CASE AUTH/3848/11/23

COMPLAINANT v GILEAD

Activities of Gilead at a European conference

CASE SUMMARY

This case was in relation to the Wi-Fi network at a European conference sponsored by Gilead Sciences Europe Ltd. Upon entering the password, attendees were directed to a homepage owned by Gilead's US parent company. The complainant alleged that this homepage "prominently featured a press release about an investigational indication for a product from Gilead", which they considered promotion of lenacapavir, and for an unlicensed indication.

The outcome under the 2021 Code was:

Breach of Clause 5.1	**Failing to maintain high standards**
Breach of Clause 11.2	**Promoting a medicine for an unlicensed indication**
Breach of Clause 26.1	**Advertising a prescription only medicine to the public**

No Breach of Clause 2	**Requirement that activities or materials must not bring discredit upon, or reduce confidence in, the pharmaceutical industry**

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 about Gilead was received from an anonymous, non-contactable complainant who described themselves as a UK-based health professional.

COMPLAINT

The complaint wording is reproduced below with some typographical errors corrected:

> "I am writing to express my concern as a UK based healthcare professional regarding the activities of Gilead Sciences at the [named European society] conference in Warsaw, which took place on [dates], 2023. During the conference, I observed a concerning practice related to Gilead's activities that I believe warrants investigation and attention.
>
> To access the [conference] WiFi network, conference attendees were required to enter the password [password, including "Gilead"]. However, upon doing so, it redirected all

users to a landing page intended for a US audience. This landing page prominently featured a press release about an investigational indication for a product from Gilead. I found this method of promotion to be highly inappropriate for several reasons.

Firstly, this approach effectively forced all conference attendees, including a substantial community component of people living with HIV from the UK, to view a promotional website for an investigational indication, irrespective of their intention or interest. There was no disclaimer suggesting that the landing page redirected to a promotional website. Equally there was no choice. It almost felt like forced promotion.

Secondly, it appeared that Gilead aimed to promote their products through this landing page, which may not align with established regulations or ethical standards for promotional activities at medical conferences. Specifically in the lower part of the landing page, a recent news section was included. Within this the headline ‘Gilead sciences announces new clinical trial in Europe to assess lenacapavir for HIV prevention as part of landmark purpose programme.’

Lenacapavir is licenced as part of HIV treatment but does not have a licence for the prevention of HIV as a pre-exposure prophylaxis (PrEP) agent. I worry about the use of the words ‘landmark purpose’ as it suggests that the study will yield some fantastic result; not only predicting the results of the study but also suggesting some special property of this medicine, both in HIV treatment and prevention.

The [named] conference is well known to have significant community involvement and regularly lists community activities as part of the programme (see below from the 2021 conference).

[URL provided]

The HIV community is broad and includes both people living with HIV and a wider activist community including those who may benefit from novel HIV prevention. I worry that people living with HIV and HIV negative individuals who may be the target of the ‘Landmark purpose programme’ have effectively been promoted to; both in promotion of the study and promotion of lenacapavir as a ‘landmark’ drug.

The only disclaimer that was included on the landing page, was a statement that some of the content on the site is not intended for people outside the United States. This seemed odd, given that [named conference] is a European conference. [It] made me worry that directing to this page was a mistake and suggested that Gilead do not [have] the right procedures in place. Why did they not direct to a UK or European based site?

Whilst I understand the PMCPA's primary focus is not Europe or Poland, I attended the conference as a UK based healthcare professional. Additionally many people attending; both healthcare professionals and community were from the UK. I am unsure whether Gilead proactively brought any healthcare professionals to the meeting but as this is their usual practice, I anticipate this was the case.

I kindly request that the PMCPA investigates this matter thoroughly and considers whether Gilead's actions at the conference were in compliance with the applicable codes of practice and ethical guidelines.”

When writing to Gilead, the PMCPA asked it to consider the requirements of Clauses 2, 5.1, 11.2 and 26.1 of the 2021 Code.

GILEAD'S RESPONSE

The response from Gilead is reproduced below:

> "The Complaint relates to a press release published on Gilead's Global Corporate website [URL provided] ("**the Site**") which is owned and managed by Gilead Sciences Inc ("**GSI**"), a US company.
>
> The Complainant was directed to the Site when using the wireless internet access ("**Wifi Access**") provided by the organiser of a major scientific HIV conference that he/she attended as a delegate. Gilead Sciences Europe Limited ("**GSEL**") agreed to support the provision of the Wifi Access for conference delegates as a part of GSEL's conference sponsorship package. As such, I am responding to the Complaint on behalf of GSEL.
>
> For the reasons set out in detail below, we do not agree with the Complainant's assertions in the Complaint and do not consider that there has been a breach of the ABPI Code.
>
> Background
>
> The [named conference] took place in [town], Poland from [date range] 2023. [Named conference] is a major international scientific conference on HIV and co-infections and attracts HCPs and attendees from all over the world.
>
> As indicated, GSEL was a sponsor of [named conference]. GSL [Gilead Sciences Ltd] supported 10 UK HCPs to attend [named conference].
>
> As a part of its sponsorship package, GSEL agreed to sponsor the Wifi Access for delegates at [named conference]. The Wifi Access was provided by the [conference] Secretariat's appointed service provider. Below are the details of the sponsorship opportunity provided as set out in the Sponsorship Brochure:
>
> > 'Wireless access to the Internet for all delegates will be available at the Conference.
> > Sponsor's benefits:
> > • Sponsor's website will be the default homepage.
> > • Sponsor can provide delegates with password for Wi-Fi access (to be given at the exhibition booth, for example).
> > Wireless Internet access will be provided by the Conference Secretariat.'
>
> [Conference] delegates were offered the opportunity to use the Wifi Access whilst at [the conference] and provided with access details in various ways, including the pocket programme and on the back of the delegate badge. An example of the WiFi Access information provided is shown here:

[Image of text:
'Stay connected wherever you are!
Wi-Fi name: [conference acronym]
Password: Gilead@[conference acronym]

Wifi T&Cs can be found here: [URL provided]. The T&Cs were linked to the Polish partner/network – WiBI Network services.

To gain Wifi Access, delegates would select [conference acronym] Conference Wifi and delegates would then be directed to the login, asked to agree to the T&C's and then be asked to enter a password – this was Gilead@[conference acronym]. After adding the password, delegates would then be taken to the Site landing page with the pop-ups. [Gilead submitted screenshots, including the pop-ups as they would appear on the mobile version of the webpage].

The homepage used for the Wifi Access was the homepage of the Site – Gilead's Global Corporate website ([URL provided]). Gilead does not have a separate European corporate website nor did GSEL have its own microsite for [the conference]. [Named conference] is a major international scientific conference attracting delegates from around the world, including from the United States, and so a Global corporate website was considered appropriate as the homepage. The Site is not directed to or limited to a health professional audience and is not intended to advertise or promote to a health professional audience.

[Gilead submitted] screen shots of the home page of the Site when viewed from a desktop on the [date of the conference]. As you will see, the Site contains the information typically found on a Corporate website.

[Gilead submitted] an example of the home page if accessed on a mobile device in Poland. We do not have screen shots of the mobile home page on the [date of the conference].

Upon landing on the Site (whether via mobile which is most likely or via desktop), each visitor receives a pop-up notification as follows – 'Welcome. Some content on this site is not intended for people outside the United States' – and the visitor must acknowledge the notification by clicking on the large red box that says 'ACCEPT' before they can navigate to content on the Site. Alternatively they can move to the website they were intending to visit or just close the Gilead.com page and continue to use the internet access as they planned. There was no requirement for delegates to interact with the Site to gain internet access.

The Complainant argues that the approach for providing Wifi Access adopted by the Conference organiser 'effectively forced all conference attendees … to view a promotional website for an investigational indication'. For the reasons set out above, we do not agree. Delegates choosing to use the Wifi Access had a choice as to whether they viewed the Site they landed on and this website is a Global corporate website and not a promotional website.

Complaint raised by the Complainant.

We will now respond to the specific ABPI Code issues raised by the Complainant in the Complaint following his/her visit to the Site using the [named conference] Wifi Access. The Complaint relates to the content of a press release relating to the announcement of a new clinical study as part of Gilead's PURPOSE Program ("**the Press Release**").

As described above, delegates that chose to use the [named conference] Wifi Access landed on the homepage of the Site and were then able to either (i) leave the Site and continue to access the internet and visit the websites they were looking for or (ii) to view more of the Site as they wished.

If delegates chose to view more of the Site and decided to scroll down the landing page, then at the bottom of the landing page they would see a section headed 'Recent News' with a short description of two news items, with each news item linking to a press release.

The wording for each link is factual and balanced and does not promote any prescription only medicine. The first news item relates to the Press Release and says – 'Gilead Sciences Announces New Clinical Trial in Europe to Assess Lenacapavir for HIV Prevention as Part of Landmark Purpose Program'.

If the delegate then decides to click on the link for this news item, they are taken to a page within the News and Press section of the Site which is prominently labelled 'Press Releases' and displays the full Press Release. We also attach screen shots as to how the Press Release looks on the Site.

We do not agree with the Complainant that the Press Release is prominently featured on the landing page of the Site – it is referenced at the bottom of the landing page and the reference is only visible if the visitor scrolls down to the bottom of the landing page and the Press Release itself is only accessible if the visitor clicks through to the 'Press Releases' section of the Site. If the visitor is using a mobile device, a significant amount of scrolling is needed to reach the Recent News Section at the foot of the homepage.

The Complainant argues that 'Gilead aimed to promote their products through this landing page' and refers to the Recent News section at the lowest part of the landing page. We respond to this complaint below by addressing this in relation to Clause 26.1 and Clause 11.2 as requested.

1) Clause 26.1 – Prescription only medicines must not be advertised to the public

Clause 26.1 of the ABPI Code requires that 'Prescription only medicines must not be advertised to the public. This prohibition does not apply to vaccination and other campaigns carried out by companies and approved by the health ministers'.

We have described above how delegates may reach the landing page of the Site and the additional steps (at least 2) they must take to reach the Press Release. The purpose of supporting the [named conference] Wifi Access was not to drive the [named conference] delegates to the Press Release. We do not consider that this was the

consequence of the use of the Site as the landing page for the Wifi Access as delegates needed to take repeated deliberate action to read the detail in the Press Release. In placing the Press Release in a specific section of the Site labelled 'Press Releases' and intended for the Media and Investors, Gilead is not directing this information to the general public.

The Complainant suggests that the Press Release is promoting a prescription only medicine to the public without identifying specifically any wording that is promotional in nature. We disagree and consider that the Press Release is non-promotional, newsworthy, factual and balanced and provides in a responsible way the appropriate information expected by the media and investor community it is aimed at.

The Press Release displayed was prepared by the Gilead Global HQ public affairs team and reviewed in accordance with their review process for press releases. The Press Release was sent out over Business Wire and posted on the Site on [date corresponding to the first day of the conference], as is customary with GSI global press releases.

The Complainant highlights specifically the use of the words 'landmark purpose' and asserts that 'these suggest the study will yield some fantastic results; not only predicting the results of the study but also suggesting some special property of this medicine, both in HIV treatment and prevention'. The Complainant later suggests that the Press Release is promoting lenacapavir as a 'landmark' drug.

The Press Release is in fact sharing news of the fifth and latest study in a series of investigational studies, the PURPOSE Program, evaluating lenacapavir as a prevention option in people who could benefit from HIV pre-exposure prophylaxis (PrEP). The Press Release is communicating a topical issue of genuine interest.

The word 'landmark' is used in relation to the PURPOSE Program and not in relation to the medicine lenacapavir. It is described in this way as it is the most comprehensive and diverse program for an investigational HIV PrEP program to date and is specifically evaluating use in a number of understudied populations, responding to patient calls for greater inclusion/representation, and also has the potential to generate the data needed to enable lenacapavir to be a prevention option for as many of those who could benefit as possible. The term 'landmark' is commonly used in relation to clinical studies that are the first major clinical trials of their type that have the potential to contribute valuable understanding about related issues, including population/ethnicity differences, and which potentially change the way things will be done going forwards. The term is not being used in the context of the medicine being studied and the Press Release does not predict or imply any particular outcome.

Whilst the Press Release is primarily sharing information on the latest PURPOSE study, it does also provide reference information on lenacapavir, the medicine being studied for preventative use. In a factual way, the Press Release includes the fact that lenacapavir is approved, in combination with other antiretrovirals, for HIV treatment in persons with multidrug-resistant HIV-1 infection. However this is not the focus of the Press Release and the information shared is factual and balanced, and is not promotional in content or tone. The Complainant does not specifically identify that any

of the wording used to describe lenacapavir as an approved medicine for treatment is promotional, beyond incorrectly connecting the term 'landmark' to lenacapavir.

The Press Release is very clear that it relates to a Phase 2 clinical trial assessing lenacapavir for use in HIV prevention and it does so with clear language in a balanced way – for example it states '[Lenacapavir] is also under investigation for HIV prevention', 'The safety and efficacy of lenacapavir for HIV prevention has not been established', 'The use of lenacapavir for HIV prevention is investigational and the safety and efficacy of lenacapavir for this use have not been established'.

We therefore do not accept that there was a breach of Clause 26.1.

2) Clause 11.2 – Promotion of a medicine must be in accordance with the terms of its MA

Again, this part of the Complaint relates to the Press Release.

Clause 11.2 of the ABPI Code relates to Promotion to Health Professionals and Other Relevant Decision Makers and requires that 'The promotion of a medicine must be in accordance with the terms of its marketing authorisation and must not be inconsistent with the particulars listed in its summary of product characteristics subject to the provisions of Clause 11.3 below'.

Supplementary Information for 11.2 says 'The promotion of indications not covered by the marketing authorisation for a medicine is prohibited'.

We repeat our view that the Press Release highlighted by the Complainant is non-promotional, newsworthy, factual and balanced and provides in a responsible way the appropriate information expected by the media and investor community. The Press Release is also located on a page of the Site that is not directed to or limited to a health professional audience and is not intended to advertise or promote to a health professional audience.

The Press Release is sharing news of the fifth and latest clinical trial in a series of investigational studies, the PURPOSE Program, evaluating lenacapavir as a prevention option in people who could benefit from HIV pre-exposure prophylaxis (PrEP).

The information provided on the details of the trial and the potential use of lenacapavir for prevention is clearly set in the context of this being an investigational use for the medicine.

We have discussed earlier the use of the word 'Landmark' in relation to the PURPOSE Program (and not in relation to the medicine lenacapavir) and the explanation that the study program is described in this way as it is the most comprehensive and diverse program for an investigational HIV PrEP program to date and is specifically evaluating use in a number of understudied and/or underserved populations. The term is not used in the context of the medicine being studied and the Press Release does not predict or imply any particular outcome.

The Press Release does not in any way promote an indication for lenacapavir not covered by its marketing authorisation and is instead clearly announcing a Phase 2 clinical trial in a responsible way – the phrases 'PURPOSE 5 trial will evaluate lenacapavir as twice-yearly prevention option' and 'the first Phase 2 clinical trial to evaluate an investigational long-acting HIV prevention option' appearing in the sub heading and initial sentence of the Press Release. The Press Release is clear in distinguishing between the current licensed indication for the treatment of HIV and the unlicensed indication under investigation for HIV prevention – for example by stating '[Lenacapavir] is currently approved, in combination with other antiretrovirals, for HIV treatment in persons with multidrug-resistant HIV-1 infection. It is also under investigation for HIV prevention'.

We therefore do not agree that there was a breach of Clause 11.2.

3) Clause 5.1 and Clause 2 of the ABPI Code

Clause 5.1 of the ABPI Code requires that 'High standards must be maintained at all times'. For all the above reasons, we do not agree that there was a failure to maintain high standards and do not agree that there was a breach of Clause 5.1 of the ABPI Code.

Clause 2 of the ABPI Code requires that 'Activities or materials must never be such as to bring discredit upon, or reduce confidence in the pharmaceutical industry.'

In relation to Clause 2, we note that a ruling of breach of Clause 2 is a sign of particular censure, reserved for such circumstances. We do not consider that Gilead's activities in relation to the Site and/or activities relating to the support of the [named conference] Wifi Access are such that they bring discredit upon, or reduce confidence in, the pharmaceutical industry and so we do not agree that they amount to a breach of Clause 2."

PANEL RULING

This complaint related to the Wi-Fi network at a European society's conference, where, upon entering the password, attendees were directed to the homepage of the US-owned Gilead Global Corporate website. The complainant alleged that the webpage "prominently featured a press release about an investigational indication for a product from Gilead" which they considered promotional and that conference attendees, including non-health professionals, were forced to view this website if they wished to access the conference Wi-Fi.

Gilead Sciences Europe Ltd (GSEL), a UK-based company, was a sponsor of the conference. As part of the sponsorship package, GSEL supported the provision of Wi-Fi access. The Panel considered that, as GSEL was a UK-based company, the activity had to comply with the UK Code and the national code of the country in which the conference took place. The Panel determined that this complaint was therefore within the scope of the ABPI Code.

GSEL had responded to the complaint, however, Gilead Sciences Ltd (GSL) was the ABPI member company. GSL was responsible for the acts and omissions of its UK-based European affiliate that came within the scope of the ABPI Code. The respondent company is referred to in this ruling as "Gilead" for ease of reference.

The Panel noted Gilead's submission that:

1. the conference, held in Poland in 2023, was a major international scientific conference that attracted attendees from all over the world,

2. the details of the Wi-Fi sponsorship package included that "the sponsor's website will be the default homepage", and

3. the webpage used was the homepage of Gilead's Global Corporate website, owned and managed by Gilead Sciences Inc (a US company).

In the Panel's view, most conference attendees would likely want to use the conference's Wi-Fi network and so would be taken to the homepage of the Gilead corporate website.

The Panel considered the series of screenshots submitted by Gilead showing the process of connecting to the Wi-Fi on a mobile device. Gilead had not provided the PMCPA with screenshots showing how Wi-Fi would be accessed on a laptop, so the Panel has based its ruling on the mobile device screenshots:

1. Users were first directed to read and agree with the terms and conditions, via a screen that stated "Wi-Fi brought to you by Gilead HIV".

2. After entering the password, which included "Gilead", users were taken to the homepage of Gilead's Global Corporate website.

3. Upon arriving at the homepage, users would see a cookie notice partly overlaying a pop-up box. The pop-up box stated "Welcome. Some content on this site is not intended for people outside the United States.". It included a button labelled "Accept" and the option to 'Close' in the top right corner. All the text of the pop-up box was visible to the reader before and after the cookie notice had been dismissed (in the screenshots provided to the Panel). There was also the option to click 'Done' at the top right of the screen.

4. Beneath the pop-up box, the homepage of the Gilead corporate website could be seen.

The Panel noted Gilead's submission that there was no requirement for users to interact with the Gilead website to gain internet access – users could choose, at this point, to either continue to the Gilead website or navigate away from the page and continue to use the internet.

Given the speed at which a user might click through the various steps involved in connecting to the Wi-Fi, the Panel considered that it was important that the intended audience of the default homepage was made unambiguously clear. The Panel noted that the pop-up stated 'some' content was not intended for people outside the US but there was no reference on the homepage to the intended audience. The headline of the press release in question appeared on the homepage under the heading 'Recent news' and the impression given from the homepage was that this news was intended for all visitors to the website.

The Panel considered that by sponsoring the Wi-Fi and choosing the global corporate webpage as the default homepage, Gilead was directing delegates to that webpage. The Panel accepted that delegates did not have to read the homepage in order to use the Wi-Fi. However, the Panel

considered that, as a UK-based pharmaceutical company had chosen to direct delegates to the global corporate homepage, which was owned by a US company, it had brought that homepage in scope of the ABPI Code. Furthermore, the Panel considered that Gilead would have reasonably expected some delegates to read the homepage otherwise they would not have selected it as the default webpage.

Based on the information provided by both parties, the Panel considered that the conference delegates likely included both health professionals and members of the public from multiple countries, including the UK.

Clause 26.1: Alleged promotion of a prescription only medicine to the public

The Panel noted that the headline in the 'Recent News' section of the default homepage, cited by the complainant, read:

> "Gilead Sciences Announces New Clinical Trial in Europe to Assess Lenacapavir for HIV Prevention as Part of Landmark Purpose Program"

The linked press release included the following sub-heading:

> "PURPOSE 5 trial will evaluate lenacapavir as twice-yearly prevention option in people who could benefit from HIV pre-exposure prophylaxis (PrEP) in France and the United Kingdom"

The press release included:

> "Current PrEP options may not meet the diverse needs of everyone who could benefit from PrEP, hindering the potential impact those medicines could have on reducing new infections. Lenacapavir is a first-in-class HIV capsid inhibitor that can be administered as a twice-yearly subcutaneous injection. It is currently approved, in combination with other antiretrovirals, for HIV treatment in persons with multidrug-resistant HIV-1 infection. It is also under investigation for HIV prevention. If approved, lenacapavir with its twice-yearly dosing could offer a potential long-acting option to help address the differing needs and preferences of individuals who could benefit from PrEP. The safety and efficacy of lenacapavir for HIV prevention has not been established."

It further included a quote from Gilead which stated:

> "There is a critical need to bring forward new PrEP options that are informed by and designed for the communities that could benefit from PrEP in Europe. We are excited to engage with communities and broader stakeholders to inform PURPOSE 5 and partner with them in our goal to develop person-centered innovations that can help end the HIV epidemic in Europe."

The Panel took account of the references to limitations of current PrEP options combined with use of the statements "critical need to bring forward new PrEP options" and "innovations that can help end the HIV epidemic in Europe". The Panel further took account of the term "landmark" in the headline and considered that the headline on the homepage and linked press release used emotive language that promoted lenacapavir.

The Panel bore in mind:

1. That a UK-based company had sponsored the Wi-Fi at a conference held in Europe and directed all conference delegates who used the Wi-Fi to the US-owned Gilead global corporate homepage, thus bringing that webpage in scope of the ABPI Code.
2. The pop-up alerted users to the fact that "some" content on the site was not intended for people outside the US but the homepage did not state the intended audience, nor did it give any indication about which content was for a US audience only.
3. The headline of the press release, and a link to it, was on the homepage. In the Panel's view, this implied that the intended audience of the press release included all visitors to the website.
4. The press release made specific reference to a trial in the UK.
5. The delegates at an international HIV conference would likely include health professionals and members of the public. Both of these groups of delegates would likely be attracted to the press release headline.
6. The headline on the homepage and linked press release referred to lenacapavir for HIV prevention and used emotive language (such as "landmark" and "innovations that can help end the HIV epidemic in Europe") which rendered it promotional.

The Panel considered the circumstances were such that a prescription only medicine had been advertised to the public and **a breach of Clause 26.1** was ruled.

Clause 11.2: Alleged promotion of a medicine to health professionals outside the terms of its marketing authorisation

The Panel had determined above that the news headline on the homepage and linked press release were promotional for lenacapavir and that the conference attendees included health professionals who had been directed towards that webpage by Gilead.

The Panel noted that use of lenacapavir for HIV prevention was outside the terms of its marketing authorisation and it ruled **a breach of Clause 11.2**.

Clause 5.1

There was no allegation about whether it was appropriate for a pharmaceutical company to sponsor Wi-Fi at the conference and therefore the Panel made no determination in that regard.

While noting that the default homepage was Gilead's global corporate website, the Panel queried whether a website owned by Gilead's US parent company was the most appropriate choice of default homepage for a conference held in Europe and sponsored by a UK-based company. The Panel queried why Gilead did not choose a different website/microsite given the differences in rules and regulations between the US and Europe.

The Panel acknowledged that the press release headline was not immediately visible on the default webpage and that delegates would have to scroll down the page before reaching the 'Recent News' section. The Panel also accepted that, while Wi-Fi users would be directed to the Gilead homepage, they were not required to remain there or to scroll down the page in order to gain internet access.

Nevertheless, the press release was present on the landing page to which all delegates using the Wi-Fi were directed. The Panel determined above that the news headline on the homepage and linked press release referred expressly to lenacapavir HIV prevention studies, including in the UK, and used emotive language that rendered it promotional. For those reasons, and because delegates at a HIV conference were directed to a webpage that promoted lenacapavir outside the terms of its marketing authorisation, the Panel concluded that high standards had not been maintained. The Panel ruled a **breach of Clause 5.1** in that regard.

Clause 2

Clause 2 was a sign of particular censure and reserved for such use. The Panel considered that the complainant's allegations were adequately covered by its rulings above and the matter was not such that Gilead had brought discredit upon or reduced confidence in the industry. The Panel therefore ruled **no breach of Clause 2**.

Complaint received **7 November 2023**

Case completed **6 March 2025**