CASE AUTH/3736/2/23

COMPLAINANT v ADVANCED ACCELERATOR APPLICATIONS

Alleged promotion of Pluvicto on company website

CASE SUMMARY

This case concerned information for the public on a company website which the complainant alleged was promotional and allegations that aspects of information on the website did not meet the requirements of the Code and in relation to Pluvicto's licensing status in Northern Ireland was out-of-date.

The Panel ruled a breach of the following Clauses of the 2021 Code for AAA's failure to ensure that information regarding a product's licensing status was accurate and a failure to maintain high standards in relation to governance of a website:

Breach of Clause 5.1	**Failing to maintain high standards**
Breach of Clause 6.1	**Providing inaccurate, out-of-date information**

The Panel ruled no breach of the following Clauses of the 2021 Code in relation to information provided to the public, the display of black triangles and the provision or omission of certain clinical information and the omission of a sign-in function:

No Breach of Clause 2	**Requirement that activities or materials must not bring discredit upon, or reduce confidence in, the pharmaceutical industry**
No Breach of Clause 5.1	**Requirement to maintain high standards**
No Breach of Clause 6.1	**Requirement that information must be accurate, up-to-date and not misleading**
No Breach of Clause 12.10	**Requirement to include the black triangle in promotional material**
No Breach of Clause 26.1	**Requirement not to advertise prescription only medicines to the public**

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 who described themselves as a health professional about a website produced by Advanced Accelerator Applications, a Novartis company.

COMPLAINT

The complainant stated that they would like to report an email they received on 2 February 2022 from Medscape titled - Promotional AAA - Visit the RLT Hub for more information on Pluvicto (lutetium (177Lu) vipivotide tetraxetan).

This email invited them to visit a website titled, RLT hub, to learn more about Pluvicto. After clicking on the link, a website opened with a pop-up that asked them to confirm whether they were a GB healthcare professional or a member of the public. After clicking that they were a healthcare professional, the website loaded.

The complainant stated that what caught their eye was the following bold statement – '**this page/content is for Great Britain healthcare professionals only. Pluvicto is not licensed in Northern Ireland**'. The complainant stated that this was not true. Pluvicto received EMA [European Medicines Agency] approval mid-December last year and thus had been licensed in Northern Ireland for more than two months. Looking at the bottom of the RLT [Radioligand Therapy] hub which was sponsored by AAA and it was last updated on 6 February 2023 [sic].

The complainant stated that this company was embarrassing the pharmaceutical industry by inviting people to visit a website that did not get their own licences right. Surely regulatory statements must be accurate and up-to-date at minimum?

The complainant queried where their colleagues based in Northern Ireland should go if this website was for GB healthcare professionals only? Could their colleagues trust anything on here if the licence statement was wrong?

Furthermore, at the very top of the website it stated this website was intended for GB healthcare professionals and to click on a link if you were a member of the public. This click led them to a 'public website', which only had the SPC [Summary of Product Characteristics], EPAR [European Public Assessment Report] and PIL [Patient Information Leaflet] for two prescription only medicines – Lutathera (lutetium (177Lu) oxodotreotide) and Pluvicto. The complainant stated 'This was blatant promotion to the public, surely? Members of the public, come here! Read about our two cancer treatments'.

A few other topics suggested this website was of low standard:

1. Black triangles seemed to be placed randomly around the website without consistency.
2. Although there was a register and sign in function, one did not need to sign in to access the website.
3. It stated that - Pluvicto targeted PSMA-positive cells, including prostate cancer cells. Yet it did not explain where else PSMA positive cells exist or the consequences of targeting these non-cancerous cells.

The complainant hoped PMCPA would look into this matter and that it would lead to a website of higher standard, considering the audience was medical professionals.

When writing to Advanced Accelerator Applications, the Authority asked it to consider the requirements of Clauses 2, 5.1, 6.1, 12.10 and 26.1 of the 2021 Code.

RESPONSE

Advanced Accelerator Applications stated that it took any complaint about its conduct or the content it produced very seriously and the company set out its response below.

Although the complaint did not directly specify which parts of the Code were said to be breached, the PMCPA had picked out the areas of the Code that Advanced Accelerator Applications should consider in its response to the complaint. Advanced Accelerator Applications was grateful for these areas of focus to be identified and the company had addressed these in its substantive response below.

Advanced Accelerator Applications noted that the tone taken by the complainant in this instance had been quite combative. The complaint contained several rhetorical questions and subjective opinions about the Advanced Accelerator Applications' web portal that were not directly linked to any asserted breach of the Code. As the complaint veered into general areas of quality and trust and the company had not been told to ignore these in its response, Advanced Accelerator Applications had had to invest significant resources into preparing a full defence to all matters raised in the complaint.

1. Background

Advanced Accelerator Applications stated that the RLT Hub was a promotional website now intended for UK Healthcare Professionals (at the time of the complaint it was intended for GB Healthcare Professionals only and the disclaimer stated as such). It was a website intended to host educational content on Advanced Accelerator Applications products, including Pluvicto. Content ranged from information on mCRPC [metastatic castration resistant prostate cancer] and PSMA [prostate-specific membrane antigen] including how Pluvicto worked and the supporting trial data. The maintenance of the RLT Hub (GB HCP Website and the Public Website at the time of complaint) was managed by a third party.

The complainant stated that they 'would like to report an email… received on 2 February 2022'. Advanced Accelerator Applications believed this was referring to the email sent on 2 February 2023 via the third-party Medscape. The email in question (the '**Email**') was sent to those who had consented to receive promotional emails from pharma companies through Medscape. It was restricted to Great Britain (GB) only, meaning that no one outside of GB would have received this email. It was also restricted to healthcare professionals who had recently interacted with prostate cancer content, ie. to those recipients who would deem the content relevant on the Medscape website. The email contained links to both the PI [prescribing information], as well as the homepage of the Pluvicto (Lutetium (177Lu) vipivotide tetraxetan) section of RLT Hub.

2. Summary of the Alleged Breaches

As requested, in responding to the complaint, Advanced Accelerator Applications bore in mind the requirements of Clauses 2, 5.1, 6.1, 12.10 and 26.1 of the Code.

3. Advanced Accelerator Applications Response

Advanced Accelerator Applications responses were given below:

Clause 26.1

('This click leads me to a 'public website', which only has the SPC, EPAR and PIL for two prescription only medicines – Lutathera and Pluvicto. This is blatant promotion to the public, surely? Members of the public, come here!')

The complainant alleged that Advanced Accelerator Applications was promoting to the public on the RLT Hub. Advanced Accelerator Applications strongly rejected this allegation for the reasons set out below.

Audience Validation

The RLT Hub was not actively optimized on search engines. The website was not advertised on any Advanced Accelerator Applications patient or public facing materials.

Entry to the website was not permitted until completion of an audience-validating landing page (the '**Landing Page**'). This Landing Page identified the visiting audience (GB Healthcare Professional or member of the public) and ensured selective redirection to the audience-appropriate page of the website. Specifically, the Landing Page, stated 'Welcome to the Radioligand Therapy Hub'; there was no product information, branding or promotional content on this page. The site visitor was required to confirm their 'GB Healthcare Professional' status before progressing onto GB Healthcare Professional-specific page of the website ('**GB HCP Website**') and therefore accessing product specific material. If a concerned public visitor had navigated to the GB Healthcare Professional RLT site in error by inappropriately selecting 'GB Healthcare Professional' option, efforts had been made to ensure the public was promptly re-directed to a public-appropriate page by inclusion of the header 'if you are a member of the public, please click here' at the top of the GB Healthcare Professional page. On selecting this link, the concerned public visitor was again taken to the Landing Page, stating 'Welcome to the Radioligand Therapy Hub', where audience status was re-confirmed. At this Landing Page, if the option of 'No, I am a member of the public' was selected (note the intentional response of the site visitor when making this choice), the visitor was taken to a public page of the website ('**Public Page**').

The RLT Hub was set-up correctly and managed the risk of any member of the public from accessing content that they should not see. It was compliant with Code and industry standards.

Requirements for Reference Information on Public Page

Clause 26.4 and the supplementary information (SI) to Clause 26 of the Code gave a very clear indication as to what must be included on a public facing material/webpage. Furthermore, information to the public could be categorised into one of three categories; Proactive information, Reference information or Reactive information. The Public Page fell into the category of Reference Information and as such, had the following requirements:

- Primary purpose was to be a library of resources.
- Could only be used for products with marketing authorisations.
- Non-promotional presentation.
- Considered good practice to have a minimum of; SPC, PIL, PAR.
- Could also include; registration studies used for the marketing authorisation (MA), material supplied for health technology assessment, medicines guides, information about diseases, information about specific medicines.

Other relevant sections of the SI were:

- Separate sections for public and healthcare professionals.
- Black triangle requirements.

The Public Page met all the criteria listed above, it contained 'reference information' (SPC, EPAR and PIL) for two radioligand therapies; which was not promotional in nature. No branding, indication or claims for the products were mentioned on this public page, which would, as per Case AUTH/3303/1/20 – Anonymous complainant v Vifor, and Case AUTH/3357/5/20 – Complainant v Colonis, suggest this page was promotional. Thus, provision of reference information by means of provision of SPC, EPAR and PIL was considered acceptable by the Code; inclusion on the RLT Hub website aligned with ABPI recommended good practice and ultimately posed no risk to the public in any way whatsoever. There was no obligation on Advanced Accelerator Applications to provide further information contrary to the understanding that the Complaint [sic].

Clause 12.10

('Black triangles seem to be placed randomly around the website without consistency')

Advanced Accelerator Applications rejected this allegation for the reasons set out below.

Clause 12.10 stated that 'The symbol **should** appear once and be located adjacent to the most prominent display of the name of the product.', rather than 'must'. Furthermore, the Code stated that 'Digital communications are also covered by this requirement, and the black triangle symbol should be located adjacent to the first mention of the product as this is likely to be considered the most prominent display of the name of the product. The size must be such that it is easily noticed.' The Code did not prohibit multiple black triangles and there was no case precedent around multiple black triangles, only missing black triangles. This was therefore read as guidance, rather than an absolute requirement to only have one black triangle on a page. In this case, the black triangle was present beside the first mention of the product name, and whilst it also appeared a number of other times on the website in question, it did not appear every single time the product name was mentioned, there was a valid rationale for this.

Also, a black triangle would be placed in a webpage naming convention which was then replicated across the whole site which resulted in it being replicated in a menu.

Advanced Accelerator Applications stated that it had taken the informed and considered decision to display the black triangle more than once due to the particular nature of digital content and bearing in mind digital content accessibility concerns. In reality, a user might view this webpage across different devices (tablet, mobile, phone); the user viewed content in different ways. More than one prominent display of the black triangle would ensure it was not missed depending on the frames captured by the various underlying technical platforms supporting the devices used to access the website. Different devices presented a different format and black triangles needed to be in multiple locations to meet the requirements to ensure visibility, for example reading from desktop vs mobile. The intention of placing these black triangles was to assure readers were notified of the black triangle regardless of the reading platform.

The first mention was located in different sections of the website, hence the need for black triangles in both the navigation menu and top of the page. The menu text, which included the

black triangle, had been replicated for consistency across various platforms in order to include the black triangle on first mention of each page.

Advanced Accelerator Applications firmly believed that Clause 12.10 had not been breached.

Clause 6.1

('Pluvicto received EMA approval mid-December last year and thus has been licenced in Northern Ireland for more than two months. Looking at the bottom of the RLT hub which is sponsored by AAA and it was last updated on 6 February 2023')

Advanced Accelerator Applications rejected this allegation for the reasons below.

The marketing authorisation date for GB was 10 August 2022. The marketing authorisation date for Northern Ireland was 9 December 2022 (EMA). European Commission approval was on 12 December 2022. Following granting of the marketing authorisation for Northern Ireland, Advanced Accelerator Applications initiated the process to begin update of the website and in doing so emailed the third-party to update the GB Healthcare Professional Website to change the statement in relation to Northern Ireland. This email chain was provided.

Advanced Accelerator Applications wished to highlight that whilst timely review or re-certification of regulatory statements (as defined by the complainant) were encouraged, there was no specific time-period in relation to review or recertification of updates of this nature. As explained in the internal re-certification dates above and below, the process of updating the website to accommodate NI marketing authorisation was underway prior to the date of complaint.

Advanced Accelerator Applications believed that in the circumstances, there were sufficient guardrails in place to mitigate any impact of this statement:

i. In order to get to this page a user would have confirmed that they were a GB healthcare professional, not a Northern Irish healthcare professional (or for that matter a healthcare professional based in the United States or China, or any other jurisdiction outside of GB). The material was not intended for the Northern Irish audience (or any other audience outside of GB) and therefore had no impact on patient safety and did not threaten inaccurate, unsafe GB product prescribing. The allegation therefore was unfounded.

ii. The Advanced Accelerator Applications brand team were in the process of updating the website and evidence had been provided to support this. The delay was due to the Northern Ireland PI not making it through approval until mid-January following licensing and subsequent updates to the Lutathera (lutetium Lu 177 dotatate) PI. This delayed the overall update of the website.

For the avoidance of doubt, the referenced statement of: 'last updated: 06/02/23 06:08:41' did not refer to medical certification of the website material, but to updates of non-certifiable material, none of which if changed would cause the material to differ from the certified version. No new certified material was deployed on this date and evidence had been provided to support this.

The website material reviewed by the complainant was certified on the 25 October 2022 . EMA granted the marketing authorisation to Pluvicto on 13 December 2022. Thus, the time of medical certification was pre-EMA marketing authorisation; the material was certified to accurately reflect the current evaluation of the marketing authorisation in Northern Ireland.

In response to the EMA marketing authorisation, an updated version of the website was uploaded into the Veeva approval system on the 11 January 2023, accounting for the holiday period. This updated version was certified on the 16 February 2023. Preparation of the website began shortly after the EMA update in mid-December 2022 indicating company responsiveness to the EMA regulatory update and demonstrating a timely effort to maintain an up-to-date and accurate website.

Statements on the Northern Ireland marketing authorisation should not influence, nor concern, a GB Healthcare Professional where product prescription should occur within GB-Health Authority regulations only (as much as any other statement of similar kind regarding and from a different jurisdiction); the approvals of other regulatory bodies should not 'complete' a Healthcare Professional's opinion on the therapeutic value of the medicine, and thus the statements offered on the website continued to comply with Clause 6.1 in offering material which was 'sufficiently complete to enable recipients to form their own opinion of the therapeutic value of the medicine'.

In addition, having already taken steps to assess that there was no patient safety impact, the Advanced Accelerator Applications brand team worked with the nominated signatory agency to ensure this would be updated across the entire site. Given that EMA marketing authorisation would convert a previously GB Healthcare Professional only website to a UK Healthcare Professional website, these considerations were multifaceted, involving several website changes; time had to be made to accommodate these updates. There were no turnaround times specified in the Code for these types of website updates. AAA therefore proceeded based on case precedent. Case AUTH/2960/6/17 – Hospital Doctor v A Menarini cites a 2-year re-certification mandate. Given that the RLT website remained within the case and SOP defined 2-year re-certification mandates, the content of updating the RLT website was within acceptable timeframes; particularly where no safety concern had been demonstrated for the Northern Ireland marketing authorisation statements.

Additional responses

('Although there is a register and sign in function, one does not need to sign in to access the website')

This statement was correct, a login was not required, the box to 'self-check' an individual was a healthcare professional was the minimum requirement, as set out in the Code, industry standard and case precedent. The process was set out above in the section 'Audience Validation' above.

('Looking at the bottom of the RLT hub which is sponsored by AAA and it was last updated on 6 February 2023.')

This statement required clarification. As above this update did not refer to medical certification of the website material. Any editorial, even the technical one would trigger the information about when it had happened as 'the last update', which was the case on 6 February 2023.

('It states that - Pluvicto targets PSMA-positive cells, including prostate cancer cells. Yet it does not explain where else PSMA positive cells exist or the consequences of targeting these non-cancerous cells.')

This statement required clarification. The claim that 'Pluvicto targets PSMA-positive cells, including prostate cancer cells' was not an inaccurate description of the product's mechanism of action.

As required by the Code, the product PI was available, one-click away, and contained all relevant information to ensure a healthcare professional could make a sufficiently complete 'opinion of the therapeutic value of the medicine' as per Clause 6.1. This included relevant safety information by means of warning/precautions and undesirable side effects. Describing the exact location of all PSMA positive cells throughout the body would be pharmacological and physiological detail beyond the scope of a website aiming to provide salient and readily accessible information on the product. Nevertheless, if the website visitor did require information on sites of PSMA-expression, there was capacity to contact the Advanced Accelerator Applications Medical Information Response team, or indeed, review the SPC which offered pharmacokinetic information on the biodistribution of Pluvicto and its primary uptake sites.

Furthermore, relevant safety information was additionally offered in the immediacy of the initial statement of 'Pluvicto targets PSMA-positive cells' via a link to 'safety profile and efficacy' which described pertinent adverse events (AE) data; thus the offending statement was paired with easily accessible comprehensive and unambiguous claims. A healthcare professional seeking information on the 'consequences of targeting non-cancerous cells' would be reasonably assumed to understand that this information substantiated 'treatment-related' side-effects/AEs, which was provided in 'safety profile and efficacy'.

Advanced Accelerator Applications stated that it was under no obligation under the Code to explain where else PSMA positive cells existed or the consequences of targeting these non-cancerous cells in the context of this website.

4. Clause 5.1

Advanced Accelerator Applications refuted any breach of Clause 5.1; high standards had always been maintained. Advanced Accelerator Applications had upheld the highest standards having considered the accessibility needs of any and all of its potential readers by placing the black triangle in multiple places to meet all of the requirements of Clause 12.10.

5. Clause 2

Advanced Accelerator Applications stated that it saw no evidence that the websites in question could bring discredit upon, or reduce confidence in, the pharmaceutical industry. Advanced Accelerator Applications did not accept a breach of Clause 2, which would be a severe finding in the context of this Complaint. Clause 2 Supplementary Information stated that 'Examples of activities that are likely to be in breach of Clause 2 include prejudicing patient safety and/or public health, excessive hospitality, inducements to prescribe, unacceptable payments, inadequate action leading to a breach of undertaking, promotion prior to the grant of a marketing authorisation, conduct of company employees/ agents that falls short of competent care and multiple/ cumulative breaches of a similar and serious nature in the same therapeutic area

within a short period of time.' Advanced Accelerator Applications had not committed any such breaches.

6. Conclusion

Advanced Accelerator Applications stated that it took its responsibilities under the Code extremely seriously and invested significant resources to respond to complaints. The view of Advanced Accelerator Applications was that there had been no breach of Clauses 2, 5.1, 6.1, 12.10 and 26.1.

Advanced Accelerator Applications stated that it had clearly demonstrated the robust processes in place to ensure websites were accessed by the appropriate audience and contained information relevant to that audience in accordance with the Code. Similarly, Advanced Accelerator Applications had a process in place for updating websites; as evidenced this process was well underway and had now been finalised.

PANEL RULING

The Panel noted that Advanced Accelerator Applications was a Novartis company with Novartis providing a number of services including drug safety and medical information on its behalf.

The Panel noted the complainant referred to an email they received from Medscape but their complaint concerned the content of a linked website accessed via the email which invited readers to visit the RLT Hub for more information on Pluvicto. No complaint was made about the email itself. After clicking on the link, a website opened with a pop-up box that asked the reader to confirm whether they were a GB health professional or a member of the public. The text stated that the website was not suitable for health professionals outside of the UK. After clicking that they were a GB health professional, readers were taken to a product webpage.

The Panel noted the layout of the webpage in question; at the very top of the webpage was a statement that the webpage was intended for GB health professionals and that the viewer should click on a link if they were a member of the public. Information about the intended audience was repeated immediately above a pale blue promotional banner for Pluvicto. A link to the prescribing information appeared beneath the banner, together with the statement in bold font **'This page/content is for Great Britain healthcare professionals only. Pluvicto is not licensed in Northern Ireland'.** Links to information about Pluvicto's mechanism of action, its safety profile and efficacy data, and to information about dosing and administration were provided further down the webpage.

The complainant alleged that the statement regarding the licensing status of Pluvicto in Northern Ireland was not true as the medicine had received EMA approval mid-December 2022 and thus had been licensed in Northern Ireland for more than two months. In response to this allegation Advanced Accelerator Applications submitted that following the grant of the marketing authorisation for Northern Ireland in December 2022 it initiated the process for updating the website in conjunction with a third party. The Panel noted Advanced Accelerator Applications' submission that the marketing authorisation date for GB was 10 August 2022 and that the marketing authorisation date for Northern Ireland was 9 December 2022 (EMA). European Commission approval was on 12 December 2022. Advanced Accelerator Applications subsequently submitted that EMA granted the marketing authorisation for Pluvicto on 13 December 2022.

The Panel noted that, among other things, Clause 6.1 required information to be accurate and up-to-date and contrary to Advanced Accelerator Applications' assumption there was no provision permitting a grace period for such updates to be made. The Panel ruled a **breach of Clause 6.1** in relation to the statement about the licensing status of Pluvicto in Northern Ireland.

The Panel noted the complainant's allegation that the provision of a 'public website', which contained only the SPC, EPAR and PIL for two prescription only medicines – Lutathera and Pluvicto constituted blatant promotion to the public.

The Panel noted that the landing page of the RLT Hub clearly separated the link intended for GB health professionals from the link intended for members of the public and directed each to the information tailored for them. The Panel noted Advanced Accelerator Applications' submission that if a concerned public visitor had navigated to the GB Health Professional RLT site in error by inappropriately selecting the 'GB Healthcare Professional' option, the inclusion of the header 'if you are a member of the public, please click here' at the top of the GB Health Professional page re-directed that reader to a public-appropriate page.

The supplementary information to Clause 16.1 stated that unless access to promotional material about prescription only medicines was limited to health professionals and other relevant decision makers, a pharmaceutical company website or a company sponsored website must provide information for the public as well as promotion to health professionals with the sections for each target audience clearly separated and the intended audience identified. This was to avoid the public needing to access material for health professionals unless they chose to. The MHRA Blue Guide states that the public should not be encouraged to access material that was not intended for them. A closely similar provision appeared in the supplementary information to Clause 26.2.

The Panel noted Clause 26.1 prohibited the advertising of prescription only medicines to the public while Clause 26.2 permitted information to be supplied directly or indirectly to the public but that such information had to be factual and presented in a balanced way. The supplementary information to Clause 26.2 allowed for the provision of non-promotional information about prescription only medicines to the public as reference information made available by companies on their websites or otherwise as a resource for members of the public and referred to, the SPC, the PIL and the public assessment report (UK or European) where such a document existed.

The Panel noted that companies should provide adequate information on their public facing websites directed at both the public and health professionals so that members of the public do not have to go to the health professional webpages to satisfy their information needs. The Panel noted the complainant's narrow allegation was that the publication of the SPC, EPAR and PIL for two prescription only medicines – Lutathera and Pluvicto on the webpages directed at members of the public was promotional. The Panel noted that the regulatory documents in question were public documents and their publication in the webpages directed at the public was not promotional as alleged and on this ground the Panel ruled **no breach of Clause 26.1**.

In relation to the complainant's allegation that black triangles seemed to be placed randomly around the website without consistency Advanced Accelerator Applications had been asked to consider Clause 12.10 in relation to the health professional webpages. The company had not been asked to consider Clause 24.6 in relation to the public webpage.

The Panel noted that Clause 12.10 set out requirements for the use of the black triangle to denote that additional monitoring was required in relation to adverse reactions stating, amongst other things that the symbol should appear once and be located adjacent to the most prominent display of the product name. Digital promotional material must clearly show an inverted black equilateral triangle to be located adjacent to the first mention of the product as this was likely to be considered the most prominent display of the product name, and to be of such size that it will be easily noticed.

The Panel noted that the inverted black triangle was a well-known and established symbol. Its appropriate use was an important part of medicines regulation. In the Panel's view, companies should use the black triangle judiciously in accordance with the Code such that there was no possibility of being misled in any way as to its meaning. In the event that the inverted black triangle is used more than once companies should ensure that they can justify additional uses of the symbol. The Panel noted that on the product webpage at issue the inverted black triangle did not appear adjacent to each mention of the product; it appeared adjacent to the product name in the navigation menu at the top of the webpage, in the menu at the side of the webpage, within the promotional banner, and as part of a sub-heading. The Panel noted Advanced Accelerator Applications' submission that it had taken the decision to display the black triangle more than once due to the particular nature of the digital content and bearing in mind digital content accessibility issues. Noting Advanced Accelerator Applications' explanation, the Panel did not consider that the display of the black triangles on the webpage at issue was contrary to the requirements of Clause 12.10. The Panel ruled **no breach of Clause 12.10** accordingly.

The Panel noted the complainant's concern in relation to how individuals could access the website. They commented that although there was a register and sign in function, one did not need to sign in to access the website. The Panel noted that beyond suggesting that this was evidence of low standards there was no further allegation made on this point. The Panel noted its ruling of no breach of Clause 26.1 above in relation to the webpages directed at the public. The Panel noted that there was no requirement under the Code that websites which were directed at both health professionals and the public required a sign in function to access the website and thus its absence did not indicate that high standards had not been maintained. The Panel ruled **no breach of Clause 5.1**.

The complainant's final concern related to the statement 'Pluvicto targets PSMA-positive cells, including prostate cancer cells' which appeared above a link to further information about Pluvicto's mechanism of action. The complainant alleged that the webpage did not provide any further information to explain where else PSMA positive cells exist or the consequences of targeting these non-cancerous cells. The Panel noted that the complainant bore the burden of proof; it did not consider that the complainant had provided evidence to demonstrate, on the balance of probabilities, why the statement itself or the omission of additional information was misleading in respect of PSMA positive cells. The Panel therefore considered that the statement was not misleading as alleged and ruled **no breach of Clause 6.1**.

The Panel noted its comments above concerning Advanced Accelerator Applications' failure to ensure that its website was up-to-date; it noted Advanced Accelerator Applications had intended to make amendments to the website but considered that its response indicated a lack of urgency to ensure its website was up-to-date and thus demonstrated a lack of knowledge of the requirements of the Code. In this regard, the Panel considered that it remained unclear why the website had not been updated in December 2022. The relevant email correspondence was not

entirely consistent with Advanced Accelerator Applications' response. The Panel queried whether Advanced Accelerator Applications' governance procedures were adequate. In the Panel's view, Advanced Accelerator Applications had failed to maintain high standards and ruled **a breach of Clause 5.1**.

The Panel noted that Clause 2 was used as a sign of particular censure and reserved for such use. The Panel did not consider that the circumstances in this particular case warranted a ruling of a breach of Clause 2. **No breach of Clause 2** was ruled.

During its consideration of this case, the Panel was concerned with certain aspects of Advanced Accelerator Applications' response. The Panel noted that Clause 8.5 of the Code required that material that is still in use must be recertified at intervals of no more than two years. The Panel noted that this interval did not apply when an update to material was required, say as a result of updated prescribing information. In such circumstances, the material should be amended and up-to-date and accurate when used.

Complaint received **12 February 2023**

Case completed **22 March 2024**