CASE AUTH/3205/6/19

VOLUNTARY ADMISSION BY BOEHRINGER INGELHEIM

Lack of certification and obligatory information

Boehringer Ingelheim admitted breaches of the Code in that e-learning material for the Respimat device, was made live on a third party agency's website before it had been certified. In addition, the agency involved which was contracted by Boehringer Ingelheim emailed health professionals on its database alerting them to the material. Boehringer Ingelheim had no prior knowledge of, nor had it approved/certified, the promotional email. The email sent by the agency did not contain prescribing information or other obligatory information for promotional materials. The Respimat device was a type of inhaler used for several Boehringer Ingelheim respiratory medicines.

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 Boehringer Ingelheim.

The detailed response from Boehringer Ingelheim is given below.

The Panel noted that instead of one piece of material ('How to use' downloadable pdf), the agency uploaded the whole e-learning course to its live website. The emails between the agency and Boehringer Ingelheim were confusing and not particularly clear in relation to what had and what had not been approved. The emails showed that Boehringer Ingelheim was asked to check the website and confirm that it was ready to make the course live in a particular area for a three-month trial. In the Panel's view, given the content of the correspondence from Boehringer Ingelheim, it was not unreasonable for the agency to assume that it could make the whole e-learning course live.

The Panel noted that Boehringer Ingelheim described the material for the website as educational and non-promotional in nature to assist pharmacists with supporting patients who might be on a product using a Respimat device. Three Boehringer Ingelheim products were available in this device, Spiolto (tiotropium and olodaterol), Spiriva (tiotropium) and Striverdi (olodaterol).

The Panel noted that although some of the materials for the e-learning had been approved individually for different uses, such as in sales aids, the material made available on the website had been published prior to certification for such use by Boehringer Ingelheim. The Panel therefore ruled a breach of the Code as acknowledged by the company.

The Panel noted that the agency had also emailed those registered on its database. The email referred to the training course 'How to support patients with a Spiriva Respimat Device'. The Panel noted that the agency did not appear to have contacted Boehringer Ingelheim about the email; the agency had let down Boehringer Ingelheim in that regard. The email had not been certified and did not meet the requirements for the provision of prescribing information. In addition, the email did not include the required statement regarding the reporting of adverse events and the non-proprietary name was not adjacent to the first appearance of the brand name. Although the date of sending the email was included on the email it was not clear whether this was the date that the content was drawn up. The Panel therefore ruled breaches of the Code as acknowledged by the company.

Boehringer Ingelheim Limited admitted breaches of the Code in that e-learning material for the Respimat device was released for use before it had been certified, and an email alerting health professionals to the material did not contain prescribing or other obligatory information.

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 Boehringer Ingelheim.

VOLUNTARY ADMISSION

Boehringer Ingelheim submitted that in April 2019, its ethics & compliance team was alerted to a potential non-compliance with the Code and so it started its investigatory procedure. Immediate corrective actions to rectify the situation were taken as detailed below.

Boehringer Ingelheim stated that its investigation established that:

- A third party agency was contracted by Boehringer Ingelheim to develop an e-learning course for local pharmacists related to education materials on the Respimat device, an inhaler type used for several Boehringer Ingelheim respiratory medicines. Before any activity, Boehringer Ingelheim required the agency to undertake Code training, which had happened.

- The e-learning materials proposed to be added to the third party agency website were in the development/certification process by Boehringer Ingelheim following its documented procedures.

- Unfortunately, the agency made the e-learning course live on its website before it had all been certified. Before the agency did that, it emailed Boehringer Ingelheim to ask if the e-learning training could go live, and a member of staff emailed back to confirm that it could. However, there was a misunderstanding as to what was being made live – the member of staff

thought that the agency had only referred to a downloadable pdf (the only part of the e-learning course which had been certified for that purpose), which was in fact the subject heading of the email chain.

- Unfortunately, the agency interpreted the email as confirmation of being able to go live with the entire e-learning course. When it went live on the agency website, not all of the e-learning material had been certified with this intent (in breach of Clause 14.1).

- The agency emailed health professionals on its database to invite them to take the Respimat e-learning course. Boehringer Ingelheim had no prior knowledge of nor had it approved/certified the promotional email. The email sent by the agency did not contain prescribing information or other obligatory information for promotional materials (in breach of Clauses 14.1, 4.1, 4.3, 4.8 and 4.9).

Boehringer Ingelheim stated that the agency was immediately instructed to remove the whole website from live status so that it was no longer visible. This was confirmed as completed on the same day that the non-compliance was identified by Boehringer Ingelheim.

The final investigation report, following a comprehensive process where all relevant parties were interviewed, was presented to the Compliance Investigation Review Committee in May. The Committee would decide on any formal action. The report would be sent to the country managing director, the medical director and the head of ethics & compliance.

Boehringer Ingelheim submitted that whilst it wished to complete its investigation swiftly, as it needed to investigate the processes undertaken by both the company and the agency and undertake extensive interviews, it had taken some time to complete the process. Additionally, it had also reviewed similar programmes supported by Boehringer Ingelheim to be assured of compliance with the Code; the non-compliance reported here appeared to be an isolated incident.

The root cause of this non-compliance could be summarised as a misunderstanding involving the agency and a member of staff as to what had been certified and secondly the agency inappropriately emailing pharmacists without either permission or knowledge of Boehringer Ingelheim.

In addition to the immediate corrective actions which ensured compliance and no further activity on this project, other preventative actions included specific re-training for relevant staff and details were provided.

Boehringer Ingelheim stated that it took compliance with the Code very seriously. It was committed to enhancing the quality and compliance of its interactions with third parties and with health professionals and considered that robust certification underpinned effective self-regulation.

Boehringer Ingelheim noted that despite insisting on Code training in advance of starting work, it felt let down by the agency particularly with respect to the second root cause as listed above. As soon as the company knew about the situation it put in place the corrective and preventative actions (CAPA) as summarised above.

Boehringer Ingelheim was asked to provide the Authority with any further comments in relation to the requirements of Clauses 4.1, 4.3, 4.8, 4.9 and 14.1 of the Code.

RESPONSE

Boehringer Ingelheim explained that in early 2018, the respiratory team discussed a project with a third party agency to help deliver educational training on the Respimat inhaler device to pharmacists in a named area. A brief was provided to Boehringer Ingelheim by the agency.

As Boehringer Ingelheim had not worked with the third party agency before, it mandated that the agency demonstrate Code knowledge before any activity started. Details were provided. The contract with the agency included the requirements for compliance with the ABPI Code and mandatory Boehringer Ingelheim Code.

An extension of the contract was required as there had been significant change in the Boehringer Ingelheim respiratory marketing team. The project was therefore put on hold, although a 'How to use' downloadable pdf was asked to be put through the approvals process.

In February 2019, a Boehringer Ingelheim member of staff emailed the agency to let it know that a 'How to use' downloadable pdf had now been certified specifically for the website. This was the only component of the project that this member of staff had been asked to assist with. Over the course of the next few days, the email chain continued. The subject title of the email chain throughout was 'Downloadable HowTo Use Page – Approved for use'. It was unfortunately this e-mail chain misunderstanding that led the agency to consider that the whole website could go live, whereas the Boehringer Ingelheim member of staff only meant to confirm that this specific element was approved. It should also be noted that the member of staff's involvement was limited to facilitating the certification of the downloadable pdf, to which he/she thought the email conversation still related.

The live status of the website only became clear to Boehringer Ingelheim on 2 April 2019, when a manager was tasked with resuming the project. In talking to the agency, he/she was shocked to hear that the e-learning course had been live since 1 March 2019, by which time several pharmacists had already accessed it. The manager alerted another manager, who convened an urgent meeting to understand the situation, called the agency to request the website be immediately removed from public view and alerted the ethics & compliance department.

Boehringer Ingelheim summarised the content of the e-learning course which it submitted was intended to be educational and non-promotional and assist pharmacists in supporting patients who might be using the Respimat device, a soft mist type of inhaler.

Despite the content of the e-learning being educational and never intended to go live before certification, in the spirit of self-regulation Boehringer Ingelheim accepted that the website became accessible before certification and so for the short duration it was live, was in breach of Clause 14.1 of the Code.

After Boehringer Ingelheim found out about the website going live on 2 April 2019, it became apparent that the agency had proactively and without Boehringer Ingelheim's knowledge or permission alerted its database of registered pharmacists to courses on its website. This included Boehringer Ingelheim's Respimat device training. The mailing was sent on 7 March 2019.

Boehringer Ingelheim provided metrics from the agency in relation to the numbers sent the email, opened it, looked at the course and completed it.

As noted above, Boehringer Ingelheim stated that it was let down on this specific element that despite insisting on Code training in advance of starting any work, the agency failed to get the company's permission or even inform it of its plans to send a mailing to its registered pharmacist database.

Boehringer Ingelheim nonetheless accepted that it had to take responsibility for the actions of any third parties acting on its behalf and therefore in the spirit of self-regulation it accepted that the mailing was not certified, in breach of Clause 14.1. Furthermore, as the Respimat course referred to Spiriva (tiotropium) Respimat and as the mailing was sent without reference to prescribing information and other required information, the mailing was also in breach of Clauses 4.1, 4.3, 4.8 and 4.9 of the Code.

Boehringer Ingelheim stated that it strove at all times to comply with the spirit and letter of the Code. The company had ensured the contract with the agency could not proceed until the agency had demonstrated recent training in the Code, which it had undertaken.

Furthermore, Boehringer Ingelheim noted that it had taken immediate (same day) corrective actions to re-establish compliance and had further preventative actions to minimise the risks of this occurring again, as outlined above.

Boehringer Ingelheim acknowledged that it was of paramount importance to maintain high standards at all times and it sincerely apologised for the unfortunate situation which arose from two root causes for which it put in place a robust CAPA.

PANEL RULING

The Panel noted that instead of one piece of material ('How to use' downloadable pdf), the third party agency uploaded the whole e-learning course to its live website. The emails between the agency and a Boehringer Ingelheim member of staff were confusing and not particularly clear in relation to what had and what had not been approved. The emails showed that Boehringer Ingelheim was asked to check the website and confirm that it was ready to make the course live across pharmacies in a particular area for a three-month trial. In the Panel's view, given the content of the correspondence from Boehringer Ingelheim, it was not unreasonable for the agency to assume that it could make the whole e-learning course live.

The Panel noted that there was some confusion as to whether the materials for the e-learning were promotional or not.

The Panel noted that Boehringer Ingelheim described the material for the website as educational and non-promotional in nature to assist the pharmacists with supporting patients who might be on a product using a Respimat device. Three Boehringer Ingelheim products were available in this device, Spiolto (tiotropium and olodaterol), Spiriva and Striverdi (olodaterol).

Boehringer Ingelheim submitted that some of the individual items were non promotional; it accepted that the failure to certify the e-learning was a breach of Clause 14.1 of the Code. This clause referred to the need to certify promotional material. According to the response from Boehringer Ingelheim the landing page for the e-learning stated 'How to support patients with a Spiriva Respimat Device' followed by 'Do you know how to load, prime and use the Spiriva Respimat device and can you help your patients?' and 'Do you know why particle size and velocity is important in an inhaler?' Some of the material referred only to the Respimat device, in that regard the Panel noted the supplementary information to Clause 4.1 Advertisements for Devices referred to advertisements relating to the merits of a device used for administering medicines, such as an inhaler, which was supplied containing a variety of medicines, the prescribing information for one only need be given if the advertisement made no reference to any particular medicine. The Panel noted that it appeared from the correspondence that the company expected prescribing information to be used on the website.

The Panel noted that although some of the materials for the e-learning had been approved individually for different uses, such as in sales aids, the material made available on the website had been published prior to certification for such use by Boehringer Ingelheim. The Panel therefore ruled a breach of Clause 14.1 of the Code as acknowledged by the company.

The Panel noted that the agency had also sent an email to people registered on its database. The email referred to the training course 'How to support patients with a Spiriva Respimat Device'.

The Panel noted that the agency did not appear to have contacted Boehringer Ingelheim with regard to the email and considered that Boehringer Ingelheim

had been let down by its agency in that regard. The email had not been certified and did not meet the requirements for the provision of prescribing information. In addition, the email did not include the required statement regarding the reporting of adverse events and the non-proprietary name was not adjacent to the first appearance of the brand name. Although the date of sending the email was included on the email it was not clear whether this was the date that the content was drawn up. The Panel therefore ruled a breach of Clauses 14.1, 4.1, 4.3, 4.8 and 4.9 as acknowledged by the company.

Complaint received	**11 June 2019**
Case completed	**10 September 2019**