

ANONYMOUS, NON-CONTACTABLE NURSE v MERCK SERONO

Call frequency

An anonymous, non-contactable complainant who described themselves as a senior multiple sclerosis (MS) nurse specialist in an NHS trust, complained about the frequency with which Merck Serono sales representatives came to see him/her, often without an appointment. This was made more inconvenient by the various people they frequently brought with them. The complainant stated that although he/she had repeatedly objected to the additional visitors, the visits had not only continued but actually increased. The complainant noted that his/her colleagues had reported similar issues with the company.

The detailed response from Merck Serono is given below.

The Panel noted that market research commissioned by Merck Serono had shown that customers were being called on more frequently by competitors. In response the company created a sales team incentive as a 'short term fix' for the whole of March 2015 to help the team achieve a target of 6 contacts/day with all MS customers, including MS specialist nurses. Merck Serono submitted that this had a positive effect on the sales teams.

The Panel noted the contact and call rates with MS nurses and neurology customers submitted by the company. The percentage solicited calls with all neurology customers varied between 96% and 100% from November 2014 to March 2015. The Panel noted that the percentage of solicited calls during March was 98%, the second lowest percentage of solicited calls during the six-month period from November 2014 to April 2015. An increase was also seen in the market research findings of the frequency of visits to MS specialists from January to March 2015.

The Panel noted the complainant's concern about the frequency with which the representative came to see him/her, often without an appointment. In the Panel's view the data provided by the company was consistent with the complainant's comment that calls were of increasing frequency.

The Panel noted that a communication sent in December 2014 to the key account managers (KAMs) stated that a key performance indicator for 2015 was 3 contacts/day. The customer target spreadsheet created by the KAMs referred 'to no more than 3 unsolicited calls per customer in line with ABPI Code'.

The Panel noted that an incentive scheme was generally understood to, *inter alia*, encourage increased productivity; it was therefore not a mandatory requirement. Merck Serono provided several emails to the sales team sent on 30 April

2015. It was of concern that, contrary to Merck Serono's submission that the incentive scheme ran during March 2015, the emails showed that, at the very least, it had continued throughout April and KAMs were expected to continue to achieve 6 contacts/day thereafter. The emails linked the contact rate of 6 per day to the team's business objectives for 2015. In the Panel's view, the KAMs had been given the impression that the contact rate of 6 per day applied not only to March 2015 but to the rest of the year. Each KAM had 50-60 MS specialists in their territory which meant each specialist would need to be contacted, on average, 2-3 times/month. The Panel considered this appeared to be a high contact rate.

The Panel considered that the KAMs appeared to have been given little comprehensive and consistent guidance on how to achieve 6 contacts/day and comply with the Code. This was a significant omission. The Panel was concerned that the terminology used in the emails about contacts and calls which was sent to certain KAMs on 30 April was inconsistent; in response to a specific request Merck Serono had been unable to provide its definition of call and contact rates and associated representatives' briefing. Solicited calls were only described in the briefing to KAMs on how to enter their contact rate in the CRM system. The Panel noted the company's submission that it was able to distinguish between call and contact rates on its in-house data system but considered that this did not alter the fact that the KAMs had not been adequately advised in this regard.

The Panel noted its comments above. The Panel noted that the March incentive scheme was, in reality, a requirement. The Panel considered that achieving this would mean that, on the balance of probabilities, the representatives would breach the Code; in the absence of consistent terminology and briefing on how to achieve 6 contacts/day and remain compliant with the Code, the frequency of representatives' calls would cause inconvenience. On the balance of the evidence breaches of the Code were ruled.

The Panel noted Merck Serono's submission that the sales team also recorded accompanied visit data, to the best of its knowledge all such visits were infrequent and pre-arranged with the MS specialist involved. Merck Serono provided data on accompanied calls. Merck Serono further submitted it was unaware of any trusts/hospitals which did not allow visitors and was equally unaware of any breaches or potential breaches of trust policies in the period January 2014 to April 2015. The Panel noted any breach of trust policy was a serious matter. The complainant had not provided a copy of

the relevant trust policy. The Panel considered that there was no evidence to support the allegation that a trust policy had been breached; the complainant bore the burden of proof in this regard. The Panel therefore ruled no breach of the Code.

An anonymous, non-contactable complainant who described themselves as a senior multiple sclerosis (MS) nurse specialist in an NHS trust complained about the call frequency of Merck Serono Limited's sales representatives.

COMPLAINT

The complainant noted that in previous years he/she had enjoyed a very cordial relationship with Merck Serono; the company had been very supportive of both him/her and his/her unit, but increasingly over the last few months the complainant had found the activities of the company and its representatives overpowering.

The complainant stated that he/she was most concerned about the frequency with which the sales representative came to see him/her, often without an appointment. This was made more inconvenient by the various people they frequently brought with them, including managerial, medical, marketing and administrative staff. The complainant stated that he/she had repeatedly explained that he/she would rather not have these additional visitors as they added no value to clinical care, threatened patient confidentiality and such visits were against trust policy; despite his/her requests the visits had not only continued, but actually increased.

The complainant noted that he/she had recently met with some fellow nurses at a UK nurse association who reported that they had experienced similar issues with Merck Serono and believed the problems to be part of a wider change in the company's sales and marketing policy.

The complainant noted that he/she had spoken with the hospital pharmacist about his/her concerns, and it was suggested that as he/she had already spoken to the Merck Serono representative and not seen any improvement, he/she should draw his/her concerns to the PMCPA's attention.

When writing to Merck Serono, the Authority asked it to respond in relation to Clauses 15.2 and 15.4 of the Code.

RESPONSE

Merck Serono stated that for many years it had benefitted from having an experienced, professional neurology sales team which currently consisted of eight key account managers (KAMs) and a manager. Their accounts covered approximately 385 MS specialist doctors and nurses throughout the UK and Ireland with approximately 33 MS specialist nurses in each territory. Merck Serono stated that it was unable to categorise the subgroup *senior* MS specialist nurse as it was unfamiliar with how this was defined in the NHS.

Merck Serono explained that for almost two decades there had been relative stability and minimal

competition as limited therapeutic options for MS were available. In 2014 there was a significant change to the environment in a short space of time as several newly licensed MS medicines became available. This had negatively impacted the sales of Merck Serono's MS product, Rebif, (interferon beta-1a) which had previously led the market for many years. With the rise of competitor activity and an increasing pool of MS stakeholders, the sales force had been challenged to not only review its current activities with known MS customers (such as MS specialist nurses) but to contact a wider group which might be potential prescribers or influence the use of MS therapies.

According to internal market research performed in January 2015, customers were being called upon more frequently by competitors. Only 20% of the 30 MS specialists who took part in an online survey reported seeing a Merck Serono representative at least once a month. This appeared to signal an urgent need to increase the representatives' activities to remain competitive. Additionally, with regard to MS specialist nurses specifically, a significant downward trend was noticed in the performance of the team as measured by their average 'daily contact' rates, with 'contact' meaning solicited or unsolicited face-to-face, email and telephone contacts, as well as contacts at meetings. Between November 2014 and January 2015, the team's average daily 'contact' rate was as low as 0.82.

Merck Serono stated that to help address this concern, changes were made to the head office team including the recruitment of a new director from January 2015. A new sales campaign was launched and a time-limited incentive was offered to the sales team between 1 and 31 March 2015 inclusive, to help achieve a target of 6 contacts per day to all MS customers, including MS specialist doctors and nurses but also other MS stakeholders such as pharmacists and general neurologists.

The incentive was created as a 'short-term fix' to ensure Merck Serono remained competitive and to improve the team's average contact rate which was falling. It was clear that the 'contact' rates improved as a result. The average daily contact rates for the three months February to April 2015 increased to 1.29 from 0.82 in the preceding three months. Despite these changes, the percentage of solicited calls to MS nurses specifically remained consistently high between 97% and 99%. This suggested that conversely the number of unsolicited calls was low and in line with the requirements of the Code.

The team also recorded which Merck Serono personnel had accompanied them on customer visits. These might include head office staff such as managers, marketing and medical but never administrative staff. One of Merck Serono's strategic pillars that drove the competency model for all employees was to become more 'customer-focused'. As a result, the leadership team (ie managers, directors) were encouraged to occasionally accompany KAMs on visits to customers so that they had a better insight into the needs of health professionals and patients and understood how best Merck Serono could support their goals towards

improving patient care. Merck Serono provided details of the staff involved and the rationale for their respective visits. Merck Serono stated that, to the best of its knowledge, these visits were infrequent and always prearranged with the MS specialist involved.

Merck Serono stated that with regard to trusts/hospitals which did not allow additional visitors, neither the head office team nor the sales force knew of any such rules being present. Between January 2014 and April 2015, Merck Serono had not been informed of any breaches or potential breaches to trust policies. On further questioning, none of Merck Serono's representatives recalled any conversations with their customers around problems with the increased frequency of contacts, or of potential breaches to trust policy as indicated by the complainant.

Based on the above, Merck Serono submitted that although recent initiatives had increased the number of customer contacts with representatives, the company had no reason to believe that such contacts had caused any inconvenience. The total recorded numbers of unsolicited calls by the representatives had remained compliant with the Code. Merck Serono submitted therefore that it had not acted in breach of Clause 15.4. Merck Serono had also no reason to believe that the representatives had not continued to demonstrate the high standard of ethical conduct required by the Code and Merck policies. Merck Serono thus denied a breach of Clause 15.2.

In response to a request for further information, Merck Serono submitted the following:

1 Briefings and communications regarding the incentive scheme:

Merck Serono submitted a copy of a letter which was sent to all the neurology KAMs which outlined the details and conditions of the bonus scheme.

2 Merck Serono's definition of call and contact rates, and solicited and unsolicited calls including associated communications and/or briefings. Also an explanation of how a solicited or unsolicited call was documented in Merck Serono's customer relationship management (CRM) system:

Merck Serono submitted an approved and certified copy of a briefing to the KAMs on how to enter their contact rate in the Merck Serono CRM system on which all KAMs were trained.

The briefing set out the mandatory information which was required to be completed by the KAMs for each of their contacts, including whether or not this was a 'solicited call'. The briefing included a clear definition of solicited calls (and by implication unsolicited calls). The briefing also reminded the KAMs that no more than three proactive, promotional calls per health professional could be made in a 12-month period.

The briefing did not set out a definition of call and contact rates. However, the system required the

KAMs to record their contacts as either face-to-face meetings, meetings, telephone contact or email contacts. Using the type of interaction recorded on the CRM system, Merck Serono could distinguish between call and contact rates. Merck Serono stated that call rates included all KAMs' face-to-face meetings, and contact rates included all face-to-face meetings, contact at meetings, telephone and email contacts with customers.

3 Data on KAM contact and call rates on all neurology customers from November 2014 to March 2015:

Merck Serono submitted details of the KAMs' monthly average contact and call rates on all customers from November 2014 to March 2015. Merck Serono split the contacts according to those which related to purely to face-to-face meetings (call rate) and those related to all customer contacts, including face-to-face meetings, contacts at meetings, telephone or email contacts (contact rate).

The rates were marginally different to those supplied in Merck Serono's original response because the CRM system was a live system. Since Merck Serono last ran the analysis, a few more calls had been entered. The company believed that all relevant calls had now been fully entered onto the CRM system for the time period specified.

4 Data on KAM contact and call rates on MS nurses from November 2014 to March 2015:

Merck Serono submitted details of the KAMs' monthly average contact and call rates on MS nurses from November 2014 to March 2015 and the monthly number of contacts which were accompanied. The same distinction was made between call and contact rates as defined above.

When comparing the total contact and call rate on all neurology customers between November 2014 and March 2015, and the total contact and call rate on MS nurses only during the same period, the proportion of calls made to MS nurses represented 35% of the total number of calls made to all neurology customers. Also the proportion of all contacts made to MS nurses represented around 30% of the total number of contacts made to all neurology customers.

In response to a further request for information Merck Serono submitted that an email was sent to the KAMs which detailed the quarter 2 targets; these targets were based on new patient numbers achieved on a monthly basis as illustrated. The targets were set for each KAM and region as indicated by the initials for the 8 KAMs. The targets for quarter 2 were not based on health professional contact rates – these were used only during March, as previously indicated. This email was not certified as it related to an internal briefing on field force financial targets rather than a salesforce briefing *per se* on their promotional activities with customers. In addition, the letter detailing the KAM sales incentive scheme (dated 31st January) was not certified as it related to internal team financial targets and did not specifically detail field force activity with customers.

The letter outlined the financial aspects of the KAM bonus scheme and did not indicate activity and metrics on call or contact rates with health care providers.

The email dated 2nd May that was sent by a new senior director to the KAM team should have been reviewed and certified; the language and tone of the email would not have been approved by the company's signatories and would have been amended. Unfortunately, the briefing material had not been put through the approval process in this instance which was an oversight. Merck Serono stated that it had addressed this issue with a senior director (who was new in the post at the time) and had reminded the whole commercial team that all field force briefings, which detailed activity with customers, had to be reviewed and approved by its signatories for certification purposes before distribution to KAMs.

The impact that the incentive scheme and associated communication had had on the call/contact rates with health professionals (including MS nurses), as recorded in the CRM system were detailed in the resultant KAM call rates which were provided. The company had not collected any additional evidence that the email of 2 May had led to any KAM breaching the Code in relation to their activities with health professionals. In summary Merck Serono did not believe that this had led the KAM team to have breached Clauses 15.2, 15.4 and 15.9 of the Code.

PANEL RULING

The Panel noted the similarities between this case and Case AUTH/2756/5/15. The Panel, nonetheless, considered each case separately. The Panel noted that the complainant was anonymous and non-contactable. Like all complaints, anonymous complaints were judged on the evidence provided. The complainant bore the burden of proving his/her complaint on the balance of probabilities.

The Panel noted that Clause 15.4 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 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.

The Panel noted that the complainant referred to the increasing frequency of representatives' visits over the last few months. The complaint was dated 30 April 2015. The Panel noted that Merck Serono had an incentive scheme for 2015 and had submitted that it had run a short-term incentive scheme in March 2015.

The Panel noted Merck Serono's submission that it had responded to recent changes in the MS therapy environment with various sales and marketing activities and changes to the head office team.

Merck Serono commissioned market research; an on line survey of 30 MS specialists, carried out in three monthly waves; January, February and March 2015. The data for January showed customers were being called on more frequently by competitors. To address this Merck Serono stated that it had created an incentive to the sales team as a 'short term fix' from 1 – 31 March 2015 inclusive to help the sales team achieve a target of 6 contacts per day with all MS customers, including MS specialist nurses. Merck Serono submitted that this had a positive effect on the sales teams.

The Panel noted that some of the contact/call rates provided in the company's responses to requests for further information differed from those provided in the company's initial response as the CRM system had been updated with further contacts. These differences did not, in the Panel's view, appear to be significant. Overall, the contact rate with MS nurses was 1.05 (May 2014), 1.0 (November 2014), 0.6 (December 2014), 0.8 (January 2015), 1.3 (February 2015) and 1.4 (March 2015). The corresponding call rates were 0.7, 0.6, 0.6, 0.9 and 1.2 from November 2014 through to March 2015. The percentage solicited calls with MS nurses according to the company's initial response dated 22 May 2015 was 98% (May 2014), 99% (November 2014) and 97% (February 2015). The monthly daily contact rate with all neurology customers was 2.9 (November 2014), 2.5 (December 2014), 2.4 (January 2015), 4.6 (February 2015), 5.2 (March 2015). The corresponding call rates were 1.8, 1.5, 1.5, 3.2 and 3.6 from November 2014 through to March 2015. The percentage solicited calls with such customers varied between 96% and 100% over the same period. The Panel noted that the percentage of solicited calls during March was 98%, the second lowest percentage of solicited calls during the six-month period from November 2014 to April 2015.

An increase was also seen in the market research findings with MS specialists which showed that the frequency of representatives' visits classified as 'often/once a month' was 50 in both March and February 2015 and 20 in January 2015. The frequency of representatives' visits classified as 'sometimes/ every 3 months' was 30 in March 2015, 27 in February 2015 and 20 in January 2015.

The Panel noted the anonymous complainant's submission that the activities that he/she found most concerning were the frequency with which the sales representative came to see him/her, often without an appointment. In the Panel's view the data provided by the company was consistent with the complainant's comment that calls were of increasing frequency.

The Panel noted that a communication sent in December 2014 to the KAMs stated that a key performance indicator for 2015 was 3 contacts per day. The customer target spreadsheet created by the KAMs referred 'to no more than 3 unsolicited calls per customer in line with ABPI Code'.

The Panel noted that an incentive scheme was generally understood to be, amongst other things, a scheme which *encouraged* increased productivity; it was therefore not a mandatory requirement. Merck Serono provided several emails from a senior manager to the sales team sent on 30 April 2015, which included, *inter alia*: 'Please can you let me know your plan to return activity to the required standard, I'd like to see improvements each week until 6 is achieved and please see that your activity levels are raised appropriately and urgently'. It was of concern that, contrary to Merck Serono's submission that the incentive scheme ran during March 2015, the aforementioned emails showed that, at the very least, it had continued throughout April and KAMs were expected to continue to achieve a contact rate of 6 per day thereafter. The emails linked the contact rate of 6 per day to the team's business objectives for 2015. In the Panel's view, the KAMs had been given the impression that the contact rate of 6 per day applied not only to March 2015 but for the remainder of 2015.

The Panel noted the neurology sales team currently consisted of 8 KAMs each of whom had approximately 385 MS specialist doctors and nurses in their territory, approximately 264 of whom were specialist nurses (33 per territory) with the remaining 121 being specialist doctors (15 per territory). This would mean each KAM would have approximately 48 specialists per territory. The Panel noted this was an approximation but was similar to the 50-60 MS specialists per territory submitted by Merck Serono in Case AUTH/2756/5/15. March 2015 had 22 working days, if a KAM was to achieve the 6 contacts a day this would give an overall contact volume of 132 contacts for that month. Each KAM had approximately 50-60 MS specialists in their territory which would mean each specialist would need to be contacted on average 2-3 times in the month. The Panel considered this appeared to be a high contact rate. The supplementary information to Clause 15.4 included that 'the number of calls made on a doctor or other prescriber and the intervals between successive visits are relevant to the determination of frequency. Companies should arrange that intervals between visits did not cause inconvenience'. The Panel further noted Merck Serono's MS medicine Rebif had been available for over ten years, and for the six months November 2014 to April 2015 the KAM team had an average of 98.5% of all contacts documented as solicited. It seemed odd that the percentage of solicited calls in March 2015 at 98% during the incentive scheme was the second lowest during the period November 2014 to April 2015. Merck Serono defined a solicited call within their CRM training document as a call where the health professional requested/solicited the visit.

The Panel considered that the KAMs appeared to have been given little comprehensive and consistent guidance on how to achieve 6 contacts/day and comply with the Code. This was a significant omission. The Panel was concerned that the terminology used in the emails about contacts and calls which was sent to certain KAMs on 30 April from a senior manager and a senior director was inconsistent. It was of concern that in response to a specific request the company had been unable to provide its definition of call and contact rates and associated representatives' briefing. The supplementary information to Clause 15.4 required companies when briefing representatives to clearly distinguish between expected call and contact rates. Solicited calls were only described in the briefing to KAMs on how to enter their contact rate in the CRM system. The Panel noted the company's submission that it was able to distinguish between call and contact rates on the CRM system but noted that such ability did not alter the fact that the KAMs had not been adequately advised in this regard.

The Panel noted its comments above. The Panel noted that the March incentive scheme was, in reality, a requirement. The Panel considered that achieving this would mean that, on the balance of probabilities, the sales representatives would breach the requirements of the Code; in the absence of consistent terminology and briefing on how to achieve the contact rate of 6 per day and remain compliant with the Code, the frequency of representatives' calls would cause inconvenience. On the balance of the evidence a breach of Clause 15.4 was ruled. The Panel noted the requirements of Clause 15.2 which stated, *inter alia*, that 'Representatives must at all times maintain a high standard of ethical conduct in the discharge of their duties and must comply with all relevant requirements of the Code'. The Panel noted the ruling above and on balance ruled a breach of Clause 15.2.

The Panel noted Merck Serono's submission that the sales team also recorded accompanied visit data, to the best of its knowledge all such visits were infrequent and pre-arranged with the MS specialist involved. Merck Serono provided data on accompanied calls: May 2014 -19 calls, November 2014 – 5 calls and February 2014 – 8 calls. Merck Serono further submitted it was unaware of any trusts/hospitals which did not allow visitors and was equally unaware of any breaches or potential breaches of trust policies between January 2014 and April 2015. The Panel noted any breach of trust policy was a serious matter. The complainant had not provided a copy of the relevant trust policy. The Panel considered that there was no evidence to support the allegation that a trust policy had been breached; the complainant bore the burden of proof in this regard. The Panel therefore ruled no breach of Clauses 15.2 and 15.4.

Complaint received **5 May 2015**

Case completed **24 July 2015**