

**CASE AUTH/3384/9/20**

## **COMPLAINANT v BAYER**

### **Promotion of Ventavis**

A complainant, who described him/herself as a concerned UK health professional, complained about a 'Dear Pharmacist' letter (ref UK.PH.GM.VEN.2012.004) about the distribution and supply of Ventavis (iloprost trometamol) on Bayer Plc's website.

Ventavis was a nebuliser solution indicated for the treatment of adults with primary pulmonary hypertension, classified as NYHA functional class III, to improve exercise capacity and symptoms.

The complainant alleged that materials on Bayer's website were visible to all and appeared to be extremely out-of-date. The complainant provided a link to the 'Dear Pharmacist' letter at issue which appeared to show that it had been available via the media section of Bayer's website and appeared to have been placed in 2012 and had not been updated since. It appeared that the material had not been certified every two years, nor had the prescribing information been updated as required.

The detailed response from Bayer is given below.

The Panel noted Bayer's submission that the letter identified by the complainant was intended for pharmacists to inform them of changes to the supply arrangements for Ventavis that were to take effect in May 2012. The letter was certified for distribution in May 2012 and was first used on 14 May 2012.

The Panel noted from Bayer that the letter had never been available on the corporate website although it had, for reasons unknown to the company, been located in the 'resource area' of the website. The resource area was not intended for direct access by anyone external to the company and appeared to essentially be a storage area. The Panel noted Bayer's submission that it had previously considered that information kept in the resource area but not linked to a webpage could not be accessed by anyone outside the company. Bayer had not found any evidence that access to the resource area for the purpose of accessing the letter was ever granted to anyone outside the company.

The Panel noted Bayer's submission that the letter could not be found by navigating any of the content available on the website when the complaint was received nor had it found any evidence that the letter was ever accessible by navigation from the website in 2012, or subsequently. Following further enquiry, Bayer understood that the letter could be found and accessed by an online search using specific search criteria, eg by searching on Google using the word 'Ventavis' and the name of the employee who signed the letter.

**Bayer understood that was possible because search engines such as Google could index all websites globally by using web crawlers that 'spider' the entire website including content not intended for public viewing, eg from the resource area where the letter was located. Once created, the index was stored in the search engine's online search library which rendered the information searchable even though the content could not be accessed directly by searching the website itself.**

**The Panel noted that the complainant had not submitted his/her search strategy. The search strategy provided by Bayer relied on the person searching the internet to know not only the name of the medicine but also the name of the employee who signed the letter. The Panel considered that, on the evidence before it, the balance of probabilities was that the letter was not visible to all on the Bayer website as alleged. It appeared that due to indexing by Google, the complainant had indirectly accessed an area of the Bayer website which was intended for direct access only by company personnel and not health professionals or members of the public.**

**Although the Panel was concerned that material which did not appear to meet the requirements of the Code could be accessed via a Google search, it seemed reasonable in this case to consider the letter as material on an internal company page rather than that which was intended for UK health professionals. The Panel decided that in the particular circumstances of this case, the now out-of-date prescribing information on a stored document which was not 'live' on the company website did not amount to a breach of the Code as alleged and no breach was ruled.**

**Similarly, the Panel considered that the circumstances of this case did not amount to the promotion of a prescription-only medicine to the public and no breach of the Code was ruled.**

**The Panel noted that the letter was certified in May 2012 and had not been recertified since. In that regard, however, given that the letter was not still in use, it did not need to be recertified and so the Panel ruled no breach of the Code.**

**The Panel was concerned that, due to web crawlers over which Bayer had no control, the letter could be found via a Google search but, nonetheless, given its comments and rulings above, it considered that in the specific circumstances of this case, the company had not failed to maintain high standards. No breach of the Code was ruled.**

A complainant, who described him/herself as a concerned UK health professional, complained about a 'Dear Pharmacist' letter (ref UK.PH.GM.VEN.2012.004) about the distribution and supply of Ventavis (iloprost trometamol) which he/she found on Bayer Plc's website (bayer.co.uk).

Ventavis was a nebuliser solution indicated for the treatment of adults with primary pulmonary hypertension, classified as NYHA functional class III, to improve exercise capacity and symptoms.

## **COMPLAINT**

The complainant referred to materials on Bayer's website which he/she submitted were visible to all and appeared to be extremely out-of-date. The complainant provided a link to the 'Dear

Pharmacist' letter at issue which appeared to show that it had been available via the media section of Bayer's website. The complainant noted that the letter appeared to have been placed in 2012 and had not been updated since. The complainant stated that he/she did not believe that the material had been certified every two years, nor had the prescribing information been updated as required. This appeared to be evidence of poor document management.

When writing to Bayer, the Authority asked it to consider the requirements of Clauses 4.1, 9.1, 14.5 and 26.1 of the Code.

## **RESPONSE**

By way of background, Bayer explained that the online link provided by the complainant was to a letter entitled 're: Supply of Ventavis (Iloprost Trometamol [sic]) 168 x 1ml and 30 x 1ml vials'. The letter was intended to inform pharmacists about changes to the supply arrangements for Ventavis that were to take effect in May 2012. The letter was certified as a promotional item for email and postal distribution in May 2012. It was first used on 14 May 2012. A copy of the electronic approval certificate was provided. In accordance with Bayer's document retention policy, the hard copy certificate for the letter in its final printed form was not available.

Bayer noted that when it received the complaint, the letter could not be found by navigating any of the content available on the website. Viewers could not see a link to the documents page from the media page on the UK website. Furthermore, Bayer had found no evidence that the letter was ever accessible by navigation from the website in 2012, or anytime subsequently. In that sense, it was not accurate for the complainant to state that the letter was 'visible to all' on Bayer's website.

However, Bayer had established that the letter was located as a pdf document in what was known as a 'resource area' of the website when the complainant accessed it. The resource area was a storage area for images, documents and videos, but not all of that content was embedded into a webpage on the website as such. Hence, only certain content in the resource area could be accessed via navigation from the website. The letter was in the resource area but it was not embedded into a webpage on the website. Information placed in the resource area was not intended for direct access by anyone external to the company.

Following further enquiry, Bayer understood that the letter could be found and accessed online by making a search using specific search criteria on third-party internet search engines, eg a link to the letter in the resource area of the website was found via a Google search using the word 'Ventavis' and the name of the employee who signed the letter.

Bayer understood that was possible because third-party internet search engines such as Google indexed all websites globally by using web crawlers that 'spider' the entire website content including content not intended for public viewing from the resource area where the letter was located. Once the index was created this was stored in the search engine's online search library, rendering the information searchable even though the content could not be accessed directly by going to the website in question and searching for the content directly on the website itself.

Bayer had been unable to ascertain why the letter was ever stored in the resource area of the website. Bayer had previously considered that information unlinked to a webpage and kept in the resource area could not be accessed by anyone outside the company. Bayer had not found

any evidence that access to the resource area for the purpose of accessing the letter was ever granted to anyone outside the company.

The specific circumstances relating to the complaint were highly unusual and Bayer was therefore unaware of the possibility for third-party internet search engines to offer links to areas of a website that the company considered inaccessible to the public. However, Bayer must accept that because the complainant could access the letter on or about the date of the complaint (9 September 2020), the company had inadvertently breached Clauses 4.1, 9.1, 14.5 and 26.1 of the 2019 Code. Bayer very much regretted those breaches and had taken steps to ensure no repeat of this was possible in the future. The letter at issue was deleted from the resource area on 23 September 2020 and Bayer had undertaken review of the company's digital archiving processes and other websites to ensure that such material was not inadvertently made available by third-party search engines in the future.

### **PANEL RULING**

The Panel noted Bayer's submission that the letter identified by the complainant was intended for pharmacists and informed them of changes to the supply arrangements for Ventavis that were to take effect in May 2012. The letter was certified as a promotional item for email and postal distribution in May 2012 and was first used on 14 May 2012.

The Panel noted from Bayer's submissions that the letter had never been available on the corporate website although it had, for reasons unknown to the company, been located in the 'resource area' of the website. The resource area was not intended for direct access by anyone external to the company. The resource area appeared to essentially be a storage area and while some of that content was embedded into webpages on the website, some of it, eg the letter in question, was not. The Panel noted Bayer's submission that it had previously considered that information kept in the resource area but not linked to a webpage could not be accessed by anyone outside the company. Bayer had not found any evidence that access to the resource area for the purpose of accessing the letter was ever granted to anyone outside the company.

The Panel noted Bayer's submission that the letter could not be found by navigating any of the content available on the website when the complaint was received nor had it found any evidence that the letter was ever accessible by navigation from the website in 2012, or subsequently.

The Panel noted Bayer's submission that following further enquiry, it understood that the letter could be found and accessed by an online search using specific search criteria, eg by searching on Google using the word 'Ventavis' and the name of the employee who signed the letter. Bayer understood that was possible because search engines such as Google could index all websites globally by using web crawlers that 'spider' the entire website content including content not intended for public viewing, eg from the resource area where the letter was located. Once created, the index was stored in the search engine's online search library which rendered the information searchable even though the content could not be accessed directly by searching the website itself.

The Panel noted that the complainant had not submitted his/her search strategy. The search strategy provided by Bayer relied on the person searching the internet to know not only the name of the medicine but also the name of the employee who signed the letter. The Panel

considered that, on the evidence before it, the balance of probabilities was that the letter was not visible to all on the Bayer website as alleged. It appeared that due to indexing by Google, the complainant had indirectly accessed an area of the Bayer website which was intended for direct access only by company personnel and not health professionals or members of the public.

Although the Panel was concerned that material which did not appear to meet the requirements of the Code could be accessed via a Google search, it seemed reasonable in this case to consider the letter as material on an internal company page rather than that which was intended for UK health professionals. The Panel decided that in the particular circumstances of this case, the now out-of-date prescribing information on a stored document which was not 'live' on the company website did not amount to a breach of the Code as alleged. No breach of Clause 4.1 was ruled.

Similarly, although it was unfortunate that the letter could, using very specific search terms, be accessed by members of the public via Google, the Panel noted that it could not be accessed directly from Bayer's website; it was stored in an area that was not intended to be accessible to users outside of the company. The Panel considered that the circumstances of this case did not amount to the promotion of a prescription-only medicine to the public. No breach of Clause 26.1 was ruled.

The Panel noted that the letter was certified in May 2012 and had not been recertified since. In that regard, however, given that the letter was not still in use, it did not need to be recertified and so the Panel ruled no breach of Clause 14.5.

The Panel noted Bayer's submission that the letter at issue was deleted from the resource area on 23 September 2020 and that the company had reviewed its digital archiving processes and other websites to ensure that such material was not inadvertently made available by third-party search engines in the future. In the Panel's view, this case illustrated that companies should exercise extreme caution and, wherever possible, ensure that documents which were not intended for viewing on their websites were not uploaded at all or if, for whatever reason, they were placed on parts of the website which were for internal use only then they were securely hidden from view and thus inaccessible to people outside of the company.

The Panel was concerned that, due to web crawlers over which Bayer had no control, the letter could be found via a Google search but, nonetheless, given its comments and rulings above, it considered that in the specific circumstances of this case, the company had not failed to maintain high standards. No breach of Clause 9.1 was ruled.

**Complaint received**      **9 September 2020**

**Case completed**        **29 March 2021**