CASE AUTH/2804/11/15

ANONYMOUS HEALTH PROFESSIONAL/DIRECTOR v MERCK SERONO

Call rates and uncertified material

An anonymous, non-contactable complainant, who described themselves as a senior neurologist, alleged that for the last year Merck Serono's conduct was destructive for health professionals and threatened the correct therapy pathway for patients. In particular the complainant stated that he/she did not want constant pressure from local representatives to attend meetings with no information. The representatives had also persistently requested appointments with multiple sclerosis nurses and their attendance at meetings. The complainant referred to representatives being expected to meet targets that would breach call rates and what the Code permitted.

The complainant also alleged that promotional material such as exhibition panels and material on iPads had not been certified before use.

Call rates had been at issue in Case AUTH/2756/5/15. As the complaint thus included an implied allegation of a breach of undertaking, that part of the complaint was taken up in the name of the Director as the Authority was responsible for ensuring compliance with undertakings.

The detailed response from Merck Serono is given below.

The Panel noted that the complaint was dated 20 November 2015 ie 5 months after the completion of Case AUTH/2756/5/15 and referred to the activities in question taking place 'over the last year'.

The Panel noted the complainant's allegation that Merck Serono representatives had persistently requested appointments with MS nurses and made *ad hoc* calls to his/her centres.

Call rates had similarly been at issue in Case AUTH/2756/5/15 in which particular regard was paid to an incentive scheme which the Panel considered was, in reality, a requirement and achieving the stated call rate would mean that, in the absence of adequate briefing, the frequency of representatives' calls would cause inconvenience. Breaches of the Code were ruled and Merck Serono provided the requisite undertaking and assurance. The Panel noted that an undertaking was an important document. It included an assurance that all possible steps would be taken to avoid similar breaches of the Code in the future. It was very important for the reputation of the industry that companies complied with undertakings.

Turning to the present case, Case AUTH/2804/11/15, the Panel noted that it was impossible to determine with any precision when the representatives' persistent activity described by the complainant occurred. The Panel noted that the undertaking in Case AUTH/2756/5/15 was dated 24 July 2015. The Panel now noted, however, that the representatives were no longer incentivised on calls or contact rates. Nonetheless, the Panel noted that the complainant had referred to the conduct of Merck Serono representatives and of them being expected to meet targets that would breach call rates and what the Code permitted of them. The Panel noted the difficulty in dealing with complaints when specific details were not provided and the complainant was non contactable; it was often impossible in such circumstances to determine precisely when and what had happened. The complainant bore the burden of proof and based on the evidence provided, it was not possible to determine whether the matters raised by the complainant occurred before or after the provision of the undertaking in Case AUTH/2756/5/15.

The Panel considered that between the date of the signed undertaking in Case AUTH/2756/5/15 and the date of the current complaint, it had not been demonstrated that in contacting the complainant and other health professionals at his/her centres the representatives had caused inconvenience or had failed to maintain high standards of ethical conduct although clearly the complainant was dissatisfied. Further, briefing material trained out to the representatives in September 2015 clearly distinguished between 'calls' and 'contacts' and stated that a representative should call on a doctor or other prescriber no more than three times in a year. The complainant had not established that over calling had occurred. No breaches of the Code were ruled. The activities in question prior to 24 July 2015 were covered by the ruling in Case AUTH/2756/5/15.

The Panel noted that the complainant was further concerned that representatives had been given uncertified promotional material including a pull-up exhibition banner for Rebif and an iPad app for use by the neurology representatives. The Panel noted Merck Serono's submission that the exhibition pull-up banner was never fully reviewed or certified as it was never used. The complainant had provided no evidence to the contrary. The Panel thus ruled no breach of the Code.

The Panel noted Merck Serono's submission that the iPad app had been uploaded to the representatives' iPads before it was certified. The Panel ruled a breach of the Code as acknowledged by Merck Serono. The Panel was concerned to note that the lack of certification had only come to light when Merck Serono had finalised a new app to replace the previous version; the uncertified app was,

according to the email sent on the 1 September 2015 to withdraw it, launched to the representatives in March 2015. In the Panel's view by failing to certify the first app, Merck Serono had failed to maintain high standards and a breach of the Code was ruled.

The Panel noted its rulings above regarding the use of uncertified promotional material. This was particularly disappointing given that in Case AUTH/2756/5/15 a breach of the Code was ruled with regard to uncertified representative's briefing material. The Panel noted that certification was the process by which companies ensured compliance and it considered that Merck Serono's poor record in this regard was such as to bring discredit upon and reduce confidence in the pharmaceutical industry. A breach of Clause 2 was ruled.

The Panel noted that the complainant also generally alleged that Merck Serono had used promotional stands at two major meetings that had not been certified; no details were provided. Conversely, Merck Serono had provided a list of the materials used at the two meetings and submitted that they had all been certified. As the complainant bore the burden of proof, and bearing in mind all the evidence, the Panel considered that the complainant had not established that any materials used at the meetings had not been certified. No breach of the Code was ruled.

An anonymous, non-contactable complainant who described themselves as a senior neurologist complained about the conduct of management and promotional practices within Merck Serono.

The matters raised included the persistence of representatives calling upon health professionals trying to persuade them to attend promotional meetings. Call rates had been at issue in Case AUTH/2756/5/15. As the complaint thus included an implied allegation of a breach of undertaking, that part of the complaint was taken up in the name of the Director as the Authority was responsible for ensuring compliance with undertakings.

COMPLAINT

The complainant alleged that for the last year Merck Serono had conducted itself in a manner that was destructive for health professionals and threatened the correct therapy pathway for patients. The complainant highlighted various issues that he/she became aware of after speaking to his/her local Merck Serono representative and chose to remain anonymous so as not to compromise the identity of that representative.

The complainant explained that Merck Serono representatives had persistently requested appointments with multiple sclerosis (MS) nurses and made ad hoc calls to his/her centres which was a nuisance. After a long working relationship with the local Merck Serono representative and after not hearing from him/her for a while, the complainant believed it was courteous to meet with him/her when some time became available.

At a meeting during one of the complainant's clinic shifts, the representative informed the complainant that he/she was 'no longer working at Merck Serono due to his/her growing concerns over the new management that had taken over from the beginning of the year'. The representative proceeded to retract the statement and state that he/she 'Believed the time had come for him/her to seek new opportunities'.

The complainant asked the representative to elaborate on his/her concerns as it affected the centres indirectly. The representative explained that there had been a worrying amount of internal change within Merck Serono and more than half the team had left the company due to the misconduct of management. The team was expected to meet targets that would breach call rates and what the Code permitted; a colleague who had addressed this issue in the past was pushed out of the company. The representative explained that knowing these discussions, the director had face-to-face interactions and telephone conferences where these discussions could not be recorded. The representative mentioned that the sales manager had left the company along with various other team members due to the misconduct of the director and did not want such misconduct to affect his/her future employment.

The complainant stated that he/she had been persistently contacted by the local Merck Serono representative requesting his/her attendance at promotional meetings and wanting to secure dates against his/her availability. When the complainant asked for information about the content of the meeting, the representative informed him/her that the representatives had yet to receive the information themselves. The complainant advised the representative that he/she was busy and did not wish to attend the meeting but was then approached by another Merck Serono representative from a nearby area querying if the complainant had changed his/her mind about attending. The complainant explained that as a consultant his/her time was precious and he/she did not want constant pressure from local representatives to attend meetings with no information. The complainant had also received feedback from the nurses at different centres that they had been aggressively receiving communications from Merck Serono to attend uninformative meetings.

The complainant asked why the issues had not been addressed internally by the representatives; given the amount of time they had been with the company, their concerns should have been addressed. The representative mentioned that the new management were personal acquaintances of the director which made it difficult for the representatives to turn to anyone for support. The complainant also noted that the representative felt suppressed in the situation and obliged to terminate his/her employment with the company in order to maintain his/her professional integrity and ethical standards.

Furthermore, the representative later found out that they had been given promotional material that had not been certified by the correct copy approval process. The materials at issue were commercial

stands (REB14-0067) still being used at promotional meetings and materials used on iPads (REB15-0004) which the director was aware of and continued to promote. When another representative challenged internal management about the matter, it was stated that they were overpaid to do what they were currently doing and that it would be very simple to get contractors to do their jobs. The complainant stated that rules should not be ignored in order to sell products and a company with so much history should be very aware of the certification requirements of Clause 14.1. The complainant stated that his/her centres were upset to have lost such a highly regarded representative and to be told about the loss of ethics of a formerly well-established pharmaceutical company.

The representative went on to elaborate that this was not the only item he/she had been asked to use which was invalid; he/she had also used bigger promotional stands at major meetings such as the Multiple Sclerosis (MS) Trust, and the Association of British Neurologists (ABN) congress that had not been certified.

When writing to Merck Serono, the Authority asked it to consider Clause 14.1 as cited by the complainant and also Clauses 2, 9.1, 15.2, 15.4, 15.9 and 29. Clause 29 was referred to in relation to a potential breach of the undertaking in Case AUTH/2756/5/15 with regard to representatives' targets.

RESPONSE

Merck Serono submitted that it promoted Rebif (interferon beta-1a), for use in the treatment of relapsing multiple sclerosis. Merck Serono noted that it had accepted the rulings of breaches of the Code in relation to the recent cases about call rates and call frequency (Cases AUTH/2756/5/15 and AUTH/2754/5/15). The company had signed the forms of undertaking and immediately implemented a number of corrective and preventative actions to ensure that it fully complied with its undertakings, and that the quality of the representative briefings and the conduct of its representatives would not be called into question again. In that regard, Merck Serono strongly refuted a breach of Clause 29, and therefore also strongly refuted breaches of Clauses 2, 9.1, 15.2, 15.4, and 15.9. The reasons were detailed below.

According to the introduction to the PMCPA Constitution and Procedure, the complainant had the burden of proving his/her complaint on the balance of probabilities. As the complainant and any specific call or meeting had not been identified, investigation into this matter had been very difficult. Nevertheless, Merck Serono took any allegation of inappropriate conduct of its staff very seriously and immediately launched a full investigation based on the aspects that had been referred to by the complainant.

1 Conduct of management

Since the rulings in the cases referred to above, Merck Serono had formulated and implemented a number of corrective and preventative actions (CAPA), a copy of the CAPA plan was provided, the full details of which were discussed below. Cross-functional monthly compliance committee meetings and monthly governance meetings were established which, *inter alia*, monitored those corrective and preventative actions. The meetings were chaired by the general manager since June 2015. The actions and outcome of those meetings were communicated and discussed at leadership team meetings.

Merck Serono noted that the complainant had not mentioned any specific timeframe. Because these changes and actions were promptly implemented following the previous complaints, Merck Serono submitted that it would relate to a period prior to the corrective actions being fully implemented.

2 Call/contact frequency and targets given to representatives

a) Implementation of CAPA plan

Merck Serono submitted that the following corrective and preventive actions as set out in the CAPA plan were all completed prior to receiving this complaint:

- The customer-relationship-management (CRM) system was changed in order to better capture contact and call data, and to enable the representatives to differentiate between contact and call more easily when capturing such data. Screenshots of the amended CRM system were provided;

- A new representative briefing document on face-to-face calls and contacts with prescribers was created and certified (GEN15-0085 August 2015). The briefing introduced the changes to the CRM system and clearly set out the requirements of the Code in relation to 'contacts' and 'calls';

- The briefing document was emailed to all sales managers on 2 September 2015 with a covering note and instructions to them to cascade the information and appropriately brief their teams;

- At the national sales conference on 16 September 2015, all the representatives were trained on Merck Serono's compliance policies and on the Code requirements in relation to calls and contacts using the new briefing material. Signed training records were provided;

- All sales managers were asked to review all briefing materials which might have been sent out to the respective sales teams in the past 12 months and confirm that all such briefings complied with the company's guidance on calls/contacts and were appropriately certified.

b) Targets given to representatives

The basis on which the neurology representatives were incentivised was changed to ensure compliance with the Code and the undertakings given in Cases AUTH/2756/5/15 and AUTH/2754/5/15.

The 2015 sales incentive letter issued to the neurology representatives was sent out in January 2015. The incentive described in this letter comprised two elements:

- 75% of the bonus was based on achieving a certain number of active patients under treatment with Rebif; and

- 25% of the bonus was based on achieving a quarterly key performance indicator (KPI) to be set out and communicated separately.

The KPI set out in the first quarter of 2015 - which applied only in March 2015 - was the subject of Case AUTH/2756/5/15. That temporary incentive which was aimed at increasing the call frequency was found not to comply with the Code and was therefore not repeated.

In the second and third quarters of 2015 no additional KPIs were defined. Instead, in those quarters, the bonus paid to representatives was entirely based on the number of new or active patients starting Rebif treatment.

Neurology representatives were no longer incentivised on number of calls or contacts with health professionals. Merck Serono provided an anonymised excel spreadsheet to show the payments of quarterly bonuses to the neurology representatives for the first three quarters of 2015. Merck Serono stated that this clearly demonstrated that the incentive scheme for representatives was changed in accordance with the undertakings given in Cases AUTH/2756/5/15 and AUTH/2754/5/15

c) Meetings

Merck Serono noted the complainant's allegation that he/she was persistently contacted by Merck Serono representatives and asked to attend promotional meetings without receiving any information about the content of those meetings. Allegedly the representatives themselves did not know about the content of the planned meetings.

Before a promotional meeting or event from Merck Serono could be actively pursued, it needed to undergo a thorough internal review and approval process. The review process focused on the content of such planned meetings, the meeting requirements, hospitality and a potential disclosure of any transfers of value.

Merck Serono explained that it used CLEAR (Merck Serono Compliance Electronic Approval System) to review and approve interactions with health professionals. For each event there had to be a workflow in CLEAR to document the interaction.

Before an interaction could take place, it had to be approved by reviewers from various functions. In particular, a needs assessment had to be completed in CLEAR to evaluate why an interaction with a health professional should take place and follow a global compliance standard. The needs assessment set out specific justifications for a promotional or educational meeting/program, and for inviting a particular health professional, as well as details of accommodation, transport and meals as appropriate. The reviewers/approvers in the CLEAR workflow checked the data entered in the system by the proponent and either confirmed or rejected the interaction. The final approval came from the compliance manager. This process ensured that no meetings/events for health professionals could be set up without a clearly defined and pre-approved promotional or medical/ scientific educational content.

Representative's discussions about pre-approved meetings/events with a health professional, had to be done in a way which did not inconvenience the health professional, in accordance with the Code and in line with the health professional's wishes. This was clearly laid out in the latest certified 'Guide for all Merck Serono UK and Ireland customer-facing employees' on face-to-face calls and contacts with prescribers.

Merck Serono submitted that in summary, no evidence had been provided that any alleged breach of the Code occurred after the undertakings in the previous cases had been signed. Merck Serono was confident that the urgency of the actions taken by managers conveyed the seriousness of the matter to members of staff and it had nothing to suggest that all members of staff had not fully adhered to company guidelines and policies.

Merck Serono strongly refuted that it had breached its undertakings, and submitted that since the previous complaints it had complied with the requirements of Causes 15.2, 15.4, and 15.9 and had complied with Clause 2 and 9.1.

3 Use of uncertified promotional material

a) Promotional material ref REB14-0067

Merck Serono noted that this was a pull-up exhibition banner for Rebif developed by a marketing agency under the motto 'rain or shine' and was originally intended to be used from April 2014 onwards. It was uploaded into Zinc on 26 March 2014 but was never fully reviewed or certified, nor was it ever used or made public as the campaign was cancelled in January 2015. The job was withdrawn from Zinc on 15 January 2015.

Merck Serono thus denied a breach of Clause 14.1; the material was never used and there was no evidence to show that it was ever made public.

b) Promotional material ref REB15-004

Merck Serono submitted that this was an iPad app for use by the neurology representatives. Unfortunately the app was uploaded to the representatives' iPads before it was fully reviewed and certified. When this came to light, the app was immediately recalled on 1 September 2015. Merck submitted that unfortunately on this occasion, it could not deny a breach of Clause 14.1.

Merck Serono noted, however, that this was stopped as soon as it became apparent and an internal investigation was started to find the cause of the problem. It seemed to have been a miscommunication between the then medical director and an interim marketer about the certification status of the material under review.

This breach came to light when Merck Serono was finalising a new iPad app to replace the version referred to above. It was certified and trained out to representatives at the national sales conference on 16 September 2015.

Corrective actions were taken as soon as the breach became apparent and the material was immediately withdrawn. In addition, face-to-face refresher training on Merck Serono's compliance policies was delivered at the national sales conference on 16 September 2015.

c) Promotional material for the MS Trust meeting

As the complainant did not focus on a specific timeframe, Merck concentrated on the most recent 2015 MS Trust meeting. Merck submitted that all material used at the event was fully reviewed, approved and certified before use and thus there was no breach of Clause 14.1.

d) Promotional material for the ABN Congress

As the complainant did not focus on a specific timeframe, Merck Serono again concentrated on the most recent 2015 ABN Congress. In 2015 the main material used on the stand was a video loop which was fully reviewed, approved and certified before use thus there was no breach of Clause 14.1.

e) Other promotional materials used by neurology representatives

Merck Serono listed all promotional materials currently used by its representatives and submitted that they had all been certified on the dates given and were available upon request for inspection.

f) Final signatories

Merck Serono enclosed a copy of a letter sent to the PMCPA on 22 September 2015 listing the company's current final medical and non-medical signatories, a copy of which was also sent to the Medicines and Healthcare products Regulatory Agency (MHRA). All certified materials referred to above had been certified by the people referred to in the signatories' letter sent to the PMCPA.

Merck Serono submitted that compliance with the Code was taken very seriously across the organisation. Clear reasons had been given as to why the Code had not been breached with regard to the allegations relating to Clauses 15.2, 15.4, 15.9. Therefore as those allegations appeared currently unfounded, there was no breach of Clauses 29, 2 or 9.1 either.

Merck Serono submitted that it was extremely regrettable that Clause 14.1 had been breached. Nevertheless Merck Serono had managed this issue to ensure it would not happen again. It therefore followed that high standards had been maintained and there was no breach of Clauses 9.1 or 2.

PANEL RULING

The Panel noted that the complainant, who stated that he/she was a senior MS consultant, was anonymous. As stated in the introduction to the Constitution and Procedure, anonymous complaints were accepted and like all complaints, judged on the evidence provided by both parties. Although the Panel accepted that a high degree of dissatisfaction was usually required before a complainant was moved to submit a complaint, complainants nonetheless had the burden of proving their complaint on the balance of probabilities. The complainant had not provided any evidence to substantiate his/her allegations and as he/she was non-contactable it was not possible to ask for further information. The complainant referred to the activities in question taking place 'over the last year' but had not provided further details about when the activities took place. The Panel noted that the complaint was dated 20 November 2015 ie five months after the completion of Case AUTH/2756/5/15.

The Panel noted the complainant's allegation that Merck Serono representatives had persistently requested appointments with MS nurses and made ad hoc calls to his/her centres.

Call rates had similarly been at issue in Case AUTH/2756/5/15 in which particular regard was paid to an incentive scheme which required six calls per day which Merck Serono had submitted ran during March 2015. In that case the Panel considered that the incentive scheme was, in reality, a requirement and achieving it would mean that, on the balance of probabilities, representatives would breach the Code in that, 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. Breaches of the Code were ruled and Merck Serono provided the requisite undertaking and assurance. The Panel noted that an undertaking was an important document. It included an assurance that all possible steps would be taken to avoid similar breaches of the Code in the future. It was very important for the reputation of the industry that companies complied with undertakings.

Turning to the present case, Case AUTH/2804/11/15, the Panel noted that it was impossible to determine with any precision when the representatives' persistent activity described by the complainant occurred. The Panel noted its comments above in this regard. The undertaking in Case AUTH/2756/5/15 was dated 24 July 2015. The Panel noted Merck Serono's submission that the incentive scheme in question in the previous case applied only in March 2015 was incorrect. In the previous case the Panel had noted that representatives had been briefed in May 2015 to achieve six calls per day. The Panel now noted, however, that the representatives were no longer incentivised on calls or contact rates.

Nonetheless, the Panel noted that the complainant had referred to the conduct of Merck Serono representatives and of them being expected to meet targets that would breach call rates and what the Code permitted of them. The Panel noted the difficulty in dealing with complaints when specific details were not provided and the complainant was non contactable; it was often impossible in such circumstances to determine precisely when and what had happened. The complainant bore the burden of proof and based on the evidence provided, it was not possible to determine whether the matters raised by the complainant occurred before or after the provision of the undertaking in Case AUTH/2756/5/15.

The Panel noted its comments above in relation to the timeframe of the activities in question. The Panel considered that between the date of the signed undertaking in Case AUTH/2756/5/15 and the date of the current complaint, it had not been demonstrated that in contacting the complainant and other health professionals at his/her centres the representatives had caused inconvenience or had failed to maintain high standards of ethical conduct although clearly the complainant was dissatisfied. Further, briefing material trained out to the representatives in September 2015 clearly distinguished between 'calls' and 'contacts' and stated that a representative should call on a doctor or other prescriber no more than three times in a year. The complainant had not established that over calling had occurred. No breach of Clauses 15.2, 15.4 and 15.9 were ruled. Consequently, no breaches of Clauses 29, 9.1 and 2 were also ruled. The activities in question prior to 24 July 2015 were covered by the ruling in Case AUTH/2756/5/15.

The Panel noted that the complainant was further concerned that representatives had been given uncertified promotional material including a pull-up exhibition banner for Rebif and an iPad app for use by the neurology representatives. The Panel noted Merck Serono's submission that the exhibition pull-up banner was never fully reviewed or certified as it was actually never used and the campaign was cancelled in January 2015 and the job was withdrawn from the Zinc system on 15 January 2015. The complainant had provided no evidence to the contrary. The Panel thus ruled no breach of Clause 14.1 in relation to this piece of material.

The Panel noted Merck Serono's submission that the iPad app had been uploaded to the representatives' iPads before it was fully reviewed and certified. The Panel ruled a breach of Clause 14.1 as acknowledged by Merck Serono. The Panel was concerned to note that the lack of certification had only come to light when Merck Serono had finalised a new iPad app to replace the previous version; the uncertified app which, according to the email sent on the 1 September 2015 to withdraw it, was launched to the representatives in March 2015. In the Panel's view by failing to certify the first app, Merck Serono had failed to maintain high standards and a breach of Clause 9.1 was ruled.

The Panel noted its rulings above regarding the use of uncertified promotional material. This was particularly disappointing given that in Case AUTH/2756/5/15 a breach of Clause 15.9 was ruled with regard to uncertified representative's briefing material. The Panel noted that certification was the process by which companies ensured compliance and it considered that Merck Serono's poor record in this regard was such as to bring discredit upon and reduce confidence in the pharmaceutical industry. A breach of Clause 2 was ruled.

The Panel noted that the complainant was further concerned that Merck Serono had also used promotional stands at major meetings such as the MS Trust, and the ABN congress that had not been certified. The complainant had neither referred to any specific material nor provided any material to substantiate his/her allegations. Conversely, Merck Serono had provided a list of the materials used at the two meetings and submitted that they had all been certified. As the complainant bore the burden of proof, and bearing in mind all the evidence, the Panel considered that the complainant had not established that any materials used at the MS Trust, and the ABN congress had not been certified. No breach of Clause 14.1 was ruled.

During the consideration of this case the Panel was concerned to note that although Merck Serono had implemented a number of corrective and preventive actions following Case AUTH/2756/5/15, the undertaking was signed on 24 July 2015 but the representatives were not re-briefed about calls until 16 September 2015. Whilst the Panel appreciated the time required to prepare a briefing, it was important to ensure that staff were briefed forthwith following a breach of the Code to avoid a possible breach of undertaking. The Panel requested that Merck Serono be advised of its concerns in this regard.

Complaint received **30 November 2015**

Case completed **5 February 2016**