CASE AUTH/3015/1/18

VOLUNTARY ADMISSION BY DAIICHI-SANKYO

Notification of signatories

Daiichi-Sankyo UK voluntary admitted that due to an administrative error, three of its medical staff had acted as nominated signatories before their names and qualifications had been notified to the Medicines and Healthcare products Regulatory Agency (MHRA) and the PMCPA.

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 Daiichi-Sankyo.

The detailed submission by Daiichi-Sankyo is given below.

The Panel noted Daiichi-Sankyo's submission that it had failed to notify the MHRA and PMCPA of three medical nominated signatories which resulted in nearly 300 items being certified prior to notification of their details to the MHRA and PMCPA as required by the Code. Consequently, the materials had not been certified in accordance with the Code. The Panel ruled breaches of the Code.

Daiichi-Sankyo UK Ltd voluntary admitted breaches of the Code in that three of its medical staff had acted as nominated signatories before their names and qualifications had been notified to the Medicines and Healthcare products Regulatory Agency (MHRA) and PMCPA.

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 Daiichi-Sankyo.

VOLUNTARY ADMISSION

Daiichi-Sankyo noted that Clause 14.4 required, *inter alia*, the names of those nominated as signatories as set out in Clause 14.1, together with their qualifications, to be notified in advance to the Medicines and Healthcare products Regulatory Agency (MHRA) and to the PMCPA. However, with regard to three medical staff appointed in 2017, this formal notification did not take place until 22 January 2018. One other member of staff was the only current signatory whose name had been correctly notified.

Daiichi-Sankyo explained that the situation was the result of an administrative error which arose due to staff leaving the company and a lack of handover. The issue had come to light in a complaint from Pfizer/Bristol Myers-Squibb (Case AUTH/3010/1/18) about the promotion of Lixiana. In that case the PMCPA requested the signed certificates for a particular piece of material, the certificate was signed by one of the three medical staff in question.

Daiichi-Sankyo stated that the three staff members had certified 296 pieces of material between them. All three signatories were experienced pharmaceutical physicians who had previously acted as signatories with other companies.

It followed that in addition to being in breach of Clause 14.4, Daiichi-Sankyo was in breach of Clause 14.1 which stated that materials must be certified in the correct manner.

In light of these discoveries, Daiichi-Sankyo immediately informed the PMCPA and MHRA of its current signatories, submitted this voluntary admission, updated the standard operating procedure (SOP) to clarify responsibilities and ensure appropriate personnel were trained for notifying the PMCPA and MHRA respectively and ensured that the company's response to Case AUTH/3010/1/18 included a mention that its review of the materials revealed that the name of one of the signatories was not previously notified to the PMCPA or MHRA, and that a voluntary disclosure had been made.

Daiichi-Sankyo was asked to respond in relation to Clauses 14.1 and 14.4 of the Code.

RESPONSE

Daiichi-Sankyo submitted that it was satisfied that the three members of staff met the requirements for acting as signatories under Clause 14.1, as they were all registered medical practitioners. They were all experienced and competent pharmaceutical physicians who had acted as medical signatories for other companies before joining Daiichi-Sankyo. The company was also satisfied that the materials which they certified before notification of their names and qualifications in January 2018, did not require recertification. Had their names and qualifications been notified earlier, there would be no question that these materials had not been certified in an appropriate and robust manner.

Daiichi-Sankyo noted that its SOP on the 'Approval of Materials and Activities Undertaken in the UK', clearly stated that the names and qualifications of nominated signatories must be provided to the MHRA and the PMCPA. However, unfortunately no specific job role was assigned this responsibility in the SOP.

Previous notifications up to and including 9 March 2017 were coordinated by a former member of the medical department, as part of a verbal understanding between him/her and the former medical director. When the three members of staff became signatories at Daiichi-Sankyo, it was assumed that the former member of the medical department would notify the PMCPA and MHRA as before but unfortunately he/she did not do

so for reasons unknown; he/she left the organisation in 2017, shortly after a previous senior director in the department took up an overseas position within the organisation. It was clear that responsibilities and oversight regarding the external communication of signatories did not meet the required standards, as no specific person was responsible under the SOP for notifying the MHRA and PMCPA of the names and qualifications of nominated signatories, no handover of this responsibility took place. The omissions were discovered as part of the company's investigation into the response to Case AUTH/3010/1/18.

As soon as the omissions were discovered the following mitigating steps were put in place:

1 The PMCPA and MHRA were informed of the names and qualifications of the current signatories so that materials from that date could continue to be certified in compliance with the Code.

2 A voluntary admission was sent to the PMCPA.

3 A Corrective and Preventative Action (CAPA) plan was initiated, intended to understand the root cause of the omission, correct it, and put in place actions that would prevent it occurring again.

As detailed above, the CAPA plan had uncovered the root cause of the omissions, ie that no specific job role was specified in the 'Approval of Materials and Activities Undertaken in the UK' SOP to clarify who must inform the PMCPA and MHRA of the names and qualifications of nominated signatories.

The corrective action had been to immediately inform the MHRA and PMCPA of the names and qualifications of nominated signatories. The preventative action involved an update to the 'Approval of Materials and Activities Undertaken in the UK' SOP and this step was ongoing in line with Daiichi-Sankyo's internal SOP update process.

The SOP update would give responsibility for notifying the PMCPA and MHRA of the names and qualifications of nominated signatories to the scientific information coordinator. The SOP will also specify that before any new signatories were assigned responsibility for certifying materials, acknowledgement of receipt of notification must be received from the PMCPA and MHRA and filed electronically by the scientific information coordinator. This new process in the SOP will ensure that omissions did not occur in future. Relevant staff members would be trained on the updated SOP, including the scientific information coordinator, nominated signatories, and the staff responsible for administering the approval and certification process.

Daiichi-Sankyo confirmed that a hard copy notification of signatories was sent to the PMCPA in March 2017. The notification was made on the PMCPA's 'Signatories for Promotional Material' template (copy provided). A hard copy letter was also sent to the MHRA on the same day to inform it of the nominated signatories (copy provided). The nominated signatories then were two registered medical practitioners and a UK registered pharmacist; one of the medical practitioners was the member of staff whose name had previously been correctly notified.

Daiichi-Sankyo submitted that it did not hold any contemporaneous acknowledgement that either the notification form or letter was received by the PMCPA or MHRA although the MHRA had confirmed that it received the March 2017 notification letter.

Daiichi-Sankyo was sorry that the PMCPA did not receive the notification in March 2017, but there was a record that it was sent and a letter posted on the same day reached the MHRA.

As noted above, going forward, confirmation of receipt of the notification must be received from the MHRA and PMCPA, before nominated signatories would be able to certify materials.

In conclusion, Daiichi-Sankyo regretted that the omissions detailed above took place. The company took compliance with the Code very seriously and had instituted corrective and preventative actions to ensure that such omissions did not occur again.

PANEL RULING

The Panel noted that Clause 14.4 required that, *inter alia*, the names of those nominated as final signatories, together with their qualifications, be notified in advance to the Advertising Standards Unit, Vigilance and Risk Management of Medicines of the MHRA and to the PMCPA. The names and qualifications of designated alternative signatories must also be given. Changes in the names of nominees must be promptly notified.

The Panel noted Daiichi-Sankyo's submission that it had failed to notify the MHRA and PMCPA of three medical nominated signatories which resulted in two hundred and ninety-six items being certified between them prior to notification of their names and qualifications to the MHRA and PMCPA as required by the Code; the Panel thus ruled a breach of Clause 14.4 as acknowledged by Daiichi-Sankyo. Consequently, the materials that had been certified by the above medical signatories who had not been notified in advance to the MHRA and PMCPA, had not been certified in accordance with Clause 14.1 and its supplementary information. The Panel thus ruled a breach of Clause 14.1.

Voluntary admission received **29 January 2018**

Case completed **30 May 2018**