CASE AUTH/2935/2/17

ANONYMOUS EX-EMPLOYEE v SUNOVION

Promotion of Latuda

An anonymous, ex-employee of Sunovion alleged that a regional business manager (RBM) encouraged staff to pressurise customers into prescribing Latuda (lurasidone) for schizophrenia by suggesting that if Latuda was not considered as part of a patient review, they might be sued by patients or patient groups. It was alleged that the RBM also encouraged staff to quote national guidelines which stated that a medication review should be considered if a patient had side-effects. The complainant was concerned that if such an approach was shared with customers, it could bring the industry into disrepute. The complainant added that the RBM cited a medico-legal presentation by a barrister as the basis and implied authority to challenge customers' prescribing.

The detailed response from Sunovion is given below.

The Panel noted that interview transcripts from those who had attended a recent regional meeting clearly showed that the majority recalled that the RBM had verbally directed the sales team to suggest that there might be legal consequences if patients were not reviewed and alternative treatment options offered. This was contrary to Sunovion's original submission that the interviews provided a mixed and unclear impression of what the RBM had stated.

The Panel noted that certain interviewees stated that the RBM referred to the barrister and instructed the team to engage him/her in customer meetings to make customers feel uncomfortable about their medico-legal position with regard to monitoring antipsychotics. The interview transcripts also stated that the RBM said that 'if they do not offer a change of treatment and make a note of it, it could come back and bite them' and 'the barrister's presentation was mentioned by the RBM as a way of endorsing this point'.

The Panel considered that on the balance of probabilities the RBM had not maintained a high standard of ethical conduct and his/her verbal direction advocated a course of action which would be likely to lead to a breach of the Code. Breaches of the Code were ruled.

As there was no information about what Sunovion staff had said to health professionals, the Panel considered that the complainant had not shown, on the balance of probabilities, that the representatives had not maintained a high standard of ethical conduct when promoting Latuda, despite the RBM's briefing. No breach of the Code was ruled in that regard.

The Panel further noted the allegation that the RBM had encouraged his/her staff to quote national guidelines that stated that a review of medication should be considered if a patient had side-effects. In the Panel's view, it was not necessarily unacceptable for companies to refer to the guidelines provided the manner in which it was done complied with the Code. The Panel noted that one interviewee stated that the RBM asked the team to use the guidelines as a tool to inform customers that they should consider switching treatment in patients with cardiovascular risk factors. It was not necessarily unacceptable under the Code for a company to promote a simple switch from one product to another. The Panel considered that the complainant had not shown, on the balance of probabilities, that in referring to the guidelines the RBM had advocated a course of action which would be likely to lead to a breach of the Code. No breach of the Code was ruled in that regard including no breach of Clause 2.

The Panel noted Sunovion's submission that referencing medico-legal consequences was not an acceptable approach to promote Latuda either directly or indirectly. The Panel noted its rulings above including that the complainant had not proved his/her complaint on the balance of probabilities in relation to the promotion to health professionals etc. In addition the Panel considered that its ruling of a breach of the Code in relation to the RBM covered the position regarding high standards. The Panel ruled no breach of the Code. The company had not brought discredit upon or reduced confidence in the industry and therefore the Panel ruled no breach of Clause 2.

Sunovion provided the requisite undertaking and assurance and the Appeal Board received the case report as set out in Paragraph 13.4 of the Constitution and Procedure.

The Appeal Board was very concerned to note that in its initial response to the Panel Sunovion did not provide an accurate summary of the interviews about the February sales meeting. This was only discovered when the Panel requested copies of the interviews conducted. The Appeal Board noted that self-regulation relied, *inter alia*, upon the provision of complete and accurate information but considered that the company's initial response was misleading. In that regard the Appeal Board's view was that additional sanctions under Paragraph 11.1 of the Constitution and Procedure should be contemplated. Sunovion should respond to these concerns in writing and it was invited to appear before the Appeal Board when the matter was considered. Sunovion was provided with a copy of the papers.

The detailed comments from Sunovion about the possible imposition of further sanctions is given below.

The Appeal Board noted the Panel's rulings of breaches of the Code. The Appeal Board noted that the company had apologised and admitted that it had made errors.

The Appeal Board noted that contrary to the written comments made by Sunovion in response to the concerns raised by the Appeal Board, the issue was that the summary was not a fair reflection of the interview transcripts, not that the transcripts had not been provided with the company's original response.

The Appeal Board asked the Sunovion representatives to explain how the interview transcripts from the six representatives could be summarised as giving a mixed and somewhat unclear impression of the verbal direction provided by the RBM when 5 of the 6 supported the complainant. This point had not been addressed by Sunovion.

The Appeal Board noted that in response to questioning the Sunovion representatives stated that the interviews were conducted by a senior UK director solely responsible for investigating this complaint. That director's findings were that although the picture was mixed and unclear there was a strong probability that the RBM had done something wrong and that, on the balance of probabilities, this was in breach of the Code. According to the company representatives, this was included in the initial draft of the company's response to the complaint which was sent to the US parent company. The US parent company decided, based on external legal advice that, in spite of self-regulation, it was not Sunovion's responsibility to prove the complaint. Although the US parent company did not see the interview transcripts it, nonetheless, altered the UK company's draft and denied breaches of the Code stating that the interviews provided a mixed and somewhat unclear impression of the verbal direction provided. Before signing the amended draft of the company's response, a senior European executive requested sight of the interview transcripts. Sunovion's representatives stated that when the senior UK investigating director had been shown the revised draft and advised of the legal opinion from the US he/she still stood by his/her original draft. The Appeal Board noted that the senior European executive stated that he/she was not an expert on the Code.

The Appeal Board considered that the responses of the company representatives to its questions were contrary to Sunovion's written submissions to the Panel and the Appeal Board and to the company's submission at the consideration of this matter that the summary of the interviews provided with the company's response to the complaint was a good faith attempt to set out the relevant facts. The company's presentation also stated that Sunovion supported the Code, was committed to compliance, self-regulation and transparency.

The Appeal Board noted that the senior UK investigating director's findings had been undermined by the US parent company which had not even seen the interview transcripts. At the Appeal Board hearing the US parent company representative acknowledged that it had compromised the professional integrity of the senior European executive. It did not stand behind the letter today. The US parent company representative also stated that many lessons had been learned and apologised. The Appeal Board was extremely concerned about the company's explanation. It considered that such a deliberately inaccurate, misleading and disingenuous response brought discredit upon and reduced confidence in the pharmaceutical industry. Whilst it might not be the respondent company's responsibility to prove a breach of the Code, it was the respondent company's responsibility to provide accurate information. Self-regulation relied, *inter alia*, upon the provision of complete and accurate information from pharmaceutical companies. The Appeal Board noted the submissions from the Sunovion representatives and it considered that the company's conduct in altering its response, contrary to that of the investigator and the clear evidence from the interviews, raised very serious concerns about system failure and company culture.

The Appeal Board decided that in accordance with Paragraph 11.3 of the Constitution and Procedure, Sunovion should be publicly reprimanded for providing inaccurate and misleading information to the Panel and Appeal Board. The Appeal Board also decided to require an audit of Sunovion's procedures in relation to the Code. The audit should include interviews with staff at the US and Japanese parent companies. The audit would take place in November 2017 and on receipt of the report the Appeal Board would consider whether further sanctions were necessary.

Sunovion was audited in November 2017 and on receipt of the audit report in January 2018 the Appeal Board questioned how seriously the whole Sunovion organisation was taking its commitment to self-regulation. The culture with regard to the Code and leadership on compliance matters needed to urgently improve across the organisation. The company in the US, Sunovion Pharmaceuticals Inc, and in particular the parent company in Japan, Sumitomo Dainippon Pharma Co, needed to demonstrate that the seriousness of the situation was understood and appropriate action taken.

The Appeal Board noted that the audit report highlighted many issues and concerns to be addressed including arrangements for advisory boards, certification, updating and compliance with standard operating procedures, role of medical science liaison staff, control and updating of material and attention to detail and management of all third-party service providers. Significant commitment was required to address these issues.

On receipt of further information in February and March 2018, and on noting the dates for completion of some of the actions etc, the Appeal Board decided that the company should be re-audited in June 2018.

On receipt of the report for the re-audit the Appeal Board would decide whether further sanctions were necessary.

Sunovion was re-audited in June 2018 and on receipt of the report of the re-audit in September 2018 the Appeal Board noted that Sunovion had made some meaningful progress and that there appeared to be a genuine wish to create a more sophisticated compliance infrastructure and to build on the improvements made. The Appeal Board noted that Sunovion had committed greater staff resource to help address its compliance needs. The Appeal Board welcomed the reported improved relationship between Sunovion and its US parent company.

The Appeal Board was again concerned about the inaccurate responses from the company with regard to its disclosure of payments to patient organisations at the re-audit and it noted the related issues that arose in Case AUTH/3027/3/18. It was paramount that Sunovion ensured its responses to the PMCPA were accurate.

The Appeal Board noted that the report of the re-audit still highlighted further important issues and concerns to be addressed including a review of its material, updating standard operating procedures, urgently address the company's apparent lack of understanding of the definition of promotion, review of the active materials list and further training. Significant ongoing commitment was required to address these issues.

The Appeal Board decided that Sunovion Pharmaceuticals Europe should be re-audited in April 2019. On receipt of the report of the re-audit the Appeal Board would decide whether further sanctions were necessary.

Sunovion was re-audited in April 2019 and on receipt of the report of the re-audit in July 2019 the Appeal Board noted that there had been significant progress at Sunovion since the re-audit in June 2018. The Appeal Board noted that Sunovion had a compliance action plan to address recommendations from the re-audit. The Appeal Board noted some actions were already completed and that others were due to be completed very shortly. On the basis that this work was completed, the progress shown to date was continued and a company-wide commitment to compliance was maintained, the Appeal Board decided that no further action was required.

An anonymous, ex-employee of Sunovion Pharmaceuticals Europe Ltd alleged that one of the company's regional business managers (RBMs), encouraged his/her sales staff to exert undue pressure on customers to get them to prescribe Latuda (lurasidone). Latuda was an atypical antipsychotic indicated for the treatment of schizophrenia in adults aged 18 years and over.

COMPLAINT

The complainant alleged that the RBM in question encouraged sales staff to suggest to customers that if they did not consider Latuda as part of a patient review, prescribers could be open to being sued by patients or patient groups. The complainant considered that such behaviour was unethical; the sales team was being encouraged to use this approach to put pressure on the customer.

The complainant added that, in addition to the above, the RBM also encouraged his/her staff to quote Commissioning for Quality and Innovation (CQUIN) measures that stated that a review of medication should be considered if a patient had side-effects. The complainant queried whether this was part of a wider marketing strategy or supported by the senior staff. The complainant was concerned that if such an approach was shared with customers it could bring the industry into disrepute.

The complainant added that Sunovion used a named barrister to discuss medico-legal practice, as a presentation. The regional manager cited this in team meetings as the basis and implied authority to challenge customers' prescribing.

When writing to Sunovion, the Authority asked it to consider the requirements of Clauses 2, 9.1, 15.2 and 15.9 of the Code.

RESPONSE

Sunovion submitted that it was committed to compliance with the Code and took its obligations under the Code very seriously. Sunovion did not accept, endorse or encourage the manner of promotion described in the complaint. All employees received annual ABPI Code refresher training and training on the global code of conduct. The code of conduct encouraged open dialogue if an employee had any concerns, and also described a process for reporting concerns anonymously.

Sunovion stated that it placed a strong focus on providing effective training/clear briefings for its sales force. The company held three national cycle meetings per year led by head office and these were supplemented by local regional sales meetings led by RBMs but supported by head office as required.

In addition to product training/briefing on Latuda, Sunovion also endeavoured to train its staff to a high standard on the broader NHS policy requirements that health professionals might need to consider in daily practice so that staff were knowledgeable about the NHS and could better understand the challenges that health professionals might face.

Sunovion stated that following the investigation described below, it appeared that the main focus of the complaint was on a regional sales meeting that took place in February 2017. For thoroughness Sunovion had gone back to April 2016 to review briefing materials for all meetings, where there might have been content relating to promotion which involved the regional sales team in question. Sunovion explained that antipsychotics differed in their propensity to influence cardiovascular (CV) risk factors such as body weight, serum lipids and blood sugar. One of the national goals for the CQUINs scheme in 2016/2017 was improving the physical

health of patients with severe mental illness. This included identifying patients with schizophrenia who were at risk of CV disease and offering interventions. These interventions would include lifestyle modification and could also include considering a change in treatment to an antipsychotic with a lower metabolic-risk. Guidelines issued in 2016 by the British Association of Psychopharmacology (BAP) also endorsed this approach.

The promotional strategy for Latuda included discussion of the effects on blood lipids, blood glucose, and body weight and that the medicine might be an appropriate option for patients with CV risk factors.

Sunovion submitted that at the first national sales cycle meeting of the 2016/2017 business year (April 2016), the sales force was briefed on the strategy and campaign for the coming year led by head office. The presentations given during this meeting covered the metabolic consequences of antipsychotic treatment and focussed on the clinical and health economic benefits of low-metabolic risk antipsychotics. The presentations did not refer to medico-legal risk.

The second and third national sales cycle meetings took place in September 2016 and January 2017 respectively. The presentations given to the sales force did not refer to medico-legal risk. Refresher training on the Code was also provided by an external consultant.

With regard to regional sales meetings, three had taken place led by the RBM in question, June and December 2016 and February 2017.

The briefing/training presentation on In Call Quality was presented to the regional sales team in June 2016 and described a way of identifying patients for whom Latuda might be considered an appropriate treatment by referring to CQUINs. No reference was made to medico-legal risk. The briefing training presentation, 'Starting a Patient on Latuda' was presented at the same meeting and covered the high metabolic risk patient and described how to switch to Latuda from other antipsychotics. There was no reference to medico-legal risk. The sales meeting which took place in December 2016 was attended by the whole sales force ie both regional sales teams. There was no reference to medico-legal risk. Copies of all of the presentation was provided.

The presentations by the barrister were educational and intended to inform health professionals about the legal aspects of their work in treating patients with mental health problems. The barrister was an expert in the medico-legal aspects of managing mental health patients and had regularly spoken on this subject to NHS audiences in recent years, independent of Sunovion sponsored events. Sunovion provided one example of such an event.

In particular, one of the presentations covered the legal aspects of informed patient choice when prescribing. The barrister presented at Sunovion-sponsored meetings in October and November 2015 and March and September 2016.

The most recent regional sales meeting took place in February 2017. Sunovion interviewed three key account managers, a hospital sales representative and a market development manager, all of whom reported directly to the RBM and had been at the meeting. Sunovion also interviewed a medical science liaison (MSL) who reported to the medical department but also attended the regional sales meeting. The meeting agenda and a summary of the meeting written by the RBM was provided. Due to the workshop style of the meeting, and the nature of the agenda (ie a focus on team building and best practice sharing) there were no slides presented. In his/her interview the RBM gave a full and detailed account of his/her instruction and briefing to the sales team at this meeting. This involved identifying customer needs in a non-directive fashion, and the importance of understanding and acknowledging that different customers had different needs. One of the needs that might be identified was a requirement for a low metabolic-risk antipsychotic. The RBM stated that he/she did not direct the team to focus on this need, and did not direct the team to discuss the medico-legal implications of not intervening in patients at high risk. The RBM stated that he/she did not link high risk patients and treatment with Latuda with risk of legal consequences. He/she stated that he/she did not direct the team to use the barrister's presentation unless it was thought to be relevant to the educational needs of health professionals in their territories. This was consistent with the email summary of the meeting sent to the sales team after the meeting by the RBM.

Sunovion stated that the interviews with other members of the sales team provided a mixed and somewhat unclear impression of the verbal direction provided by the RBM at the meeting in February. While some thought that he/she had directed them to suggest that there might be legal consequences if patients were not reviewed and alternative treatment options offered, others did not.

Sunovion noted that it had found no evidence to suggest that the subject of the complaint had ever been used with health professionals.

In summary, Sunovion stated that:

- the sales force had received clear, periodic briefings/direction at a national level on the Latuda promotional campaign which were in line with the company's promotional strategy and with the Code. All presentations that related to promotion had been reviewed and certified.
- the sales force had received regular and periodic training on the Code, and their responsibilities (ie twice in the last 6 months).
- Sunovion had sponsored health professional meetings at which the barrister had spoken about medico-legal issues; he/she was a respected speaker in that area, the content of the presentations was in line with the Code and the presentations were certified.
- all presentations at all regional sales meetings in the current business year which related to Latuda promotion were in line with the company's promotional strategy and with the Code.

All presentations which related to promotion had been reviewed and certified.

- with regard to verbal discussion/direction from the RBM to the sales team, in particular at the regional sales meeting in February 2017, whilst there was no conclusive evidence either way, it was apparent that some of those at the meeting interpreted this verbal direction in a way not consistent with Sunovion's approved promotional campaign ie that referencing 'medico-legal consequences' was not an acceptable approach to promoting Latuda, either directly or indirectly. Sunovion also considered that the written email follow up summary of the meeting from the RBM to the sales team was not as clear as required to ensure total clarity in line with the approved company approach to promotion.

Sunovion submitted that there was no conclusive evidence that the alleged approach (ie a focus on 'medico-legal consequences' matters in the promotion of Latuda) had led to inappropriate conduct with health professionals. Sunovion noted that it was notified of this complaint on 15 February 2017 and it rapidly responded to investigate the complaint and in parallel it had re-briefed sales staff to reinforce the company's approved approach to promoting Latuda, specifically and that it was not acceptable to refer to 'medico-legal consequences' either directly or indirectly.

Sunovion denied breaches of Clauses 9.1, 15.2, 15.9 and 2. As detailed above Sunovion submitted that it had robust procedures in place, had investigated the matter thoroughly and had taken appropriate action to reinforce the high standards that it expected of all of its staff at all times.

In response to a request for further information, Sunovion reiterated that referring to 'medico-legal consequences' was not an acceptable approach to promoting Latuda, either directly or indirectly and this approach had never been communicated or endorsed by Sunovion or senior management. This approach had never been part of the strategy or brand plan for Latuda, and had never been part of any training or briefings delivered by the head office team. As noted above, verbal direction provided by the RBM to his/her team was interpreted by some individuals as asking them to follow the above approach, and the interviews reflect this.

Sunovion noted that the RBM at issue was no longer employed by Sunovion.

Sunovion addressed each point raised in the request for further information in turn:

1 Details of the five meetings at which the barrister presented

Sunovion provided details of the number of attendees at each meeting, the venue and the presentations delivered.

At one meeting, organised by the academic function of an NHS organisation, Sunovion only sponsored the barrister's session which was made clear on the agenda and was in line with the company's standard operating procedure (SOPs) for sponsoring meetings with health professionals. Sunovion was not involved in the other sessions/presentations at the meeting.

All of the other meetings were organised by members of the sales team from a logistics perspective which was in line with Sunovion's documented process and SOPs for sponsoring meetings with health professionals. The head office team was responsible for reviewing and certifying the speaker's presentation in advance of the meeting.

The meeting attendees were mainly psychiatrists, together with a small number of pharmacists and psychiatric nurses. The meeting objectives were as follows:

October 2015, to provide education on:

- the medico-legal issues faced by psychiatrists during their routine clinical practice.
- the clinical data on the use of Latuda in the treatment of schizophrenia in adult patients.

November 2015, to understand:

- the legal framework of the First Tier Mental Health Review Tribunal and hospital manager's hearings.
- the expectations of the different members of the panels when giving evidence.
- the importance of shared decision making in prescribing for mental health problems, including clinical data on the use of Latuda for the treatment of schizophrenia in adult patients and
- to allow attendees to be more confident when presenting evidence at mental health review tribunals and hospital manager's hearings.

March 2016, to provide education:

- the medico-legal issues faced by psychiatrists during their routine clinical practice.

September 2016, (two meetings) to provide education on:

- the medico-legal issues faced by psychiatrists during their routine clinical practice.
- the metabolic adverse effects of antipsychotics, including relevant data on Latuda for the treatment of schizophrenia in adult patients.

At the five meetings listed above, the barrister gave one of the two presentations Sunovion provided originally:

1 'Report writing and Presenting Evidence'.
2 'The Importance of Informed Patient Choice'.

Presentation 1 was delivered by the barrister at the meetings in October 2015, November 2015 and March 2016. Other presentations were delivered at these meetings either by an MSL or independent speaker. Sunovion noted that the presentation delivered by the MSL in October 2015, was a pre-

approved and certified slide deck used by the MSL team in the majority of its promotional presentations at the time. It was not tailored or specific to the event in question.

Presentation 2 was delivered by the barrister at the two meetings in September 2016 together with a presentation on the metabolic adverse effects of antipsychotics delivered by an MSL.

Copies of the meeting agendas, slides presented by Sunovion employees or Sunovion-sponsored speakers, and speaker contracts, were provided.

2 Briefing of sales force on how to use the barrister's presentation

Sunovion stated that it had a documented SOP and process for conducting sponsored meetings with health professionals in line with the Code, and members of the sales force had been trained, both as part of the induction process when they joined the company, and then approximately annually thereafter.

Sunovion submitted that it did not provide individual documented briefings to the sales force on how to hold a sponsored speaker meeting with each and every single potential individual speaker.

Sunovion trained/briefed the sales force on the SOP and process for conducting sponsored meetings with health professionals in line with the Code, and as part of this process, if there was a third-party speaker, (eg the barrister in this case), then that speaker's slides had to be reviewed and certified by head office in advance of the meeting to ensure that the context and content of the speaker's presentation was appropriate and code compliant.

There was no written briefing provided by the RBM regarding the use of the barrister's presentations. As noted above, Sunovion did not provide written briefings on how to use each and every individual speaker. Any 'briefing' was provided verbally as part of conversations with members of the team and was therefore not documented.

The barrister was used infrequently as a speaker for Sunovion. Sunovion did not provide written briefing or training on the use of his/her slides, but did review, approve and certify them in line with its SOP and processes.

Copies of speaker presentations were not routinely provided to the representatives or market development managers ie within the company's SOP, the MSL team and head office were responsible for liaising with speakers on slide presentations to review and certify in advance of the meeting.

Sunovion provided anonymised copies of the interviews conducted with members of the sales team, the MSL, market development manager, and RBM.

PANEL RULING

The Panel noted that the complainant was anonymous. 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 Panel noted the difficulty in dealing with complaints based on one party's word against the other; it was often impossible in such circumstances to determine precisely what had happened.

In relation to the allegation that the RBM had encouraged sales staff to suggest to customers that if they did not consider Latuda as part of a patient review, prescribers could be open to being sued by patients or patient groups, the Panel noted the comments made by staff interviewed about the regional sales meeting in February. The Panel considered that it was disingenuous of Sunovion in its original response to state that the interviews with members of the sales team provided a mixed and somewhat unclear impression of the verbal direction provided by the RBM at the regional sales meeting in February. The Panel noted that anonymised copies of the interviews conducted with members of the sales team, the MSL, market development manager, and RBM were provided only in response to a request for further information and it was clear from these interviews that the majority of individuals at the meeting recalled that the RBM's verbal direction was that the sales team should suggest that there might be legal consequences if patients were not reviewed and alternative treatment options offered.

The Panel noted that despite the content of the email follow up summary from the RBM and one interviewee's impression, the remainder of the staff (five) at the February sales meeting were clearly concerned about the impression given by the RBM. The Panel was concerned that staff recalled phrases 'if you don't do this, you might be sued' and 'to make this message personal as their customers could be sued. Using lurasidone could reduce the risk'.

The Panel further noted the complainant's allegation that Sunovion used a named barrister to discuss medico-legal practice as a presentation and the regional manager cited this in a team meeting as the basis and implied authority to challenge customer's prescribing. The Panel noted that certain interviewees stated that the RBM referred to the barrister and instructed the team to engage him/her in customer meetings with the intention of making customers feel uncomfortable about their medico-legal position with regard to monitoring antipsychotics. It was also stated that the RBM said that 'if they do not offer a change of treatment and make a note of it, it could come back and bite them'. The barrister's presentation was mentioned by the RBM as a way of emphasising this point. Another interviewee stated that the RBM had been insistent about using the barrister to present at meetings 'in order to put pressure on customers'.

The Panel noted its comments above and considered that on the balance of probabilities the RBM had not maintained a high standard of ethical conduct and his/her verbal direction advocated a course of action

which would be likely to lead to a breach of the Code. Breaches of Clause 15.9 and 15.2 were ruled. There was no information about what Sunovion staff had said to health professionals etc. Therefore, the Panel considered that the complainant had not shown, on the balance of probabilities, that the representatives had not maintained a high standard of ethical conduct when promoting Latuda to health professionals etc, despite the RBM' briefing. No breach of Clause 15.2 of the Code was ruled in that regard.

The Panel further noted the complainant's allegation that the RBM had encouraged his/her staff to quote CQUIN measures that stated that a review of medication should be considered if a patient had side-effects. The Panel noted the complainant's concern that if such an approach was shared with customers it could bring the industry into disrepute. In the Panel's view, it was not necessarily unacceptable for companies to refer to CQUIN provided the manner in which it was done complied with the Code. The Panel noted that one interviewee stated that the RBM asked the team to use CQUIN as a tool to inform customers that they should consider switching treatment in patients with cardiovascular risk factors. It was not necessarily unacceptable under the Code for a company to promote a simple switch from one product to another. The Panel considered that the complainant had not shown, on the balance of probabilities that in referring to CQUIN the RBM's verbal direction advocated a course of action which would be likely to lead to a breach of the Code. No breach of Clause 15.9 was ruled in that regard. The Panel also ruled no breach of Clause 2 for similar reasons.

The Panel noted Sunovion's submission that referencing medico-legal consequences was not an acceptable approach to promote Latuda either directly or indirectly. The Panel noted its rulings above including that the complainant had not proved his/her complaint on the balance of probabilities in relation to the promotion to health professionals etc. In addition the Panel considered that its ruling of a breach of Clause 15.2 in relation to the RBM covered the position regarding high standards. The Panel ruled no breach of Clause 9.1. The company had not brought discredit upon or reduced confidence in the industry and therefore the Panel ruled no breach of Clause 2.

During the consideration of this case, the Panel was concerned to note that in its initial response Sunovion did not provide an accurate summary of the interviews carried out regarding the February sales meeting. This was only discovered when the Panel requested copies of the interviews conducted. The Panel queried why anonymised copies of these interviews had not been provided in the first instance. The Panel was disappointed by the conduct of Sunovion. Self-regulation relied, *inter alia*, upon the provision of complete and accurate information to the Panel.

In the Panel's view the barrister's presentation about the importance of informed patient choice appeared to be inconsistent with the company's submission that referencing medico-legal consequences was not an acceptable approach to promoting Latuda either directly or indirectly.

The Panel requested that Sunovion be advised of these concerns.

Sunovion provided the requisite undertaking and assurance and the Appeal Board received the case report as set out in Paragraph 13.4 of the Constitution and Procedure.

APPEAL BOARD CONSIDERATION OF CASE REPORT

The Appeal Board was very concerned to note that in its initial response to the Panel Sunovion did not provide an accurate summary of the interviews about the February sales meeting. This was only discovered when the Panel requested copies of the interviews conducted. The Appeal Board noted that self-regulation relied, *inter alia*, upon the provision of complete and accurate information but considered that the company's initial response was misleading. In that regard, the Appeal Board's view was that additional sanctions under Paragraph 11.1 of the Constitution and Procedure should be contemplated. Sunovion should respond to these concerns in writing and it was invited to appear before the Appeal Board when the matter was considered. Sunovion was provided with a copy of the papers.

COMMENTS FROM SUNOVION

Sunovion submitted that it was committed to full compliance with the Code and took its obligations very seriously. Sunovion had fully taken into account the Panel's findings and the Appeal Board's comments. Sunovion submitted that it had acted in good faith throughout the complaint process.

Sunovion noted that in response to Case AUTH/2850/6/16, it had provided a summary of interviews rather than submitting full interview transcripts with the initial response. Sunovion had followed that practice in relation to this complaint and did not know that this was an incorrect approach.

Sunovion submitted that it did not deliberately mislead the Panel in any way in relation to the February sales meeting. The summary of the interviews provided with the company's response to the complaint was a good faith attempt to set out the relevant facts. Sunovion did not try to hide any, or make any misleading comments about, the facts and it apologised if that impression had been given.

Sunovion submitted that it had always been prepared to cooperate fully and to provide any information that was requested. If Sunovion had known that the full interview transcripts were required with its initial response, they would have been provided.

In all the circumstances, and given that the company had fully taken everything on board, Sunovion submitted that any additional sanctions would be inappropriate and unwarranted.

At the consideration of this matter the Sunovion representatives stated that the company fully accepted the Panel's findings and took full responsibility for this matter. Sunovion had already briefed all employees on the learnings from the case and had planned additional training on the Code. Sunovion supported the Code and was committed to compliance, self-regulation and transparency.

Sunovion Pharmaceuticals Inc. was based in the US, UK and Canada, and its parent company, Sumitomo Dainippon Pharma Co., Ltd was based in Japan. Sunovion submitted that it had an extremely strong culture of compliance, ethics and business integrity supported by a comprehensive global compliance and ethics program. One of the senior executives of the parent company currently, and had previously, held office in the Japan Pharmaceutical Manufacturers Association (JPMA).

The Sunovion representatives stated that Sunovion's initial response to the complaint and summary of interviews was fact-based and made in good faith with no intent to mislead. Sunovion understood and accepted the Appeal Board's position that, given the standard of 'the balance of probabilities', the response could be viewed as misleading. Upon the PMCPA's request, Sunovion had promptly provided the interview notes.

In view of the helpful clarification and comments from the Panel and the Appeal Board, in the unlikely event of a future complaint, Sunovion would submit any interview notes with its initial response.

APPEAL BOARD CONSIDERATION

The Chairman noted that the Appeal Board now had before it the correspondence and submissions in relation to this case and Sunovion's response to the Appeal Board's consideration of the case report and Panel minute (received in accordance with Paragraph 4.1 of the Constitution and Procedure at its meeting in July).

The Appeal Board noted the Panel's rulings of breaches of Clauses 15.2 and 15.9 of the Code and that the company had apologised and admitted that it had made errors.

The Appeal Board noted that contrary to the written comments made by Sunovion in response to the concerns raised by the Appeal Board, the issue was that the summary was not a fair reflection of the interview transcripts, not that the transcripts had not been provided with the company's original response.

The Appeal Board asked the Sunovion representatives to explain how the interview transcripts from the six representatives could be summarised as giving a mixed and somewhat unclear impression of the verbal direction provided by the RBM when 5 of the 6 supported the complainant. This point had not been addressed by Sunovion.

The Appeal Board noted that in response to questioning the Sunovion representatives stated that the interviews were conducted by a senior UK director who was solely responsible for investigating this complaint. That director's findings were that although the picture was mixed and unclear there was a strong probability that the RBM had done something wrong and that, on the balance of probabilities, this was in breach of the Code. According to the company representatives, this was included in the initial draft of the company's response to the complaint which was sent to the US parent company. The US parent company decided, based on external legal advice that, in spite of self-regulation, it was not Sunovion's responsibility to prove the complaint. It altered the UK company's draft and denied breaches of the Code stating that the interviews provided a mixed and somewhat unclear impression of the verbal direction provided. When making the changes the US parent company had no sight of the interview transcripts. Before signing the amended draft of the company's response, a senior European executive requested sight of the interview transcripts. Sunovion's representatives stated that when the senior UK investigating director had been shown the revised draft and advised of the legal opinion from the US he/she still stood by his/her original draft. The Appeal Board noted that the senior European executive stated that he/she was not an expert on the Code.

The Appeal Board considered that the responses of the company representatives to its questions were entirely contrary to Sunovion's written submissions to both the Panel and the Appeal Board and to the company's submission at the consideration of this matter that the summary of the interviews provided with the company's response to the complaint was a good faith attempt to set out the relevant facts. The company's presentation also stated that Sunovion supported the Code, was committed to compliance, self-regulation and transparency.

The Appeal Board noted that the senior UK investigating director's findings had been undermined by the US parent company which had not even seen the interview transcripts. At the Appeal Board hearing the US parent company representative acknowledged that it had compromised the professional integrity of the senior European executive. It did not stand behind the letter today. The US parent company representative also stated that many lessons had been learned and apologised. The Appeal Board was extremely concerned about the company's explanation. It considered that such a deliberately inaccurate, misleading and disingenuous response brought discredit upon and reduced confidence in the pharmaceutical industry. Whilst it might not be the respondent company's responsibility to prove a breach of the Code, it was the respondent company's responsibility to provide accurate information. Self-regulation relied, *inter alia*, upon the provision of complete and accurate information from pharmaceutical companies. The Appeal Board noted the submissions from the Sunovion representatives and it considered that the company's conduct in altering its response, contrary to that of the investigator and the clear evidence from the interviews, raised very serious concerns about system failure and company culture.

The Appeal Board decided that in accordance with Paragraph 11.3 of the Constitution and Procedure, Sunovion should be publicly reprimanded for

providing inaccurate and misleading information to the Panel and Appeal Board. The Appeal Board also decided to require an audit of Sunovion's procedures in relation to the Code. The audit should include interviews with staff at the US and Japanese parent companies. The audit would take place in November 2017 and on receipt of the report the Appeal Board would consider whether further sanctions were necessary.

APPEAL BOARD FURTHER CONSIDERATION

Sunovion was audited in November 2017 and on receipt of the audit report in January 2018 the Appeal Board questioned how seriously the whole Sunovion organisation was taking its commitment to self-regulation. The culture with regard to the Code and leadership on compliance matters needed to urgently improve across the organisation. The company in the US, Sunovion Pharmaceuticals Inc, and in particular the parent company in Japan, Sumitomo Dainippon Pharma Co, needed to demonstrate that the seriousness of the situation was understood and appropriate action taken.

The Appeal Board noted that the audit report highlighted many issues and concerns to be addressed including arrangements for advisory boards, certification, updating and compliance with standard operating procedures, role of medical science liaison staff, control and updating of material and attention to detail and management of all third-party service providers. Significant commitment was required to address these issues.

On receipt of further information in February and March 2018, and on noting the dates for completion of some of the actions etc, the Appeal Board decided that the company should be re-audited in June 2018. On receipt of the report for the re-audit the Appeal Board would decide whether further sanctions were necessary.

Sunovion was re-audited in June 2018 and on receipt of the report of the re-audit in September 2018 the Appeal Board noted that Sunovion had made some meaningful progress and that there appeared to be a genuine wish to create a more sophisticated compliance infrastructure and to build on the improvements made. The Appeal Board noted that Sunovion had committed greater staff resource to help address its compliance needs. The Appeal Board welcomed the reported improved relationship between Sunovion and its US parent company.

The Appeal Board was again concerned about the inaccurate responses from the company with regard to its disclosure of payments to patient organisations at the re-audit and it noted the related issues that arose in Case AUTH/3027/3/18. It was paramount that Sunovion ensured its responses to the PMCPA were accurate.

The Appeal Board noted that the report of the re-audit still highlighted further important issues and concerns to be addressed including a review of its material, updating standard operating procedures, urgently address the company's apparent lack of understanding of the definition of promotion, review of the active materials list and further training. Significant ongoing commitment was required to address these issues.

The Appeal Board decided that Sunovion Pharmaceuticals Europe should be re-audited in April 2019. On receipt of the report of the re-audit the Appeal Board would decide whether further sanctions were necessary.

Sunovion was re-audited in April 2019 and on receipt of the report of the re-audit in July 2019 the Appeal Board noted that Sunovion Pharmaceuticals Europe had continued to build on the improvements described in the report of the June 2018 re-audit in Case AUTH/2935/5/17. Staff had spoken positively about the steps taken by Sunovion Pharmaceuticals Europe to improve its compliance infrastructure. Compliance was now the top priority for the global Japanese parent, Sumitomo Dainippon. Sunovion Pharmaceuticals Inc in the US accepted that Sunovion Pharmaceuticals Europe was the subject matter expert on the Code. It was noted that the general manager continued to give strong and consistent messages about the importance of compliance and that compliance was now part of everybody's objectives.

The Appeal Board noted that the re-audit report still highlighted concerns including with regard to updating standard operating procedures and policies.

The Appeal Board noted that there had been significant progress at Sunovion since the re-audit in June 2018. The Appeal Board noted that Sunovion had a compliance action plan to address recommendations from the re-audit. The Appeal Board noted some actions were already completed and that others were due to be completed very shortly. On the basis that this work was completed, the progress shown to date was continued and a company-wide commitment to compliance was maintained, the Appeal Board decided that no further action was required.

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Appeal Board consideration	**7 September 2017, 11 January, 7 February, 22 March 2018, 13 September, 11 July 2019**
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