CASE AUTH/3444/12/20

COMPLAINANT v TAKEDA

Alleged promotion of TAK-620 (maribavir) on LinkedIn

A complainant who described him/herself as a concerned UK health professional, complained about the promotion of TAK-620 (maribavir) on LinkedIn by Takeda UK Limited.

The complainant provided a screenshot of and link to a Takeda employee's profile on LinkedIn. The employee, with global responsibility, was based in the UK. The LinkedIn profile included links to a news release in the employee's 'Activity' section due to him/her 'liking' and sharing it. From the screenshot provided, it appeared that the article was partially entitled 'We're proud to announce top-line data from our phase 3 trial of TAK-620 (maribavir) in transplant recipients with refractory/resistant....'.

The complainant alleged that the employee had promoted the company's medicines in the UK to the general public.

The detailed response from Takeda is given below.

The Panel noted Takeda's submission that in December 2020, and without the prior knowledge or permission of the company, an employee working in a global role, but physically located in the UK, used his/her private LinkedIn account to share and 'like' a post published on the Takeda Pharmaceuticals Global LinkedIn account which was managed from Japan. Takeda's investigation further revealed that an employee of Takeda UK had also 'liked' the original employee's post, again without the prior knowledge or permission of the company. Both employees had a large number of connections many of whom were based in the UK, including members of the public.

The Panel noted that the article associated with the LinkedIn post, entitled:

'New Phase 3 Data Show TAK-620 (maribavir), an Investigational Drug for the Treatment of Transplant Recipients with Refractory/Resistant Cytomegalovirus(CMV) Infections, Meets Primary Endpoint' discussed the positive trial results for maribavir and concluded with the statement 'We look forward to discussing these data with global health authorities including the U.S. Food and Drug Administration and European Medicines Agency as we work to bring maribavir to patients.'

The Panel noted that maribavir was not classified as a prescription only medicine when the LinkedIn post was shared and 'liked' by the global UK-based employee and liked by a UK employee. Clause 26.1 only applied to prescription only medicines. On that very narrow technical point the Panel did not consider that a prescription only medicine had been promoted to the public and so it ruled no breach of the Code.

The Panel understood that employees might feel inclined to endorse articles related to their senior colleagues on LinkedIn or their company's corporate/global social media posts but noted that depending on the content such activity might or might not fall within the scope of the Code; companies would be well advised to cover the possibility of that activity in their social media policies. This was particularly important if UK employees were likely to follow the social media accounts of overseas affiliates which might have Codes, laws and regulations that differed to the UK.

The Panel noted the Takeda Global Social Media Policy, dated January 2017, and a local (UK) supplement to its global social media policy issued in July 2019 and a table of Q&As. The Panel considered that the instructions to UK employees and UK-based employees not to refer to or engage with posts relating to company products on social media were clear and unambiguous. The Panel noted Takeda's submission that the two employees in question had completed training and passed assessments for both the Global Social Media Policy and the UK Social Media Policy Supplement.

The Panel noted its comments above and considered that it was unfortunate that Takeda had been badly let down by two of its employees who had, in contravention of UK company policy and their training, shared and 'liked' the LinkedIn post in question resulting in, on the balance of probabilities, the subsequent proactive dissemination of information about an unlicensed medicine to their LinkedIn connections; an action that resulted in an investigational medicine being promoted prior to the grant of its marketing authorisation. In that regard high standards had not been maintained. A breach of the Code was ruled.

The Panel considered that in the particular circumstances of this case a ruling of a breach of Clause 2 was not warranted. The company had the requisite UK social media policy supplement in place and both employees had been trained and assessed on it. No breach of the Code was ruled.

A complainant who described him/herself as a concerned UK health professional, complained about the promotion of TAK-620 (maribavir) on LinkedIn by Takeda UK Limited.

The complainant provided a screenshot of a Takeda employee's profile on LinkedIn. The employee, with global responsibility, was based in the UK. The LinkedIn profile included links to a news release in the employee's 'Activity' section due to him/her 'liking' and sharing it. From the screenshot provided, it appeared that the article was partially entitled 'We're proud to announce top-line data from our phase 3 trial of TAK-620 (maribavir) in transplant recipients with refractory/resistant....'. The complainant also provided a link to the employee's LinkedIn profile.

COMPLAINT

The complainant alleged that the named member of staff at Takeda had promoted the company's medicines in the UK to the general public.

When writing to Takeda, the Authority asked it to consider the requirements of Clauses 2, 9.1 and 26.1 of the Code.

RESPONSE

Takeda noted that the complainant had alleged that a Takeda employee had promoted a medicine to the general public by virtue of sharing and 'liking' a post on his/her LinkedIn account. The complainant provided a screenshot showing that the employee had shared and 'liked' a post entitled 'We're proud to announce top-line data from our Phase 3 trial of TAK-620 (maribavir) in transplant recipients with refractory/ resistant cytomegalovirus (CMV) infections. Learn more here: [link].

Takeda explained that, on or around 19 December 2020 and without the prior knowledge or permission of the company, an employee working in a global role, but physically located in the UK, used his/her private LinkedIn account to share and 'like' the post at issue (copy provided). The post which he/she shared was published on the official Takeda Pharmaceuticals Global LinkedIn account which was managed from Japan. That post linked to an article entitled 'New Phase 3 Data Show TAK-620 (maribavir), an Investigational Drug for the Treatment of Transplant Recipients with Refractory/Resistant Cytomegalovirus (CMV) Infections, Meets Primary Endpoint' (copy provided). That article was published on the Takeda Pharmaceutical Company Limited (Global) website and was uploaded by the Takeda organisation in Japan; it included top-line clinical trial results for a medicine being developed by Takeda (maribavir) which did not currently have a marketing authorisation either in the UK or any other jurisdiction. The employee's private LinkedIn account had over 550 connections, mainly members of the public, many of whom were based in the UK. Takeda accepted that the complaint fell within the scope of the Code and that members of the public could have viewed the material in question.

Takeda stated when it received this complaint on 23 December 2020 it immediately tried to contact the employee via email and LinkedIn to instruct him/her to take down the post in question and on 4 January 2021, he/she confirmed that the shared post had been deleted. However, on 6 January that the article in question was still accessible via the employee's profile page as showing as being 'liked'. The compliance manager immediately contacted the employee, and this was remedied.

Takeda submitted that during its investigation it was further identified that an employee of Takeda UK (UK affiliate) had 'liked' the original employee's post, again without the prior knowledge or permission of the company. The second employee was immediately emailed and instructed to remove that 'like'. The second employee's private LinkedIn account had over 650 connections, including both members of the public and health professionals, many of whom were based in the UK. Takeda accepted that that matter also fell under the scope of the Code and that members of the public could have viewed the materials in question.

Takeda explained that it had robust systems in place to ensure compliance with internal policies and industry codes of practice around the world. Globally, all staff members at induction and at regular intervals thereafter were required to complete training on the company's 'Global Social Media Policy'. That policy educated employees on their responsibilities when using social media and provided clearly defined principles and rules for personal conduct when engaging online and using social media platforms. In addition, all Takeda UK employees were trained on a 'UK Social Media Policy Supplement' to ensure compliance specifically with the ABPI Code. That additional training had to be completed by Takeda employees who did not work for the UK affiliate but were physically located in the UK. The supplement stated clearly that an employee located in the UK could not 'post, 'like', share, retweet and comment on... content on Takeda's Corporate channels that reference Takeda products or treatments, including announcements

about product approval, study results about an investigational product, clinical trials recruitment or product launch... *or*... press releases directly from Takeda.com'.

Takeda submitted that the two staff members in question had completed training and passed assessments for both the Global Social Media Policy and the UK Social Media Policy Supplement. Takeda thus considered that the problems which had arisen were related to human error on the part of two employees, rather than any systematic deficiencies in Takeda's policies or training.

Given that two employees had inappropriately shared/'liked' a social media post related to an unlicensed medicine, an opportunity was taken during a Takeda UK and Ireland 'all employees' meeting in January 2021 to inform the organisation of the complaint and reiterate the importance of adhering strictly to the company's social media policy. This was followed up by an email to all Takeda UK employees and to employees of other Takeda entities who lived in the UK.

Takeda stated that as the two employees who shared/'liked' the LinkedIn post were based in the UK, it accepted that their activity fell within the scope of the Code. Members of the public could have viewed the relevant posts, which contained information about an unlicensed Takeda medicine, in breach of Clause 26.1.

However, Takeda considered that that breach had occurred as a result of human error by two employees, without the prior knowledge or permission of the company. Takeda was confident that there were policies in place which should adequately mitigate the risk of employees inappropriately using social media in that way, and that those policies were properly trained out to employees across the UK. Therefore, Takeda did not accept that high standards had not been maintained (Clause 9.1) or that the company had brought discredit to, or reduced confidence in, the industry (Clause 2).

PANEL RULING

The Panel noted that LinkedIn was different to some other social media platforms in that it was a business and employment-orientated network and was primarily, although not exclusively, associated with an individual's professional heritage and current employment and interests; its application was not limited to the pharmaceutical industry or to health care. In the Panel's view, it was of course not unacceptable for company employees to use personal LinkedIn accounts; the Code would not automatically apply to all activity on a personal account. The Panel noted that compliance challenges arose when the personal use of social media by pharmaceutical company employees overlapped with their professional responsibilities or the interests of the company. The Panel noted that material could be disseminated or highlighted by an individual on LinkedIn in a number of ways, by posting, sharing, commenting or 'liking'. The Panel understood that if an individual 'liked' a post it increased the likelihood that the post would appear in his/her connections' LinkedIn feeds, appearing as '[name] likes this'. In the Panel's view, activity conducted on social media that could potentially alert one's connections to the activity might be considered proactive dissemination of material. In addition, an individual's activity and associated content might appear in the individual's list of activities on his/her LinkedIn profile page which was visible to his/her connections; an individual's profile page was also potentially visible to others outside his/her network depending on the individual's security settings. Company employees should assume, that such activity would therefore potentially be visible to both those who were health professionals or other relevant decision makers and those who were members of the public. In that regard it was imperative that they acted with extreme caution when using all social media platforms, including LinkedIn, to discuss or highlight issues which impinged on their professional role or the commercial/research interests of their company. Whether the Code applied would be determined on a case-by-case basis, taking into account all of the circumstances including, among other things, content and distribution of the material. If an employee's personal use of social media was found to be in scope of the Code, the company would be held responsible. The Panel considered that companies should assume that the Code would apply to all work-related, personal LinkedIn posts/activity by their employees unless, for very clear reasons, it could be shown otherwise. Any material associated with a social media post, for example a link within a post, would be regarded as being part of that post. Companies must have comprehensive and up to date social media policies that provide clear and unequivocal guidance on what was, and what was not, acceptable and it was extremely important that employees were trained upon them and followed them.

The Panel noted Takeda's submission that in December 2020, and without the prior knowledge or permission of the company, an employee working in a global role, but physically located in the UK, used his/her private LinkedIn account to share and 'like' a post published on the Takeda Pharmaceuticals Global LinkedIn account which was managed from Japan. Takeda's investigation further revealed that an employee of Takeda UK had also 'liked' the original employee's post, again without the prior knowledge or permission of the company. The Panel noted Takeda's submission that both employees had a large number of connections many of whom were based in the UK, including members of the public.

The Panel noted that the article associated with the LinkedIn post, entitled

'New Phase 3 Data Show TAK-620 (maribavir), an Investigational Drug for the Treatment of Transplant Recipients with Refractory/Resistant Cytomegalovirus(CMV) Infections, Meets Primary Endpoint' discussed the positive trial results for maribavir and concluded with the statement 'We look forward to discussing these data with global health authorities including the U.S. Food and Drug Administration and European Medicines Agency as we work to bring maribavir to patients.'

The Panel noted that maribavir was not classified as a prescription only medicine when the LinkedIn post was shared and 'liked' by the global UK-based employee and liked by a UK employee. Clause 26.1 only applied to prescription only medicines. On that very narrow technical point the Panel did not consider that a prescription only medicine had been promoted to the public and so it ruled no breach of Clause 26.1.

The Panel understood that employees might feel inclined to endorse articles related to their senior colleagues on LinkedIn or their company's corporate/global social media posts but noted that depending on the content such activity might or might not fall within the scope of the Code; companies would be well advised to cover the possibility of that activity in their social media policies. This was particularly important if UK employees were likely to follow the social media accounts of overseas affiliates which might have Codes, laws and regulations that differed to the UK.

The Panel noted that the Takeda Global Social Media Policy, dated January 2017 stated:

'DO engage with (e.g. like) and share officially approved Takeda content from official Takeda accounts; create a public career profile on sites like LinkedIn and link it to the

official main Takeda company page; accurately reflect your role and job title on any public profiles and use a professional image as you will be associated with and linked to Takeda'.

The Panel noted, however, that in July 2019 Takeda had issued a local (UK) supplement to its global social media policy. That policy stated:

'Please remember that use of social media and in particular LinkedIn carries significant risk to Takeda and our business – this case [Case AUTH/3038/4/18] is a reminder that just 'sharing' and/or 'liking' other people's posts about Takeda prescription only medicines, even items already in the public domain, such as press releases can and will be in scope of the ABPI Code and potentially ruled in breach – and when they are, there is the potential for multiple breaches including those relating to the promoting [sic] prescription only medicines to the general public, which of course is against the law in the UK.'

In a table of Q&As, and in response to the question 'Can I post/like/share/retweet or comment on content on Takeda's Corporate channels that reference Takeda products or treatments, including announcements about product approval, study results about an investigational product, clinical trials recruitment or product launch?' the answer was stated in large bold red font as 'No'. The Panel considered that the instructions to UK employees and UK-based employees not to refer to or engage with posts relating to company products on social media were clear and unambiguous. The Panel noted Takeda's submission that the two employees in question had completed training and passed assessments for both the Global Social Media Policy and the UK Social Media Policy Supplement.

The Panel noted its comments above and considered that it was unfortunate that Takeda had been badly let down by two of its employees who had, in contravention of UK company policy and their training, shared and 'liked' the LinkedIn post in question resulting in, on the balance of probabilities, the subsequent proactive dissemination of information about an unlicensed medicine to their LinkedIn connections; an action that resulted in an investigational medicine being promoted prior to the grant of its marketing authorisation. In that regard high standards had not been maintained. A breach of Clause 9.1 was ruled.

The Panel noted that a ruling of a breach of Clause 2 of the Code was a sign of particular censure and reserved for such. The supplementary information to that clause stated that one of the activities likely to be in breach of Clause 2 was promotion prior to the grant of a marketing authorisation. Although noting its comments and ruling above, the Panel considered that in the particular circumstances of this case a ruling of a breach of Clause 2 was not warranted. The company had the requisite UK social media policy supplement in place and both employees had been trained and assessed on it. No breach of Clause 2 was ruled.

Complaint received 19 December 2020

Case completed 4 June 2021