CASE AUTH/2857/7/16

ANONYMOUS, NON CONTACTABLE v DAIICHI-SANKYO

Promotional activities and call rates

An anonymous non-contactable complainant raised four issues about the promotional activities and call rates by Daiichi-Sankyo UK.

The complainant alleged that market access consultants at Daiichi-Sankyo were sending emails to customers without prescribing information.

The complainant provided email correspondence between a market access consultant and a pharmacist from an NHS foundation trust in which a regional patient information leaflet was discussed.

The first email from the market access consultant referred to a change of role and his/her new role working on edoxaban (Daiichi-Sankyo's product Lixiana) and an error in a new oral anti-coagulant (NOAC) patient information regarding the need to take rivaroxaban (Bayer's product Xarelto) with food. The pharmacist's reply stated that the document had been updated. The next email from the market access consultant asked for a revised copy and confirmation that a new drug chart in the hospital contained three NOACs but not edoxaban (Daiichi- Sankyo's product Lixiana). The pharmacist sent the updated leaflet and stated that drug charts were outside his/her remit but that there was ongoing work on a unified chart for the region and that it would be best to liaise with pharmacists on a trust-by-trust basis.

The detailed response from Daiichi-Sankyo is given below.

The Panel noted that the complainant was anonymous and non-contactable. The Constitution and Procedure stated that anonymous complaints would be accepted, but that like all other complaints, the complainant had the burden of proving his/her complaint on the balance of probabilities. All complaints were judged on the evidence provided by the parties. The complainant could not be contacted for more information.

The Panel examined the emails provided by the complainant. The Panel noted the market access consultant's concern that the guidance stated 'This document doesn't cover the need to take rivaroxaban with food as has generalised for all NOACs as below… The medication can be taken with or without food and should be swallowed whole with water'. A link to the rivaroxaban SPC was provided and the relevant section which stated 'The tablets are to be taken with food' was included in the email.

The Panel noted that it was not clear from the emails which doses were being referred to, it appeared from the summary of product characteristics (SPC) that rivaroxaban 10mg and 2.5mg could be taken with or without food whereas rivaroxaban 15mg and 20mg had to be taken with food. Although the Panel was concerned about the provision of the information, particularly due to the lack of clarity about the dose, it did not consider that the lack of prescribing information was a breach of the Code as alleged. The email did not require certification. The Panel did not consider that there had been a failure to maintain high standards on the points alleged. No breaches of the Code were ruled.

The Panel noted the generality of the allegations. Daiichi-Sankyo had provided a selection of emails from its staff. The Panel did not consider that the complainant had demonstrated on the balance of probabilities that promotional emails were being sent by Daiichi-Sankyo market access consultants without the requisite prescribing information. No breaches of the Code were ruled.

The complainant alleged that new staff members were doing validation examinations before any product training. A hospital sales manager was referred to by name.

The Panel noted Daiichi-Sankyo's submission that the named individual, had passed the ABPI Medical Representatives Examination. The hospital manager was, according to Daiichi-Sankyo, trained on the Lixiana SPC and not required or expected to promote to customers.

The Panel did not consider that the complainant had established on the balance of probabilities that the training of the named individual was in breach of the Code. It thus ruled no breaches of the Code.

The complainant alleged that the market access staff were insisting on doing promotional calls alongside medical liaison scientist (MLS) appointments. Medical liaison scientists refused to do this, an example of a named individual refusing to do so was given.

The Panel noted Daiichi-Sankyo's submission that joint calls had not been made by market access consultants and medical liaison scientists. One market access consultant had requested such a meeting but it appeared from an email to a customer that '…MSLs can't do joint calls with market access because of compliance'. The market access consultant had suggested to the customer that he/she and the MSL came to the pharmacy at the same time. The MSL would '…spend some time on his own with you answering the questions you have around the data and leave'. The market access consultant would then 'see you all to finish in a separate call at the end just to sense check next steps for our support, which shouldn't take long. This is good in a way because I can show you the patient material available and discuss what else you may need'.

The Panel considered that the arrangements as set out in the email might be seen as similar to the market access staff doing promotional calls alongside MSL appointments as alleged. In this regard the Panel noted that the market access consultant would arrive with the MSL. The MSL would see the health professional separately and then leave. The Panel was concerned about the arrangements but did not consider that the complainant had proven his/her complaint on the balance of probabilities. No breaches of the Code including Clause 2 were ruled.

The complainant explained that Daiichi-Sankyo had reduced geographical areas and therefore reduced the target list. The company had introduced healthcare outcomes manager's call rate of three per day/contact rate four per day, hospital call rate four per day/contact six per day. The company had threatened performance improvement plans and disciplinaries if staff did not achieve those rates. In some areas this would mean calling on target customers in excess of six times in one year and sometimes as many as ten.

The Panel noted there was no definition of call or contact rates in the materials provided by Daiichi-Sankyo nor were the relevant requirement of the Code clearly referred to. It could, of course, be perfectly possible for Daiichi-Sankyo staff to meet the expected call and contact rates depending on the total number of prescribers on the territory. These had recently been reduced due to the reduced geographical areas. There was no evidence that representatives had over-called but the expected rates had not been clearly defined and thus were not clearly distinguished nor had they been placed in the context of the limitations in the relevant supplementary information. The Panel ruled a breach of the Code. In the Panel's view such omissions meant that on the balance of probabilities the briefing materials indirectly advocated a course of action which would be likely to breach the Code. A breach of the Code was ruled.

An anonymous non-contactable complainant submitted a complaint about the promotional activities and call rates by Daiichi-Sankyo UK Limited. The complainant raised four issues.

Daiichi-Sankyo was disappointed that one of its employees had reported an issue to the PMCPA. Daiichi-Sankyo encouraged employees to report issues to their line manager and operated a confidential whistle blowing line. Daiichi-Sankyo submitted that even with two recent restructures, it had introduced processes to ensure continuous compliant conduct of its business without compromising on safety and training of staff.

1 Emails to customers

COMPLAINT

The complainant alleged that market access consultants at Daiichi-Sankyo were sending emails to customers, including emails in which competitor information was referred to without prescribing information attached.

The complainant provided email correspondence between a market access consultant and a pharmacist at an NHS foundation trust, in which a regional patient information leaflet was discussed.

The first email from the market access consultant referred to a change of role and her new role working on edoxaban (Daiichi-Sankyo's product Lixiana) and an error in a new oral anti-coagulant (NOAC) patient information regarding the need to take rivaroxaban (Bayer's product Xarelto) with food. The pharmacist replied stating that the document had been updated. The next email from the market access consultant asked for a revised copy and confirmation that there was a new drug chart in the hospital containing three NOACs but not edoxaban (Daiichi-Sankyo's product Lixiana). The pharmacist sent the updated leaflet and stated that drug charts were outside his/her remit but that he/she thought there was ongoing work on a unified chart for use in the region. It would be best to liaise with pharmacists on a trust-by-trust basis.

When writing to Daiichi-Sankyo in relation to this allegation, the Authority asked it to consider the requirements of Clauses 4.1, 9.1 and 14.1.

RESPONSE

Daiichi-Sankyo submitted that its policy was that all promotional material sent to customers had to be certified in line with the Code and its standard operating procedure (SOP). This included emails. Emails to customers were only transactional in nature. Daiichi-Sankyo had a specific scheme for customers that opted in to promotional emails, the content of these emails were certified and centrally managed. Daiichi-Sankyo submitted that the email exchange mentioned in the complaint was a specific exchange regarding a NOAC patient information leaflet developed by the regional NHS foundation trust. There was also a question asked about the drug charts and their inaccuracy. Neither of these emails were promotional and related to documents that would otherwise be inconsistent with the most up-to-date information. The market access consultant had been working with internal colleagues on this project but was the contact with the lead pharmacist.

Daiichi-Sankyo submitted that the market access consultant initially contacted the pharmacist in June 2016 to highlight inaccuracies within the NOAC patient information leaflet relating to rivaroxaban and advice that was inconsistent with the summary of product characteristics (SPC). As no response was received, a director followed up by email. A response was received. The pharmacist confirmed that the document had been updated and thanked the market access consultant for his/her input. The market access consultant followed up the outstanding issue relating to drug charts and his/her final communication was to the internal team as the regional documents were considered of national importance. The email exchange was project specific and consistent with the Code, not promotional.

Daiichi-Sankyo submitted that it reviewed emails sent from the market access consultants to

customers and provided copies. It denied breaches of Clauses 4.1, 9.1 and 14.1.

PANEL RULING

The Panel noted that the complainant was anonymous and non-contactable. The Constitution and Procedure stated that anonymous complaints would be accepted, but that like all other complaints, the complainant had the burden of proving his/her complaint on the balance of probabilities. All complaints were judged on the evidence provided by the parties. The complainant could not be contacted for more information.

The Panel examined the emails provided by the complainant. The Panel noted that the market access consultant had raised a concern about the content of the NOAC guidance with regard to rivaroxaban stating 'This document doesn't cover the need to take rivaroxaban with food as has generalised for all NOACs as below … The medication can be taken with or without food and should be swallowed whole with water'. A link to the rivaroxaban SPC was provided and the relevant section which stated 'The tablets are to be taken with food' was included in the email.

The Panel noted the definition of promotion at Clause 1.2 and did not consider that this exchange amounted to promotion of any Daiichi-Sankyo medicine and thus did not require prescribing information. Companies should be careful if staff were commenting on competitor products such references should comply with the Code, particularly Clause 7. It was not clear from the emails which doses were being referred to, it appeared from the SPC that rivaroxaban 10mg and 2.5mg could be taken with or without food whereas rivaroxaban 15mg and 20mg had to be taken with food. Although the Panel was concerned about the provision of the information, particularly due to the lack of clarity about the dose, it did not consider that the lack of prescribing information was a breach of Clause 4.1 as alleged. The Panel ruled no breach of Clause 4.1. The email did not require certification and no breach of Clause 14.1 was also ruled. The Panel did not consider that there had been a failure to maintain high standards on the points alleged and no breach of Clause 9.1 was ruled.

The Panel noted the generality of the allegations. Daiichi-Sankyo had provided a selection of emails from its staff. The Panel did not consider that the complainant had demonstrated on the balance of probabilities that promotional emails were being sent by Daiichi-Sankyo market access consultants without the requisite prescribing information. No breach of Clauses 4.1, 14.1 and consequently 9.1 was ruled.

2 Training

COMPLAINT

The complainant alleged that there was an issue with new staff members doing their validation examinations before having had any product training. A hospital sales manager was referred to by name.

When writing to Daiichi-Sankyo in relation to this allegation, the Authority asked it to consider the requirements of Clauses 9.1 and 15.1.

RESPONSE

Daiichi-Sankyo submitted that the specific training schedule for market access consultants was put in place whereby basic training would be delivered to all newcomers as befitted their role with comprehensive training courses to be held roughly four times a year. Daiichi-Sankyo noted that it was undergoing another restructure and two dedicated training heads were being introduced.

Daiichi-Sankyo submitted that the arrival of market access consultants corresponded to the former period, all were trained on the disease area, products and were validated. With regard to the named individual, Daiichi-Sankyo submitted that he/she recently joined the organisation (a copy of the ABPI Medical Representative Examination certificate was provided). The role was a hospital manager and therefore he/she was not required or expected to promote to customers (a copy of the job profile was provided).

The training record for the hospital sales manager was provided, training on company policies and procedures and on the product SPC had been provided. Given the scope of the role he/she would not be expected to participate in a full validation examination as per a hospital sales representative.

Daiichi-Sankyo denied breaches of Clauses 9.1 and 15.1.

PANEL RULING

The Panel noted its general comments above about the status of the complainant and burden of proof.

The Panel noted Daiichi-Sankyo's submission that the named individual had passed the ABPI Medical Representatives Examination. The individual was a hospital manager and, according to Daiichi-Sankyo, was trained on the Lixiana SPC and was not required or expected to promote to customers.

The Panel noted that the general requirements in Clause 16.1 of the Code that staff concerned in any way with the preparation or approval of materials or activities covered by the Code must be fully conversant with the Code and the relevant laws and regulations.

The Panel did not consider that the complainant had established, on the balance of probabilities, that the training of the named individual was in breach of the Code. It thus ruled no breach of Clause 15.1 and consequently no breach of Clause 9.1 of the Code.

3 Market access consultants'/medical liaison scientists' calls

COMPLAINT

According to the complainant the market access staff were insisting on doing promotional calls alongside

medical liaison scientist (MLS) appointments. Medical liaison scientists refused to do this, an example of a named individual refusing to do so was given but market access said it would happen.

When writing to Daiichi-Sankyo in relation to this allegation, the Authority asked it to consider the requirements of Clauses 2, 3.1, 3.2 and 9.1.

RESPONSE

Daiichi-Sankyo noted that the complainant made it clear that joint calls by the market access consultants and the medical liaison scientists had not happened. Daiichi-Sankyo reassured the Panel that there was no plan for it to occur even in its new restructured organisation. Daiichi-Sankyo reiterated that medical access consultants were new to the organisation and in the case of the market access consultant, he/she had requested such a meeting which was turned down by the named medical liaison scientists. The company submitted that there was evidence to support its position.

In addition to training upon arrival, the medical department regularly conducted training to show how best to interact with medical liaison scientists and details were provided.

Daiichi-Sankyo denied breaches of Clauses 3.1, 3.2, 9.1 and 2.

PANEL RULING

The Panel noted its general comments on point 1 about the status of the complainant and the burden of proof.

The Panel noted Daiichi-Sankyo's submission that joint calls had not been made by market access consultants and medical liaison scientists. One market access consultant had requested such a meeting but it appeared from an email to a customer that '…MSLs can't do joint calls with market access because of compliance'. The market access consultant had suggested to the customer that she and the MSL came to the pharmacy at 2pm. The MSL would '…spend some time on his own with you answering the questions you have around the data and leave'. The market access consultant would then 'see you all to finish in a separate call at the end just to sense check next steps for our support, which shouldn't take long. This is good in a way because I can show you the patient material available and discuss what else you may need'.

The Panel considered that the arrangements as set out in the email might be seen as similar to the market access staff doing promotional calls alongside MSL appointments as alleged. In this regard the Panel noted that the market access consultant would arrive with the MSL. The MSL would see the health professional separately and then leave. The Panel was concerned about the arrangements but did not consider that the complainant had proven his/her complaint on the balance of probabilities. No breach of Clauses 3.1, 3.2, 9.1 and 2 were ruled.

4 Call rates and targets

COMPLAINT

The complainant explained that Daiichi-Sankyo had reduced geographical areas for the healthcare outcomes managers and hospital representatives and therefore the target list was reduced. The company had introduced healthcare outcomes manager's call rate of three per day/contact rate four per day, hospital call rate four per day/contact six per day. The company had threatened performance improvement plans and disciplinaries if staff did not achieve those rates. In some areas this would mean calling on target customers in excess of six times in one year and sometimes as many as ten.

When writing to Daiichi-Sankyo in relation to this allegation, the Authority asked it to consider the requirements of Clauses 15.4 and 15.9.

RESPONSE

Daiichi-Sankyo submitted that it operated a key account management model, specifically meaning that representatives were to see whichever health professionals in the key account that were involved in the decision on the use of the product be they prescriber or non-prescriber. There was therefore no limit on the number of customers within the account that could be seen. There was no bonus payment linked to activity.

With regard to allegations made by the complainant that Daiichi-Sankyo had been performance managing individuals that had not been meeting required overall performance standards, Daiichi-Sankyo noted that the complainant specifically cited activity and although not a primary consideration with respect to performance for the purpose of refuting the allegation it provided the following information.

Daiichi-Sankyo stated that the historic activity levels within the company (the average per day was provided) were considered suboptimal. As a consequence a verbal briefing was given to the entire sales team in June 2016 that that level of activity along with other performance measures was unacceptable. At no time was there any direction to breach the guidance in relation to the Code or that there would be a reduced target list of customers. Daiichi-Sankyo acknowledged that geographies had changed but was not consistent with a reduction in the target list of customers seeing as the group of customers that were appropriate to be informed about the product spread across multiple specialities ie cardiology, stroke, care of the elderly, general medicine, GP, pharmacy medicines management etc.

As a follow-up to the briefing, each representative also had a one to one discussion with his/her manager to address specific performance issues and where expectations were set. Daiichi-Sankyo accepted that performance improvement plans had been put in place prior to further action where overall individual performance had not been acceptable. That was not linked specifically to achievement of activity rates as alleged.

PANEL RULING

The Panel noted its general comment above at point 1 about the status of the complainant and the burden of proof.

The Panel noted that Clause 15.4 of the Code required representatives to ensure that the frequency, timing and duration of calls on, *inter alia*, health professionals, together with the manner in which they were made, did not cause inconvenience. The supplementary information to that clause stated, *inter alia*, that companies should arrange that intervals between visits did not cause inconvenience. The number of calls made on a doctor or other prescriber by a representative each year should normally not exceed three on average excluding attendance at group meetings and the like, a visit requested by the doctor or other prescriber or a visit to follow up a report of an adverse reaction. Thus although a representative might speculatively call upon or proactively make an appointment to see a doctor or other prescriber three times on average in a year, the annual number of contacts with that health professional might be more than that. The supplementary information to Clause 15.4 also advised that when briefing representatives companies should distinguish clearly between expected call rates and expected contact rates. Targets must be realistic and not such that representatives breached the Code in order to meet them. Clause 15.9 stated that briefing material must not advocate directly or indirectly any course of action which would be likely to lead to a breach of the Code.

The Panel noted Daiichi-Sankyo's expectations regarding activity standards. Hospital representatives were expected to do four face-to-face calls and six contacts per day. Market access staff were expected to do three face-to-face calls and four contacts per day. There was no definition of call or contact rates in the materials provided by Daiichi-Sankyo nor were the relevant requirement of the Code clearly referred to. It could, of course, be perfectly possible for Daiichi-Sankyo staff to meet the expected call and contact rates depending on the total number of prescribers on the territory. These had recently been reduced due to the reduced geographical areas. There was no evidence that representatives had over-called but the expected rates had not been clearly defined and thus were not clearly distinguished nor had they been placed in the context of the limitations in the relevant supplementary information. The Panel ruled a breach of Clause 15.4. In the Panel's view such omissions meant that on the balance of probabilities the briefing materials indirectly advocated a course of action which would be likely to breach the Code. A breach of Clause 15.9 was ruled.

Complaint received **1 July 2016**

Case completed **30 September 2016**