ANONYMOUS CONSULTANT ONCOLOGIST v MERCK SERONO

Conduct of representative

An anonymous, non-contactable complainant who described themselves as a consultant oncologist complained about the conduct of a representative from Merck Serono with regard to the promotion of Erbitux (cetuximab).

The complainant's concerns were frequent email contact, frequent requests for appointment, often monthly, representatives arriving in the day unit or out-patients clinic, without an appointment or prior permission which was against trust policy and wasted valuable clinic time. The complainant also referred to presentation of old data when the appointment was granted on the understanding that new data would be discussed. As cetuximab was a well-established medicine, it was not necessary to meet frequently to discuss established data that offered no new clinical value. The final concern was a failure to provide paper copies of information presented during appointments, despite requests.

The detailed response from Merck Serono is given below.

The Panel noted that the complainant was anonymous and non-contactable. The Constitution and Procedure for the Prescription Medicines Code of Practice Authority 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.

The Panel was concerned about the allegations made by the anonymous complainant but he/she had provided no supporting detail such as the relevant hospital location. The company was unable to properly investigate the allegations.

The Panel examined the materials provided by Merck Serono. The representatives' training (dated August 2015) reflected the restrictions in the Code on calls. The representatives' briefing materials provided made no mention of the number of calls/contacts. The company had received recent NICE guidance for use of Erbitux in a particular type of patient. This was likely to be of interest to health professionals but it was unlikely that this related to new clinical data. The job description for a key account manager stated that they should act with integrity to ensure compliance with company and industry guidelines and requirements.

The Panel noted that the complainant bore the burden of proof and considered that he/she had failed to prove any of the allegations on the balance of probabilities. The Panel therefore ruled no breaches of the Code.

An anonymous, non-contactable complainant who described themselves as a consultant oncologist complained about the conduct of a representative from Merck Serono Limited with regard to the promotion of Erbitux (cetuximab). Erbitux was for the treatment of certain forms of metastatic colorectal cancer and for the treatment of squamous cell cancer of the head and neck.

COMPLAINT

The complainant stated that he/she had enjoyed a cordial relationship with the pharmaceutical industry over many years, and had valued the support provided to his/her clinic and patients. However, he/she had recently become concerned by the conduct of Merck Serono. The complainant stated that, in summary, his/her concerns were:

- Frequent email contact. While he/she had given the representative permission to contact him/her via email, the rate of contact was more than could be viewed as reasonable.
- Frequent requests for appointment, often monthly, with him/herself, junior doctors and nursing staff.
- Representatives arriving in the day unit or out-patients clinic, without an appointment or prior permission, in the anticipation that they might be able to see someone. This practice was against trust policy and wasted valuable clinic time.
- Presentation of old data when the appointment was granted on the understanding that new data would be discussed.
- Cetuximab was a well-established medicine; the complainant did not consider it necessary to meet frequently to discuss established data that offered no new clinical value.
- Failure to provide paper copies of information presented during appointments, despite requests.

The complainant firmly believed that this behaviour was unprofessional and not of the standard that he/she had come to expect from the pharmaceutical industry. The complainant stated that on several occasions he/she had made his/her concerns clear to the representative, but they claimed that Merck expected them to see clinicians frequently and present their data in this way, regardless of clinicians' individual preferences.

When writing to Merck Serono, the Authority asked it to consider the requirements of Clauses 7.1, 7.5, 9.1, 11.2, 15.2, 15.4 and 15.9 of the Code.

RESPONSE

Merck Serono stated that it took any allegation of inappropriate conduct of its staff very seriously.

On being advised of the complaint, it immediately launched an internal investigation into the allegations.

Merck Serono noted that according to the introduction of the PMCPA Constitution and Procedure, the complainant had the burden of proving his/her complaint on the balance of probabilities. As the complainant had not identified a specific representative or location, the investigation was challenging and the company could not investigate the specific representative involved.

Merck Serono submitted that all of its representatives were trained on the requirements of the Code regarding calls. The training also covered frequency and manner of calls on doctors and other prescribers which outlined that calls must not be inconvenient in terms of frequency, duration, interval between calls, timing, nature and that calls must be in line with individuals' wishes and with local requirements/ procedures. Merck Serono provided a copy of relevant guidance for its customer-facing employees and submitted that through its investigation it did not find any evidence that it had breached Clause 15.4 or 11.2.

As detailed in the guidance, representatives were responsible for complying with hospital requirements. With regard to trusts which did not allow cold calling, Merck Serono emailed its representatives to ask them if any hospital trusts had policies which prohibited representatives from going to the day unit or out-patients without a specific appointment or which restricted representative activity in other ways.

A sample of some of the responses from the oncology sales team showed that there were many hospitals that had restrictions to prohibit representatives from entering different parts of the hospitals. Some trusts prohibited representatives from calling without an appointment. Many trusts had introduced the Medical Industry Accredited (MIA) card which representatives must carry if they had an appointment. One trust required sign in via the procurement department, a badge was then issued and the appointment confirmed with the relevant health professional etc. If representatives were seen anywhere in the hospital without the lanyard they were required to leave the hospital and banned for six months.

Merck Serono submitted that its representatives were well-trained and all understood their obligations under the Code and that they must always maintain a high standard when dealing with health professionals and other decision-makers. The job description for a representative clearly outlined obligations about integrity and compliance with company and industry guidelines. Merck Serono submitted that its investigation had found no evidence that any of its representatives had not acted in line with their job description or had been in breach of Clause 15.2.

Merck Serono submitted that its representatives were not rewarded nor did they receive bonuses related to number of calls or contacts. A copy of the key account manager (KAM) Incentive Plan was provided which Merck Serono stated demonstrated the lack of such rewards/bonuses.

Merck Serono submitted that its promotional material was accurate and relevant and frequently updated to ensure it was current.

The data to support the use of cetuximab had evolved over recent years with, for example, further understanding of how biomarkers could be better used to target metastatic colorectal cancer patients who were the most likely to benefit; such data had led to changes in the marketing authorisation. Further new data were presented at major congresses, such as the American Society of Clinical Oncology (ASCO) and the European Society for Medical Oncology (ESMO) each year. In order to reflect the most relevant and up-to-date evidence, the marketing campaigns were updated, to provide the sales teams and therefore customers with the most relevant data. In December 2016 the detail aid was updated to include data on tumour location which were initially presented at the ASCO and ESMO conferences. A briefing document was approved in December for the sales team, Tumour Location Data KAM Briefing. This was the latest certified briefing on the technical aspects of Erbitux. Merck Serono believed this demonstrated that there could be no breach of Clause 15.9.

In addition to the latest clinical data, in the first quarter of 2017, the National Institute for Health and Care Excellence (NICE) issued a final appraisal determination related to Erbitux, which was important information about funding and practice in the UK. This had also been communicated and briefed to the KAMs and marketing materials provided. Merck Serono submitted that this further demonstrated that KAM material, and subsequently the content of their visits to customers, was up-to-date and relevant. Merck Serono provided an agenda for the meeting in March where this was communicated. Additionally, a leavepiece was approved to communicate this to health professionals.

Merck Serono stated that it made great efforts to tailor its interactions to the preferences of individual clinicians. Its electronic detail aid contained 178 pages, and was configured into several sections so that representatives could flexibly tailor the conversation to customers' individual needs. The use and functionalities of the electronic detail were most recently demonstrated to representatives in April 2016. KAMs were clearly directed that the content of their calls should be tailored to customer needs and that there was no pre-specified or mandated call flow. As noted above, customer-facing employees were given guidance on interactions, and in addition, the latest guidance around motivational customer messaging was trained in January 2017.

Merck Serono thus considered that the information it provided was relevant and accurate and therefore not in breach of Clause 7.1.

Merck Serono stated that it was unable to comment about the complainant's concern about the presentation of old data as no specific information had been provided about the data itself or the timeframe which the complainant believed constituted old data.

With regard to the provision of information, Merck Serono stated that if a health professional requested information that had been presented electronically then the representative would contact the medical information department as the content of a digital sales aid could not be provided by the representative to a customer.

If a written response was received by the medical information department, it would email the health professional to confirm his/her question by the next working day. If no response was provided within 10 working days the request would be closed. Health professionals were routinely advised that they needed to respond for the information to be sent. The email response from the health professional provided further evidence of an unsolicited request for information; the information would be sent by medical information in 5 days. Merck Serono provided a copy of a standard operating procedure (SOP) which outlined this process.

Merck Serono noted that the complainant stated that it had not provided information when requested to do so, however, without specifics the company was unable to investigate this further and it refuted a breach of Clauses 7.1 or 7.5.

Merck Serono reiterated that compliance with the Code was taken very seriously across the organisation. The company hoped that its explanation and supporting documentation provided clear reasons as to why it had not breached Clauses 7.1, 7.5, 11.2, 15.2, 15.4, 15.9 or 9.1.

PANEL RULING

The Panel noted that the complainant was anonymous and non-contactable. The Constitution and Procedure for the Prescription Medicines Code of Practice Authority 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 had provided no evidence to support his/her allegations and could not be contacted for more information.

The Panel was concerned about the allegations made by the anonymous complainant but he/she had provided no supporting detail such as the relevant hospital location. The company was unable to properly investigate the allegations.

The Panel examined the materials provided by Merck Serono. The representatives' training (dated August 2015) reflected the restrictions in the Code on calls as set out in Clause 15.4 and its supplementary information. The company defined calls and contacts. The incentive plan (August 2016) had both quantitive and qualitive elements. In relation to one element of the incentive, the sales commitment, there was no benefit from under or over commitment. The representatives' briefing materials provided made no mention of the number of calls/contacts. The company had received recent NICE guidance for use of Erbitux in a particular type of patient. This was likely to be of interest to health professionals but it was unlikely that this related to new clinical data. The job description for a key account manager stated that they should act with integrity to ensure compliance with company and industry guidelines and requirements.

The Panel noted that the complainant bore the burden of proof and considered that he/she had failed to prove any of the allegations on the balance of probabilities. The Panel therefore ruled no breach of Clauses 7.1, 7.5, 11.2, 15.4 and 15.9 of the Code. Neither the representatives nor the company had failed to maintain high standards. No breach of Clauses 15.2 and 9.1 were ruled.

Complaint received **21 March 2017**

Case completed **28 June 2017**