CASE AUTH/3286/12/19

VOLUNTARY ADMISSION BY BRISTOL-MYERS SQUIBB

Failure to certify advertisement

Whilst responding to Case AUTH/3241/8/19, Bristol-Myers Squibb Pharmaceuticals Limited noted that the material in question, a promotional article for Opdivo (nivolumab) and Yervoy (ipilimumab), had not been correctly certified. Opdivo and Yervoy were both indicated in the treatment of renal cell carcinoma.

As Paragraph 5.6 of the Constitution and Procedure required the Director to treat a voluntary admission as a complaint, the matter was taken up with Bristol-Myers Squibb.

In Case AUTH/3241/8/19 Bristol-Myers Squibb voluntarily admitted that a promotional article published in Urology News contained the wrong numerical data on overall survival rates related to the outcome of a clinical trial. As part of its admission, Bristol-Myers Squibb had stated when checking the Urology News website to confirm the removal of the original article, Bristol-Myers Squibb noted that an amended article with corrected data was placed online. During the course of a subsequent investigation, it was determined that in the interests of speed and urgency, the originator of the material had given the agency the corrected data; in the meantime, the corrected advertisement was sent for certification. However, the amended piece was republished online before certification. Bristol-Myers Squibb asked the communications agency to remove the amended, uncertified version. With regard to the print version, Bristol-Myers Squibb noted that neither the original nor the corrected version was sent in its final form for check and signature before publication.

Bristol-Myers Squibb considered that it had breached Clause 14.1.

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

The Panel noted that in Case AUTH/3241/8/19 Bristol-Myers Squibb had been ruled in breach of the Code as a promotional article failed to accurately reflect overall survival data. The company's investigation into that matter prompted this voluntary admission as it revealed that a corrected version of the promotional article published online was not certified, and that neither the original or the corrected printed version was checked and signed in its final form. The Panel ruled a breach of the Code as acknowledged by Bristol-Myers Squibb.

The Panel was concerned about the repeated failure to properly certify the materials and noted the company's explanation that this was primarily due to human error. The Panel, whilst noting that companies were responsible for agencies acting on their behalf, noted that it did not have a copy of the company's communications with its then agency and thus was unable to determine whether the agency had been appropriately instructed in relation to the publication of the revised digital article. The Panel also noted the company's failure to adhere to the relevant SOP. Certification was an important element

of self-regulation and the company's failures in this regard were such that high standards had not been maintained; a breach of the Code was ruled.

Whilst noting its comments above, the Panel did not consider that the circumstances warranted a ruling of a breach of Clause 2 which was reserved as a sign of particular censure; no breach of the Code was thus ruled.

Whilst responding to Case AUTH/3241/8/19, Bristol-Myers Squibb Pharmaceuticals Limited noted that the material in question, a promotional article for Opdivo (nivolumab) and Yervoy (ipilimumab), had not been correctly certified. Opdivo and Yervoy were both indicated in the treatment of renal cell carcinoma.

As Paragraph 5.6 of the Constitution and Procedure required the Director to treat a voluntary admission as a complaint, the matter was taken up with Bristol-Myers Squibb.

VOLUNTARY ADMISSION

In Case AUTH/3241/8/19 Bristol-Myers Squibb voluntarily admitted that a promotional article published in Urology News contained the wrong numerical data on overall survival rates related to the outcome of a clinical trial. As part of its admission, Bristol-Myers Squibb had stated that the online and print version of the advertisement would be corrected and re-published with an apology and explanation of the error. When checking the Urology News website to confirm the removal of the original article, Bristol-Myers Squibb noted that an amended article with corrected data was placed online. During the course of a subsequent investigation, it was determined that in the interests of acting with speed and urgency, the originator of the material had provided the agency with the corrected data; in the meantime, the corrected advertisement was sent for certification. However, the amended piece was republished online before certification. Bristol-Myers Squibb contacted the communications agency to request removal of the amended uncertified version. With regard to the print version, Bristol-Myers Squibb noted that neither the original nor the corrected version was sent in its final form for check and signature before publication.

Bristol-Myers Squibb considered that it had breached Clause 14.1.

When writing to Bristol-Myers Squibb, the Authority asked it for any further comments it might have with regard to the requirements of Clause 14.1 and also Clauses 2 and 9.1 of the Code.

RESPONSE

Bristol-Myers Squibb noted that it had acknowledged a breach of Clause 14.1 due to the failure to check and sign the final hardcopy forms of the printed article, and the corrected reprint, in Urology News. Bristol-Myers Squibb noted that both versions of the article had been correctly certified in the electronic approval system and had corresponding electronically signed certificates. Further, in an effort to rapidly correct the data error, a version of the amended article was published online before certification. Bristol-Myers Squibb acknowledged that the failure to certify the final form was an unacceptable breach of the Code. As a result, it had acted quickly to ensure all necessary follow-up measures and safeguards were implemented (as outlined in Case AUTH/3241/8/19) to prevent such an incident from being repeated. Certification formed a critical part of the company's approval process and was a key component of the relevant standard operating procedure (SOP).

Bristol-Myers Squibb stated that it continually strove to operate to, and maintain, high standards for the safe promotion of its medicines and the delivery of high quality care. All originators and signatories were trained on the SOPs which detailed the requirements for referencing the certification. The company submitted that it provided a strong, ongoing and multi-faceted Code compliance programme, including, but not limited to, case review sessions, signatory workshops, Code masterclasses and quality checks to ensure that both originators and reviewers were fully conversant with the Code and its requirements. Therefore, due diligence and internal scrutiny were expected and exercised to ensure that the type, style and method of promotion was acceptable and in line with the Code. Bristol-Myers Squibb submitted that in line with its culture of fostering compliance, the original data error was identified internally and promptly escalated for action and correction.

Bristol-Myers Squibb stated that when it identified the error it acted with purpose and urgency to demonstrate its commitment to maintaining high standards, both for the company and on behalf of the industry. In line with this commitment, a corrective and preventative action plan was implemented. A complete account of measures and actions was detailed in Case AUTH/3241/8/19 and included:

- Direct communications with the agency and the journal to ensure immediate removal of original (data error) and the corrected uncertified online article.
- Publishing the amended article in the subsequent print edition of the journal (September edition), containing a clear apology and identifying the error.
- Re-training the activity originator responsible for both the original and amended article in relation to the Promotional Materials SOP, which included the expectations for certification.
- The company performed quality checks to ensure high standards were maintained and any errors identified were swiftly corrected. As per the company's commitment in Case AUTH/3241/8/19, it was undertaking a quality review of a sample of materials checked for accuracy by its external vendor.

Bristol-Myers Squibb stated that a full and thorough investigation of the data error showed that the key contributing factor was human error. Considering the prompt action taken by the company on identifying the error and the full investigation and robust corrective measures, Bristol-Myers Squibb strongly considered that it had not failed to maintain high standards and it denied a breach of Clause 9.1.

Bristol-Myers Squibb considered that as the data error included in the original article understated the magnitude of the survival benefit of nivolumab in combination with ipilimumab compared with the comparator arm, patient safety had not been compromised. In addition, the breaches in this case did not amount to unacceptable promotion, excessive hospitality, lack of transparency, inappropriate payments or any other such actions which would warrant a breach of Clause 2.

Bristol-Myers Squibb stated that whilst human error had occurred, it had the appropriate procedures, processes, regular training sessions and governance measures in place to facilitate stringent compliance. The data error was self-identified, and appropriate, well considered actions were taken quickly to remedy the situation including correction, re-training and audit. Through this voluntary admission, the company considered that it had acted in a manner to ensure full transparency, of the article amendment itself, but also in its intention to preserve the

confidence and faith in the pharmaceutical industry. Bristol-Myers Squibb thus did not consider that the cumulative effect of the errors noted in this case were such as to bring discredit upon, or reduce confidence in, the pharmaceutical industry and therefore a ruling of a breach of Clause 2 would be disproportionate.

Bristol-Myers Squibb accepted a breach of Clause 14.1, but it did not consider that it was in breach of either Clause 9.1 or 2 for the reasons stated above.

PANEL RULING

The Panel noted that in Case AUTH/3241/8/19 Bristol-Myers Squibb had been ruled in breach of Clause 7.2 of the Code as a promotional article failed to accurately reflect overall survival data. The company's investigation into this matter prompted this voluntary admission as it revealed that a corrected version of the promotional article published online was not certified and the final form of both the original and corrected printed version of the promotional article were not checked and signed in their final form. The Panel therefore ruled a breach of Clause 14.1 of the Code as acknowledged by Bristol-Myers Squibb.

The Panel was concerned about the repeated failure to properly certify the materials. The Panel noted the company's explanation that it occurred primarily due to human error. The Panel, whilst noting that companies were responsible for agencies acting on their behalf, noted that it did not have a copy of the company's communications with its then agency and thus was unable to determine whether the agency had been appropriately instructed in relation to the publication of the revised digital article. The Panel also noted the company's failure to adhere to its Promotional Materials SOP. In the Panel's view, certification was an important element of self-regulation and the company's failures in this regard were such that high standards had not been maintained; a breach of Clause 9.1 was ruled.

Whilst noting its comments above, the Panel did not consider that the circumstances warranted a ruling of a breach of Clause 2 which was reserved as a sign of particular censure; no breach of Clause 2 was thus ruled.

Voluntary admission received **12 September 2019**

Case completed **2 November 2020**