

## Prescription Medicines Code of Practice Authority

### Case report

<b>Case number</b>	Case/0466/01/25
<b>Complaint received</b>	31 January 2025
<b>Case title</b>	A video on the website of a medical journal
<b>Company</b>	Voluntary admission by Pierre Fabre Ltd
<b>Applicable ABPI Code</b>	2024
<b>Clauses raised</b>	2, 5.1, 5.6, 8.1, 11.2, 12.1, 12.6, and 15.6
<b>Panel decision</b>	20 November 2025
<b>Respondent undertaking</b>	28 November 2025
<b>Appeal Board review</b>	17 December 2025 [All completed cases are reviewed by the Appeal Board – see Paragraph 15.4 of the Constitution and Procedure]

### Case summary

This voluntary admission related to a video that appeared on the website of a medical journal. Pierre Fabre submitted that the video had, in error, been promoted to UK health professionals by email.

The Panel considered that, in the voluntary admission, Pierre Fabre acknowledged that:

- The arrangements for the activity were not strictly arm's length.
- The promotional video for Braftovi (encorafenib) had not been certified (Clause 8.1).
- The video contained no prescribing information (Clause 12.1) or adverse event reporting statement (Clause 12.6).
- The declaration of involvement was not sufficiently clear as to Pierre Fabre's involvement (Clause 5.6).
- The promotional nature of the video had been disguised (Clause 15.6).
- The video promoted Braftovi for an unlicensed indication (Clause 11.2).
- High standards had not been maintained (Clause 5.1).
- The Panel may want to consider the requirements of Clause 2.

The outcome under the 2024 Code was:

<b>Breach of Clause 5.1</b>	Failing to maintain high standards
<b>Breach of Clause 5.6</b>	Failing to be sufficiently clear as to the company's role and involvement

<b>Breach of Clause 8.1</b>	Failing to certify promotional material
<b>Breach of Clause 11.2</b>	Promoting a medicine for an unlicensed indication
<b>Breach of Clause 12.1</b>	Failing to include prescribing information
<b>Breach of Clause 12.6</b>	Failing to include the prominent adverse event reporting statement
<b>Breach of Clause 15.6</b>	Disguising promotional material

<b>No Breach of Clause 2</b>	Requirement that activities or materials must not bring discredit upon, or reduce confidence in, the pharmaceutical industry
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**This summary should not be relied upon in isolation.  
For full details, please see the full case report.**

## Full case report

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## Case preparation

1. The PMCPA received a voluntary admission from Pierre Fabre Ltd.
2. The voluntary admission is at [Annex A](#).

3. This case related to a video that appeared on the website of a medical journal. Pierre Fabre submitted that the video had, in error, been promoted to UK health professionals by email.
4. The Panel considered that, in the voluntary admission, Pierre Fabre acknowledged that:
  - a. The arrangements for the activity were not strictly arm's length.
  - b. The promotional video for Braftovi (encorafenib), had not been certified (Clause 8.1).
  - c. The video contained no prescribing information (Clause 12.1) or adverse event reporting statement (Clause 12.6).
  - d. The declaration of involvement was not sufficiently clear as to Pierre Fabre's involvement (Clause 5.6).
  - e. The promotional nature of the video had been disguised (Clause 15.6).
  - f. The video promoted Braftovi for an unlicensed indication (Clause 11.2).
  - g. High standards had not been maintained (Clause 5.1).
  - h. The Panel may want to consider the requirements of Clause 2.
5. The PMCPA case preparation manager asked Pierre Fabre to provide any further comments on this matter in relation to the requirements of Clauses 2, 5.1, 5.6, 8.1, 11.2, 12.1, 12.6 and 15.6 of the 2024 Code.
6. The response from Pierre Fabre is at [Annex B](#). Pierre Fabre accepted breaches of Clauses 5.1, 5.6, 8.1, 11.2, 12.1, 12.6 and 15.6 in relation to the above allegations.
7. The case preparation manager referred the case to the Code of Practice Panel to consider and provide its ruling. The Panel considered the information provided by Pierre Fabre in full.

### Panel ruling

8. Pierre Fabre submitted that a medical journal had approached its parent company, Pierre Fabre Medicament, with a sponsorship proposal for an activity associated with a European medical conference taking place in September 2024.
9. The written proposal described the activity as an:
 

*"...educational project focused on advancements in the treatment of BRAFV600-mutant metastatic non-small cell lung cancer (NSCLC) and the latest insights on targeted therapies for metastatic melanoma."*
10. One of the outputs from the project was a video recording of interviews with several key opinion leaders ("KOLs"). That video would then be placed on the medical journal's website and promoted through a targeted email campaign to oncology specialists who had subscribed to its platform.

11. Pierre Fabre submitted that, in error, UK health professionals had been included in the distribution of the email. Pierre Fabre voluntarily admitted to several breaches of the Code in relation to the video.
12. The Panel considered that the first three questions to be addressed were:
  - a. Was the video within the scope of the UK Code?
  - b. Had the intended arm's-length arrangements been compromised?
  - c. Was the video promotional?

### Was the video within scope of the UK Code?

13. Pierre Fabre Medicament (headquartered in France) had instructed the medical journal that UK health professionals should be excluded from the distribution list for the email notification. The Panel noted that this instruction had been recorded in a briefing document to the medical journal. In answer to the question *"Any countries excluded from promotional activities"*, the briefing document stated: *"UK to be excluded from send out"*. Pierre Fabre submitted that it appeared that there was limited or no contact by Pierre Fabre Medicament to check if these instructions had been followed.
14. Pierre Fabre submitted that the video was made available on the medical journal website on 26 September 2024. On 10 October 2024, a UK employee registered as a health professional on the medical journal's website received an email directing them to the video.
15. On investigation with the medical journal, Pierre Fabre submitted that:
  - a. the email distribution list had been created before the briefing document, and
  - b. due to an oversight by the medical journal's project manager, the distribution list had not been updated to exclude UK health professionals.
16. The Panel concluded that the video was in scope of the UK Code because:
  - a. The sponsorship agreement was between Pierre Fabre Medicament and the medical journal (a UK company).
  - b. Pierre Fabre Medicament was the parent company of Pierre Fabre Ltd.
  - c. It is a well-established principle of the Code that UK pharmaceutical companies are responsible for the activities of their overseas affiliates, including parent companies, if such activities relate to UK health professionals.
  - d. The email notification directing recipients to the video had been sent to 30,000 health professionals, of which 2,523 were based in the UK.

### Were the sponsorship arrangements arm's length?

17. Pierre Fabre submitted that the arrangements for the sponsored activity between Pierre Fabre Medicament and the medical journal had been intended to be arm's length.
18. The Panel considered that a company could sponsor material produced by an independent organisation which mentioned that company's products. However, for a

company to avoid being responsible under the Code for the content of that material, it is essential that there is a strictly arm's-length arrangement between the parties.

19. Pierre Fabre conceded that any arm's-length arrangement had been compromised because Pierre Fabre Medicament provided a list of suggested KOLs to participate in the interviews and would also receive a "...*statistics report, a QR Code and invitations for Pierre Fabre to share content*" as specified in the sponsorship agreement.
20. Based upon the following extracts from the sponsorship documentation, the Panel did not consider this arrangement to be strictly arm's length:
  - a. Pierre Fabre was referred to as "*the client*" in the proposal from the medical journal.
  - b. The medical journal agreed to provide Pierre Fabre with "*a content analytics breakdown that gives statistics on performance*".
  - c. At no additional cost to Pierre Fabre, the medical journal agreed to host a recording of Pierre Fabre's symposium from the same European conference and promote it through its digital channels.
  - d. A section of the sponsorship agreement relating to the video stated: "*KOL Interview Video Recording during a key conference to amplify communications on a topic of **your** choice*" (emphasis added by the Panel).
  - e. A section of the sponsorship agreement titled 'Sponsorship Benefits' stated:
    - i. "*In exchange for the Sponsorship, Recipient [medical journal] agrees to provide to Sponsor [Pierre Fabre] tangible benefits...*" and
    - ii. "*Sponsorship benefits include a statistics report, a QR code and invitations for Pierre Fabre to share content, along with a clear disclaimer*".
  - f. Email correspondence indicated that Pierre Fabre was expected to:
    - i. "*Fill in the briefing document for the KOL Interview Recordings with topic expectations and the 2 KOLs details ... This will then allow Pierre Fabre to take on the hands-off approach after as our medical writer will put together the outline for the interview*".
    - ii. "*Secure both KOLs and inform [named medical journal] to when we're able to reach out*".
21. In combination, these factors convinced the Panel that there had not been a strictly arm's length agreement between the parties because of Pierre Fabre's ability to influence significantly the content of the video, suggest which KOLs should be interviewed, and liaise directly with those KOLs. Pierre Fabre also received benefits, such as detailed reports containing analytical data and having its own symposium hosted on the medical journal's website.
22. The Panel concluded that Pierre Fabre was liable for the content of the video under the Code, given the actions of its overseas parent company, as acknowledged in the voluntary admission.

### Was the video promotional for Braftovi (encorafenib)?

23. Pierre Fabre admitted that the video was promotional because it referred to the use of BRAF inhibitors in the treatment of NSCLC and melanoma, and Pierre Fabre had a medicine in this class (encorafenib).
24. The video was titled 'Shared insights on treating BRAFV600-mutant metastatic cancers' and featured the following statements from the KOLs being interviewed:
  - a. "...encorafenib turned out to be statistically significantly better..."
  - b. "...encorafenib is by far the strongest of BRAF inhibitors..."
  - c. "...for encorafenib and [other named drug] there is no specific adverse event which you can dedicate to the BRAF inhibitor..."
  - d. "...so in general the toxicity is nicely [sic] to manage..." (in relation to encorafenib)
  - e. "...no long-term toxicities which have been described..." (in relation to encorafenib).
25. In the context of a video discussing the treatment of BRAFV600-mutant metastatic cancers, the Panel considered these positive statements about encorafenib to be clearly promotional.

### Requirements for promotional material

#### Certification (Clause 8.1)

26. Clause 8.1 stated:
 

*"Promotional material must not be issued unless its final form, to which no subsequent amendments will be made, has been certified by one person on behalf of the company..."*
27. Pierre Fabre admitted that this promotional video had not been certified as required by Clause 8.1.
28. The Panel ruled a **breach of Clause 8.1**.

#### Prescribing information (Clause 12.1)

29. Clause 12.1 required that:
 

*"The prescribing information listed in Clause 12.2 must be provided in a clear and legible manner in all promotional material for a medicine except abbreviated advertisements."*
30. Pierre Fabre admitted that the promotional video did not include prescribing information.
31. The Panel agreed and ruled a **breach of Clause 12.1**.

#### Adverse event reporting statement (Clause 12.6)

32. Clause 12.6 required that:
 

*"All promotional material must include the prominent statement 'Adverse events should be reported. Reporting forms and information can be found at [website address which*

*links directly to the MHRA Yellow Card site]. Adverse events should also be reported to [relevant pharmaceutical company].”*

33. Pierre Fabre admitted that the promotional video did not include the adverse event reporting statement.
34. The Panel agreed and ruled a **breach of Clause 12.6**.

### Promoting an unlicensed indication (Clause 11.2)

35. Pierre Fabre submitted that the video broadly covered the BRAFV600 mutation in both NSCLC and melanoma, and how BRAF inhibitors might be utilised as treatment.
36. Although the video did not refer directly to using encorafenib to treat NSCLC, it did refer to the medicine class. Given encorafenib was not licensed for the treatment of NSCLC at the time the video was first published, Pierre Fabre admitted that the video was in breach of Clause 11.2.
37. Clause 11.2 required that:  
*“The promotion of a medicine must be in accordance with the terms of its marketing authorisation and must not be inconsistent with the particulars listed in its summary of product characteristics...”*
38. The Panel agreed that the video breached this clause because it referred to encorafenib in the context of metastatic NSCLC *and* melanoma, without any clear reference to the fact that encorafenib was only licensed for metastatic melanoma, not metastatic NSCLC, at the time.
39. The Panel concluded that the video promoted encorafenib outside the terms of its marketing authorisation and therefore ruled a **breach of Clause 11.2**, as acknowledged by Pierre Fabre.

### Declaration of involvement (Clause 5.6)

40. Pierre Fabre submitted that the statement on the video relating to the involvement of Pierre Fabre was not sufficiently clear as to Pierre Fabre Medicament’s involvement, contrary to the requirements of Clause 5.6.
41. Clause 5.6 required that:  
*“Material relating to medicines and their uses, whether promotional or not, and information relating to human health or diseases which is sponsored by a pharmaceutical company or in which a pharmaceutical company has any other involvement, must clearly indicate the role of that pharmaceutical company”.*
42. The supplementary information to Clause 5.6 stated, among other things:  
*“The wording of the declaration of involvement must be unambiguous so that readers are immediately able to understand the extent of the company’s involvement and influence”.*
43. The Panel noted that the following declaration appeared on screen, after the opening visuals of the video. The declaration was also read out by the moderator from the medical journal:



*“This session has been funded by Pierre Fabre; where the position and discussions may not represent the position of Pierre Fabre or [named medical journal] and the content is intended for healthcare professionals. Considering the nature of our discussion, please always consult your local Summary of Product Characteristics before making any prescription decisions”*

44. The Panel noted Pierre Fabre’s submission that once the UK had “*flagged there could be an issue*”, the declaration of involvement on the medical journal website (but not the video itself) had been amended to state:

*“This independent educational activity has been supported by Pierre Fabre Laboratories; where the position and discussions may not represent the policies and position of Pierre Fabre or [named medical journal]. The content has been developed independently by [named medical journal] and is intended for healthcare professionals only (except those within UK and ROI). Considering the nature of our discussions, please always consult your local Summary of Product Characteristics before making any prescribing decisions”*

45. The Panel noted that it had not been provided with a copy of the website and could only rule on the evidence before it.
46. The Panel considered that the impression given by both versions of the declaration was that Pierre Fabre’s only involvement was to financially support the production of the video. However, this was not the case because Pierre Fabre had provided topic expectations and suggested which KOLs should be interviewed. The Panel considered that the wording of the declaration was insufficient to enable a reader to immediately understand the extent of Pierre Fabre’s involvement and influence.
47. The Panel ruled a **breach of Clause 5.6**, as acknowledged by Pierre Fabre.

### Disguised promotion (Clause 15.6)

48. Pierre Fabre admitted that the promotional nature of the video was disguised given the extent of its involvement was not clear.
49. Clause 15.6 required that: *“Promotional material and activities must not be disguised”*.
50. The Panel did not have a copy of the notification email which directed UK health professionals to the video, nor the webpage on which the video was hosted. The Panel was therefore unaware of how the video was described or what information a viewer would have been provided with before proceeding to watch the video (other than the declaration text provided by Pierre Fabre, as described above).
51. The Code does not require promotional material to necessarily be labelled as such; however, the fact that material is promotional must not be disguised.
52. The Panel concluded that the video was disguised promotion because:
  - a. The declaration of involvement implied misleadingly that Pierre Fabre had simply funded the video without any further involvement. The Panel considered that the reader/viewer would be unlikely to assume that the video would contain promotional information from the wording of this declaration.



- b. The moderator introduced the session as a “*round table discussion on shared perspectives on targeted therapies for metastatic BRAF V600 mutations*”. There was no reference to the promotional nature of the video.
  - c. The updated declaration on the website referred to the video as an “*independent medical activity*” and that the “*content had been developed independently*”.
- 53. The Panel considered that the impression given to a viewer was that the video was independent, non-promotional material. Having already concluded that the video was promotional for encorafenib, the Panel concluded that it was disguised promotion.
- 54. The Panel ruled a **breach of Clause 15.6**, as acknowledged by Pierre Fabre.

## Overall

### High standards (Clause 5.1)

- 55. Given the number of breaches as part of this voluntary admission, Pierre Fabre also admitted that it had failed to maintain high standards.
- 56. The Panel agreed and relied upon the following:
  - a. The promotional nature of the video had been disguised and the extent of Pierre Fabre’s involvement in the activity was unclear to the audience. The Panel considered that transparency was an important means of building and maintaining confidence in the industry.
  - b. Important safety information required in promotional material had not been provided (prescribing information and adverse event reporting statement).
  - c. Encorafenib had been promoted outside the terms of its licence to a significant number of UK health professionals.
- 57. Noting the well-established principle that UK pharmaceutical companies are responsible for the activities of their overseas affiliates that come within the scope of the ABPI Code, the Panel considered that Pierre Fabre had failed to maintain high standards.
- 58. The Panel ruled a **breach of Clause 5.1**, as acknowledged by Pierre Fabre.

### Upholding confidence in the industry (Clause 2)

- 59. Pierre Fabre had volunteered that the Panel may want to consider the requirements of Clause 2.
- 60. In determining whether Pierre Fabre had brought discredit upon, or reduced confidence in, the pharmaceutical industry, the Panel considered the following:
  - a. Pierre Fabre Ltd had been let down by its overseas parent company and the medical journal: the video was not intended to reach UK health professionals.
  - b. Upon becoming aware of the video being directed to UK health professionals, Pierre Fabre Ltd recognised that there were potential breaches of the Code.
  - c. Pierre Fabre Ltd recognised that the arrangements were not strictly arm’s length and that the video was promotional for encorafenib.

- d. While not sufficient to fulfil the requirements of the Code, the video did include a declaration indicating that Pierre Fabre had been involved in some capacity.
  - 61. Clause 2 is a sign of particular censure and reserved for such use. The Panel considered that the matters raised in the voluntary admission were adequately covered by its rulings above and did not consider that a breach of Clause 2 was warranted. The Panel ruled **no breach of Clause 2**.
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## Annex notes

The Panel used square brackets in Annex A and Annex B to anonymise and redact information in the voluntary admission and response. This is for the purposes of:

- protecting the confidentiality of named individuals,
- protecting company information that is commercially sensitive or confidential,
- anonymising third parties that have not had a chance to comment on the case, and/or
- ensuring that material that may be a breach of the Code is not made publicly available when the case report is published.

For similar reasons, any attachments provided to the PMCPA with the voluntary admission are not included in this case report.

The wording of the voluntary admission (Annex A) and the company response (Annex B) is otherwise copied in full below.

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## Annex A – The voluntary admission

“Further to our letter of 24 October 2024, Pierre Fabre Ltd regretfully inform the PMCPA of an activity conducted on behalf of our parent company, Pierre Fabre Medicament, which we consider falls into the scope, and be contrary to several requirements, of the ABPI Code.

### **Background**

In January 2024, the [named medical journal] (based in London) approached Pierre Fabre Medicament with a sponsorship proposal for an activity associated with the [named European medical conference] taking place in [non-UK location] in September 2024. The activity planned was described in the written proposal (please see **Enclosure 1**) as an “*educational project focused on advancements in the treatment of BRAFV600-mutant metastatic non-small cell lung cancer (NSCLC) and the latest insights on targeted therapies for metastatic melanoma*” and involved a recording of interviews with a number of key opinion leaders (KOLs) to “*capture the real-time excitement and relevance of [named medical conference]*” and “*allow key experts to provide immediate insights into the latest advancements in NSCLC, Melanoma and innovative treatments, offering a timely and authentic perspective to your audience*”. The video was then to be placed on the [named medical journal] website and [named medical journal] would maximize “...audience engagement by amplifying the content through a targeted email campaign”. The proposal further stated that the audience was comprised of “*30,000 senior healthcare professionals*” who were “*Oncology specialists who have subscribed to the [named medical journal] platform*”; 58.9% of this proposed audience were apparently based in Europe.

A sponsorship agreement was put in place in March 2024 between Pierre Fabre Medicament and [named medical journal] (**Enclosure 2**). The agreement states in clause 1.1 that the project is “*Independent medical education*” and that Pierre Fabre Medicament “...will not have no editorial control over the content” [sic]. However, clause 4, Sponsorship benefits, also states that Pierre Fabre Medicament will be provided with “...statistics report, a QR code and invitations for Pierre Fabre to share content”. We also understand from speaking to the [named medical journal] that Pierre Fabre Medicament also provided a list of suggested KOLs to participate in the interviews.

### **Scope of the ABPI Code**

- In June 2024 the project manager for the video from the [named medical journal] met with a member of the Pierre Fabre Medicament medical affairs team to discuss the details of the KOL interviews; a summary of the meeting was captured by [named medical journal] in [a named medical journal] briefing document template (**Enclosure 3**) and emailed to the medical affairs member of staff on 11 June 2024 (**Enclosure 4**). It can clearly be seen from the briefing document and the covering email that the of and instruction from Pierre Fabre Medicament was to exclude UK health professionals (HCPs) from the distribution list of the email notification for the video once it had been placed on the [named medical journal] website. It is acknowledged that Pierre Fabre Medicament relied on [named medical journal] to implement procedures that would ensure compliance with Pierre Fabre’s instructions. It appears there was limited or no contact by Pierre Fabre Medicament to check if these instructions had been followed.

However, on 10<sup>th</sup> October 2024, following production of the video and placing it on the [named medical journal] website, a member of staff from Pierre Fabre Ltd UK affiliate registered as an HCP on the [named medical journal] website received an email directing them to the video.

Preliminary investigation indicated that UK HCPs were not in fact excluded from the distribution of the notification for this video and we thus consider that the video therefore falls within the scope of the ABPI Code. In addition, given that Pierre Fabre Medicament provided input into the choice of KOLs participating in the video and the contract with [named medical journal] required certain data relating to views of the video to be provided to Pierre Fabre Medicament, we consider that any intended arms-length arrangement has been compromised and Pierre Fabre is therefore responsible under the Code for the content of the video.

### ***Notification distribution***

We have spoken to [named medical journal] and it seems that, despite meeting with Pierre Fabre Medicament and as a result documenting on email and in the briefing document that the UK should be excluded from distribution of the notification for the video, UK HCPs were in fact notified. The distribution for the notification email had already been set up in the [named medical journal] project management system by the time of the meeting with Pierre Fabre Medicament and, as a result of what has been described as “an oversight” by the [named medical journal] project manager, this was not amended as a result of this meeting.

The notification email was sent to approximately 30,000 HCPs, 2523 of which were based in the UK. The video was made available on the website 26<sup>th</sup> September 2024.

Given the distribution of the notification, we consider that the sponsorship by Pierre Fabre Medicament of the video falls within the scope of the Code and we therefore recognise that Pierre Fabre UK are responsible. Further, as described above, the arms-length arrangement that Pierre Fabre Medicament intended to have with the sponsored activity was compromised, for example by Pierre Fabre Medicament suggesting a number of KOLs to participate in the video and by a contractual term that required the provision of certain reports to Pierre Fabre Medicament. We therefore also consider that Pierre Fabre is responsible for the content of the video that was placed on the [named medical journal] website.

### ***Issues with the video***

The video has now been removed from the [named medical journal] website; however a copy is enclosed for reference (**Enclosure 5**). Having viewed the video, we have a number of concerns about the content and approval

The video refers to the use of BRAF inhibitors in the treatment of non-small cell lung cancer and melanoma. Pierre Fabre has a medicine in this class (encorafenib) and we therefore consider that the video is promotional:

- The video has not been certified, contrary to the requirements of Clause 8.1
- There is no prescribing information provided, either on the video or via a link, as required by Clause 12.1
- There is no adverse event reporting statement, as required by Clause 12.6

The statement on the video relating to the involvement of Pierre Fabre is not sufficiently clear as to Pierre Fabre Medicament’s involvement, contrary to the requirements of Clause 5.6: Initially the declaration on the video itself and on the [named medical journal] website stated

- “This session has been funded by Pierre Fabre; where the position and discussions may not represent the position of Pierre Fabre and the content is intended for [sic] healthcare professionals. Considering the nature of our discussion, please always consult your local Summary of Product Characteristics before making any prescription decisions”

Once the UK became aware of the video on 14 October and flagged that there could be an issue, the disclaimer on the [named medical journal] website (although not the video itself) was revised to state:

- “This independent educational activity has been supported by Pierre Fabre Laboratories; where the position and discussions may not represent the policies and position of Pierre Fabre or [named medical journal]. The content has been developed independently by [named medical journal] and is intended for healthcare professionals only (except those within UK and ROI). Considering the nature of our discussions, please always consult your local Summary of Product Characteristics before making any prescribing decisions”

We do not however consider either of these statements fully represent the involvement of Pierre Fabre Medicament in the production of the video. Given that this was not clear we also consider that the promotional nature of the video was disguised and therefore not in line with the requirements of Clause 15.6.

The KOL discussion on the video broadly covers the BRAFV600 mutation in both NSCLC and melanoma and how BRAF inhibitors might be utilised as treatment in that regard. Although there is no direct reference to the use of encorafenib specifically in the treatment of NSCLC, there is reference to the class in which this medicine sits. Given that, at the time that the video was first published, encorafenib did not have a licence for the treatment of NSCLC, we consider that this is therefore contrary to the requirements of Clause 11.2.

Given all of the above, we consider that there has been a failure to maintain the high standards required of pharmaceutical companies in Clause 5.1. We also understand that the Panel may want to consider the requirements of Clause 2.

To inform our decision as to whether we should contact the health professional recipients of the email alert, we analysed enquiries to Medical Information to assess whether there was any indication of an increase in questions as a result of the video. This does not appear to be the case. Based on no increase in medical information enquiries, we did not consider that the video had caused confusion in the relevant medical community and therefore decided there was no need to contact recipients of the email.

Finally, please find enclosed the Braftovi (encorafenib) Summary of Product Characteristics (**Enclosure 6**).

I trust that the above and enclosed provides sufficient information for the Panel to consider this matter. I am of course aware that we will be asked to respond to this voluntary admission and to provide any additional information considered necessary in that regard.”

## **Annex B – Pierre Fabre’s response**

“Thank you for your letter of 14<sup>th</sup> February regarding the above cited voluntary admission by Pierre Fabre.

In relation to your request for a transcript for the video, this video was not intended for a UK audience and was not originated by the UK. As such there is no transcript available.

Additional internal remedial action that has now taken place is external bespoke mandatory training has been provided for Global colleagues within Medical, Marketing, Market Access, Regulatory and Patient Centricity with a focus on when activities fall within the scope of the Code and their responsibilities in relation to third parties. This training will also now form part of future onboarding for Global colleagues within the roles mentioned above. Please find enclosed a list of attendees. It also shows the date the training was delivered (Enclosure 1). Please also find enclosed a copy of the training that was delivered (Enclosure 2).

We have no further comment on the clauses referred to in our letter of 31st January. We note that we have been asked to respond to the requirements of Clause 2; as previously stated we understand that the Panel may want to consider this clause in relation to this matter.

I trust that the above and enclosed provides sufficient information for the Panel to consider this matter. I am of course aware that we will be asked to respond to this voluntary admission and to provide any additional information considered necessary in that regard.”

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