting SPCs and extensions to SPCs and not for the grant of marketing authorisations, in my role as Hearing Officer dealing with applications for SPCs and extensions for SPCs, I have developed a working knowledge of the procedure for granting MAs valid in the UK, via the national or centralised routes[5,6]. MAs represent one of the two essential requirements to obtain an SPC – one requires a valid MA to go with a valid patent (to obtain an SPC (see Article 3 of the SPC Regulation). I am satisfied that I have a sufficient knowledge of the procedure for the grant of MAs as they relate to extensions for SPCs to be able to consider the applicants argument on this point.

48 I am not persuaded by the applicant's argument regarding the delay to the PIP. I consider that this is likely to be a simplification of the situation. The approval of an agreed PIP is a matter between the applicant and the EMEA and it is likely to involve a number of iterations between application and approval. Indeed, I consider that it would be quite likely that there will be quite a bit of to-ing and fro-ing between the applicant and the EMEA in relation to a PIP application – either the original PIP-01 or the later PIP-02, before an agreed PIP is achieved. This will involve the applicant and the EMEA working out what studies need to be performed in the paediatric population taking account of the balance between outcomes (deferrals, waivers useful data on safety and efficacy in children) and resources (such as time, cost). I have summarised the steps that the applicant has taken to investigate the use of Abilify in the paediatric population in Table 1. It appears to me that in their consideration of the application, the EMEA were doing what they are required to do – assessing the material provided by the applicant in support of a variation to the MA for Abilify for the treatment of schizophrenia in childfree aged 13-17 and finding that it was only partly justified in relation to children aged 15-17. Thus it was necessary to ask the applicant to provide additional data in support of how this medicinal product worked in children aged 13-14 with schizophrenia. The applicant already had made a PIP application to carry out studies in children with bipolar type 1 disorder. It seems to me that it is not unreasonable that the EMEA would suggest to the applicant that they might want to include a new indication in the PIP application already made in order to address the treatment of schizophrenia in children agreed 13-14. The applicant states in their letter dated 2 September 2013, that "*The inclusion of a new indication into a PIP was considered difficult as no agency interaction after day 60 would have been possible. For this reason PIP application EMEA/00235/PIP01-08 was withdrawn on December 22, 2009."* The applicant then submitted a new PIP application 3 months later covering both indications – schizophrenia and bipolar type 1 disorders – from the start. The Paediatric

Committee reviewed this application and based on its feedback, the PIP was modified by the applicant in December 2010. The PIP was approved on April 14, 2011, by the EMEA following a recommendation from the Paediatric Committee.

49 I am not persuaded by the applicant's argument that the delay in obtaining an MA with a section 28(3) compliance statement is "*due in large part to the withdrawal and resubmission of the original PIP application at the request of the EMEA*". The decision to withdraw an application for a PIP is one that is made by the applicant taking account of all the circumstances at that time including the likelihood of delay and based on any discussions they have had with the competent body. Indeed withdrawal of a PIP applications and subsequent submission of an updated application with changes – such as occurred here – appears to be quite common because it avoids applications being refused and, I assume, improves chances of success. The applicant could have left the original PIP application in progress and adapted it but chose not to, for what I would assume was based on their best assessment of the situation at the time. The EMEA is the competent body tasked by the member states with making sure that the medicines used in children are safe, effective and of suitable quality. Thus if they conclude that there is insufficient evidence then surely that is part of their role and they must take the necessary steps to notify the applicant that there is an issue to address and discuss how best to address it this. This they clearly did in relation to the need for further data to determine if Abilify was appropriate for use in children agreed 13-14 to treat schizophrenia. Thus, it appears to me that the EMEA was doing the job it was required to do. Also, as the applicant indicates, the new PIP application – PIP-02 also went through some iterations such as scrutiny by the Paediatric Committee which resulted in the applicant having to modify the PIP before approval. If the original PIP-01 had been maintained, I think that it is likely there would have also been such further iterations with it before approval, so I do not think that to apportion all the time to the role of the EMEA is not to take account of the fact that some time will elapse while both applicant and EMEA work together to agree a PIP.

50 The court in *DuPont* decided that the applicant should not be disadvantaged in obtaining the reward for carrying out all the studies in the paediatric population and gaining the updated MA including the Article 28(3) compliance statement, because of too restrictive an approach to when this information has to be provided. However, the court in *DuPont* determined first of all that the applicant had actually completed all the necessary studies and that the results of these studies had been included in the MA and the inclusion of a compliance statement by the reference member state had been approved and agreed by reference member states. Thus all the necessary steps needed to qualify for the reward under Article 36 of the paediatric regulation had been completed and it was only the actual process of updating in the respective member states that was outstanding. The court determined that this should not cause a problem for the applicant in gaining the extension to the SPC. In the present case, however, we are not in a comparable situation because the applicant had not completed all the studies agreed in the PIP, the MA does not include the results of all studies in the paediatric population and thus the EMEA cannot issue an Article 28(3) compliance statement at a point in time only 5 weeks before expiry of the SPC. On the balance of probabilities, I consider that the applicant would not have completed these steps before the expiry date of the SPC.

51 While I accept that the applicant has completed a number of studies in the paediatric population and that this has involved time and expense on their part, he has not completed all the studies required. The reward that the six month extension to the SPC provides is a significant one which reflects the significant effort involved in carrying out the testing in the paediatric population, assessing the outcomes from these tests and making these outcomes known in all. The reward is not just for testing the efficacy of the medicinal product in the paediatric population, it is also for making the results of all these studies available in all the member states via the updated MA. The latter is an important point that was brought out by the court in *DuPont.*

52 The importance of obtaining the compliance statement under Article 28(3) of the paediatric regulation and an updated MA with all the results from the testing in children was considered in some detail in the *DuPont* judgment. One argument before the court was that an Email from the Dutch medicines regulatory authority, acting as a reference member state for the grant of a MA under the Mutual Recognition Procedure, was sufficient to meet the requirement of Article 28(3) of the paediatric regulation. Jacob LJ found, at paragraphs 30-38 of this judgment, that the only way Article 36(1) of the paediatric regulation can be satisfied is by an updated MA containing an Article 28(3) statement, i.e.:

> *30. The key provision is Article 36(2) of the Paediatric Regulation. It says the inclusion of an Article 28(3) statement in a MA "shall be used". Miss May says that means that is the only way of proving compliance with Article 36(1). And for a range of convincing reasons.*
>
> *31. First because the system is meant to be practical, open and transparent. All a Patent Office has to do is to look at the MA to see whether the PIP has been complied with. If one could prove the results of and compliance with the PIP in some other way, that would not necessarily be so. Potentially, for instance, if du Pont's wide meaning were adopted, the non-expert authority in the Member State could be faced with an applicant who tried to prove before it that it had complied with the PIP. That would mean going into the requirements of the PIP and examining what had been done in purported compliance with it. The national authority would have to consider the same issues as the Paediatric Committee. That cannot be right.*
>
> *32. It might be suggested (though du Pont did not do so) that there is a halfway house: that it is good enough for the applicant to show that the Paediatric Committee agrees the PIP has been complied with, but not good enough to demonstrate compliance by reference to the underlying materials The trouble with such a suggestion is that there is no room for it on the language of Art 36(1). Either you have to go by the MA or you don't. If you don't, the language is incapable of limiting the means of proof only to showing that the Committee has agreed.*
>
> *33. Miss May's next point is based on the language of Article 36(2) itself – "shall be used". She says that it is mandatory language – you have got to use the MA. Mr Purvis submitted not so – taking us to some of the other language versions of Art.36(2). These were French: "est utilisée"; German: "dient"; Italian: è utilizzato"; Portuguese: "serva" and Spanish: "servirá." The suggestion was that at least some of these versions, the Portuguese and Spanish particularly,*

which mean "will serve" did not convey the mandatory flavour of the English "shall be".

34. There might have been something in this, but for the recitals to the Paediatric Regulation. Miss May took us to a number of them, For present purposes it will suffice to set out the following:

> *(4) This Regulation aims to facilitate the development and accessibility of medicinal products for use in the paediatric population, to ensure that medicinal products used to treat the paediatric population are subject to ethical research of high quality and are appropriately authorised for use in the paediatric population, and to improve the information available on the use of medicinal products in the various paediatric populations. These objectives should be achieved without subjecting the paediatric population to unnecessary clinical trials and without delaying the authorisation of medicinal products for other age populations.*
>
> *(17) To provide healthcare professionals and patients with information on the safe and effective use of medicinal products in the paediatric population and as a transparency measure, information on the results of studies in the paediatric population, as well as on the status of the paediatric investigation plans, waivers and deferrals, should be included in product information. When all the measures in the paediatric investigation plan have been complied with, that fact should be recorded in the marketing authorisation, and should then be the basis upon which companies can obtain the rewards for compliance.*
>
> *(21) This Regulation should include measures to maximise access by the Community population to new medicinal products tested and adapted for paediatric use, and to minimise the chance of Community-wide rewards and incentives being granted without sections of the Community paediatric population benefiting from the availability of a newly authorised medicine. An application for a marketing authorisation, including an application for a Paediatric Use Marketing Authorisation, which contains the results of studies conducted in compliance with an agreed paediatric investigation plan should be eligible for the Community centralised procedure set out in Articles 5 to 15 of Regulation (EC) No 726/2004.*
>
> *(26) For products falling within the scope of the requirement to submit paediatric data, if all the measures included in the agreed paediatric investigation plan are complied with, if the product is authorised in all Member States and if relevant information on the results of studies is included in product information, a reward should be granted in the form of a 6-month extension of the supplementary protection certificate created by Council Regulation (EEC) No 1768/92 [6]. Any decisions by Member States' authorities as regards the setting of prices for medicinal products or their inclusion in the scope of national health insurance schemes have no bearing on the granting of this reward.*

35. Of most direct relevance to this point is recital 17 – saying as it does that when the measures in the PIP have been recorded in the MA, that <u>should then</u> be the basis for the rewards for compliance. There is simply no getting around that. Mr Purvis tried: suggesting that the "then" referred only to the fact of PIP

compliance. But that will not do – it is simply pretending that the "then" is not there.

36. But Miss May had even more to her argument. She submitted that there was a reason for the rule that you only get your reward once you have not only complied with your PIP but also got your MA which reflects the information gained. It is that the Paediatric Regulation is concerned not only with creation of that information but its Community-wide dissemination and availability. Only when the MAs for each Member State have been brought into line with the PIP information– so that the packaging and information leaflets carry it as well - can you have your reward. She pointed out (it is not necessary to set them all out here) that both the travaux préparatoires and the Explanatory Memorandum to the Regulation are unambiguous about that.

37. She summarised her submissions thus. First that the aims and objectives of the Regulation are three-fold – as set out in the key recital (4). They are:

> *i) To facilitate the development and accessibility of medicinal products for use in the paediatric population.*
>
> *ii) To ensure that medicinal products that are used to treat the paediatric population are subject to ethical research of high quality and are appropriately authorised for use in the paediatric population.*
>
> *iii) To improve the information available on the use of medicinal products in the various paediatric populations.*

And these objectives are to be achieved by the following substantive requirements:

> *1. All the measures in the agreed PIP must have been compiled with [Recitals 9-11, 17, 26; Articles 7-8, 28(3), 36(1); Explanatory Memorandum].*
>
> *2. The authorised product information must include relevant information on the results of the studies [Recitals 17, 26, 28; Articles 28(3), 36; Explanatory Memorandum].*
>
> *3. The product must be authorised in all Member States [Recitals 17, 21, 26; Article 36(3); all travaux].*

38. I accept those submissions. I think they are inescapable. Mr Purvis tried to answer the need for dissemination of information point by showing us other provisions for dissemination of information. But in the end it is what is on and in the packet which counts. And that is not determined finally until the MA is settled.

53 As I do not consider that the applicant has meet the necessary requirements under Article 8(1)(d) of the SPC regulation and, as I have already discussed above, it is unlikely that all the necessary studies and related steps concerning approval of the updated MA would be completed before expiry of the SPC. This then leads me to consider if it is possible for the applicant to provide the necessary data after the expiry date of the SPC? As noted in *DuPont* the six month extension to the SPC is a

reward for complying with the PIP and getting the necessary MA (see para 52) and that the timing of achieving this is not so important, i.e., it is not necessary that it must be completed before the date of application for the extension according to Article 7 of the SPC Regulation. The court also felt that third parties did not need to be aware of what the situation was in regard to an application for an extension on an SPC, because the application itself was sufficient notice that they needed to take note and if any time period to address an irregularity in an extension application is set, then third parties will not be disadvantaged – they are still aware that an extension has been applied for and is still being pursued. The court in *DuPont* also made clear that "*on any rational view, the importance of research into paediatric uses of medicines stands ahead of the purely commercial interests of third parties. The importance of that research being conducted and the results disseminated is the whole point of the Paediatric Regulation. A narrow construction of "irregularity" is inimical to that fundamental purpose*."

54 In offering some guidance to the Comptroller on how late an applicant can be in supplementing their application with material to correct an irregularity, the Court suggested *"that in setting the Article 10(3) period the Comptroller can and should take into account all relevant factors. These will include the reasons for the failure to include all the Article 8(1) materials in the application, the extent to which the applicant is guilty of unreasonable conduct or delay, and how close to the date of expiry of the SPC full compliance with Article 8(1) is expected. The guiding principle is the purpose of the Regulation. The upshot is that unless the applicant has behaved unreasonably, time should be extended so that it gets its reward*."

55 I accept that the applicant has to carry out the studies in the paediatric population first and get approval from the EMEA. This involves a commitment of time and resources up front. I accept that if the applicant carries out the necessary steps, then they should be entitled to the reward without taking too restrictive a view of how and when the applicant meets the requirements to qualify for an extension to the SPC.

56 However, I do not take this to mean that this should extend beyond the expiry date of the SPC. I think that it is reasonable to expect that matters in relation to an extension to an SPC are decided before the SPC expires, even if this decision is taken on the last day of the SPCs existence! Once the SPC expires, others are entitled to enter the market. Because of this, I think that, after the expiry date of the SPC, one must take account of the interest of third parties. Knowing when the SPC will expire is important for the entry of third parties, such as generic medicine companies, into the market because once the SPC expires; they are free to bring their own versions of the medicines comprising this active ingredient to market. If an application for an extension to a granted SPC was still considered to be capable of rectification after the expiry date of the SPC and the grant of an extension could be back-dated, this would, in my view, introduce uncertainty and, even, the potential for abuse. It would not be clear in such a situation when the paediatric studies would have to be completed by and when the updated MA would be available. There needs to be some clarity as to when matters are complete and others can enter the market. This seems to me to represent an appropriate balance, as referred to in recital 10 of the SPC regulation, to take account of all the interests at stake "*in a*

sector as sensitive and complex as pharmaceuticals" while also making sure that research into paediatric uses of medicines is given the necessary incentive.

57 In this case, I consider that the applicant has not complied with the necessary requirements to obtain an extension under Article 8(1)(d) of the SPC regulation and that they have had the opportunity to supplement the application in the period between the date of application for the extension and the date of expiry of the SPC. However, having reached the date of expiry of the SPC, and with the applicant still not in a position to supplement their application to address the identified irregularity, I consider that this application should be considered to have run out of time for this irregularity to be addressed.

Conclusion

58 Taking account of all of the above, I conclude that in the absence of an updated MA comprising the results of all studies carried out in the paediatric population and including a compliance statement under Article 28(3) of the paediatric regulation at the time that the deadline passed for the application for an extension to the SPC, i.e., two years prior to expiry of the SPC as set down in Article7(4) of the SPC regulation, the application for an extension to SPC/GB/04/039 did not meet the requirements of Article 8(1)(d)(i) of the SPC Regulation.

59 The lack of an updated MA comprising the results of all studies carried out in the paediatric population and including a compliance statement under Article 28(3) of the paediatric regulation was identified, by the examiner, as an irregularity with this application under Article 10(3) of the SPC regulation and a deadline of 17 July 2014 was set within which to rectify this irregularity. The applicant was unable to rectify this irregularity within the stated time as required under Article 10(3).

60 On the basis of the information provided by the applicant, this irregularity was still not rectified by 17 September 2014. On the balance of probabilities, I consider that this irregularity would not be rectified before the expiry date of the SPC on 26 October 2014, the latest date on which I find the application may be amended.

61 As the application did not meet the requirements of Article 8(1)(d) of the SPC regulation and, as the applicant failed to rectify the irregularity under Article 10(3) within the stated time, I reject this application for an extension to granted SPC/GB/04/039 under Article 10(4) of the SPC Regulation.

Appeal

62 Any appeal must be lodged within 28 days

Dr L Cullen

Deputy Director, acting for the Comptroller