CASE AUTH/3805/7/23 ***NO BREACH OF THE CODE***

COMPLAINANT v VIIV HEALTHCARE UK LTD

Alleged promotion of Apretude to the public

CASE SUMMARY

This case was in relation to an advertisement being visible to a member of the public in the UK while they were using a dating app. The advertisement was for Apretude (cabotegravir), an injectable medication which at the time of the complaint was licensed for use in the USA for HIV-1 PrEP to reduce the risk of getting HIV-1 infection.

There was an appeal by Viiv Healthcare UK of one of the Panel's rulings.

The outcome under the 2021 Code was:

No Breach of Clause 5.1 [Panel's breach ruling overturned at appeal]	**Requirement to maintain high standards at all times**
No Breach of Clause 8.3	**Requirement to certify non-promotional material**
No Breach of Clause 26.1	**Requirement not to advertise prescription only medicines to the public**
No Breach of Clause 26.2	**Requirement that information about prescription only medicines which is made available to the public must be factual, balanced, must not raise unfounded hopes of successful treatment or encourage the public to ask their health professional to prescribe a specific prescription only medicine.**

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, non-contactable complainant, who described themselves as a member of the public/media, about ViiV Healthcare UK Limited.

COMPLAINT

The complaint wording is reproduced below:

> "While on the gay dating app [named], one of the adverts that popped up was for Apretude, an HIV injectable approved in the US. Brand name was clearly seen and obviously intended for a US audience. Website/advert did not appear certified for a UK audience. This would be promotion of a prescription medication to general public

and/or promotion of unapproved medicine to the public (I do not believe the product in question is approved in the UK/Europe – Only US prescribing information was included). Advert should have been geotargeted to only include US users as it names the product (this is easy as [dating app] is a location based dating app so knows whether the user is US based or not) Website in question is below and a screenshot of the advert has been attached."

When writing to ViiV, the PMCPA asked it to consider the requirements of Clauses 5.1, 8.3, 26.1, 26.2 and 26.4 of the 2021 Code.

VIIV HEALTHCARE UK LTD'S RESPONSE

The response from ViiV is reproduced below:

"Executive Summary

ViiV UK is committed to ABPI Code compliance, and we take the subject-matter of the complaint very seriously. As such, we are grateful for the additional time the PMCPA granted to investigate the matter.

ViiV US commissioned a reputable media placement agency ("Media Agency"), to place US-only in-app product advertisements on [dating app]. The US-only geo-restrictions that were initially in place for these adverts fell away mid-campaign, resulting in certain Apretude US advertisements becoming visible to ex-US app users. According to reports from the Media Agency the geo-restrictions fell away due to a vendor error ([dating app]), outside ViiV US's or the Media Agency's control. We wish to reassure the Authority that as soon as ViiV US became aware of these issues, all impacted in-app advertising was halted and that suspension remains in place. In the spirit of openness and responsible self-regulation, our response below summarises our findings relating to this matter.

ViiV UK holds itself to the highest applicable standards. We are both troubled and disappointed that US-only advertising coming from ViiV US became visible to ex-US app users. ViiV US feels let down by the third-party vendor ([dating app]), whose technical errors caused this to happen. No matter the root cause, these incidents do not align with our ethos. We are deeply regretful and apologise unreservedly.

Based on ViiV UK's findings and further consideration we do not believe the [dating app] Complaint falls within the scope of the ABPI Code or the PMCPA's UK jurisdiction. With respect, we believe the Case Preparation Manager should not pass either matter on to the Panel for adjudication since the Code is not applicable. The reasons for this are set out below.

We do not raise arguments regarding the scope of the Code or UK jurisdiction irresponsibly or with evasive intent. We fully appreciate the gravity of ViiV US's vendors failing to maintain US-only geo-restrictions. However, Clause 1.2 sets an important benchmark for the industry as a whole and finding this material in scope would be inconsistent with the Code itself, general jurisdictional principles and guidance from the PMCPA. Should the PMCPA disagree with our arguments with respect to the scope of

the Code, we also provide our response to the complaint and submit the results of our investigation.

Factual Background

The following background facts have become clear from our internal review.

1. In late 2022, ViiV US worked with the Media Agency to develop a US-only advertising campaign for a US-licensed ViiV product: Apretude (cabotegravir). ViiV US and the Media Agency intended this campaign to run through 2023. This was a US-only campaign, organised independently of ViiV UK.

2. Apretude is licensed in the USA and may therefore be advertised to the public under US rules.

3. Apretude was not licensed in the UK at the time of the complaint.

4. The US advertising campaign included the placement of product advertisements on the dating and social networking app [dating app]. Such adverts were only to be directed to US-located app users. In other words, the campaign involved location-restricted "in-app advertising".

5. ViiV US engaged the Media Agency to organise and run the campaign. The Media Agency then engaged directly with [dating app] to place each individual advert.

6. The Media Agency commenced placing adverts from late December 2022/early January 2023. The campaign was designed to be geo-restricted to US users. Project documents between ViiV US and the Media Agency are clear that the scope of advertising is limited to the USA and that the target audience for the in-app advertising is USA users of the app. The Media Agency's written terms with [dating app] also expressly require restricting advertising to US-based app users.

7. At commencement of the campaign, [dating app] applied US-only geo-restrictions to the Apretude advert. However, we understand that unknown errors within the [dating app] systems resulted in certain geo-restrictions falling away or being superseded. These errors caused certain Apretude advertisements to be visible in-app to both US and ex-US app users. This occurred without ViiV US's knowledge or approval. Below we set out further details from our investigation findings.

[Dating app]

ViiV UK received the [dating app] Complaint on 1 August 2023. The [dating app] Complaint related to an Apretude advertisement, published on the [dating app] app. On the same day, (1 August 2023) and as a precaution, ViiV US suspended all advertising on [dating app].

Investigation into the [dating app] complaint revealed that the vendor error caused the Apretude advertisement to be visible to both US and ex-US users for three days (27 July 2023 through 29 July 2023). This was a "three day flight" advertisement: publication had in the ordinary course ended on 29 July 2023. Notwithstanding that, the suspension on all [dating app] advertising remains in place.

All of the affected advertisements self-evidently related to US medicines and were US-focused with no reference to any other country. In our view, any reasonable app user from the UK would instantly recognise the advertisement was not intended for them; and indeed, the complainant also noted this.

Our understanding from enquiries is that the root cause for the US geo-restrictions falling away was a change in algorithms. Certain US-only Apretude adverts became visible to ex-US app users because of a technical error by a "twice-removed" third party (i.e., a third-party vendor ([dating app]) who was engaged by the Media Agency, who was working on behalf of ViiV US).

The [dating app] Complaint is not within the scope of the Code

As set out in Clause 1.2 of the ABPI Code, information or promotional material about medicines which is placed on the internet outside the UK will be regarded as coming in scope of the Code if it was placed there by:

- Clause 1.2 (a) – A UK company or with a UK company's authority; or

- Clause 1.2 (b) – An affiliate of a UK company, or with the authority of such a company, and makes specific reference to the availability or use of the medicine in the UK.

With regard to Clause 1.2(a), the adverts in question were not placed on the internet by ViiV UK or with its authority. ViiV UK was unaware of the placement of these advertisements, had no involvement in the placements, and did not give authority for the placements. ViiV US commissioned the advertising independently of ViiV UK, as is routine with US-only advertising campaigns. Clause 1.2(a) is therefore not engaged.

Clause 1.2(b) has two elements: (i) placement authority; and (ii) specific reference to the availability or use of the medicine in the UK. Both must be satisfied for material to come within scope of the Code. As discussed further below, Clause 1.2(b) cannot be engaged because – at the very least – the adverts make no reference to the availability or use of a medicine in the UK.

Specific Reference to the Availability or Use of the Medicine in the UK

The advert in question contained no reference whatsoever to the availability or use of the medicine in the UK. In fact, as the complainant concedes, it was "obviously intended for a US audience". The advertisements plainly state they were "Produced in the USA". Moreover, the product that is the subject of the [dating app] Complaint was neither licensed nor available in the UK during the relevant period.

If an app-user engages with the ad by clicking “Find a Provider” or “Explore Now” the resulting webpages bear no mention of the use or availability of Apretude in the UK. The relevant landing page includes “For US Healthcare Professionals” and “PrEP Locator” tabs, which only reference US prescribing information and US healthcare providers for Apretude. All cultural references highlight the advert is for a US audience. For instance, in one case, there is an “En Espanol” tab – something clearly associated with Hispanic populations in the US, not the UK. Similarly, the reference to weight is in “lbs”, and there is an icon and headline referencing “$” (US currency) and “co-pay”.

As illustrated above, it is clear that the only references to the use or availability of the medicine in any specific market relate exclusively to the USA. There is no reference whatsoever to the use or availability of Apretude in the UK. Clause 1.2(b) is therefore not engaged, and the adverts fall outside the scope of the Code and UK jurisdiction.

We note this aligns with broader regulatory principles regarding web-based advertising. [dating app] is a US-origin apps, albeit accessible to users globally. This is analogous to a US-hosted webpage or medical journal that is accessible to global visitors. It is well-established that such globally accessible platforms may display US product advertising, without engaging the ABPI Code, provided the target (US) audience is clear and there is no reference to the use or availability of the medicine in the UK. Although undesirable, an app-user would simply be seeing a US advert on a US-origin platform. That could also happen if the complainant browsed the internet or decided to read an article in a US-based open-access medical journal.

The only difference here is that the content was initially geo-restricted (which is also possible for websites) but due to a technical error beyond ViiV US’s or ViiV UK’s control the restrictions fell away. This was a deeply unfortunate occurrence, but not one that instantly brings the material within the scope of the Code.

ViiV UK submits that the materials in question continue to be outside the scope of Clause 1.2 and the UK regulatory framework. The scoping rule for internet content under Clause 1.2 is an important issue not just for this complaint, but for the industry as a whole, particularly overseas affiliates who lawfully advertise medicines on the internet or web-based platforms.

ViiV UK’s analysis of the materials also aligns with the PMCPA’s Social Media Guidance. The Guidance confirm that the scoping rule under Clause 1.2 is key to determining whether or not social media posts fall under the Code, such that there is a UK nexus. According to the Guidance, “[t]he content and intended geographical audience may be relevant when determining whether there is a UK nexus.” The content here is exclusively US-focused, and the intended geographical audience is also clearly the USA. The materials under consideration here have no UK nexus.

Placement Authority

In relation to placement authority within Clause 1.2(b), ViiV US did not authorise the adverts to be made available for non-US consumption (as outlined earlier in our response).

First, the only media placement that ViiV US in fact "authorised" was in-app advertising geo-restricted to US-app users. This media placement operated on such a basis for several months. ViiV US did not authorise the later falling away of the US geo-restrictions. Indeed, it was unaware of this happening until the problem was flagged internally. The ex-US visibility of the ads was the result of a technical error by a "twice removed" third party working in direct opposition to the scope of the project.

Second, under Clause 1.24 of the Code, companies are responsible for the acts and omissions of their agents and agencies that fall within the scope of the Code. Those latter words are key. Here, as noted above, there is no UK nexus and no mention of the use or availability of the medicines in the UK. While it is unfortunate that the materials were made visible to a global rather than US-only audience, the materials have no connection to the UK and their dissemination cannot be a third-party act/omission attributed to ViiV UK.

For these reasons, ViiV UK believes this in-app advertising is outside the scope of the ABPI Code and respectfully requests that the Case Preparation Manager does not forward this case to the Panel. However, for completeness, we set out a response to the points raised in the complaint letter at Section III below. ViiV UK raises the Section III points only if the Panel disagrees with ViiV UK and finds the subject matter within the scope.

If the Panel Determines that the Complaint is within Scope of the Code

A non-contactable complainant who does not identify as a health professional but a member of the public/media, complained that an advert pop-up for Apretude was displayed whilst on the dating app, [dating app]. This knowledgeable complainant was aware that the product is "an HIV injectable approved in the US" and was clear that the viewed ad was "obviously intended for a US audience." The Authority asked ViiV UK to consider possible breaches of Clauses 5.1, 8.3, 26.1, 26.2 and 26.4.

Clause 26.1

ViiV UK asserts that it cannot be in breach of Clause 26.1, which relates to prescription only medicines licensed in the UK.

Apretude is a US-licensed prescription-only medicine. It is indicated for use in at-risk adults for pre-exposure prophylaxis to reduce the risk of sexually acquired HIV-1 infection. Apretude is not authorised for use in the UK. During the period relevant to the [dating app] Complaint, Apretude was not licensed in the UK.

The complainant alleges that "Brand name was clearly seen" and concludes "[t]his would be promotion of prescription medication to the public and/or promotion of unapproved medicine to the public" but does not provide any supporting evidence or rationale.

ViiV UK believes that a US advert mentioning a US brand name visible to a UK user does not automatically equate to UK advertising. Rather, the complainant has simply seen a US advert on a US-origin platform with a global user-base. We refer to Section

II – there is no reference to the use or availability of Apretude in the UK and no indication that anything other than US audiences are targeted.

The non-UK nature of the piece is clear both from the perspective of the advertiser and the recipient, as acknowledged by the complainant. The contents of the ad further make clear that neither ViiV UK nor ViiV US intended to promote Apretude in the UK. For example, the materials directed users to "Find a Provider" that only identified clinics based exclusively in the USA.

Clause 26.4

Clause 26.4 relates to material intended for patients taking a particular medicine. The material was not intended for patients already taking Apretude and as such would not require the side effect reporting statement or black triangle information. As discussed, the medicine is not authorised in the UK, so there were no patients already taking the medicine who needed this information. ViiV UK denies breaching Clause 26.4.

Moreover, we believe there is no breach of Clause 26.4 because that clause relates to information to be supplied with advertising for medicines licensed in the UK. Apretude was not approved in the UK during the relevant time.

Clause 8.3

For the same reasons as above, there is no breach of Clause 8.3. Apretude was not approved in the UK during the relevant time.

Clause 5.1

Maintenance of High Standards – Clause 5.1. We firmly believe that ViiV UK has maintained high standards throughout this difficult matter.

The ViiV group had no intention whatsoever of advertising Apretude outside the USA or to UK audiences. ViiV US developed the campaign only for US audiences and in compliance with applicable US rules, regulations and codes. The scope of the campaign agreed to by ViiV US and the Media Agency was clear to target a US-only audience.

The Media Agency's written terms with [dating app] make clear reference to restricting dissemination to US IP addresses. The adverts were initially correctly restricted. The error by which the geo-restrictions fell away mid-campaign was a purely technical one, in the hands of a "twice removed" third party (a third-party vendor ([dating app]) engaged by another third-party vendor, the Media Agency, who was engaged by ViiV US to facilitate media placements). In that respect, ViiV US was badly let down by a third party, acting against the agreed campaign scope. Once ViiV US became aware of third-party issues, it acted promptly to suspend all advertising, rectify the situations, and commence a thorough investigation.

The ViiV group constantly works to refine its internal process and monitors and reviews its arrangements with third-party vendors. As such, we believe ViiV has maintained high standards to the greatest extent possible, and – although deeply regrettable – it is

only due to an unpredictable third-party error that any visibility of the adverts to ex-US users occurred. ViiV US mitigated against the risk of any such occurrence by the written instructions in place with the third-party vendors. Although the error was not predictable, both ViiV US and ViiV UK took corrective action as soon as possible.

With the above in mind, we are confident that ViiV UK has acted prudently and responsibly and maintained high standards in accordance with Clause 5.1.

Conclusion

On behalf of the entire ViiV organisation, we apologise once again for US product adverts being inadvertently visible to ex-US app-users. Such an error is entirely contrary to our organisation's ethos, and we feel let down by third parties who are somewhat removed from us. We are currently reviewing arrangements with third-party media providers. This includes: (i) the future of this and other campaigns; (ii) potential legal remedies; and (iii) our obligations in respect of confidentiality. As such, we respectfully ask the PMCPA to keep confidential the commercial details of the third-party arrangements."

PANEL RULING

The complaint related to an advertisement being shown to a member of the public in the UK while they were using a dating app [named]. The advertisement was for Apretude (cabotegravir), an injectable medication which at the time of the complaint was licensed for use in the USA for HIV-1 PrEP to reduce the risk of getting HIV-1 infection.

Firstly, the Panel had to decide whether the advertisement in question was subject to the Code. The Panel considered that the advertisement placed on a mobile application could be considered "material placed on the internet", as referred to in Clause 1.2. Accordingly, the advertisement placed on a mobile app outside of the UK would be within the scope of the Code if it was placed there by Viiv UK/with Viiv UK's authority, or if it was placed there by an affiliate to Viiv UK (or with its authority) and specifically referred to the availability or the use of a Viiv medicine in the UK. Further, material directed at a UK audience would be within the scope of the Code.

Viiv provided the complete animated advertisement in individual frames. The Panel noted that the first four frames mimicked a dating app conversation with a potential 'match'. At the top of this imitation chat window was the name and profile picture of the fictitious match, with the words "2 miles away" directly below their name, implying that the match was 2 miles away from the UK user's current location. These first four frames did not refer to any medication. The final frame of the animation and the static end frame were identical. They contained the text "Looking for another option?" in large text in the middle of the screen, followed by "Ask your doctor about Apretude cabotegravir" in large text. Below this was a large orange button which had the text "learn more" for the user to click. At the bottom of the advertisement was signposting text for the reader to view the prescribing information, patient information and boxed warning on the Apretude website. It was unclear whether this was a link although the Panel noted that Viiv appeared to refer to material on the medicine home page as though it was part of the advertisement. Below this in very small font size was the Viiv Healthcare logo, text about trademarks, copyright and the statement "Produced in USA."

The Panel considered that [dating app] was a location-based dating app and most users would find matches within a given location range. In the Panel's view, the advertisement in question gave the impression that it was relevant to and targeted at the specific user. The advertisement incorporated a location-related element (showing the fictitious match as being 2 miles away and was an integral part of a location-based mobile app used by members of the public in the UK, primarily to meet people locally. The advertisement finished by directing the user to ask their doctor about Apretude.

The Panel noted that the features identified by Viiv as signifying that the advertisement was directed at a US audience (including the "En Espanol" tab, the reference to weight is in "lbs", and an icon and headline referencing "$" and "co-pay") appeared on what appeared to be the linked webpage rather than being a substantive part of the advertisement within the dating app and so may not have been seen by most viewers of the advertisement. The Panel noted that the complainant described the material as a US advertisement.

The Panel did not agree with Viiv's submission that this matter was analogous to a US-hosted webpage or medical journal that is accessible to global visitors. In the Panel's view, given the way a location-based dating app was primarily used to meet people locally, the situation was more analogous to an advertisement appearing in a UK-specific print run of a global journal, which therefore had to comply with the UK Code.

Bearing in mind its comments above and the fact that the complainant was using the mobile app in the UK, the Panel deemed that the material was in scope and subject to Code requirements.

The Panel noted Viiv's submission that Viiv USA had appointed a media agency to place US-only in-app product advertisements within the [dating app] application. Viiv submitted that the geo-restrictions that were in place for this advertisement had fallen away due to a vendor error, outside of Viiv USA or the media agency's control, resulting in the advertisement being visible to application users outside the US. The Panel noted that Viiv received the complaint in August 2023 and the same day, Viiv USA halted all advertising on the [dating app] app.

The Panel noted that it was an established principle that pharmaceutical companies were responsible for the acts and omissions of their third parties which came within the scope of the Code, even if such acts and omissions were contrary to the instructions which they had been given. Furthermore, UK companies were responsible for the acts and omissions of their overseas affiliates that came within the scope of the Code.

The Panel noted that Clause 26.1 prohibited the promotion of a prescription only medicine to the public and that Clause 26.2 stated that information made available to the public about prescription only medicines must be factual and presented in a balanced way. The Panel noted, however, that Clauses 26.1 and 26.2 only applied to prescription only medicines. As Apretude was not licensed in the UK at the time of the complaint, it was not classified as a prescription only medicine. On that very narrow technical point, the Panel ruled **no breach of Clauses 26.1 and 26.2** of the 2021 Code.

Clause 26.4 stated, among other things, that any material which relates to a medicine and which is intended for patients taking that medicine must include a reporting of side effects statement. Noting the wording of the advertisement, "Looking for another option? Ask your doctor about Apretude cabotegravir", the Panel considered that the advertisement was not material intended

for patients taking Apretude and, therefore, the requirements of Clause 26.4 were not relevant. The Panel ruled **no breach of Clause 26.4**.

The Panel noted that the complainant alleged that the advertisement did not appear to be certified for a UK audience. The Panel noted that it had been asked to consider this matter under Clause 8.3 which applied to non-promotional material and thus did not apply to the advertisement in question. The Panel therefore ruled **no breach of Clause 8.3**.

In the Panel's view, it appeared that Viiv had been let down by a third party and technology that had failed. The fact that this advert became visible to a UK audience misleadingly implied that Apretude was indicated for use in the UK which, at the time of the complaint, was not so and was a serious matter. The advertisement was not approved for UK use. The Panel noted that Viiv only became aware of this matter on receipt of the complaint. The Panel considered that Viiv therefore had failed to maintain high standards and a **breach of Clause 5.1** was ruled.

APPEAL BY VIIV HEALTHCARE UK LTD

ViiV's written basis for appealing is reproduced below.

> "**Appeal against the ruling of breach of Clause 5.1 in Case AUTH/3805/7/23**
>
> I am writing to formally appeal the ruling of a breach of Clause 5.1 in the above-referenced case, concerning the alleged advertisement of Apretude on the international social networking [named dating] app. We respectfully ask the Code of Practice Appeal Board to reconsider this decision as we firmly believe it is out of scope of the Code and as such, ViiV UK cannot be held responsible for the acts and omissions of our US counterparts in this case and cannot be judged to have breached high standards.
>
> We were pleased to note that all other allegations were found not in breach.
>
> **Background**
>
> The advertisement itself was for a medicine (Apretude) that was not licensed in the UK at the time. The name would not have been familiar to a UK audience and there was no mention of indication or any further information about the product. We acknowledge there may be times where name alone may be considered promotional in the rare instances where the public would be familiar with a product and its indication (e.g. Botox Case AUTH 3441/12/20), but the Panel have repeatedly ruled that it is the inclusion of further information (usually indication) in conjunction with the name that makes a material promotion and this is the informal advice given in the PMCPA social media guidance.
>
> In the footnotes to this advertisement on the international web-based app [dating app], it stated, "Produced in the USA". If the reader clicked on the "Learn more" button, they would have been taken to the Apretude.com website, a US website targeted to a US audience and with clear signage saying, "This site is intended for US residents only" and other cultural indicators that it was targeted to a US audience.
>
> The Panel appeared to make their decision based on the advertisement alone, as they felt that the indicators of US-targeting were on "*what appeared to be the linked*

webpage rather than being a substantive part of the advertisement within the dating app and so may not have been seen by most viewers of the advertisement.", although they did acknowledge that the advert itself stated "Produced in the USA" and the complainant described the material as a US advertisement.

We believe the Case should have been found to be outside the scope of the Code rather than interpreting the playful creative and wording of the advertisement as meaning it "*was relevant to and targeted at the specific user"* and therefore making it "*analogous to an advertisement appearing in a UK-specific print run of a global journal".* We believe the determination should have been based on whether the advertisement made "*specific reference to the availability or use of the medicine in the UK*" and whether it was placed by a UK company or with its authority as per Clause 1.2.

The advertisement is "material placed on the internet outside the UK"

The Panel acknowledged they had to consider whether the material was in scope and determined that rather than being defined as "*material placed on the internet outside the UK*" (Clause 1.2), that it was *"more analogous to an advertisement appearing in a UK-specific print run of a global journal, which therefore had to comply with the UK Code*". They appear to have come to this conclusion based on the wording in the advertisement which mimicked a chat with a 'match' who was "2 miles away". The Panel felt this" *gave the impression that it was relevant to and targeted at the specific user."*

We believe this to be an overreach and in direct contradiction to Clause 1.2 that is unambiguously clear that material that is placed on the internet outside the UK (as in this case) will be "*regarded as coming in scope if it was placed there by:*

- *A UK company/with a UK company's authority (*not the case here)
- *An affiliate of a UK company, or with the authority of such a company* ***and it makes specific reference to the availability or use of the medicine in the UK*** (not the case here) [our bold].

The advert is not analogous to a UK-specific print run of a global journal

The advert is not in print, it is a digital advertisement available only on the internet via the [named dating] app. The Panel cannot arbitrarily decide to determine something is akin to a print version when it is undeniably a digital asset that has been placed on the internet as described in Clause 1.2.

The Panel "*considered that [dating app] was a location-based dating app and most users would find matches within a given location range"* and it may be this assumption that led them to believe it was equivalent to a UK-specific print run of a global journal. However, [dating app] is a global online app where users are encouraged to interact with members from all over the world, not just from their specific location. [Dating app] advertises itself to allow members to "chat with [dating app] members from your neighborhood (sic) or around the world" and unlike the Panel's theoretical "*UK-specific print run of a global journal*", [dating app] does not have a UK-specific version, there is only one global web-based platform and this advertisement was not targeting a UK

audience. The filtering by location can be done by individual users not the publisher as in the journal analogy.

The description of the app makes clear one can interact with people all over the world which is part of its attraction to users as conversations can be virtual as well as in person.

The ad did not give the impression it was "relevant to and targeted at the specific user"

Making an advertisement that is clearly an advertisement mimicking a dating app conversation and referring to "2 miles away" does not "*make specific reference to the availability or use of the medicine in the UK"* as required by Clause 1.2*.* At most it makes reference to an individual being available 2 miles away, which is not the same as referring to a specific medicine being available in the UK. Users of this app who may have seen the advertisement would be familiar with the chat format as it is familiar across many dating apps so would recognise this as a fun way for an advertiser to engage and would not think the advertiser was referring to the distance between themselves and a medicinal product. The advertisement was clearly an advertisement, and the execution was such to mimic a [dating app] chat. To do that convincingly it needed to have a photo and location included in the profile.

The advertisement then goes on to offer 'another option', which is not specified how far away it is but is on a page whose footnote clearly states 'Produced in the USA' so using the Panel's logic readers would be clear that this advertisement was for a product available in the USA and targeted to a USA audience. In fact, the complainant themselves makes clear that it was "*obviously intended for a US audience"* so there is no evidence that any reader was misled in to thinking this advertisement was targeted to UK users or that Apretude was available in the UK. It is a well-established principle that the complainant has the burden of proof and they have not provided any evidence that aligns with the Panel's thinking but have directly contradicted it by making clear they knew it was for a US audience.

[Dating App] is a social networking site

As it is an online community and application, it would also fall within the PMCPA's own definition of social media – "*websites and applications that enable users to create and share content and to interact with one another in social networks"* rather than a UK-specific print run of a global journal. Numerous cases have found that material placed on social media networks by non-UK companies are not in scope of the Code and only appear at the Panel when interacted with by UK employees which the PMCPA interpret as "with the authority of a UK company" and as such bring it in scope of Clause 1.2. This is not the case here.

[Dating app] is only available whilst online and as such requires internet connection to access. For the advertisement to appear, our US colleagues needed to place it on the internet as per Clause 1.2. The target audience for the advertisement (created by ViiV US in line with US regulations) was US users of [dating app]. As described by the Panel in their deliberations, it would be within the scope of the Code if "*it was placed there by Viiv UK/with Viiv UK's authority, or if it was placed there by an affiliate to Viiv*

UK (or with its authority) and specifically referred to the availability or the use of a Viiv medicine in the UK. Further, material directed at a UK audience would be within the scope of the Code." None of those factors applied in this case and this should have been enough to determine it was not in scope of the Code.

Inconsistent with recent rulings

Although every case is considered on its own merits, in a recent case, **AUTH 3821/9/23**, the Panel gave a very clear ruling on US internet materials being out of scope:

In the case under consideration today, the complainant themselves acknowledged that the advertisement was *"obviously intended for a US audience"*, and as in the above Novo Nordisk case, there was a clear footnote in the advertisement stating, "Produced in the USA". ViiV UK had no input in to the advert or its placement, and did not direct anyone to [dating app] or the advertisements. In case AUTH 3821/9/23 Novo Nordisk did not respond to the complainant's point relating to geo-blocking and were still found out of scope. In our case our US colleagues had put geo-blocking in place originally, but due to third party error this fell away and the ad became visible in the UK. ViiV should not be penalised for having tried to ensure the advert did not reach UK audiences (despite it being out of scope) and when that technology failed to be found not to have maintained high standards. "*In the Panel's view, it appeared that Viiv had been let down by a third party and technology that had failed. The fact that this advert became visible to a UK audience misleadingly implied that Apretude was indicated for use in the UK which, at the time of the complaint, was not so and was a serious matter. The advertisement was not approved for UK use. The Panel noted that Viiv only became aware of this matter on receipt of the complaint. The Panel considered that Viiv therefore had failed to maintain high standards and a breach of Clause 5.1 was ruled."*

The advertisement did not imply that Apretude was indicated for use in the UK any more than the Saxenda and Wegovy websites implied these prescription medicines can be advertised to the public in the UK in case AUTH 3821/9/23.

In case **AUTH 3707/11/22** the Appeal Board overturned the Panel ruling that a post on LinkedIn (a global social networking site) from a UK employee on secondment to the US business was in scope of the Code. It celebrated the FDA approval of a new combination of treatments with an embedded video and link to the US press release. AZ accepted the interactions with the post by UK employees brought it into scope, but not that the original post was. The post had been made on the instruction of the US affiliate and been approved by it and was in line with US social media guidance. The Appeal Board upheld AZ's appeal, considering the post was made by a senior employee, placed by a US company and made no specific reference to the availability of use of the medicine in the UK. We contend that this is akin to the case being appealed today; the advert was placed by the US company on a global platform, it was in line with US regulations and approved as such and made no specific reference to the availability or use of the medicine in the UK. No UK employees interacted with it and the company did not direct anyone to it. As such, ViiV UK cannot be held responsible for it.

Another recent case, **AUTH 3810/8/23,** a GSK employee working for the Italian affiliate posted about the approval by the FDA of a licence expansion for GSK's Jemperli. It linked to a US press release discussing the benefits and was viewed by the Panel as promotional. The press release stated "Issued: London UK" and included information that the new indication was under review in other countries including the UK. Neither the post or the press release made direct reference to the intended audience being US, and the Panel felt it wasn't sufficiently clear that the press release was intended for a US-only audience, but still ruled that the post and its associated press release was not in scope of the Code. In comparison, the case under consideration today did not have any reference to UK in the advert or the associated website, both of which made clear they were US materials and the complainant themselves was clear they were *"obviously intended for a US audience".*

High standards

The internet is global and with all its benefits do come risks that UK residents may see content for which they are not the intended audience. UK affiliates cannot be expected to be the gatekeepers of all material placed on the internet by their non-UK colleagues, and Clause 1.2 provides clear guidance on when material does come in scope, none of which apply in this case.

The PMCPA have long had to grapple with the internet providing potential access to materials previously sent as print only to individuals, but now available to a wider audience on the internet and they have had to balance the risks of the public seeing advertisements for prescription medicines in open access journals or promotional websites with the practical and commercial considerations of access-restricting everything and they have managed to walk this tightrope successfully with the requirements of self-validation, labelling of target audience etc. Similarly, the introduction of the clause outlining the scope of the Code as it applies to internet materials that was introduced in 2001 (now Clause 1.2) has provided helpful clarity in navigating this area, which should not be muddied by the Panel determining this [dating app] internet advertisement should come under the print requirements rather than internet.

In finding ViiV in breach of Clause 5.1, the Panel stated *"…it appeared that Viiv had been let down by a third party and technology that had failed. The fact that this advert became visible to a UK audience misleadingly implied that Apretude was indicated for use in the UK which, at the time of the complaint, was not so and was a serious matter. The advertisement was not approved for UK use. The Panel noted that Viiv only became aware of this matter on receipt of the complaint. The Panel considered that Viiv therefore had failed to maintain high standards and a breach of Clause 5.1 was ruled."*

The advertisement was targeted to US users, not UK users, and only became available to the latter when the geo- blocking technology failed. Just because the advertising was viewed in the UK on the [DATING APP] app and mentioned the phrase "2 miles away" does not mean it was targeted at a UK audience. The complainant themselves noted it was "*obviously intended for a US audience*" and provided no evidence that any users were misled in to thinking it was targeted to a UK audience in the way the Panel determined.

The analogy to a UK-specific print run is flawed as the material is digital not print, there is no UK-specific [named dating] app, there was no UK involvement, no specific UK targeting, and no directing UK users to the site.

The Panel appeared concerned that "*Viiv only became aware of this matter on receipt of the complaint. The Panel considered that Viiv therefore had failed to maintain high standards and a breach of Clause 5.1 was ruled."* ViiV UK does not monitor social networking sites or the internet to check whether it is possible to access US advertising as we know our US colleagues put geo-blocking in place even though it is not mandated by US or UK regulations, and have historically understood the PMCPA Code Clause 1.2 makes clear that material placed on the internet by an affiliate would only have been considered in scope if put their with our authority or if it mentioned the UK use or availability of the specific medicine. In this case, as in many Code cases, we became aware of the error when a complaint was lodged. This does not indicate lack of high standards of ViiV UK as we were not monitoring [dating app] for inappropriate advertising and should not be expected to unless ViiV UK had placed material on it for a UK audience.

ViiV UK take compliance with the Code seriously and believe we have maintained high standards with respect to this advertisement. As soon as the company became aware of the issue, all in-app advertising was stopped while an investigation was undertaken and a determination whether it was in scope of the Code was made internally. Geo-blocking restrictions had been in place as is customary for the US advertising materials, although it is not mandated in the ABPI Code or the US regulations that our US colleagues have to comply with, and it was only when a third-party error removed the geo-blocking that the advert became visible outside the US. In efforts to further reduce risk, our US colleagues have put in place further, more frequent check-ins of geo-blocking protections for all future in-app advertising.

As outlined in our original defence letter, Clause 1.2 sets an important benchmark for the industry. The advertisements in question were not placed on the internet by ViiV UK or with its authority. ViiV UK was unaware of the placement of these advertisements, had no involvement in the placements, and did not give authority for the placements.

The adverts made no reference to the availability or use of the medicine in the UK, and thus, Clause 1.2(b) cannot be engaged.

Conclusion

In conclusion, we respectfully request the Appeal Board to reconsider the ruling of a breach of Clause 5.1 primarily because the advertisements in question were not within the scope of the UK ABPI Code.

It is unfortunate that this incident happened and was not the intent of ViiV US or ViiV UK. However, even the complainant recognised this was a US advertisement and in this global world there will be occasional times that unfortunately a UK audience may see material not intended for them. We believe that the initial placement of geo-blocking (which unfortunately fell away) and the immediate actions taken by ViiV UK

upon discovering the issue demonstrate our commitment to maintaining high standards and compliance with the Code. Indeed, if this is deemed in scope of the Code, UK pharma companies would need to review and approve all materials placed on the internet/social networking sites by global affiliates which is beyond the requirements of Clause 1.2 and an impossible workload for UK pharma businesses."

APPEAL BOARD RULING

The Appeal Board considered that, given ViiV's basis for appeal, the first determination to be made was whether the advertisement at issue came within the scope of the Code. If the Appeal Board agreed with the Panel's determination that the matter was within the scope of the Code, it would then go on to decide whether or not there had been a failure to maintain high standards.

The Appeal Board accepted the complainant's assertion that they had been in the UK when they saw the advertisement, taking account of ViiV's acknowledgment that the advertisement had, in error, been visible in the UK as the geo-blocking technology had failed.

The Appeal Board carefully considered the wording of Clause 1.2, which stated:

"Information or promotional material about medicines which is placed on the internet outside the UK will be regarded as coming within the scope of the Code, if it was placed there by:

- a UK company/with a UK company's authority, or
- an affiliate of a UK company, or with the authority of such a company, and it makes specific reference to the availability or use of the medicine in the UK."

The Appeal Board took account of ViiV's submission that ViiV USA had appointed a media agency to place US-only in-app product advertisements within the [dating app] application. The geo-restrictions that were in place for this advertisement had fallen away in error resulting in the advertisement being visible to application users outside the US. The Appeal Board decided that the advertisement was promotional material about a medicine that was placed on the internet outside the UK with the authority of the US company, which was an affiliate of a UK company.

The Appeal Board considered the wording of the final part of Clause 1.2, particularly the word "specific". While the Appeal Board considered that the wording "Produced in USA" in small font at the bottom of the advertisement was not sufficient to indicate that the advertisement was intended for a US audience only, the Appeal Board considered that there was nothing in the content of the advertisement that made "specific reference to the availability or use of the medicine in the UK". The Appeal Board considered that the words "2 miles away" and the fact that the app was location-based (which were factors relied on by the Panel) did not amount to a specific reference to the availability or use of the medicine in the UK, and did not meet the particular requirements of Clause 1.2.

Taking everything into account, particularly that the advertisement did not make specific reference to the availability or use of the medicine in the UK, the Appeal Board considered that the advertisement was not within the scope of the Code. The Appeal Board therefore ruled **no breach of Clause 5.1**. The appeal was successful.

Complaint received 29 July 2023

Case completed **13 February 2025**