Intellectual Property Office

BL O/0023/26

15 January 2026

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

**and**

**THE HUMAN MEDICINES REGULATIONS 2012**

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| APPLICANT | DANA-FARBER CANCER INSTITUTE, INC. & GENETICS INSTITUTE LLC |
| ISSUE | Whether the application for a six-month paediatric extension to granted UK supplementary protection certificate SPC/GB17/071 is a valid application |
| HEARING OFFICER | Dr Rowena Dinham |

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## DECISION

### Background

1 This decision relates to the issue of whether an extension of time should be granted in order to allow Dana-Farber Cancer Institute, Inc. & Genetics Institute LLC ("the Applicant") to provide the necessary documentation to demonstrating that their application for a six-month extension to the period of protection provided by supplementary protection certificate, SPC/GB17/071 ("the SPC"), meets the requirements of Council Regulation (EC) No 469/2009 ("the SPC Regulation").

2 The SPC was granted on 17 August 2018 for the product avelumab, relying upon basic patent EP (UK) 1210428 B1, filed on 23 August 2000 and granted on 18 March 2015, and centralised European marketing authorisation (MA) (EU/1/17/1214), granted to Merck Serono Europe Ltd on 18 September 2017 and relating to the medicinal product Bavencio[1]. The basic patent expired on 22 August 2020, and the SPC entered into force on 23 August 2020. The SPC expired on 22 August 2025.

3 On 18 August 2023 the Applicant applied for a six-month extension to the UK SPC. In support of their application, the Applicant provided:

[1] Bavencio is a Registered Trade Mark in the United Kingdom.

a. the relevant Patents Form SP4;

b. copies of the updated current marketing authorisations for GB and NI comprising:

   i. Commission Decision C(2017)6419 (final), dated 18 September 2017, granting a centralised marketing authorisation for “Bavencio - avelumab” (EU/1/17/1214);

   ii. The Summary of product Characteristics (SmPC) associated with the decision.

   iii. Commission Decision C(2023)2381 (final), dated 31 March 2023, amending the marketing authorisation granted by Decision C(2017)6512(final) for “Bavencio - avelumab”;

   iv. The SmPC associated with the above;

   v. The SmPC for “converted EU MA” PLGB 11648/0262 (indicating 1 January 2021 as the “Date of first authorisation/renewal of the authorisation”);

c. a copy of the grant certificate of the original SPC in UK.

4 On 18 June 2024 the Examiner issued an examination report refusing to grant the SPC extension on the basis that the application did not include a compliance statement (for GB or NI) as required by Regulation 58A(2)(a) of the Human Medicines Regulation (“HMR”) (and thus implicitly did not satisfy Article 8(1)(d)(i) of the SPC Regulation), precluding grant of a reward under Regulation 58A(3) of the HMR. Requests for extensions to the deadline for replying to the examination report were made by the Applicant in writing on 16 October 2024 and verbally on 10 December 2024, 17 February 2025, 15 April 2025 and 20 June 2025. These requests were granted, resulting in the latest date for replying to the examination report being extended to 22 August 2025. However, a request for a further, discretionary extension (made verbally on 15 and 18 August 2025 and in writing on 21 August 2025) was refused, as confirmed in letters from the Office dated 18 August 2025 and 22 August 2025.

5 Prior to the final request for an extension, a request to be heard was filed by the Applicant on 18 August 2025. As a consequence of the refusal of the final request, this matter came before me at a hearing on 6 November 2025.The Applicant was represented at the hearing by Mr Mike Snodin of Park Grove IP and Mr Gareth Morgan and Ms Natalie Coan of Pinsent Masons LLP. DeAnn Smith, from Foley Hoag LLP, and Steve Caltrider, of Dana-Farber Cancer Institute, Inc., joined remotely as observers.

6 In addition to the points made during the hearing, this decision will draw on the Applicant’s skeleton arguments provided on 30 October 2025 and the pre-hearing report provided by the Examiner on 22 August 2025. I shall also consider the

evidence provided following the hearing[2], demonstrating the shortening of the period within which the Paediatric Investigation Plan (PIP) for Bavencio was expected to be completed, from June 2031 to September 2025, as well as the further evidence provided[3] demonstrating an extension to the completion date of the PIP to September 2026.

**The Law**

**Council Regulation (EC) 469/2009 Concerning The Creation of a Supplementary Protection Certificate for Medicinal Products**

***Article 8: Content of the application for a certificate***

*1. The application for a certificate shall contain:*

*(a) a request for the grant of a certificate, stating in particular:*

*(i) the name and address of the applicant;*
*(ii) if the applicant has appointed a representative, the name and address of the representative;*
*(iii) the number of the basic patent and the title of the invention;*
*(iv) the number and date of the UK, GB or NI authorisation, or where there is more than one such authorisation, of each authorisation as referred to in Article 3(b) and (d);*
*(v) the number and date of the earliest of any EEA authorisation, the granting of which predates the granting of the UK, GB or NI authorisation as referred to in Article 3(b) and (d);*

*(b) a copy of the UK, GB or NI authorisation or, where there is more than one such authorisation, of each authorisation to place the product on the market, as referred to in Article 3(b) and (d), in which the product is identified, containing in particular the number and date of the authorization and the summary of the product characteristics listed in Article 11 of Directive 2001/83/EC, Article 14 of Directive 2001/82/EC, Article 35 of Regulation (EU) 2019/6, Part 2 to Schedule 8 of the Human Medicines Regulations 2012 or Part 1 of Schedule 1 to the Veterinary Medicines Regulations 2013;*

*(c) where the product is the subject of one or more EEA authorisations granted prior to the UK, GB or NI authorisation referred to in Article 3(b) and (d), the applicant must provide in relation to the earliest of any such EEA authorisations-*

*(i) information regarding the identity of the product thus authorised;*
*(ii) information regarding the legal provision under which the authorisation procedure took place; and*
*(iii) a copy of the notice publishing the authorisation in the appropriate official publication;*

[2] With the letter dated 7 November 2025
[3] With the letter dated 24 December 2020

***(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 regulation 58A(2)(a) of the Human Medicines Regulations 2012;***

*(ii) details of the territory in respect of which the statement referred to in sub-paragraph (i) has been made.*

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.*

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.*

***Article 10: Grant of the certificate or rejection of the application for a certificate***

*1. Where the application for a certificate and the product to which it relates meet the conditions laid down in this Regulation, the comptroller shall grant the certificate.*

*2. The comptroller 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 or any prescribed fee is not paid.*

***3. Where the application for a certificate does not meet the conditions laid down in Article 8 or the prescribed fee relating to the application has not been paid, the comptroller 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 comptroller shall reject the application.***

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

7 With EU exit, relevant provisions of Council Regulation (EC) No 1901/2006 were incorporated into the HMR, with appropriate modification to take account of the Northern Ireland Protocol. These changes were achieved through the statutory instrument The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (SI 2020/1488). Regulation 58A of the HMR as amended in this respect states:

***Paediatric rewards***

*58A.—(1) Paragraph (2) applies if—*

*(a) an application—*
*(i) to which regulation 50A (requirement for certain applications to include the results of a paediatric investigation plan) applies, and in relation to which there is an agreed paediatric investigation plan; or*
*(ii) to which Article 7 or 8 of the Paediatric Regulation applies, and in relation to which there is an EU agreed paediatric investigation plan,*
*is granted by the licensing authority; and*
*(b) the licensing authority is satisfied that the material provided by the applicant pursuant to—*
*(i) regulation 50A(3), where paragraph (1)(a)(i) applies; or*
*(ii) Article 7 or 8 of the Paediatric Regulation, where paragraph (1)(a)(ii) applies,*
*demonstrates compliance with the agreed paediatric investigation plan.*

*(2) Where this paragraph applies, the licensing authority must—*
***(a) include in the UK marketing authorisation a statement to the effect that it is satisfied as set out in paragraph (1)(b); and***
***(b) ensure that the results of all studies referred to in the paediatric investigation plan are included in the summary of product characteristics and, if the licensing authority considers that the information would be useful to patients, in the package leaflet.***

*(3) Where—*
*(a) paragraph (2) applies; or*
*(b )an application to which Article 7 or 8 of the Paediatric Regulation applies—*
*(i) includes the results of all studies conducted in compliance with an EU agreed paediatric investigation plan; or*
*(ii) confirms completion of an EU agreed paediatric investigation plan which failed 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, the package leaflet of the medicinal product,*

*the holder of a patent or supplementary protection certificate covering the medicinal product to which the application relates is entitled to a six month extension of the period referred to in Articles 13(1) and 13(3) of Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products (subject to paragraphs (4) to (5)).*

**The Patents Act 1977**

8 The procedural provisions that apply to SPCs under UK law are found in the Patents Act 1977, as amended, (hereinafter referred to as “the Act”) and its related Rules, the Patent Rules 2007, as amended (hereinafter referred to as “the Rules”).

9 Section 128B of the Act provides as follows:

***Supplementary protection certificates***

*128B.-(1) Schedule 4A contains provision about the application of this Act in relation to supplementary protection certificates and other provision about such certificates.*

*(2) In this Act a "supplementary protection certificate" means a certificate issued under –*

*(a) Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6th May 2009 concerning the supplementary protection certificate for medicinal products, or*

*(b)……*

10 Paragraphs 1(1) and 1(2) of Schedule 4A set down which of provisions of the Act apply to applications for extensions of the duration of an SPC:

***SCHEDULE 4A (section 128B)***
***SUPPLEMENTARY PROTECTION CERTIFICATES***

*References to patents etc*

*1.-(1) In the application to supplementary protection certificates of the provisions of this Act listed in sub-paragraph (2) –*

*(a) references to a patent are to a supplementary protection certificate;*

*(b) references to an application or the applicant for a patent are to an application or the applicant –*
*(i) for a supplementary protection certificate, or*
*(ii) for an extension of the duration of a supplementary protection certificate*

*……*

*(2) The provisions referred to in sub-paragraph (1) are –*

*……*

*sections 117 to 118 (administrative provisions);*

*section 123 (rules);*
*…*

11 Thus, the provisions that are applied to applications for an extension to the duration of an SPC include Section 117B:

***Extension of time limits specified by comptroller***

*117B.-(1) Subsection (2) below applies in relation to a period if it is specified by the comptroller in connection with an application for a patent, or a patent.*

*(2) Subject to subsections (4) and (5) below,* ***the comptroller shall extend a period to which this subsection applies if –***

*(a) the applicant or the proprietor of the patent requests him to do so; and*
***(b) the request complies with the relevant requirements of rules.***

*(3) An extension of a period under subsection (2) above expires –*
*(a) at the end of the period prescribed for the purposes of this subsection, or*
*(b) if sooner, at the end of the period prescribed for the purposes of section 20 above.*

*(4) If a period has already been extended under subsection (2) above –*

*(a) that subsection does not apply in relation to it again;*
*(b)* ***the comptroller may further extend the period subject to such conditions as he thinks fit.***

*(5) Subsection (2) above does not apply to a period specified in relation to proceedings before the comptroller.*

A period may be extended only once under s.117B(2); further extensions are at the comptroller's discretion and may be subject to conditions. A request for a further extension should include a statement of reasons for the request.

12 Section 117B(2) of the Act indicates that a request under this section has to comply with the relevant "requirements of the rules". Paragraphs 1(1) and 1(2) to Schedule 4A of the Act also apply Section 123, entitled 'Rules', to applications for paediatric extensions. Section 123(1) and 123(3A) of the Act read as follows:

***Rules***

*123.-(1) The Secretary of State* ***may make such rules as he thinks expedient for regulating the business of the Patent Office in relation to patents and applications for patents*** *(including European patents, applications for European patents and international applications for patents) and for regulating all matters placed by this Act under the direction or control of the comptroller; and in this Act, except so far as the context otherwise requires, "prescribed" means prescribed by rules and* ***"rules" means rules made under this section****.*

*…….*

***(3A) It is hereby declared that rules –***

***(a) authorising the rectification of irregularities of procedure, or***
***(b) providing for the alteration of any period of time, may authorise the comptroller to extend or further extend any period notwithstanding that the period has already expired.***

*…….*

13 For the purposes of the present case, Rules 107 and 109 of the Rules are relevant.

14 Rule 109 of the Rules refers to Section 117B(2) of the Act (see above) and provides more detail on how requests for extensions of time are to be made. The rule reads as follows:

> ***Extension of time limits specified by comptroller***
>
> *109.—(1) A request under section 117B(2) must be—*
>
> *(a) made in writing; and*
> *(b) made before the end of the period prescribed by paragraph (2).*
>
> *(2) The period prescribed for the purposes of section 117B(3) is two months beginning immediately after the expiry of the period to which section 117B(2) applies.*

Thus, the applicant (or proprietor) for the patent is entitled to one request for a single extension of a period that is specified by the Comptroller in connection with the application or patent, provided that the requirements of r.109(1) are satisfied, i.e., that the request is made in writing (e.g. by letter or email) and is made before the end of the extended period.

15 Rule 107 of the Rules makes provision for the correction of irregularities and reads as follows:

> ***Correction of irregularities***
>
> *107.—(1) Subject to paragraph (3), the comptroller may, if he thinks fit, authorise the rectification of any irregularity of procedure connected with any proceeding or other matter before the comptroller, an examiner or the Patent Office.*
>
> *(2) Any rectification made under paragraph (1) shall be made—*
>
> *(a) after giving the parties such notice; and*
> *(b) subject to such conditions, as the comptroller may direct.*
>
> *(3) A period of time specified in the Act or listed in Parts 1 to 3 of Schedule 4 (whether it has already expired or not) may be extended under paragraph (1) if, and only if—*
>
> *(a) the irregularity or prospective irregularity is attributable, wholly or in part, to a default, omission or other error by the comptroller, an examiner or the Patent Office; and*
> *(b) it appears to the comptroller that the irregularity should be rectified*

**Relevant Case Law**

16 The relevant case law to this decision, the Court of Appeal judgment in *EI Du Pont Nemours & Co v United Kingdom Intellectual Property Office* [2009] EWCA Civ 966 ("*Du Pont*") and the Hearing Officer's decision in BL O/019/22 *Chiesi Farmaceutici S.P.A*. ("*Chiesi*"), will for the most part be quoted as appropriate in the body of this

decision. However, given that both the Examiner and the Applicant refer to paragraph [85] of *Chiesi*, I think it useful to reproduce paragraphs [84]-[86] of *Chiesi* here:

> *Extension of Time to Correct Irregularity*
>
> *84 I consider that the argument made by the applicant in relation to Section 117B and Rule 109 has merit. I am not in full agreement with the approach proposed by the applicant in so far as their argument suggests that the Comptroller should exercise discretion to extend the time period for allowing the rectification of an irregularity with a paediatric extension application by successive periods of two months and that this can extend past the expiry date of the SPC if, as the applicant argues, there is a reasoned statement provided by the applicant explaining why this is necessary.*
>
> *85 However, I consider that the essential and operative matter here has to be that the applicant actually has the additional material that will properly and fully correct the irregularity identified. In such a situation, one is not being asked to provide an extension of time without a clear idea of whether or not some or all of it will be needed and whether there will be a further request for an additional extension of time. If, as proposed by Mr Selmi, a discretionary extension of time was granted by the Office for two months, a total of three such extensions might be sought in the period up to the 'hard' deadline when the six-month paediatric extension (if granted) would expire. Instead, it seems to me that this situation should be better considered as one where the applicant has actually obtained the documents to address the identified irregularity within the window of the possible six-month paediatric extension and is seeking to file them late, i.e. after the expiry date of the SPC. Thus, the decision to be made is whether to accept the late filled materials as correcting the irregularity rather than continuing to provide a time period within which such material could be provided but is not clear when they will be provided. The applicant should provide the documents before this potential six-month paediatric extension passes, as there is no reward left to be gained after this so-called second and 'hard' final deadline (as identified by the applicant) takes effect. I believe that such an approach will take proper account of the rights of third parties while also giving the applicant in circumstances such as in the present case the possibility to demonstrate that they are entitled to the reward of a paediatric extension in the UK.*
>
> *86 I consider, that it would be possible for the Comptroller to continue to extend the period for providing the necessary proof of updated MAs and compliance statements for the two remaining member states past the expiry date of the SPC, if the circumstances merit it, based on the discretion allowed under Section 117B(4).*

**The Examiner's view**

17 The Examiner suggests that a further extension of the time period to respond to his examination report of 18 June 2024 should not be given. He asserts that in *Chiesi* (at paragraph [85]) the decision to accept the late-filed materials for obtaining a Paediatric extension was considered to be correcting an irregularity, rather than continuing to provide a time period within which such materials could be provided (but where it is not clear when they will be provided). In particular, the Examiner distinguishes the situation in *Chiesi* from the present case because the applicant was already in possession of the material required to properly and fully correct the identified irregularity; in the present case the Applicant is not in possession of the required material, and so the Office is being asked to provide an extension of time without a clear idea of how much time will be needed nor whether further extensions would be required in the future. In the Examiner's opinion, any further extension of time would not "*do anything other than merely continue to provide a time period within which such materials could be provided, without any clear indication that they will be provided*".

18 The Examiner did not consider that decision P/0312/2024 of the European Medicines Agency ("EMA") was evidence that a compliance statement will be granted, since it appeared to him merely to set out an agreement to the modification of PIP for avelumab (Bavencio), with a statement that it needed to be completed by September 2025. The Examiner further noted that though this document was published in August 2024 no further information has been provided in relation to the compliance statement. The Examiner thus determined that the "conditions set out in *Chiesi* have not been met."

**The Applicant's view**

19 Contrary to the position of the Examiner, the Applicant submits that the facts in *Chiesi* support the applicant being provided with more time to obtain the compliance statement that would correct the "irregularity" with the extension application.

20 The Applicant argues that, according to a MHRA Final Decision Letter dated 23 October 2024, the studies of the PIP agreed with the MHRA for Bavencio were expected to be completed by 30 September 2025, and assert that this provides reasonable basis to conclude that the Statement of Compliance for Bavencio that will correct the "irregularity" for the extension application will become available in a timeframe consistent with the precedent they suggest was set by the decision of the Hearing Officer in *Chiesi* (i.e. between 4 and 5 months after expiry of the SPC).

21 The Applicant points out that the documents which corrected the "irregularity" in *Chiesi* were provided by the applicant as late as 17 November 2021 (see paragraphs [16] and [17] therein), noting that date was:

- more than 4 months after expiry of the SPC (on 13 July 2021, see paragraphs 12 and 62 of *Chiesi*); and

- more than 2 months after the date upon which an oral hearing on the matter was held (on 10 September 2021, see paragraph 14 of *Chiesi*).

22 They further note that, whilst at paragraph [85] of *Chiesi* the Hearing Officer described the decision to be made in that case as "whether to accept the late filled

materials as correcting the irregularity rather than continuing to provide a time period within which such material could be provided but is not clear when they will be provided", the decision in *Chiesi* was in fact issued on 11 January 2022. This they note was:

> - 4 months after the hearing took place in that case; and
>
> - at a point in time when the missing documents had been provided, but 6 months had not yet elapsed from expiry of the SPC.

23 The Applicant thus argues that whilst paragraph [85] of *Chiesi* might therefore correctly describe the decision that the Hearing Officer must ultimately take in connection with the present application, it does not in any way limit the discretion of the Office to provide the applicant with more time to obtain (and submit) the Statement of Compliance that would correct the "irregularity". They suggest this issue is addressed in paragraph [86] of *Chiesi*, where the Hearing Officer concluded that: "*I consider, that it would be possible for the Comptroller to continue to extend the period for providing the necessary proof of updated MAs and compliance statements for the two remaining member states past the expiry date of the SPC, if the circumstances merit it, based on the discretion allowed under Section 117B(4)".*

24 The Applicant therefore asserts that the above timeline means that *Chiesi* establishes a precedent for the grant of discretionary extensions beyond the expiry date of the SPC to the period set for an applicant to correct an "irregularity"; asserting that the period can, and indeed should, be extended "if the circumstances merit it".

25 The Applicant presents the issues to be decided as:

> - whether the circumstances merit the applicant being provided with more time to obtain (and submit) the Statement of Compliance; and, if so
>
> - how much additional time should be provided.

26 In addition to the decision in *Chiesi*, the Applicant took me to what they suggest is relevant guidance in paragraph [58] of *Du Pont*:

> *"Miss May indicated that, for future guidance, it would be helpful for the Comptroller to know just how late an applicant can be in supplementing its application with missing material. As at present advised (and of course this is strictly a question not before us) I would only say this: 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***" (emphasis added).

27 Whilst the application of this guidance to a request for an extension of time beyond the expiry date of the SPC was considered by the Hearing Officer in *Chiesi*[4], the Applicant suggests that the differences in underlying fact patterns means that this discussion is of little assistance for the present case. Instead, to determine whether a discretionary extension of time is merited in the present case, the Applicant asserts it is necessary to consider the more general factors discussed in the first half of paragraph [131] of *Chiesi*:

> "*Taking all of the above into account, I consider that the applicant is in the position where they would not be able to qualify for the reward of a paediatric extension in the UK because of delays in gaining the documents necessary to provide proof in the UK that an updated marketing authorisation describing the outcome of the paediatric testing is available in all other member states.* ***This delay*** *has occurred because the relevant competent authorities of the states concerned have not been able to carry out the relevant tasks and so* ***is not under the applicant's control****. Mindful of the factors identified by the Court in paragraph 58 of DuPont,* ***I do not think that the applicant can be said to have behaved unreasonably in terms of conduct or delay***" (emphasis added).

28 They note that there is no dispute that the Applicant has not "behaved unreasonably in terms of conduct or delay". Further, as the Applicant is not the MA holder, the reasons for the delay (to the provision of the Statement of Compliance) are clearly not "under the applicant's control". Thus, they assert assessment of the most relevant factors considered by the Hearing Officer in *Chiesi* supports the conclusion that a discretionary extension of time is merited in the present case. They also suggest there is no dispute that a Statement of Compliance issued by the MHRA would correct the "irregularity" for the present extension application, and thereby pass the test set in paragraph [85] of *Chiesi* for acceptance of "late filed materials". The Applicant therefore proposes that the further extension of time suggested would be appropriate in order to determine whether a Statement of Compliance could yet be obtained for the product.

29 On the question of how much additional time should be provided, the Applicant argues that consideration of the timeline in *Chiesi* suggests that a period of between 4 and 5 months (after expiry of the SPC) would be reasonable. Applying such a period to the present case, and accounting for office closures over the Christmas and New Year period, would result in the deadline falling in early to mid-January 2026. The Applicant submits that providing this additional period of time would be merited in the present case, as the MHRA Final Decision Letter dated 23 October 2024 provides what they regard as "reasonable basis" to conclude that the Statement of Compliance for Bavencio will become available within that period.

30 The Applicant is aware that a modification to the PIP was tabled for adoption at the 9-12 September 2025 EMA Paediatric Committee (PDCO) meeting. The PDCO agenda does not identify what modification the MA holder sought to make but they submit that it may indeed be a final amendment ahead of seeking a Statement of Compliance, and that the same may also be true for the corresponding PIP agreed

[4] See paragraphs [106]-[121] and the second half of paragraph [131]

with the MHRA. In such a case, the application for the Statement of Compliance could already be ongoing. At the hearing Mr Snodin and Mr Morgan further suggested that the period for completion of the Paediatric Investigation Plan (PIP) for Bavencio being changed from June 2031 to September 2025 supported this argument.

**Issue to be decided**

31 The issues to be decided are broadly as summarised by the Applicant:

a. whether the circumstances merit the applicant being provided with more time to obtain (and submit) the Statement of Compliance; and, if so

b. how much additional time should be provided.

**Analysis**

32 On first viewing there is much to recommend that the Applicant be granted an extension; *Du Pont* both suggests that 'irregularity' should be broadly construed and allows for a period of time to allow for rectification of irregularities, and the Hearing Officer's deliberations in *Chiesi* suggest that the absolute latest for an irregularity to be rectified would be the expiry of the maximum possible duration of the extension i.e. six months after expiry of the SPC. As I write this decision, the Applicant is still within that period for the extension of the SPC.

33 Indeed, the Applicant in their skeleton arguments emphasised the relevance of *Chiesi* and the apparent discretion it affords me in stating:

> *At paragraph 85 of Chiesi, the Hearing Officer described the decision to be made in that case as "whether to accept the late filled materials as correcting the irregularity rather than continuing to provide a time period within which such material could be provided but is not clear when they will be provided". However, the decision in Chiesi was issued on 11 January 2022, which was:*
>
> *- 4 months after the hearing took place in that case; and*
> *- at a point in time when the missing documents had been provided, but 6 months had not yet elapsed from expiry of the SPC.*
>
> *Whilst paragraph 85 of Chiesi might therefore correctly describe the decision that the Hearing Officer must ultimately take in connection with the present application, it does not in any way limit the discretion of the Office to provide the applicant with more time to obtain (and submit) the Statement of Compliance that would correct the "irregularity". This issue is addressed in paragraph 86 of Chiesi, where the Hearing Officer concluded that:*
>
> > *"I consider, that it would be possible for the Comptroller to continue to extend the period for providing the necessary proof of updated MAs and compliance statements for the two remaining member states past the expiry date of the SPC, if the circumstances merit it, based on the discretion allowed under Section 117B(4)".yet elapsed from expiry of the SPC".*

34 However, whilst the Applicant has encouraged me to note the similarities between *Chiesi* (and to a lesser extent *Du Pont*), in actual fact the present situation and the situations in both *Du Pont* and *Chiesi* differ in a fundamental aspect. In order to put that difference into some context, I believe it is worth considering what is the basis for the reward of an extension of 6 months to the duration of the SPC. This is dealt with in *Du Pont,* where Recital 17 of the Paediatric Regulation[5] is quoted by the Court. This states (my emphasis):

> *(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****.*

35 Jacob LJ then went on to state (my emphasis):

> *"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 should then 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 [acting for the Comptroller] 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."*

and later in the judgment accepted Miss May's submission on this point.

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[5] Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use "The Paediatric Regulation" and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004. Following the end of the transition period provided by the Agreement on the Withdrawal of the United Kingdom from the European Union, relevant provisions of The Paediatric Regulations were incorporated into the HMR. In particular, Articles 28(3) and 36, setting out the paediatric extension to an SPC, were replaced by Regulation 58A of the HMR. The recitals relating to the Paediatric Regulation remain relevant to interpretation of Regulation 58A of the HMR, particularly in this instance Regulation 58A(4).

36 Thus, the reward is granted on the basis of compliance with the PIP together with that information being disseminated. This is not changed by the transitional arrangements put in place prior to and following EU Exit. Regulation 58A(2)(a) and (b) of the HMR (reproduced above) make this clear.

37 In *Du Pont* the whole hearing and court procedure was expedited to allow the prospect of the extension being granted before expiry of the SPC in the event of a successful appeal; the compliance statement etc. having been provided prior to issue of the Court of Appeal judgment. In *Chiesi* the PIP had been completed, and the outstanding paperwork was purely administrative. It was a reasonable inference from the available information that the outstanding administrative niceties would be completed in time – some compliance statements had been issued and the remaining statements were obliged to be also.

38 By contrast, in the present case there is, at this point in time, no evidence that the PIP has been complied with, and thus it is not clear that the investigations set out in the PIP will have actually been completed before the 6 month duration of a paediatric extension would expire, let alone that the necessary changes to the MA SmPC will have been made and the compliance statement will have been issued. This is I consider, a significant factual distinction from either of the above decisions.

39 I have been asked by the Applicant here to infer that the MHRA may be close to recognising the PIP as having been completed by the fact that a PDCO meeting held at the EMA in September this year was likely to be discussing completion of the EU PIP. In this context, I do note the unusual and considerable shortening of the period over which the PIP was expected to be completed (at the time of the hearing)[6]. In this regard, at the point of expiry of the SPC, whilst there was nothing to indicate that the PIP had been completed, there was a suggestion in the Final Decision Letter from the MHRA, dated 23 October 2024, that the PIP would be completed by 30 September 2025. However, this is still far from offering certainty that not only will the PIP have been accepted as completed but also that the necessary administrative follow up will have been completed before the expiry of the six month paediatric extension. This looks even less likely as I have been drafting this decision, particularly in light of the Final Decision Letter of the MHRA dated 23 October 2025[7], accepting a change to the date of completion of the PIP to 30 September 2026. I note the Applicant's submission that this delay to the completion date does not preclude the possibility that a Statement of Compliance could be issued well in advance of this date, however I see nothing in any of the documentation available to me that suggests that this would in fact be the case.

40 I accept that this situation is beyond the control of the Applicant as the MA itself is held by a third party, and I therefore have some sympathy with them as they cannot influence the pace of this procedure, or provide detail on progress that is not publicly available. However, that does not change the fact that they have not been able to provide any evidence that could lead me to conclude that an extension of time would allow them to provide the outstanding documentation, and would not merely amount to a further period of uncertainty for third parties regarding the status of the SPC. In

[6] From June 2031 to September 2025, as provided in the Applicant's correspondence dated 7 November 2025

[7] Submitted by the Applicant with their letter dated 24 December 2025

other words, even if an extension of time were to be granted, the Applicant has not provided any guarantee that there would be a change in the status of the PIP, let alone the addition of the compliance statement to the MA, which is needed in order for the extension to be granted. When pressed on this point at the hearing, both Mr Snodin and Mr Morgan accepted that they could not at that point provide such a guarantee, but would ensure that that they kept the office informed of any progress. However, they did suggest that in this case the only interested party was the actual MA holder.

41 Thus, considering again the comment of the Hearing Officer at paragraph [85] of *Chiesi,* in the context of the above analysis, I agree with the Examiner that what I am being asked to do is amply described as "continuing to provide a time period within which such materials could be provided but is not clear when they will be provided". So where does this leave me in my making of a decision? The initial hearing request was because the Examiner refused to allow a further two month extension of time to allow the Applicant to submit the compliance statement as required by Article 8(1), because any further extension would extend beyond the date of expiry of the SPC. If allowed, this extension would have given the Applicant until 22 October to provide the necessary documentation and correct the irregularity. This would have been beyond the expiry of the SPC, but also would have been beyond the proposed date of completion of the PIP (of 30 September 2025) set out in the Final Decision Letter of the MHRA dated 23 October 2024, and would have given an indication of whether the PIP had been completed and whether the compliance statement was indeed forthcoming.

42 However, even if the examiner had allowed such an extension, then it would have been moot, because at its expiry there was still no indication that the PIP had been completed, and there remained uncertainty around whether a compliance statement could be provided prior to the expiry of the six month paediatric extension with the intention of meeting the requirements of Article 8(1) of the SPC Regulation.

43 In view of this lack of uncertainty about the eventual result in the present case, I do not believe that the Applicant may be allowed an extension to a period for reply purely on the basis that the circumstances might change before the end of that extended period. That would be an unacceptable situation for third parties, although in coming to this conclusion, I am mindful of Jacob LJ's statement at paragraph [56] of *Du Pont*, that "*third parties must wait for an indeterminate time – which on any view may include an Art 10(3) time extension – before knowing the result of the application for an extension*", and where he points out that there is no requirement for third parties to see details of an application for an MA or a variation of the MA, or for the national authority to make a decision a particular time after the application.

44 Nonetheless Jacob LJ's statement at paragraph [58] of *Du Pont* suggesting that "time should be extended so that [the applicant] gets its reward" does not necessarily appear to me to equate to 'time should be extended *just in case an applicant turns out to be able to* get a reward', and I further note that Jacob LJ pointed out, albeit *obiter*, that the Comptroller should take into account all relevant factors, including the reasons for the failure to include all the materials in the application, the behaviour of the applicant, and the proximity of the expiry of the SPC. In the present case, I acknowledge that the Applicant has been transparent regarding the MA and particularly the complexities of third party ownership, but I am

faced with a situation where the Applicant simply did not have the required materials at the expiry of the SPC[8], and has no indication of whether these materials will be provided before the expiry of the six month period of the paediatric extension (i.e. 22 February 2026). Furthermore, the Final Decision Letter of the MHRA, dated 23 October 2025, which extended the date of completion of the PIP to 30 September 2026 strongly suggests to me that the work, for which the paediatric extension to the SPC is the reward, is still ongoing and completion is not imminent. As such, whilst I agree that if an applicant has not behaved unreasonably then time should be extended such that they receive their reward, I believe that there must be a reward that can be given. In the present case, the investigations required for the completion of the PIP are still ongoing, and therefore there simply is no reward to be given. Whilst unfortunate, this also indicates that the requirements of Article 8(1) will not be met before the expiry of the six month extension period.

45 Therefore, taking into account all of the facts of the present case, I decline to exercise any further discretion to allow the Applicant to respond to the Examination Report dated 18 June 2024. Regardless, there would be no benefit to be had in the Office allowing any further extensions of time given that the necessary work to meet the requirements of Regulation 58A(2) of the HMR has not been completed, and as such the requirements of Article 8(1)(d)(i) of the SPC Regulation cannot be met.

**Conclusion**

46 I conclude that it would not be appropriate in this case to allow a further extension of the period for reply and thus the time available under Article 10(3) has passed. The application is therefore refused under Article 10(4).

**Appeal**

47 Any appeal must be lodged within 28 days after the date of this decision.

**DR ROWENA DINHAM**

Patent Examination Group Head

[8] i.e. a statement in the UK MA as per the requirements of Regulation 58A(2) of the HMR