

COMPLAINANT v BRISTOL-MYERS SQUIBB

Promotion of Opdivo on LinkedIn

A complainant, who described him/herself as a concerned UK health professional, alleged that material which had been posted on LinkedIn by a US-based executive director and 'liked' by a named UK employee of Bristol-Myers Squibb Pharmaceuticals Ltd, promoted Opdivo (nivolumab) to the public as well as promoting it for an unlicensed indication. The material in question read:

'Not 1 but 2 positive Ph 3 studies evaluating Opdivo have read out today in Upper-GI [gastrointestinal] Cancers, with potential to establish a new standard of care in Gastric and Esophageal Cancers...Cannot be more proud! Sincere thanks to the patients involved, their families and their treating oncologists' followed by #BMS employee #Opdivo #nivolumab.'

The LinkedIn post referred to a Phase 3 trial which had evaluated Opdivo as adjuvant therapy for patients with resected oesophageal or gastroesophageal junction cancer. The trial had met its primary endpoint of disease-free survival. In that regard, the complainant noted that the data referred to types of cancer which were difficult to treat and so this would be key information to patients who had those types of cancer.

When the complaint was submitted, Opdivo was indicated in a number of cancerous conditions but not for oesophageal cancer.

The detailed response from Bristol-Myers Squibb is given below.

The Panel noted that LinkedIn was a global business and employment-oriented platform used mainly for professional networking. In the Panel's view, it was not unacceptable for pharmaceutical companies to use LinkedIn accounts or for employees to use personal LinkedIn accounts although they needed to be mindful of the numerous compliance issues that might arise. The Panel considered that companies should assume that the Code would apply to all corporate LinkedIn posts and to work-related, personal LinkedIn posts by their employees unless, for very clear reasons, it could be shown otherwise; whether the Code applied would be determined on a case-by-case basis, taking into account all of the circumstances. The content of posted material would be a crucial factor.

The Panel noted that the LinkedIn material in question had been posted by a US-based executive director; UK employees had however 'liked' the post. In that regard, the Panel considered that actions of the UK employees meant that they had in effect further disseminated the material. The Panel considered that the UK employees' 'liking' of the post, and thus the dissemination of the material, brought the LinkedIn post within the scope of the Code.

The Panel noted that, as submitted by Bristol-Myers Squibb, the post which had been 'liked' by the named UK employee would have been available to members of the public. In that regard, the Panel considered that the post promoted Opdivo to the public as acknowledged by Bristol-Myers Squibb. A breach of the Code was ruled. Further, the Panel considered that the post would raise hopes of a successful treatment for upper GI cancers and encourage members of the public to ask their health professional to prescribe Opdivo. A breach of the Code was ruled as acknowledged by Bristol-Myers Squibb.

The Panel noted that when the LinkedIn post was published and then further disseminated by UK employees, Opdivo was not indicated for use in upper GI cancers. A further breach of the Code was ruled as acknowledged by Bristol-Myers Squibb. The Panel considered that although Bristol-Myers Squibb had training and clear procedures in place to manage employees' use of social media, it had been let down by employees who had not followed the local UK and Ireland work instruction resulting in breaches of the Code being ruled. In that regard, high standards had not been maintained. A breach of the Code was ruled.

A complainant, who described him/herself as a concerned UK health professional, complained about material which had been posted on LinkedIn by a US-based executive director and 'liked' by a named UK employee of Bristol-Myers Squibb Pharmaceuticals Ltd. The material in question read:

'Not 1 but 2 positive Ph 3 studies evaluating Opdivo have read out today in Upper-GI [gastrointestinal] Cancers, with potential to establish a new standard of care in Gastric and Esophageal Cancers...Cannot be more proud! Sincere thanks to the patients involved, their families and their treating oncologists' followed by #BMS employee #Opdivo #nivolumab.'

The LinkedIn post referred to Checkmate-557 which was a Phase 3 trial which had evaluated Opdivo as adjuvant therapy for patients with resected oesophageal or gastroesophageal junction cancer. The trial had met its primary endpoint of disease-free survival.

Opdivo (nivolumab) was indicated in certain patients with melanoma, non-small cell lung cancer, renal cell carcinoma, classical Hodgkin lymphoma, squamous cell cancer of the head and neck and urothelial carcinoma (ref summary of product characteristics (SPC) last revised 23 July 2020, provided by Bristol-Myers Squibb).

COMPLAINT

The complainant alleged that the LinkedIn post which had been liked by a named UK employee promoted Opdivo to the general public as well as promoting it off-licence, both of which were of serious concern. In that regard, the complainant noted that the data mentioned was in types of cancer which were difficult to treat with a poor response to treatment and so this would be key information to patients who had those types of cancer in the UK.

When writing to Bristol-Myers Squibb, the Authority asked it to consider the requirements of Clauses 3.2, 9.1, 26.1 and 26.2 of the Code.

RESPONSE

Bristol-Myers Squibb submitted that LinkedIn was a professional networking site, and one would expect that the majority of those who used the platform would be connected to each other in a professional or work-related capacity.

The 'like' in question was related to a posting on LinkedIn by a US-based Bristol-Myers Squibb employee working for a worldwide function; referencing two recent data readouts and links to their associated press releases (copies provided). Both the press releases mentioned were issued by the US parent company and hosted on the Bristol-Myers Squibb US corporate website; they were not directed to, nor intended for, a UK audience.

The post was written and shared by the US-based employee in a personal capacity without the UK company's knowledge or involvement and therefore did not warrant copy approval and certification in the UK. The US-based employee acted alone posting from his/her personal LinkedIn account; this posting was not part of, nor linked to, any Bristol-Myers Squibb initiated campaign or under its instruction, and was not directed specifically to a UK audience. The US-based employee's LinkedIn account profile was public; posts would also be visible to all LinkedIn users. The individual in question had 1,600 followers on 24 August 2020, the majority of whom appeared to be Bristol-Myers Squibb colleagues and employees of other pharmaceutical companies and would include members of the public and health professionals.

The named UK-based employee who subsequently 'liked' the post was an employee of the Bristol-Myers Squibb UK and Ireland organisation and worked in a non-promotional role. The decision to 'like' the post was made in a personal capacity by the UK-based employee and was not under the direction or encouragement of the company. The UK-based employee's LinkedIn account profile was public; their 'likes' would therefore be visible to all LinkedIn users.

The named individual had over 600 followers on 24 August 2020, majority of whom appeared to be Bristol-Myers Squibb colleagues and employees of other pharmaceutical companies and would include members of the public and health professionals. On receipt of this complaint on 18 August 2020, Bristol-Myers Squibb reacted with speed and urgency to investigate the complaint. The intent of the named UK employee's 'like' was not to promote a medicine but simply an enthused reaction at the data readouts and press announcements in the US. The individual in question did not further comment on, share or repost the original post.

Bristol-Myers Squibb submitted that its investigation had shown that seven additional UK-based employees had also 'liked' the post. All eight UK-based employees were contacted, made aware of the complaint and asked to remove the 'like' immediately. Mandatory retraining was reassigned for all eight employees. The US-based employee who had created the post was contacted, informed of the UK implications of the post and asked to remove it. The post was removed from LinkedIn on 19 August 2020.

Bristol-Myers Squibb recognised that whilst LinkedIn was a professional networking and work-related platform, a member of the public could have seen the post as a result of the UK employee 'liking' it. The post referred to unlicensed investigational indications for nivolumab, which were outside of its UK marketing authorisation. Bristol-Myers Squibb acknowledged the breaches of Clauses 26.1, 26.2 and 3.2 and whilst these were inadvertent and unintended, it understood the importance of these clauses and took the perceived promotion of prescription-only medicines to the public and the unintentional promotion of indications outside of marketing authorisation extremely seriously.

Bristol-Myers Squibb submitted that it was committed to not only maintaining high ethical and compliance standards, but it also continually strove to learn and strove for excellence. Bristol-Myers Squibb expected all employees to uphold its values and principles of integrity, one of which included protecting its patients.

Bristol-Myers Squibb submitted that it fully understood that 'liking' a post (in addition to commenting on or sharing it), could be seen to be a positive endorsement when actioned by an employee of a UK company and would therefore come into the scope of the Code. As a result, Bristol-Myers Squibb had taken multiple measures to ensure that comprehensive guidance, communication and training was provided on the personal use of social media for all its employees. An overarching Bristol-Myers Squibb Global standard operating procedure (SOP), 'Social Media – Employee Personal Use', which covered the use of social media by all employees globally was updated to reflect personal conduct on social media and made effective in December 2018. This clearly stated that employees; 'must not share, "like", or otherwise endorse content about BMS marketed or investigational products, regardless of who issued the content, whether BMS or a third party because it may constitute prohibited or regulated promotion'. This policy was further updated in July 2020 (copy provided).

Bristol-Myers Squibb submitted that under this Global policy sat a local work instruction, 'UK/Ireland Work Instruction – Social Media – Employee Personal Use' (copy provided). This was made effective in May 2018 and was distributed to all Bristol-Myers Squibb UK and Ireland employees to reinforce the guidance around social media use as set out in its Global SOP. The named UK employee completed the training on this local work instruction and the required assessment in 2018.

Bristol-Myers Squibb submitted that it was a mandatory requirement for all current UK/Ireland-based employees to complete training on this work instruction; training was auto-assigned in the company's online training system for all new hires of the UK company. The system sent automated reminder notifications to both the employee and line manager as the due date for the training approached, and if it went past its expected completion date. Incomplete or late completion of training was managed by the individual's line manager. The company induction for new starters had dedicated segments on the Code built into the programme and used learnings from previous Code cases to deliver robust compliance messages; social media use was also covered in this corporate onboarding.

Since the rollout of the local work instruction in 2018, Bristol-Myers Squibb had ensured the delivery of numerous training sessions covering social media, which acted as a reminder of its social media policy and expectations of the Code. This included a reminder of the guidance in the company compliance newsletter (copy provided) distributed to all employees, including the named UK employee in January 2020.

Bristol-Myers Squibb recognised that since the Covid-19 pandemic and subsequent lockdown in the UK, there had been an increase in the use of social media platforms. Therefore, the Bristol-Myers Squibb UK/Ireland organisation committed to ensuring that appropriate guidance and training was available for all employees whilst working remotely. Whilst there had been a lapse by some individuals, the company was dedicated to ensuring that it continued to provide appropriate training and guidance regarding the personal use of social media to all UK/Ireland employees. External Code experts were regularly invited to promote ongoing learning and expand the working knowledge of the Code. These included masterclasses on digital and the

internet on 8 January 2019 and digital innovations and the ABPI on 14 May 2020. Furthermore, a senior employee recently shared an email communication on 12 August 2020 with all Bristol-Myers Squibb employees globally on its Global Social Media policy.

Following the receipt of this complaint, Bristol-Myers Squibb submitted that on 25 August 2020 the UK/Ireland general manager recommunicated the email mentioned above on the Bristol-Myers Squibb Global social media policy and requested all employees to re-read the UK/Ireland local work instruction, which was also resent to all employees as an attachment. Bristol-Myers Squibb submitted that it was committed to maintaining high standards managed through a defined framework including global and local policies, continuous learning and tailored education as per the examples provided above. Previous Code cases were used to evolve practices, implement new measures and strengthen compliance culture. Bristol-Myers Squibb considered that employee expectation around the personal use of social media was well communicated through frequent and comprehensive instruction to all employees across the business, including by senior leaders in the organisation. As a result, Bristol-Myers Squibb therefore denied a breach of Clause 9.1.

PANEL RULING

The Panel noted that LinkedIn was a global business and employment-oriented platform used mainly for professional networking. In the Panel's view, it was not unacceptable for pharmaceutical companies to use LinkedIn accounts or for employees to use personal LinkedIn accounts although they needed to be mindful of the numerous compliance issues that might arise. The Panel considered that companies should assume that the Code would apply to all corporate LinkedIn posts and to work-related, personal LinkedIn posts by their employees unless, for very clear reasons, it could be shown otherwise; whether the Code applied would be determined on a case-by-case basis, taking into account all of the circumstances. The content of posted material would be a crucial factor.

The Panel noted that the LinkedIn material in question had been posted by a US-based executive director; UK employees had however 'liked' the post. In that regard, the Panel considered that actions of the UK employees meant that they had in effect further disseminated the material. The Panel considered that the UK employees' liking' of the post, and thus the dissemination of the material, brought the LinkedIn post within the scope of the Code.

The Panel noted that, as submitted by Bristol-Myers Squibb, the post which had been 'liked' by the named UK employee would have been available to members of the public. In that regard, the Panel considered that the post promoted Opdivo to the public as acknowledged by Bristol-Myers Squibb. A breach of Clause 26.1 was ruled. Further, the Panel considered that the post would raise hopes of a successful treatment for upper GI cancers and encourage members of the public to ask their health professional to prescribe Opdivo. A breach of Clause 26.2 was ruled as acknowledged by Bristol-Myers Squibb.

The Panel noted that when the LinkedIn post was published and then further disseminated by UK employees, Opdivo was not indicated for use in upper GI cancers and so in that regard it ruled a breach of Clause 3.2 as acknowledged by Bristol-Myers Squibb.

The Panel noted that the local UK and Ireland work instruction on employees' personal use of social media dated May 2018 covered, among other things, engaging with, ie 'liking', content related to Bristol-Myers Squibb's medicines using the employee's personal or professional

social media accounts eg LinkedIn etc. Employees were told not to post, like, share or comment on any information, or links to information on social media about Bristol-Myers Squibb medicines or its medicines classes, claims related to its medicines, clinical trials or data or its pipeline assets as such action would be seen as promotion of prescription-only medicines to the public. The working instruction stated that this prohibition applied even if information had appeared through any of the Bristol-Myers Squibb corporate social media channels. In a compliance newsletter of January 2020 employees were reminded of these restrictions. The Panel considered that although Bristol-Myers Squibb had training and clear procedures in place to manage employees' use of social media, it had been let down by employees who had not followed the local UK and Ireland work instruction resulting in breaches of Clauses 3.2, 26.1 and 26.2 being ruled. In that regard, high standards had not been maintained. A breach of Clause 9.1 was ruled.

Complaint received **12 August 2020**

Case completed **29 January 2021**