CASE AUTH/3861/12/23

COMPLAINANT v NOVARTIS PHARMACEUTICALS UK LIMITED

Allegations about a third-party conference email

CASE SUMMARY

This case was in relation to a promotional email sent to a health professional by a third-party medical publisher.

The outcome under the 2021 Code was:

Breach of Clause 2	**Bringing discredit upon, and reducing confidence in, the pharmaceutical industry**
Breach of Clause 5.1 (x2)	**Failing to maintain high standards**
Breach of Clause 5.5 (x3)	**Failing to be sufficiently clear as to the company's role and involvement**
Breach of Clause 11.2 (x2)	**Promoting a medicine for an unlicensed indication**
Breach of Clause 12.1	**Failing to include UK prescribing information**
Breach of Clause 12.10	**Failing to include a black triangle adjacent to the first mention of the product in digital material**
Breach of Clause 15.6 (x4)	**Disguising promotional material**

No Breach of Clause 6.1	**Requirement that information must be accurate, up-to-date and not misleading**
No Breach of Clause 11.2	**Requirement not to promote a medicine for an unlicensed indication**

This summary is not intended to be read in isolation.
For full details, please see the full case report below.

FULL CASE REPORT

A complaint was received from an anonymous, contactable complainant about Novartis.

COMPLAINT

The complaint wording is reproduced below:

> "I would like to make a complaint about this email I received from [third-party medical publisher]. I am registered on [third-party medical publisher] as a doctor based in London.

Based on the email address and tittle [sic], I opened this email as I thought it would be an unbiaised report from ESMO [European Society for Medical Oncology] and of interest as I did not attend ESMO this year. The email invites me to watch a video of [named doctor] who plans to discuss Lu-PSMA-617, AI, trial parameters and radiaton [sic] treatment.

At the very end of the email, in small print, it states this promotional communication is provided by [third-party medical publisher's parent company]. So this is a promotional email. Disguised very carefully as a prostate Ca update. And it does not even state which company is paying for it. Surely they should declare their involvement upfont [upfront]?

Based on watching video, I now know that the company must be Novartis based on the prominent Pluvicto advertisements on the web page.

How can we trust cancer updates from [third-party medical publisher] clinical insights when we don[']t know Novartis paid for it?"

FURTHER INFORMATION FROM THE COMPLAINANT

"On the 21st of November, I received an email invitation from [third-party medical publisher] to watch a video of [named doctor] discussing key prostate cancer studies from ESMO 2023.

As per my previous email, I believe this email should make it clear that this is paid for by Novartis and not disguise their involvement. But the reason I am writing to you today is regarding the link opened by that website. I believe they are using this to promote their product outside of its licensed indication.

The link 'watch now' on the email opens up the following webpage

In the first part of the webpage are two embedded videos. The first one is titled "Practise changing data in Prostate Cancer from ESMO 2023'. The second video is a video summary of the VISION study, comparing Pluvicto to placebo treatment in prostate cancer. On the right hand side is a banner advertisement for Pluvicto. Lower down are a resources section, called information from Industry. All 3 resources are about PSMA [prostate specific membrane antigen] and Pluvicto.

Scrolling down to the end of the page one can see another banner advertisement for Pluvicto. [Screenshot of upper part of webpage provided]

I have the follow observations to make about this webpage.

1. although the invitation email stated that this is a promotional communication, implying the webpage was paid for by industry to promote a medicine, there is absolutely no mention of funding or sponsorship or industry involvement mentioned on the actual webpage. However, the fact that the [third-party medical publisher's product] video and VISION study video is so closely linked, strongly suggests it was paid for by Novartis and the design of this website was planned to be this way. Furthermore, it cannot be coincidence that the banner next to these two videos advertise Pluvicto
2. The Pluvicto video ends with prescribing information for Pluvicto. But unfortunately it is the EMA [European Medicines Agency] prescribing

information and not the MHRA [Medicines and Healthcare products Regulatory Agency] version.

a. it lacks the UK price, it lacks a black triangle, it has the incorrect licensed indication for the UK. [A screenshot of the prescribing information was provided

3. Paying attention to the content of the [third party medical publisher's product] video, its clear that its promoting Pluvicto outside of this licensed indication. (outside of the UK, USA and EU licence). Practise changing data, it says. But such practise will be outside of the licensed indication!
   a. The PSMAfore study was done in patient who has not had chemotherapy yet.
   b. the ANZUP study looked at Pluvicto at a higher dose, given twice to patients at the point they comments enzalutamide treatment. Not after they progressed on an ARTA [androgen receptor targeted agent] and chemotherapy.

4. Its also noteworthy that the [third party medical publisher's product] update is only 5 minutes long and the Vision study video is twice as long, at 10:05 minutes. [Named doctor] is the principal investigator for the Vision and PSMAfore study.

Turning our attention to the banner on the right, it also has problems

1. Now approved in the UK. It was approved on the 9th of December 2022, more than a year ago.
2. the licensed indication from the EMA and not the MHRA.
3. The SPC is not the UK version

Novartis must have known that these two videos will be positioned next to each other. The video promoting Pluvicto is on branded material, with European prescribing information and licensed indication and the [third party medical publisher's product] video promotes earlier use of Pluvicto outside of its current licensed indication. It is also plausible that Novartis paid to have their two banner advertisements positioned on this webpage and not an advertisement of some other medicine. As it is plausible that Novartis paid for the Information from Industry section to only have information about their products. It is too much coincidence not to have been planned and paid for. These type of tactics give the pharmaceutical industry a bad reputation. Under the pretence of independently developed content they promote their medicine outside of the indication and it should not be allowed.

I hope you will take this up with Novartis and get them to act with more integrity in the future."

When writing to Novartis, the PMCPA asked it to consider the requirements of Clauses 2, 5.1, 5.5, 6.1, 11.2, 12.1, 12.10 and 15.6 of the Code.

NOVARTIS' RESPONSE

The response from Novartis is reproduced below:

"The Complaint relates to a [third party medical publisher's product] of the European Society for Medical Oncology ('**ESMO**') Congress 2023 conducted on the [third-party medical publisher] website for healthcare professionals. The activities which are the subject of the Complaint were conducted by Novartis' global affiliated company, Advanced Accelerator Applications International S.A (hereinafter referred to as '**Novartis Global**'). Notwithstanding the fact that Novartis Pharmaceuticals UK Limited ('**Novartis UK**') had no knowledge or oversight of the specific material in question, Novartis UK acknowledge that it is a well-established principle under the Code that UK companies are responsible for the acts or omissions of overseas parents or affiliates that come within the scope of the Code.

The PMCPA has requested that Novartis UK consider whether certain clauses of the ABPI Code of Practice for the Pharmaceutical Industry 2021 (the '**Code**') have been breached.

The Complaint causes us great concern, as Novartis UK is committed to operating in accordance with the required standards, and we have taken its contents very seriously. We have set out our response in full below.

1. Novartis' relationship with [third-party medical publisher]

The complainant refers to a healthcare professional facing website, owned by an organisation called [third-party medical publisher and its parent company] [which] describes itself as the leading online global destination for physicians and healthcare professionals worldwide, offering the latest medical news and expert perspectives; essential point-of-care drug and disease information; and relevant professional education and CME. [Third-party medical publisher] is highly regarded within the industry and by healthcare professionals as a provider of medical education. This includes both [third-party medical publisher]'s independent, editorial content and content which has been commissioned by the pharmaceutical industry.

Novartis Global and [the third party medical publisher's parent company] have a long-standing business relationship, working together on an extensive number of both promotional and non-promotional campaigns that include or exclude a UK HCP audience depending on the nature of the campaign. The vast majority of services are delivered without issues.

The material which is the subject of the Complaint relates to a [third party medical publisher's product] of the ESMO 2023 conference and accompanying materials made available on the [third-party medical publisher] platform (the '**Conference [third party medical publisher's product] content**'). Novartis Global engaged [the third party medical publisher's parent company] to provide Novartis promotional material (advertising and certain content informing viewers about certain Novartis products) alongside [third-party]'s own content on the relevant web page. Further details of the precise nature of the arrangements are set out below.

Following receipt of the Complaint, Novartis Global promptly worked with [the third party medical publisher's parent company] to immediately remove the Novartis promotional materials from the Conference [third party medical publisher's product] content concerned by the Complaint (i.e. the materials that were paid for by Novartis and/or over which

Novartis has editorial control). Prior to the removal of the Novartis material, Novartis understands from [the third party medical publisher's parent company] that the relevant webpage was accessed by 60 unique viewers from within the UK.

2. Global-led campaigns at Novartis

Novartis Global has clear policies in place governing the creation of promotional and non-promotional materials by Novartis Global associates. Section 2.1 of the '*AAA Global Materials Review and Approval Standard Operating Procedure*' clearly states the following requirements regarding local review and approval:

> *'In addition to global review and approval under this SOP as required, under no circumstances promotional or non-promotional materials may be externally used without prior local review and approval in each country where the material is intended to be used, in accordance with the applicable local governance*.'

Section 2.1 of the '*Promotional and Non-Promotional Materials Novartis Global P3 Guideline*' (a copy of which is provided also clearly requires that promotional materials, which have been created at a Global level, must be reviewed at the local level prior to dissemination at that level. This same principle is also reflected on page 13 of the standard operating procedure titled 'Novartis Pharma Global Materials Clearance Committee (GMCC) Review and Approval' (a copy of which is provided).
As a more general point, Novartis Global is aware that the requirements of the ABPI Code are more stringent than the regulatory requirements under the EFPIA Code and other European countries' local frameworks.

The local team have proactively created documents to ensure that when Global teams engage with UK healthcare professionals, the requirements of the ABPI Code are followed, such as the training slide deck *'Guideline to Engaging with or in the UK - 2021 ABPI*' . This guideline is proactively shared with global teams when they approach the UK to engage either in or with UK based healthcare professionals. The guideline was first created in July 2021 and has since been revised, with the latest version being created in August 2022.

The Novartis Global Medical Affairs team has previously issued guidance and delivered training on the specific topic of working with third party educational providers which contains a copy of a training slide deck created in August 2022 (updated in October 2022). Within this deck Slide 8 is dedicated to UK-specific considerations, demonstrating an understanding by the Global team that certain Global activities may not be permitted or appropriate in the UK. Of particular note, the training specifically states for medical education programs:

- not to target the UK (or any other country) audiences specifically if the 'global' content would not be acceptable there;
- the UK definition of 'promotion' is stricter than EFPIA;
- global associates need to have slides and content approved by the UK team if UK audiences are being targeted; and

- geo-blocking the UK is recommended where Novartis is responsible for the content and the content would be deemed inappropriate in the UK.

Novartis Global has also produced dedicated guidance on what should be considered when Novartis proposes to have its content hosted on the website of a third party. Please see Enclosure 6 which contains a copy of this guidance. Slides 10 and 11 of this guidance make clear that the UK should be geo-blocked from content that has not been locally approved.

As part of self-regulation under the Code in the UK, Novartis UK has a robust and structured method for the review and approval of our materials and activities, which includes experienced signatories working collaboratively within brand teams to ensure compliance to our material certification SOP and ABPI Code of Practice. Had the materials come under the rigorous view of the Novartis UK team, then they would have been challenged accordingly.

We have included some examples of how the interaction between Novartis UK and Novartis Global normally occurs, in order to demonstrate how the process should work in practice. In all of the matters referred to in Enclosure 7, following the interaction with the local team, Novartis Global confirmed that the UK would not be targeted by these highlighted campaigns.

However, as Novartis UK was not consulted on this occasion prior to the materials being made available due to human error, it did not have the opportunity to review and provide direction to Novartis Global. Had the Novartis UK team been consulted:

(i) Novartis UK would have confirmed that the materials are not suitable for a UK audience; and
(ii) Novartis Global would have arranged for the UK to be geo-blocked, or specifically removed the UK from the list of countries to be geo-targeted by the campaign.

3. The ESMO 2023 Conference [third party medical publisher's product]

The Complaint refers to a section of the [third-party medical publisher's] Global website providing a conference [third party medical publisher's product] of ESMO 2023 (the '**Conference [third party medical publisher's product]**').

The Conference [third party medical publisher's product] consisted of a combination of [third party medical publisher's parent company] editorially developed programs, as well as Pluvicto® (lutetium (177Lu) vipivotide tetraxetan) advertising material and content provided by Novartis Global.

Novartis Pharma AG has entered into a Master Services Agreement with [the third party medical publisher's parent company]. The services concerned by this Complaint were delivered under a Statement of Work between Novartis Global and [the third party medical publisher's parent company]. For completeness, a copy of the Statement of Work has been provided.

In the context of the specific elements referred to by the complaint, Novartis acknowledges that the 'Description of Services' in Section C of the Statement of Work does not clearly delineate exactly which elements have been paid for by Novartis Global and/or where Novartis Global has had input or control over the materials concerned by this Complaint.

[The third party medical publisher's parent company] have confirmed that [third-party] hosts many pages in a similar style and format to the Conference [third party medical publisher's product] at issue in the complaint, covering other conferences and events. Some of these contain advertising and promotional materials paid for by pharmaceutical companies, but not all. A prior agreement with a pharmaceutical company to advertise or provide additional content on a Conference [third party medical publisher's product] page does not dictate whether or not [the third party medical publisher's parent company creates such a page.

Novartis has worked with [third-party] to establish the delineation between:

1. '**[third-party medical publisher]-Controlled Content**' which is content which [the third party medical publisher's parent company] has independently created, with no payment by Novartis, and over which it had sole editorial control. [third-party medical publisher] does not allow any content that has received input from a pharmaceutical company to be published on its site without an adequate disclaimer. [third-party medical publisher]'s position is that to do so would be misleading for [third-party medical publisher]'s audience and create a sub optimal user experience, both of which could impact on [third-party medical publisher]'s reputation; and

2. '**Novartis-Controlled Content**' is content that Novartis Global has:
    a. paid for; and/or
    b. had input on; and/or
    c. had editorial control of.

    In accordance with [third-party]'s position set out above, such content will make clear that it has received input from or been paid for by a pharmaceutical company.

In an email exchange between Novartis and [third-party medical publisher]'s Vice President of Client Services and Operations, the content which is Novartis-Controlled Content and that which is [third-party medical publisher]-Controlled Content has been determined.

This is set out in Table 1 below which follows a marked-up version of the elements of the webpage and email shared by the complainant, referred to as Figures 1 to 4 below.

NB. Within Figures 1-4 below, red boundaries indicate elements which are [third-party medical publisher]-Controlled Content (as defined further below) and green boundaries indicate elements which are Novartis-Controlled Content (again, as defined more fully below)

Figure 1

[Screenshot provided]

Figure 2

[Screenshot provided]

Figure 3

[Screenshot provided]

Figure 4

[Screenshot provided]

Table 1

Name of material	**Reference in Figures 1 to 4**	**Editorial control of material**
Video titled 'Practice-Changing Data in Prostate Cancer From ESMO 2023' (the '**Conference [third party medical publisher's product] Video**').	Figure 1: Red Item 1	[third-party medical publisher]-Controlled Content Content independently created and controlled by [third-party medical publisher]. [third-party medical publisher] has highlighted that the Conference [third party medical publisher's product] Video also carries a disclaimer demonstrating that the expert contributor had full autonomy in creating the content: 'Any views expressed above are the author's own and do not necessarily reflect the views of [the third party medical publisher's parent] or [third-party medical publisher]'. Novartis Global did not pay for this content, nor did it have any control over the content, speakers or topic selection for the Conference [third party medical publisher's product] Video.
Article titled 'Practice-Changing Data in Prostate Cancer From ESMO 2023'	Figure 1: Red Item 2 Figure 2: Red Item 2	[third-party medical publisher]-Controlled Content Content produced by [third-party medical publisher] to summarise the Conference [third party medical publisher's product] Video.

(the '**Conference [third party medical publisher's product] Article**')		Novartis Global did not pay for this content, nor did it have any control over the content.
Clinical Insights email, 'Key Prostate Cancer Studies from ESMO 2023' (the '**[third-party medical publisher] Email**')	Figure 3: Red Item 3	[third-party medical publisher]-Controlled Content Content produced by [third-party medical publisher] to publicise the Conference [third party medical publisher's product] Video. Novartis Global did not pay for this content, nor did it have any control over the content.
Pluvicto Promotional Banner Adverts on the Conference [third party medical publisher's product] webpage (the '**Pluvicto Banner Advert**')	Figure 1: Green Item 2 Figure 4: Green Item 2	Novartis-Controlled Content Novartis Global reviewed and approved this promotional asset as a standalone asset in line with EFPIA Code requirements. Novartis Global paid for the banner adverts to be placed on the Conference [third party medical publisher's product] webpage. Novartis Global did not intend for the Conference [third party medical publisher's product] webpage to be highlighted to UK HCPs.
Video on the Conference [third party medical publisher's product] webpage, 'The Vision Study' (the '**Vision Study Video**')	Figure 1: Green Item 1	Novartis-Controlled Content Novartis Global reviewed and approved this promotional asset as a standalone asset in line with EFPIA Code requirements. Novartis Global paid for the Vision Study Video to be placed on the Conference [third party medical publisher's product] webpage. Novartis Global did not intend for the Conference [third party medical publisher's product] webpage to be highlighted to UK HCPs.
The section titled 'Resources' on the right-hand side of	Figure 1: Green Item 3	Novartis-Controlled Content

the Conference [third party medical publisher's product] webpage (the '**Resources**')		Novartis had editorial control over this section and supplied links to be included in the Resources section.

Intended audience for the Conference [third party medical publisher's product]

In so far as the Novartis-Controlled Content was intended to be used within Europe, its exposure was intended to be limited to healthcare professionals who:

(i) have registered through the [the third party medical publisher's parent company] network;
(ii) are practising in the **European Union** ('**EU**'); and
(iii) who specialise in haematology, oncology, nuclear medicine (or in the case of Germany, who specialise in urology), or have recently interacted with prostate cancer content through the [third-party medical publisher]'s platform.

That the Novartis-Controlled Content was intended to be accessible to EU HCPs only is supported by the following features of the Pluvicto Banner Advert:

(i) the references to approval of Pluvicto in the **European Union**;
(ii) the use of the **EU licensed indication**; and
(iii) the inclusion of a link to the **EU Summary of Product Characteristics** for Pluvicto.

Similarly, the Vision Study Video displays the **EU version of the SmPC** for Pluvicto.

However, rather than being restricted to an audience of healthcare professionals practising in the EU, the material was instead instructed to be made available to HCPs practising in 'Europe'. This was an unfortunate human error by a Novartis Global associate.
Within Novartis, 'Europe' is used to mean the 33 member countries of EFPIA as per clause 1.6 of the ABPI Code (therefore including the UK). [The third party medical publisher] use the term 'Europe' similarly (specifically in this case, to include the UK).

Regrettably, a Novartis Global associate mistakenly used the term 'Europe' when instructing [the third party medical publisher] on the location of HCPs to target, rather than specifying only those HCPs working within the European Union. This can be seen in clause 9 of Part I, Section C of the Statement of Work. This error is the root cause of the material being made available to healthcare professionals practising in the UK. Unfortunately, [third-party medical publisher] did not question this instruction.

This targeting error is the root cause of how the material came to the attention of the UK HCP who has made the current complaint.

As the material was not intended to target HCPs practising in the UK, the Novartis Global processes identified above to identify UK-facing material were not applied, and the requirement to consult with and gain prior approval from the Novartis UK team was not undertaken.

3.3 Novartis' responses to the alleged breaches

Novartis fully acknowledges and accepts that the mistake identified above should not have happened. However, the fact that it did has led directly to the unfortunate situation of an audience of UK healthcare professionals being able to access information that Novartis did not intend for them to see.

Any breaches of the ABPI Code that the PMCPA may find are a consequence of this disappointing human mistake. Novartis accepts full accountability for these occurring.

As set out above, at the prompt request of Novartis upon receiving this complaint, [third-party] immediately removed the Novartis-Controlled Content from the [third-party medical publisher] [third party medical publisher's product] webpage.

As requested by the PMCPA, we have borne in mind the requirements of Clauses 2, 5.1, 5.5, 6.1, 11.2, 12.1, 12.10 and 15.6 of the Code and set out additional context that we hope the PMCPA will find informative when considering this Complaint.

Clauses 5.5 and 6.1

The complainant's assertion that '*there is absolutely no mention of funding or sponsorship or industry involvement mentioned on the actual webpage*' is factually incorrect. As noted above, the Novartis-Controlled Content was identified as an 'Advertisement' or 'Information from Industry' in accordance with [the third party medical publisher's parent company]'s practices. While this identification was present, Novartis fully accepts that it was not sufficient to meet the requirements of clause 5.5 of the Code.

Novartis was aware that a Conference [third party medical publisher's product] Video would be prepared by [third-party] but, as explained above, this was created under [third-party medical publisher]'s sole editorial control and without funding from Novartis.

The complainant has made reference to the duration of the Conference [third party medical publisher's product] Video in comparison to the Vision Study Video. Novartis refutes the argument (upon which premise the complainant appears to base their complaint) that the length of a video should dictate whether or not the content is balanced. Whether or not an asset is balanced should be determined by reference to the content itself. As confirmed by [third-party medical publisher], it is the expert's decision as to what they want to discuss within this [third-party]-Controlled Content. [Third-party medical publisher] have explained that it provides a briefing to experts beforehand to ensure that the content is in line with [third-party medical publisher]'s best practices and policies (i.e. that the content is fair and balanced etc).

Novartis Global was aware that the Novartis-Controlled Content (which had been reviewed and approved on a standalone basis) would be displayed around the [third-party

medical publisher]-Controlled Content, but the final layout was not reviewed and approved. The positioning of these materials is very disappointing to Novartis UK in circumstances where the material has been disseminated to UK HCPs in error. Had the material been intended for a UK audience, this would have been identified and corrected as part of the final form certification by a UK final medical signatory.

The complainant alleges that the banner refers to '*now approved in the UK*' and notes in this regard that '*It was approved on the 9 of December 2022, more than a year ago*'. The banner actually states that Pluvicto is 'now approved in the EU'. It does not assert that Pluvicto is now approved in the UK; therefore, this is a factually inaccurate assertion by the complainant.

Clauses 11.2 and 12.1

Novartis agrees with the complainant's assertion that the Novartis-Controlled Content does not contain: (i) the UK Prescribing Information; (ii) the Summary of Product Characteristics for Pluvicto; (iii) the UK licensed indication for Pluvicto; or (iv) the UK list price for Pluvicto. As explained above, the material was intended for healthcare professionals in the EU and not the UK. Novartis accepts a breach of these clauses as a result of this targeting mistake arising from human error.

Clause 12.10

Due to the same reason as above, Novartis agrees that the material does not meet the requirements of Clause 12.10.

Clause 15.6

Novartis recognises that the [third-party medical publisher] Email could have been clearer from the outset that it will direct the recipient to view promotional content. However, the [third-party medical publisher] Email does expressly refer to it being promotional in nature and, as such, by following the link an HCP might reasonably expect to be directed to promotional content. In any event, the [third-party medical publisher] Email was not Novartis-Controlled Content and Novartis' position is that it should not be deemed to be responsible for content that it neither paid for nor had a right to review and which would have been created and disseminated even without the involvement of Novartis in other aspects.

Clause 5.1

As the Conference [third party medical publisher's product] material was made available to a UK audience inadvertently, the appropriate process was not followed and therefore it did not undergo review by Novartis UK for compliance with the Code. Novartis UK accepts the consequences that flow from that mistake, including that high standards were not maintained in this instance.

Clause 2

Novartis fully appreciates the seriousness of the Complaint. The relevant material was never intended for an audience of UK healthcare professionals. Novartis fully accepts any breaches of the Code that the PMCPA adjudicate to have taken place, where these are the consequence of the Novartis-Controlled Content reaching a UK HCP. However, Novartis does not believe that a human error of the type made in this matter should result in a breach of Clause 2 of the Code being established in these specific circumstances.

As identified in section 3.2 above, Novartis has a robust compliance framework, with clear policies in place governing the creation of promotional and non-promotional materials by Novartis Global associates. Novartis has recently implemented a new Global policy 'Doing Business Ethically' (effective as of 1 November 2023). The policy underpins the way in which we do business at Novartis and aims to ensure that we maintain high ethical standards in all our external interactions. Novartis is very disappointed that a targeting mistake and failure of an individual associate to follow our policies has led to this Complaint. Lessons have been learnt by the Global team leading on this project and this will be followed up with additional training for the individuals involved on the relevant Novartis policies and processes.

Although the material did not contain the relevant prescribing information or licence for a UK audience (due to the fact that this was never intended for a UK audience), the licensed indication for Pluvicto in the EU is in fact narrower than the licensed indication in the UK with more stringent dose modification recommendations and more safety monitoring criteria. Patient safety was therefore not compromised by inadvertently referring to the EU SmPC rather than the GB SmPC.

It is also of note that Pluvicto can only be prescribed by a UK HCP with experience in prescribing nuclear medicines. Further, a full multi-disciplinary consultation is required before a prescribing decision will be taken. There are a small number of such specialist HCPs in the UK that can prescribe Pluvicto and it is reasonable to assume that these specialists would be aware of the licensed indication for Pluvicto in the UK.

For these reasons, Novartis does not believe that patient safety was impacted as a result of this targeting error.

As a sophisticated pharmaceutical company operating all over the world, Novartis understands the intricacies of the varying regulatory frameworks across jurisdictions and the importance of appropriately localising materials and campaigns created at an above country level. Novartis is constantly adapting to ensure that its processes are fully aligned to the regulatory requirements and goes to great efforts to ensure that Novartis Global associates are aware of the varying intricacies of the local regulatory frameworks within which Novartis operates.

Key senior stakeholders (including the Novartis UK Head of Legal, Novartis UK Head of Ethics, Risk and Compliance, Novartis UK Chief Medical Offer, Novartis Head of Ethics Risk and Compliance and the Head of Legal for International – Region Europe) have been involved in investigating the circumstances that have given rise to this complaint, gathering the requested information, coordinating the response to this Complaint and considering what steps can reasonably and proportionately be taken to minimise the likelihood of such a situation arising again. These key senior stakeholders have asked for

it to be made known that they are incredibly concerned that this situation has come to light. Additionally, Novartis UK is very disappointed that this situation has occurred due to circumstances outside of its control. As a company, Novartis seizes opportunities to re-educate associates on the key compliance frameworks within which the company operates and proactively disseminates learnings from mistakes, such as the one concerned by this Complaint, in order to minimise any risk of recurrence. Novartis UK commits to continue its efforts in the ongoing reinforcement of the Code and to re-educate associates working on globally-led campaigns on the Code requirements.

The complaint that has led to this case has arisen because of human error. Even with a robust compliance framework in place, human errors will inevitably occur, and Novartis hopes that the PMCPA understands this. Novartis does not believe that this human error has brought discredit upon, or reduced confidence in, the pharmaceutical industry.

With regards to the queries raised in your letter dated 13 December 2023:

(i) **A colour copy of the materials at issue**: these are provided ((i) Enclosure 12 for a copy of the [third-party medical publisher] Email, the Conference [third party medical publisher's product] Article and the Pluvicto Banner Advert; and (ii) a copy of the Vision Study Video). Please note that it has not been possible to provide a separate file of the Conference [third party medical publisher's product] Video which forms part of the [third-party medical publisher]-Controlled Materials. However, this video is still available on the relevant [third-party medical publisher] webpage and can be accessed at [link provided];

(ii) **Details as to how the materials were used, the intended audience and to whom the email was distributed**: please see section 3 of our response;

(iii) **Copies of the certificate(s) approving the materials in question**: as explained in this letter of response, the material was not intended for a UK audience and has therefore not been approved locally. The Novartis-Controlled Content was reviewed and approved by Novartis Global as promotional assets. Copies of the Novartis Global record of approving the Novartis-Controlled Content under the EFPIA Code has been provided; and

(iv) **Pluvicto (lutetium (177Lu) vipivotide tetraxetan) Great Britain SPC (Summary of Product Characteristics**: Great Britan SPC

4. Conclusion

Novartis UK and Novartis Global take their responsibilities under the Code extremely seriously. Significant resources are invested to ensure its associates develop a deep understanding of the requirements of the Code, that local and global policies are in accordance with the Code and that these contain appropriate checks to ensure that where mistakes happen, these are likely to be caught prior to material being available outside Novartis. The Conference [third party medical publisher's product] material concerned by this Complaint was never intended for a UK healthcare professional audience and should not have been disseminated as it was. Novartis accept the Code breaches found by the

PMCPA as a consequence of this content reaching a UK audience, due to the targeting error.

Human error and the isolated actions of one single employee who has failed to follow our policies and provide appropriate targeting instructions does not, and should not, reflect the diligent efforts that Novartis and its associates make to ensure that the conduct of the company accords with the highest standards and therefore complies with the requirements of the Code."

PANEL RULING

This complaint was submitted by a complainant who described themselves as a doctor based in the UK and initially concerned the receipt of an email from a third-party medical publisher where the email address and subject line suggested the recipient would be receiving an unbiased update regarding the European Society for Medical Oncology ('ESMO') conference in 2023. The complainant also alleged that the promotional intent of the email was only identified at the end of the email.

The complainant subsequently alleged that the email referred to above contained a link to a webpage – the webpage contained two embedded videos and banner advertisements for Pluvicto. It was alleged that:

- Novartis were disguising their promotion of Pluvicto through the third-party medical publisher email, 'Vision' video, resource section on the linked webpage and the banner advert included on the linked webpage;
- The email, Vision video and resource section on the linked webpage did not contain a declaration of the company's involvement;
- The 'Vision study' video did not contain UK prescribing information, a UK licensed indication or the inverted black triangle;
- The '[third party medical publisher's product]' video promoted Pluvicto outside of its license indication; and
- The banner advertisement contained the term 'now approved' and reflected the EU Summary of Product Characteristics (SPC) rather than the UK version.

The Panel noted that the materials at issue were produced by Novartis Global and in this regard, Novartis UK acknowledged that it was a well-established principle under the Code that UK companies were responsible for the acts or omissions of overseas parents or affiliates that come within the scope of the Code. In this regard, the Panel noted that Novartis UK were not consulted prior to the materials being made available to a UK audience and this was due to a human error.

The Panel further noted that the PMCPA was dealing with a series of cases that involved the third party medical publisher in question and various companies. The allegations and evidence provided in each case differed and thus consequentially the rulings. Each case was considered independently on the evidence before each Panel.

<u>General comments about the Email and linked webpage</u>

The Panel noted that the email in question was dated 21 November 2023 and was sent from the following email address: [named medical publisher] Clinical Insights<clinical insights mail.[named medical publisher].com. The subject heading read 'ESMO 2023: Prostate Cancer

Update'. The body of the email was headed 'Key Prostate Cancer Studies From ESMO 2023' and provided brief bullet pointed details of five studies discussed at ESMO and referred to in the conference [third party medical publisher's product] video by a named doctor. Beneath, a link labelled 'Watch now', linked to the third party medical publisher webpage containing the [third party medical publisher's product] video and other materials, rather than directly to the [third party medical publisher's product] video as implied by the email. Beneath the outline blue box containing the substantive email text, at the bottom of the continuously scrolling email in very small font size was 'This promotional communication is provided by [named publishing company] Professional Services'.

The Panel noted that the linked webpage at issue provided by the complainant was headed '[medical publisher] Oncology' and featured adjacent links to both the Vision video and the [third party medical publisher's product] video. It appeared that the complainant had provided a copy of the webpage on which the Vision video was playing and therefore the display screen for the Vision study video appeared above the video tabs. Beneath the display screen sat adjacent links to both the Vision video and the [third party medical publisher's product] video. The [third party medical publisher's product] video link sat above associated text which read 'Practice Changing Data in Prostate Cancer from ESMO 2023'. The adjacent Vision study tab read 'The Vision study tab ^{177}Lu-PSMA-617 for PSMA- positive Metastatic Castration Resistant Prostate Cancer' and immediately beneath in small orange font 'Information from industry' and 'Significant Risk Reduction in PSMA +mCRPC'. The latter two statements also appeared as part of the display screen for playing the video. A Pluvicto advertisement sat to the right of the embedded videos section. The prominent heading 'Practice-Changing Data in Prostate Cancer From ESMO 2023' to an article briefly summarizing the [third party medical publisher's product] video appeared beneath the video tabs. To the right of the article was an outlined box headed in small grey font size 'Information from Industry', above the main heading 'Resources' in a larger and more prominent font size. This was followed by three paragraphs that appeared to be links which referred to: understanding the relevance of PSMA; seeing the difference with Pluvicto; and understanding the potential of PSMA PET imaging. A second banner advertisement for Pluvicto appeared at the bottom of the continuously scrolling webpage.

The Panel noted that the webpage provided by Novartis was headed 'the heart org [name of third-party medical publisher] cardiology' but otherwise appeared to be closely similar to that provided by the complainant. The Panel made its ruling on the version provided by the complainant.

The Panel noted Novartis' submission that the Conference [third party medical publisher's product] project consisted of a combination of the third-party medical publisher's editorially developed programs, as well as Pluvicto advertising material and content provided by Novartis Global. Novartis submitted that it had worked with the third-party medical publisher to establish the delineation between Novartis and the third party medical publisher's controlled content. It was of concern to the Panel that email correspondence provided by Novartis showed that this was done in response to the complaint rather than when the contractual arrangements were agreed, and the material was approved; it was difficult to understand how the material could be approved in the absence of such clarity. It was of further concern to the Panel that Novartis acknowledged that the 'Description of Services' in Section C of the Statement of Work between Novartis and the third-party medical publisher did not clearly delineate exactly which elements had been paid for by Novartis Global and/or where Novartis Global had input or control over the materials at issue. It appeared that Novartis and the third-party medical publisher now

considered that Novartis was responsible for the two Pluvicto advertisements, the Vision video and the Resources section.

The Panel noted that Novartis accepted certain breaches of the Code, explaining that within Novartis, “Europe” is used to mean the thirty-three member countries of EFPIA as per clause 1.6 of the ABPI Code (therefore including the UK) and that the third-party medical publishing company use the term “Europe” similarly (specifically in this case, to include the UK). A Novartis Global associate mistakenly used the term ”Europe” when instructing the third party medical publishing company on the location of health professionals to target. Novartis stated that this could be seen in clause 9 of Part I, Section C of the Statement of Work which the Panel noted described the target audience as “physicians who practice in Europe or Canada and who specialise in Hematology/Oncology, Urology (Germany only) or Nuclear Medicine, or have consumed Prostate Cancer content”. Europe did not appear to be defined in the contractual material available to the Panel.

The Panel noted the differences between the UK and EMA licensed indication. In the UK, Pluvicto was licensed for the treatment of adult patients with prostate specific membrane antigen (PSMA)-positive -metastatic castration-resistant prostate cancer who have been treated with androgen receptor (AR) pathway inhibition and taxane based chemotherapy or who are not medically suitable for taxanes. The Panel noted that the EMA Pluvicto licence was similar but only for combination treatment with androgen deprivation therapy, and when the cancer was progressive.

Disguised promotion

The Panel firstly considered disguised promotion and the impression created by the email bearing in mind the allegation that the email should make it clear that it was paid for by Novartis and not disguise their involvement. The Panel noted its description of the email above and that neither the sender email address and subject line nor email content referred to Novartis. The Panel noted that the sender and sender email address each referred to ‘Clinical Insights’ and the subject line read ‘Prostate Cancer Update’. The Panel considered that the impression given by the email was that it linked directly to a video which was a non-promotional clinical update on prostate cancer studies from ESMO and that was not so. The Panel noted that Novartis recognised that the email could have been clearer from the outset that it would direct the recipient to view promotional content, and noted that on viewing the webpage readers would see at the outset promotional banner advertisements for Pluvicto. The statement ‘This promotional communication is provided by [third-party medical publisher]’ at the very bottom of the email in very small font beneath the unsubscribe details was insufficient in terms of content and location to negate the initial misleading impression.

The Panel had to decide whether Novartis had any responsibility for the email. In the Panel’s view, noting the terms of the contract, Novartis were aware at the outset that drivers such as emails would be used by the third-party medical publishers to recruit a target audience to the webpage which would include, among other things, its promotional advertisements. Given the reference to ESMO and the nature of scientific data presented at such conferences in the Panel’s view it was reasonably foreseeable that a summary of the data presented would include reference to the unlicensed use of Novartis’ products. In addition, Novartis was aware, as set out in the statement of works, that its company material would be integrated into the webpage at issue. In the Panel’s view, given the high compliance risk potentially associated with such integration Novartis should have ensured among other things when negotiating the contractual

terms that at the very least, they had sight of such emails to ensure compliance with relevant Codes. The emails and drivers to Novartis' material could be described as an integral part of the contract. The Panel also queried whether the email could fairly be described as wholly at arm's length. To permit companies to have absolutely no responsibility in these particular circumstances might allow them to wholly circumvent the requirements of the Code. The Panel considered that relevant responsibilities might include a declaration of sponsorship and any impression given in relation to company materials.

On balance, bearing in mind its comments above the Panel considered that Novartis had certain responsibilities for the email and decided it was therefore responsible for the misleading impression given by the email address and email subject line and the impression that it linked directly to a non-promotional video rather than to a webpage containing promotional material including banner advertisements, the promotional nature of which was thereby disguised. The Panel ruled a **breach of Clause 15.6** accordingly in relation to each of the email and banner advertisements.

The Panel then considered disguised promotion and the other material on the linked webpage. The Panel noted the content and layout described above including that the two Pluvicto banner advertisements at the top and bottom of the webpage were labelled 'Advertisement' in very small font beneath each and were clearly promotional in style and content, irrespective of the impression given by the email and considered that they were covered by the Panel's ruling above in relation to the email.

In the Panel's view, the delineation between Novartis' other material (Vision video and the Resources section) and the third-party medical publisher's material was not otherwise sufficiently clear; the reference to 'information from the industry' was neither accurate nor sufficiently prominent; it did not identify the pharmaceutical company and compounded the initial impression given by the email that the linked material was a clinical update and non-promotional which Novartis had submitted was not so in relation to the Vision video. The Panel did not have copies of the linked information in the Resources section but noted from the titles that the content appeared to be promotional.

The Panel further considered that the Vision video and Resources section appeared to be an integral part of the non-promotional/information parts of the webpage. This was consistent with the Statement of Works, Section C Description of Services which described ADACAP (Novartis) material as 'integrating' within the third party medical publisher's editorially developed conference [third party medical publisher's product] program hosted on the site. Novartis submitted that its material was approved on a standalone basis, the final layout was not reviewed and approved even though Novartis Global was aware that company material would be displayed around the third party medical publishers' content. Novartis submitted that the positioning of these materials was very disappointing.

Given its comments above, the Panel considered that the Vision video and the Resources section were disguised promotional material. The initial impression given by the email irrespective of Novartis' responsibility for it was that the linked webpage was entirely non-promotional and that was not so. Further, and irrespective of that initial impression, on viewing the page it was not clear at the outset that the Vision video and Resources section were promotional and were Novartis' materials. The materials were disguised in this regard and the Panel ruled a **breach of Clause 15.6** in relation to each of the Vision video and the Resources section.

The Panel considered that the matter of disguised promotion and the banner advertisements was covered by its ruling above in relation to disguised promotion and the email.

Declaration of involvement

In relation to the email the complainant alleged that it did not state which company was paying for it and surely Novartis should declare its involvement upfront. In relation to the webpage the complainant stated, "there is absolutely no mention of funding or sponsorship or industry involvement mentioned on the actual webpage".

Clause 5.5 required, amongst other things, material relating to medicines and their uses whether promotional or not 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.

The Panel noted its comments above in relation to disguised promotion and certain responsibilities Novartis had for the email and considered that they applied here. The [third party medical publisher's product] programme in question was sponsored by Novartis and included materials produced by the third party medical publisher. Bearing in mind the importance of transparency, the Panel considered that the email ought to have included a declaration of sponsorship and **ruled a breach of Clause 5.5** of the Code.

The Panel then considered whether a declaration of sponsorship ought to have appeared on the webpage. The Panel noted Novartis' submission that its controlled content was identified as an 'Advertisement' or 'Information from Industry' in accordance with the third-party medical publisher's practices. While this identification was present, Novartis fully accepted that it was not sufficient to meet the requirements of Clause 5.5 of the Code.

The Panel considered that the declaration of involvement should cover all materials clearly covered by the sponsorship agreement on the webpage and that therefore the Vision video tab and Resources section ought to include a declaration of involvement and ruled **a breach of Clause 5.5** of the Code was ruled in relation to each item.

Vision video

The Panel noted the complainant's allegation that the Vision video did not contain the UK prescribing information, the UK price, the UK licensed indication or the inverted black triangle. The Panel noted that Novartis accepted that it was responsible for the Vision promotional video and that it was intended to be accessible to health professionals practising in the European Union only. The Panel noted Novartis' explanation about the distribution of the linked email to UK health professionals.

The Panel noted that the video contained the EU prescribing information and did not include an inverted black triangle as required by Clause 12.10. The Panel noted that the UK price was a mandatory element of UK prescribing information. The Panel noted that Novartis accepted breaches of the Code in this regard and the Panel accordingly **ruled a breach of Clause 12.1** in relation to the failure to provide UK prescribing information including the UK cost and **a breach of Clause 12.10** in relation to the failure to include the inverted black triangle.

In relation to the allegation that the video did not contain the UK licensed indication the Panel noted the differences between the UK and EU licensed indications as set out in its general comments above. It noted that the Novartis video provided an overview of the Vision study, a randomised multicentre, open-label phase 3 study to evaluate the efficacy and safety of Pluvicto in patients with progressive, PSMA-positive mCRPC. The video covered the study design (inclusion and exclusion criteria, treatment protocols for each arm, primary and secondary endpoints, baseline characteristics), the efficacy results for each endpoint were provided together with those for safety and tolerability. The Panel noted the Vision study was the pivotal registration trial for Pluvicto and was included in sections 4.8 and 5.1 of the UK SPC. Nonetheless, the Panel considered that the differences between the UK and EU licensed indications were such that for a UK audience the licensed indication should have been made clear and the material should have been consistent with the UK licensed indication. A **breach of Clause 11.2** was ruled.

Banner advertisement

The Panel noted the allegation that concerned the banner advertisement at the top right hand corner of the webpage.

The complainant noted that the advertisement read 'Now approved in the UK' and stated that it was approved on the 9th of December 2022, more than a year ago. The Panel noted that beneath the brand name, 'Now approved in the EU' appeared in prominent red font. The advertisement did not refer to approval in the UK as alleged and which Novartis submitted was a factually inaccurate assertion by the complainant. On the basis that the advertisement did not contain the claim in question and the similar claim which appeared in the advertisement 'Now approved in the EU' appeared to be correct, the Panel ruled **no breach of Clause 6.1** of the Code on this narrow point.

In relation to the allegation that the SPC was not the UK version, the Panel noted that a link to an SPC appeared in small font in the top left-hand corner of the advertisement. The Panel did not have a copy of the linked SPC but noted that both parties accepted that the linked SPC was the EU rather than the UK version. The complainant made no direct or indirect mention of the prescribing information in relation to this allegation, it appeared to be a distinct allegation about the SPC. The Panel therefore considered that Novartis had failed to maintain high standards in relation to the provision of the incorrect version of the SPC and **ruled a breach of Clause 5.1**.

In relation to the allegation that the licensed indication was from the EU the Panel noted that the advertisement in question featured three bullet points: "Progression following at least one ARPI; Progression following at least one taxane-based chemotherapy; and Confirmed PSMA+ metatastic disease". A red tick was superimposed on the bullet point symbol of the first two bullet points only. The bottom of the advertisement read 'for PSMA + mCRPC patients progressing following at least one ARPI and at least one taxane -based chemotherapy'. The Panel noted that there were differences between the UK and EU SPC as set out in the Panel's general comments above and Novartis acknowledged that its material promoted the EU rather than the UK licence. The Panel, noting the UK licensed indication, considered that the promotion of Pluvicto was therefore inconsistent with the relevant particulars listed in its UK SPC and ruled a **breach of Clause 11.2 accordingly**.

[third party medical publisher's product] video

The Panel noted the allegation that the [third party medical publisher's product] video was promoting Pluvicto outside of its licensed indication (outside of the UK, USA and EU licence) in relation to data from two studies discussed at ESMO 2023. The Panel did not have a copy of this video and noted that Novartis and the third-party medical publisher had agreed on receipt of this complaint that the [third party medical publisher's product] video was not Novartis material. The Panel also noted its general comments above about the lack of clarity in the Statement of Works. Whilst the Panel was concerned about the overall impression given by the webpage and its inconsistency with the UK licence the Panel on balance did not consider that it had been established that Novartis in the particular circumstances of this case could be held responsible for whether the clinical content of the [third party medical publisher's product] video complied with the Code and on this narrow point ruled **no breach of Clause 11.2 of the Code**.

Clause 5.1

The Panel noted its rulings of breaches of the Code set out above.

In considering whether the circumstances of this case indicated a failure to maintain high standards, the Panel noted Novartis' submission that there had been a breakdown in its internal processes such that appropriate processes had not been followed in relation to Novartis UK's review for compliance of the Code and that ESMO 2023 [third party medical publisher's product] material had been made available to a UK audience rather than being restricted to an audience of healthcare professionals practising in the EU as intended.

The Panel considered the difficulties that had arisen were foreseeable given Novartis' definition of Europe and potential differences between geographical and politically European countries and membership of EFPIA. Whilst some internal documents referred to the need for local approval they did not state why or explain the potential different meanings of the term European and thus it did not appear that this risk had been identified and managed. In such circumstances, the Panel did not consider that Novartis' explanation that the matter arose as a result of an error by one employee was a fair reflection of the situation.

The Panel was further concerned about governance noting Novartis' acknowledgement that the contract was not clear about certain matters and that the materials had not been reviewed and approved within the context of the webpage. This was of particular concern given new data and emerging scientific and clinical opinions were commonly discussed at international medical conferences and therefore it was foreseeable that the ESMO 2023 [third party medical publisher's product] webpage might contain references to the unlicensed use of the product and additionally the contract provided for certain Novartis material to be integrated within the page. In the Panel's view, Novartis ought to have been aware of the potential increased compliance risk associated with such arrangements and ensured that contractual agreements and internal governance allowed it to identify and manage any associated risk.

The Panel noted its comments above and considered that high standards had not been maintained as acknowledged by Novartis. The Panel ruled a **breach of Clause 5.1**.

Clause 2

The Panel noted that a ruling of a breach of Clause 2 was a sign of particular censure and reserved for such. The supplementary information to Clause 2 included prejudicing patient safety as an example of an activity that was likely to be in breach of this clause.

The Panel noted that the complainant had referred to the reputation of the industry, integrity and trust.

The Panel noted the differences between the UK and EU SPC set out above, noting that the EU licence was limited to combination treatment in those with progressive disease.

The Panel noted Novartis' submission that patient safety was not compromised by referring to the EU rather than the UK SPC as although the material did not contain the correct prescribing information or licence for a UK audience, the licensed indication for Pluvicto in the EU is in fact narrower than the licensed indication in the UK. The Panel also noted Novartis' submission that the EU licence had more stringent dose modification recommendations and more safety monitoring criteria than the UK SPC and the Panel queried whether this might be related to a potential higher risk associated with combination treatment in progressive disease.

The Panel queried whether the email included a potentially broad audience as according to the contract (Description of Services, Paragraph 9) the target audience would consist of [third-party medical publisher's parent company] members who were physicians practising in Europe or Canada, specialising in Hematology/Oncology, Urology (Germany only) or nuclear medicine, or who had consumed prostate cancer specific content. The Panel noted the contract also guaranteed several thousand visits to the Conference [third party medical publisher's product] content.

The Panel considered that patient safety was of the utmost importance and that health professionals should be able to rely on company produced material to be complete and unambiguous in this regard. The Panel noted that UK health professionals had received an email containing a linked webpage and embedded videos which clearly referred to the EU licence for Pluvicto from a well-known third party medical publisher and considered that some recipients might therefore at least initially consider that its content and in particular combination therapy in progressive disease was of particular relevance to UK health professionals and UK licensed use. There was potential for confusion.

Noting the complainant's allegations, all its comments and rulings above the Panel concluded, on balance, that the cumulative effect of the use of the incorrect SPC and potential for confusion, the circulation of the email to a broad audience, and the failures of the company's internal governance processes was such that Novartis had, on balance, reduced confidence in, and brought discredit upon, the industry and a **breach of Clause 2** was ruled.

During the consideration of this case, the Panel considered that companies should be on high alert when considering compliance and the integration of their material into third party material about medical conferences which was likely to discuss and/or promote off-licence indications of their products.

Complaint received **11 December 2023**

Case completed **23 April 2025**