

CASE AUTH/3603/1/22

ANONYMOUS v GILEAD

Concerns about a Gilead Europe website

CASE SUMMARY

This case was in relation to Gilead Sciences Europe's website HIV.eu.

The Panel ruled a breach of the following Clause(s) of the 2021 Code for failing to include obligatory information and because on the balance of probabilities, promotional information aimed at health professionals was available to members of the public:

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| Breach of Clause 5.1 | Failing to maintain high standards |
| Breach of Clause 12.1 | Failing to include up-to-date prescribing information |
| Breach of Clause 12.3 | Failing to include the non-proprietary name |
| Breach of Clause 12.10 | Failing to include the black triangle |
| Breach of Clause 26.1 | Advertising prescription only medicines to the public |
| Breach of Clause 26.2 | Encouraging members of the public to ask for a specific prescription only medicine |

The Panel ruled no breach of the following Clause(s) of the 2021 Code because it considered that the rulings of breaches adequately covered this matter:

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| No Breach of Clause 2 | Requirement that activities or material must not bring discredit upon, or reduce confidence in, the pharmaceutical industry |
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**This summary is not intended to be read in isolation.
For full details, please see the full case report below.**

FULL CASE REPORT

A complainant who described him/herself as a concerned UK health professional complained about Gilead Europe's website HIV.eu.

COMPLAINT

The complainant provided a screenshot of a website (HIV.eu) which he/she stated was controlled by Gilead Europe, based in the UK (and aimed at a UK audience).

The screenshot showed what appeared to be a landing page for hiv.eu/educational-resources with a box which stated 'HIV.eu is a site designed for healthcare professionals' followed by two options 'continue to site' or 'visit patient site'.

The complainant stated that clicking the patient box meant that the box disappeared, leaving the health professional site visible and eventually a message that the site could not be reached appeared. The complainant provided a screenshot showing the message.

The complainant stated that the delay was sufficiently long to start browsing the website aimed at health professionals without being aware that there should be something else which was currently missing, leading to patients and the public using a resource that was promotional. The complainant alleged that this was therefore promoting to the public due to the absence of alternative suitable material.

The complainant stated that hovering over the prescribing information bar at the top of the page displayed the following:

- Biktarvy prescribing information
- Genvoya prescribing information
- Descovy 10mg prescribing information
- Descovy 25mg prescribing information
- Odefsey prescribing information
- Truvada prescribing information
- Atripla prescribing information
- Eviplera prescribing information.

For each medicine the generic name was missing and for Biktarvy, there was also a missing black triangle. The complainant stated that in each case the link did [not do] as stated and [did not] link to the prescribing information, but to the summary of product characteristics (SPC) - although the link did not always work. There was therefore missing prescribing information for each of these items.

When writing to Gilead, the Authority asked it to consider the requirements of Clauses 12.1, 12.3, 12.10, 26.1, 26.2, 5.1 and 2 of the Code.

RESPONSE

Gilead stated that the HIV.eu website, which was the subject of the complaint, was owned and managed by Gilead Sciences Europe Limited (GSEL).

Gilead stated that upon receipt of this complaint, it had taken the precautionary step of suspending access to the HIV.eu site whilst it investigated the matters raised in the complaint, and to ensure the site was operating correctly.

Background

Gilead submitted that HIV.eu was a website intended for health professionals to support them in the management of HIV infection. Besides disease education on HIV, it also contained information on key events such as international medical conferences and some Gilead organised events.

As the site was aimed at health professionals, it was designed with an initial pop-up box to direct visitors to the site that was intended for them. The pop-up box stated 'HIV.eu is a site designed for healthcare professionals.' and then had two boxes labelled 'CONTINUE TO SITE' and 'VISIT PATIENT SITE', highlighting clearly the intended audience of the HIV.eu site and avoiding the public needing to continue to the site and accessing material intended for health professionals.

Gilead stated that as an additional mechanism to ensure members of the public were not exposed to promotional content, the site used the OneKey validation tool which required health professionals to confirm their healthcare professional status before they could proceed to those pages of the site that were behind the OneKey log in.

The HIV.eu site also made it clear at the top of the page that it was a health professional site with an adjacent banner stating 'PUBLIC SITE' to take others to a site aimed at the public.

Complaints raised by the complainant

Gilead responded to the allegations raised following the complainant's visit to the site on 20 January 2022.

1 Patients had to use a resource that was promotional and Gilead was promoting to the general public

Gilead noted that the complainant had described that when he/she visited the site on the 20 January 2022, the 'VISIT PATIENT SITE' box was not working correctly to connect the visitor to the intended site and that clicking on that 'box' instead resulted in a page being displayed which stated: 'This site can't be reached'.

The complainant stated that the delay was sufficiently long for him/her to start browsing the HIV.eu website and, whilst this was not how the site was intended to operate, Gilead accepted that, in the short time before the error page was displayed, it was technically possible to browse the site as described.

However, Gilead did not accept that this had the consequence of patients and/or the public using a resource that was promotional. This was because only non-promotional content was visible to them (content available before the OneKey login). The complainant did not himself/herself indicate what part(s) of the content was visible on the site that they considered to be promotional.

As indicated above, the site used a healthcare professional validation system to control access to promotional content and so it was not possible for patients/members of the public to access promotional resources at this time. Whilst some content was visible without OneKey validation, this content was general non-promotional and/or non-product specific HIV disease education and event and/or activity information – intended for health professionals but not unsuitable for patients and/or members of the public.

The content that was visible was:

- 1 The HIV.eu homepage, which on the date the complainant visited the site had included two headline banners which linked to further information but the detailed content itself was not accessible without a OneKey log in.
- 2 An Event homepage (via a link at the top of the homepage) which provided access to information and video highlights from key conferences, online seminars and continuing educational programmes. The only accessible content without a OneKey login was:
 - a) information about Gilead's The Voice HIV: Clinical Research Training program; and
 - b) information about the 'For a LIFE Beyond HIV: Virtual webinar series'.
- 3 The Resources homepage (via a link at the top of the homepage) which provided resources relating to HIV diagnosis and treatment. The only accessible content without a OneKey login was:
 - c) a further link to information about the 'For a LIFE Beyond HIV: Virtual webinar series';
 - d) an educational resource on Patient-reported outcomes;
 - e) information about the Gilead Research Scholars program;
 - f) a patient video – 'From the Frontline: Katherine and Justin's story';
 - g) information about HIV treatment goals;
 - h) information about starting treatment;
 - i) information about working towards viral suppression;
 - j) information about comorbidities and HIV; and
 - k) information about the importance of adherence strategies.
- 4 A tab at the top of the page which stated 'Prescribing Information' and when hovered over revealed a drop-down list of Gilead HIV products which linked to information about those products on the emc (electronic medicines compendium) website.
- 5 A tab at the top of the page which stated 'Guidelines' and when clicked linked to a section providing external open access links to the latest approved guidelines for prevention, diagnosis and treatment of HIV.

In relation to the Prescribing Information and to the Guidelines, these resources provided non-promotional reference information to the intended health professional audience and should be considered the same should it have been viewed by a patient and/or member of the public in the circumstances raised by the complainant.

Gilead therefore did not accept that there was a breach of Clause 26.1 of the 2021 Code as the parts of the site that became visible to the patient/public did not advertise prescription only medicines to the public.

Further, as indicated above, in relation to the content/information that was visible (directly or indirectly) without a OneKey validation, to the extent this information was about prescription only medicines, it was factual, presented in a balanced way and it did not raise unfounded hopes of successful treatment or mislead with respect to the efficacy or safety of any product.

The visible content was not intended for patients and/or members of the public and, to the extent that it was in fact accessible by them, such visible content was not provided for the purpose of encouraging patients and/or members of the public to ask their health professional to prescribe a specific prescription only medicine.

Gilead therefore did not accept that there was a breach of Clause 26.2 of the Code.

2 The medicines listed on the site did not also have adjacent to them the generic name

Gilead stated that this part of the complaint related to the medicine names included in a drop-down list under the 'prescribing information' tab at the top corner of the website.

Clause 12.3 of the Code required that 'The non-proprietary name of the medicine ... must appear immediately adjacent to the most prominent display of the brand name ... For electronic advertisements, the non-proprietary name of the medicine ... must appear immediately adjacent to the brand name at its first appearance ...'.

Clause 12.3 was in the Blue Section of the Code – 'Promotion to Health Professionals and Other Relevant Decision Makers'. As such, this requirement was relevant to the display of the brand name in promotional content or advertisements.

At the time that the website was viewed by the complainant, Gilead accepted that the brand names first appeared on the HIV.eu site in this drop-down list.

Whilst Gilead did not accept that including the medicine names in this list in itself constituted the promotion of these medicines, to the extent that the site, as a whole, (including content behind the OneKey log in) was to be considered in relation to this part of the complaint, then Gilead conceded that the display of brand names here without the non-proprietary name of the medicine appearing immediately adjacent was a breach of Clause 12.3 of the Code.

3 For Biktarvy there was a missing black triangle

Gilead stated that this part of the complaint, again, related to the drop-down list under the 'prescribing information' tab at the top corner of the website.

Clause 12.10 of the Code required that 'When required by the licensing authority, all promotional material must clearly show an inverted black equilateral triangle to denote that additional monitoring is required in relation to adverse reactions. ...The symbol should appear once and be located adjacent to the most prominent display of the name of the product. ... 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...'.

As for Clause 12.3 mentioned at point 2) above, Clause 12.10 was in the Blue Section of the Code – 'Promotion to Health Professionals and Other Relevant Decision Makers'. As such, this requirement was relevant to the display of the brand name in promotional content or advertisements, and this was also made clear in the requirement.

In relation to this clause and this part of the complaint, Gilead contended that the use of Biktarvy in this list was not promotional content nor an advertisement of Biktarvy.

As such, Gilead did not accept that the display of Biktarvy without the use of a Black Triangle in this list was a breach of Clause 12.10 of the Code.

4 Missing prescribing information for each medicine named

Gilead noted that the complaint raised two issues. First the complainant alleged that the links from the drop-down list of medicines in the Prescribing Information list did not always work. When Gilead tested the links on receipt of the complaint, it found that they did all work except in relation to Atripla.

However, that in itself was not a breach of Clause 12.1 of the Code unless the HIV.eu web site contained promotional information for Atripla without that content also including the necessary Prescribing Information.

The complainant did not identify any promotional information for Atripla on the HIV.eu website that required the provision of prescribing information. Atripla was mentioned in two videos available through the HIV.eu website after the OneKey login and the complete prescribing information for Atripla was provided at the end of these videos.

The second issue raised by the complainant was that the links from the other medicine names in the Prescribing Information drop-down list did not take you to the Prescribing Information but to the SPC.

The links took the website visitor to the relevant page of the emc (electronic medicines compendium) website for each medicine and provided the SPC and legal category for each medicine. However, Gilead acknowledged that the cost information was not also provided and as such accept that the prescribing information was not complete, in breach of Clause 12.1 of the Code.

Clause 5.1 and Clause 2 of the Code

In accepting that breaches of the Code had occurred in relation to the HIV.eu web site, Gilead accepted that it had not maintained high standards in breach of Clause 5.1 of the Code.

In relation to Clause 2 of the Code, Gilead noted that a ruling of a breach of Clause 2 was a sign of particular censure, reserved for such particular and serious circumstances. Gilead did not consider that Gilead Science Europe's activities in relation to the HIV.eu website were such that they brought discredit upon, or reduce confidence in, the pharmaceutical industry and so Gilead did not accept that they amounted to a breach of Clause 2 of the Code.

Gilead provided copies of the relevant materials referred to in this letter, as well as copies of certificates approving each of the items.

PANEL RULING

The Panel noted Gilead's submission that the HIV.eu website was owned and managed by Gilead Sciences Europe Limited. The Panel noted Gilead Sciences Europe Limited was based in the UK and the website was thus subject to the ABPI Code.

The Panel noted that Clause 26.1 prohibited the promotion of prescription-only medicines to the public and Clause 26.2 stated, *inter alia*, that statements must not be made for the purpose of encouraging members of the public to ask their health professional to prescribe a specific prescription only medicine.

The Panel noted Gilead's submission that the HIV.eu website was intended for health professionals to support them in the management of HIV infection; besides disease education on HIV, it also contained information on key events such as international medical conferences and some Gilead organised events.

The Panel noted Gilead's submission that the site highlighted the intended audience and was designed with an initial pop-up box to direct visitors to the site that was intended for them avoiding the public needing to continue to the site and access material intended for health professionals. The Panel noted that the pop-up box stated 'HIV.eu is a site designed for healthcare professionals.' and then had two boxes labelled 'CONTINUE TO SITE' and 'VISIT PATIENT SITE'. The Panel noted that it appeared that when the complainant visited the site in January 2022, the 'VISIT PATIENT SITE' box was not working correctly and that clicking on that 'box' instead resulted in a page being displayed which stated: 'This site can't be reached'. The Panel noted that Gilead accepted that in the short time before the error page was displayed it was technically possible to browse the site as described by the complainant. The Panel, however, did not know exactly how long this was possible for, the complainant referred to the delay as being sufficiently long and Gilead referred to a short time.

The Panel further noted Gilead's submission that the HIV.eu site also made it clear at the top of the page that it was a health professional site with an adjacent banner stating 'PUBLIC SITE' to take others to a site aimed at the public. The Panel noted that there was a 'HEALTH PROFESSIONAL SITE' and 'PUBLIC SITE' tab in the top left-hand corner of the health professional website but considered that this could easily be missed by readers and in the particular circumstances of this case, the complainant had selected the patient site from the pop up but had been presented with the health professional site until the message that the site could not be reached appeared and thus might not have noticed that the site was not intended for the public. In this regard, the Panel noted that the complainant referred to browsing the website aimed at health professionals without being aware that there should be something else which was currently missing.

The Panel noted Gilead's submission that as an additional mechanism to ensure members of the public were not exposed to promotional content, the site used the OneKey validation tool which required health professionals to confirm their healthcare professional status before they could proceed to those pages of the site that were behind the OneKey log in.

The Panel noted Gilead's submission that it did not accept that the possibility to browse the site had the consequence of patients and/or the public using a resource that was promotional because only non-promotional content was visible to them (content available before the OneKey login). Gilead noted that the complainant did not indicate what part(s) of the content was visible on the site that they considered to be promotional. The Panel noted Gilead's submission that whilst some content was visible without OneKey validation, this content was general non-

promotional and/or non-product specific HIV disease education and event and/or activity information – intended for health professionals but not unsuitable for patients and/or members of the public.

The Panel noted Gilead's response included a schedule documenting the enclosures provided and stated which could be accessed without a OneKey log in. The enclosures which could be accessed without a OneKey log in included The Voice HIV: Clinical research training, whilst the Panel did not have details of the training before it, it noted that the purpose of the training was described as to help develop future HIV research leaders. The Panel noted that the schedule also included a module on patient reported outcomes (IHQ-HIV-2020-12-0004) which did not require OneKey log in to be accessed. The module included a slide (slide 18) showing the differences in bothersome CNS and GI symptoms between BIC/FTC/TAF and DTG/AB/3TC in two Phase 3 studies which appeared to either show no difference or favoured Gilead's medicine BIC/FTC/TAF (Bictarvy) and stated at the bottom of the slide that prescribing information could be found at the end of the presentation which it was not; it thus appeared to the Panel that it was taken from a promotional presentation. The schedule explained that restricted access content had a padlock symbol and gave the BicStar study and Video highlights from CROI as examples of restricted access content but submitted that no padlock was showing on the screenshot page provided. On review, the Panel noted the screenshots of the hiv.eu Educational resources page provided by Gilead did show a padlock on the icon for Video highlights from CROI 2021: virtual conference and the BICSTaR study: a visual overview. The Panel noted, however, that the screenshot provided demonstrating what the viewer would see when the icon for the BICSTaR study: a visual overview with a padlock symbol was clicked on within the Educational Resources section of the website. The Panel noted that the information that could be seen prior to logging in was, in its view, promotional. It stated 'The 12 month results of the Bictegravir Single Tablet Regimen (BICSTaR) study indicate that bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF) [Bictarvy] is effective and well tolerated in antiretroviral therapy naïve and experienced persons living with HIV. Find out more about the 12 month study results below'. The Panel noted that it did not have similar information before it with regards to what could be seen if any of the other padlocked icons were selected before actually logging in. Nonetheless, it appeared, noting the above, that, on the balance of probabilities, information aimed at health professionals which was promotional was available to members of the public who might have selected the 'VISIT PATIENT SITE' prior to the error page appearing and thus the Panel ruled a **breach of Clause 26.1**. The Panel noted the statements above with regards to the Bictegravir Single Tablet Regimen and considered that they might encourage members of the public to ask their health professional to prescribe a specific prescription only medicine and a **breach of Clause 26.2** was ruled.

The Panel noted that it appeared that whilst Gilead did not accept that including the medicine names in the prescribing information list in itself constituted the promotion of those medicines, it appeared to accept that the site as a whole (including content behind the OneKey log in) was promotional and therefore the first mention of the brand names in the drop down list under the 'prescribing information' tab without the non-proprietary name of the medicine appearing immediately adjacent to it was a breach of Clause 12.3. The Panel therefore ruled a **breach of Clause 12.3** in relation to each of the eight products listed as acknowledged by Gilead.

Clause 12.10 stated that digital communications were also covered by the requirement to clearly show an inverted black equilateral triangle to denote that additional monitoring is required in relation to adverse reactions in all promotional material when required by the licensing authority. It stated that in digital communications, 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. In the Panel's view, noting the above, the health professional website was promotional, albeit that certain content was only available following a OneKey login. The Panel noted that the website did not include an inverted black triangle for Biktarvy as required by **Clause 12.10** and a **breach** was ruled.

Clause 12.1 required the prescribing information listed in Clause 12.2 to be provided on all promotional material. Clause 12.2 listed the components of prescribing information. The Panel noted the complainant was concerned that the links to prescribing information took readers to the SPC rather than the prescribing information. The Panel noted, however, that the supplementary information to Clause 12.2 stated that the Code defined prescribing information to consist of three parts: the legal classification, the cost and other elements (listed as i-viii) in Clause 12.2. and with an electronic advertisement, elements i-viii could be provided by a prominent, direct single click link to the summary of product characteristics. The Panel noted Gilead's submission that whilst the links took readers to the relevant page of the emc (electronic medicines compendium) website for each medicine and provided the SPC and legal category for each medicine, the cost information was not provided and as such it accepted that the prescribing information was not complete as required. The Panel therefore ruled a **breach of Clause 12.1** in relation to each of the medicines apart from Atripla (see further information below) as acknowledged by Gilead.

The Panel noted the complainant's further concern that the links to the SPCs did not always work. The Panel noted Gilead's submission that when it tested the links on receipt of the complaint, it found that they all worked except in relation to Atripla. The Panel noted Gilead's further submission that this in itself was not a breach of Clause 12.1 of the Code unless the HIV.eu website contained promotional information for Atripla without that content also including the necessary prescribing information and the complainant did not identify any promotional information for Atripla on the HIV.eu website that required the provision of prescribing information. The Panel further noted Gilead's submission that Atripla was mentioned in two videos available through the HIV.eu website after the OneKey login and the complete prescribing information for Atripla was provided at the end of these videos.

Whilst the Panel noted that the complainant had not established that the website homepage specifically promoted Atripla, the Panel noted its view that the website which was aimed at health professionals was promotional which appeared to be accepted by Gilead. The Panel further noted that Gilead had accepted that the incomplete prescribing information had not been provided for each of the products listed within the prescribing information tab in breach of Clause 12.1. The Panel noted that it did not have the entire content of the website before it, but it appeared that Gilead felt it necessary to include a link to the Atripla prescribing information on the homepage alongside the other listed medicines and if a link to prescribing information was included it should work. The Panel noted that Clause 12.4 stated that in digital material such as advertisements in electronic journals, emails, electronic detail aids and suchlike, the prescribing information as required by Clause 12.1 may be provided either by inclusion in the digital material itself, or by way of a clear, and prominent, direct, single click link. The Panel considered that failure to include a working link to the obligatory prescribing information meant that the requirements of **Clause 12.1** had not been met and a **breach** was ruled in relation to Atripla.

The Panel noted its comments and rulings above and considered that Gilead had failed to maintain high standards and a **breach of Clause 5.1** was ruled as acknowledged by Gilead.

The Panel noted its rulings above, including a breach of Clauses 12.10 and 5.1, and although it considered that it was unacceptable to omit the black triangle, where relevant on the website in question, it could, nonetheless, be viewed when the SPC was accessed from the links within the website. The Panel considered that the rulings of breaches adequately covered this matter and an additional ruling of a breach of Clause 2 would be disproportionate in the particular circumstances of this case. A ruling of a breach of Clause 2 was used as a sign of particular censure and reserved for such use. The Panel, on balance, ruled **no breach of Clause 2**.

Complaint received **20 January 2022**

Case completed **22 March 2023**