

**CASE AUTH/3282/11/19**

## **VIIV/DIRECTOR v GILEAD**

### **Breach of undertaking**

ViiV Healthcare UK Ltd alleged that Gilead Sciences Europe Ltd had breached its undertaking given in Case AUTH/3137/12/18 by continuing to use the claim that Biktarvy (bictegravir/emtricitabine/tenofovir) was 'Better tolerated than DTG [dolutegravir] – containing regimens'. Biktarvy was used in the treatment of adults infected with human immunodeficiency virus-1 (HIV-1). ViiV promoted Juluca (dolutegravir/rilpivirine) for the treatment of HIV-1 infection in adults.

ViiV noted that the claim at issue was the subject of an unsuccessful appeal by Gilead and was ruled to be in breach by the Code of Practice Appeal Board on 9 October 2019. ViiV provided screenshots from 20 November which showed that the claim was still being used on a UK accessible website. Given that Gilead owned the website, ViiV stated that it would have expected a complete and immediate withdrawal of the offending claims following the appeal decision.

The complaint was also taken up in the name of the Director as the Authority was responsible for ensuring compliance with undertakings.

The response from Gilead is detailed below.

The Panel noted that a form of undertaking and assurance was an important document. Companies had to give an undertaking that the material in question and any similar material, if not already discontinued or no longer in use would cease forthwith and give an assurance that all possible steps would be taken to avoid similar breaches of the Code in future. It was very important for the reputation of the industry that companies complied with undertakings.

The Panel noted that in Case AUTH/3137/12/18, Gilead accepted that the claim in question was in breach of the Code; its undertaking was dated 18 November 2019.

Turning to the present case, Case AUTH/3282/11/19, ViiV noticed that the claim in question was still in use on 20 November on a Gilead-owned UK accessible website. There had thus been a failure to comply with the undertaking given in Case AUTH/3137/12/18 and a breach of the Code was ruled as acknowledged by Gilead. High standards had not been maintained and a further breach was ruled as acknowledged by Gilead.

The Panel considered that Gilead's failure to comply with its undertaking brought discredit upon, and reduced confidence in, the pharmaceutical industry. A breach of Clause 2 was ruled.

ViiV Healthcare UK Ltd alleged that Gilead Sciences Europe Ltd had breached its undertaking given in Case AUTH/3137/12/18. The claim at issue was that Biktarvy (bictegravir/emtricitabine/tenofovir) was 'Better tolerated than DTG [dolutegravir] – containing regimens'. Biktarvy was used in the treatment of adults infected with human immunodeficiency virus-1 (HIV-1). ViiV promoted Juluca (dolutegravir/rilpivirine) for the treatment of HIV-1 infection in adults.

The complaint was also taken up in the name of the Director as the Authority was responsible for ensuring compliance with undertakings.

## **COMPLAINT**

ViiV noted that the claim at issue was the subject of an unsuccessful appeal by Gilead and was ruled to be in breach by the Code of Practice Appeal Board on 9 October 2019. ViiV provided screenshots from 20 November which showed that the claim was still being used on a UK accessible website. Given that Gilead owned the website, ViiV stated that it would have expected a complete and immediate withdrawal of the offending claims following the appeal decision on 10 October.

ViiV alleged a breach of Clauses 29, 9.1 and 2.

## **RESPONSE**

Gilead noted the allegation that a claim ruled in breach in Case AUTH/3137/12/18 continued to appear on a Gilead owned website on 20 November 2019, two days after the company had provided an undertaking and assurance that it would take all possible steps forthwith to avoid similar breaches of the Code occurring in future.

On being notified of Case AUTH/3282/11/19, Gilead stated that it immediately investigated the issue and identified that similar material to that ruled in breach in Case AUTH/3137/12/18 appeared on the password protected health professional only pages of Gilead's hiv.eu website. The necessary corrective action was taken on 22 November to remove claims from the website.

Gilead acknowledged that the material visible on the website two days after its undertaking was provided fell within the scope of that undertaking and, in the circumstances, was in breach of Clause 29 of the Code. Gilead also understood that it had failed to maintain high standards in breach of Clause 9.1.

Gilead understood the importance of the undertaking provided in Case AUTH/3137/12/18, and the importance of taking all necessary steps to fully and immediately comply with it.

## **PANEL RULING**

The Panel noted that a form of undertaking and assurance was an important document. Companies had to give an undertaking that the material in question and any similar material, if not already discontinued or no longer in use would cease forthwith and give an assurance that all possible steps would be taken to avoid similar breaches of the Code in future (Paragraph 7.1 of the Constitution and Procedure). It was very important for the reputation of the industry that companies complied with undertakings.

The Panel noted that in Case AUTH/3137/12/18, upon appeal by Gilead, the claim that Biktarvy was 'Better tolerated than DTG [dolutegravir] – containing regimens' was ruled in breach of the Code. Gilead was informed of the outcome of the appeal on 6 November 2019 and its undertaking, accepting the Appeal Board's decision, was dated 18 November 2019.

Turning to the present case, Case AUTH/3282/11/19, ViiV noticed that the claim in question was still in use on 20 November on a Gilead-owned UK accessible website. There had thus been a failure to comply with the undertaking given in Case AUTH/3137/12/18 and a breach of Clause 29 was ruled as acknowledged by Gilead. High standards had not been maintained and the Panel also ruled a breach of Clause 9.1 as acknowledged by Gilead.

The claim at issue remained published on a Gilead-owned website after the company had signed its undertaking stating that it would take all possible steps to avoid similar breaches of the Code in future. The Panel considered that Gilead's failure to comply with its undertaking which underpinned self-regulation, amongst other things, brought discredit upon, and reduced confidence in, the pharmaceutical industry. A breach of Clause 2 was ruled.

**Complaint received**      **21 November 2019**

**Case completed**        **29 January 2020**