CASE AUTH/2685/12/13

ANONYMOUS, NON CONTACTABLE NURSE v GALDERMA

Meeting arrangements

An anonymous, non-contactable complainant who described him/herself as a registered nurse complained about arrangements for an educational meeting about aesthetics organised by Galderma (UK) in association with a nurse support group. The complainant provided the agenda which listed four presentations, two of which were particularly relevant to medicines marketed by Galderma; one was about botulinum toxins (Galderma marketed Azzalure) and the second was about the company's product Pliaglis (tetracaine/lidocaine), a topical anaesthetic for use in dermatological procedures. The covering letter sent with the agenda stated that there was no meeting charge for members of the nurse support group but 'due to the high calibre of the speakers provided by Galderma you are required to have purchased a minimum of Two Emervel Classics from [named pharmacy] between now and the 16th November 2013'.

The complainant was disgusted that he/she was forced to buy at least two boxes of Galderma's dermal fillers to be able to attend. The complainant submitted that firstly it was just wrong and, secondly, he/she did not like or use the particular filler, and thirdly was not even trained on it.

The complainant submitted that these actions did not do the industry any favours and just lowered standards, which was exactly the opposite of what he/she hoped to achieve.

The detailed response from Galderma is given below.

The Panel disagreed with Galderma's submission that as the complaint specifically concerned the 'purchase of a medical device' in relation to attendance at an event which focused on medical devices it did not fall within the scope of the Code. The Panel noted that the Code applied, *inter alia*, to the promotion of medicines to health professionals. The Panel noted that the agenda included a presentation on botulinum toxins in aesthetics which compared the available products including Azzalure and a presentation on Pliaglis by a Galderma employee. A Pliaglis leavepiece was also available. In addition, the Panel noted that the agenda stated that the meeting provided 'an opportunity to present evidence in your prescribing portfolio relating to Toxin'. The Panel considered that the meeting clearly promoted Galderma's prescription only medicines and in this regard noted that the complainant had attended because he/she was particularly interested in the presentation on botulinum toxins.

The Panel noted that Galderma had, *inter alia*, contacted and verbally finalised arrangements and paid the speakers, two of whom were suggested by the nurse support group including a consultant oculoplastic surgeon and a senior aesthetic product developer with Galderma. Galderma provided an additional internal speaker, sourced and funded the venue, drafted and provided the flyer and agenda to the nurse support group for distribution and provided general support. The covering email to the agenda, drafted by the nurse support group described the event as a 'Galderma educational day'. Seven Galderma staff attended including five sales staff. The Panel considered that given Galderma's role and the content of the meeting, the matter of complaint came within the scope of the Code.

Whilst noting that elements of the meeting referred to medical devices, the Panel considered that the content in relation to prescription only medicines and the overall meeting arrangements had to comply with the Code. This would include the requirement for delegates to purchase a product before attending. If the meeting content was only about medical devices then it was likely that the Code would not apply.

The Panel noted that the email sent with the agenda stated that there was no charge for the meeting but certain purchases were required. The covering letter further stated that '[named pharmacy] have kindly confirmed a special offer price for us all of £74.34 per box. You will also receive a free Restylane Skin Booster and complimentaries on the day. For a cost of £150 we get a fabulous deal, equivalent to £240 worth of products plus the meeting'. Delegates had to bring their invoices to the conference as proof of purchase to gain entry. Attendees who were not members of the nurse support group were charged £40 to attend and were also required to purchase 2 packs from the named pharmacy. The Panel noted Galderma's submission that it was not uncommon within the aesthetics industry for there to be a requirement to purchase a product before attending educational or training sessions. The Panel noted its finding above that the overall arrangements had to comply with the Code. It could also be argued that attendees were paid £90 to listen to talks promoting medicines. The Panel considered that the discount offered on the obligatory purchase of Emervel together with the items received on the day meant that attendees were given a pecuniary advantage of a minimum of £90 in connection with the promotion of Azzalure and Pliaglis and a breach of the Code was ruled.

The Panel considered that patient safety was extremely important and was concerned about patient safety given that a health professional was required to purchase a product that he/she knew nothing about and upon which he/she was not trained. No training was provided at the meeting. In addition paying health professionals to attend

promotional meetings was unacceptable. The Panel considered that overall high standards had not been maintained and a breach was ruled. In addition the Panel considered that the circumstances were such that Galderma had brought discredit upon and reduced confidence in the pharmaceutical industry. A breach of Clause 2 was ruled. This ruling was appealed.

Given Galderma's conduct in this case, the Panel reported the company to the Appeal Board under Paragraph 8.2 of the Constitution and Procedure for it to consider whether further sanctions were warranted.

Upon appeal the Appeal Board noted that in Galderma's view as long as a health professional knew the general technique for injecting dermal fillers, not being trained to administer a specific filler did not have adverse implications for patient safety and thus the Panel's ruling was based on a misunderstanding. The Appeal Board noted, however, that the ruling of a breach of Clause 2 referred to all the circumstances of the case, it was not limited to matters of patient safety.

The Appeal Board was concerned to note Galderma's submission that the meeting had been organised by a sole key account manager (KAM) at short notice acting on his/her own without Galderma's knowledge; this information had not been submitted to the Panel and, that very little detail had been provided in Galderma's appeal. The Appeal Board was not convinced that the KAM was the only person who knew about the meeting; it noted Galderma's submission that six other Galderma staff were at the meeting; the employee who had presented on Pliaglis and five other sales staff. The Appeal Board queried how a single KAM was able to cooperate with a nurse support group, agree a product discount, book national and international speakers, generate meeting materials, source and fund the venue etc without a more senior member of staff having to formally agree and approve the arrangements.

The Appeal Board was extremely concerned about the overall arrangements for the meeting and the lack of control. It noted that the presentations had not been certified and there were no speaker agreements or contracts. The Appeal Board was extremely concerned that the presentation on botulinum toxins by a Galderma employee, discussed the use of botulinum toxin in a number of unlicensed indications. This was totally unacceptable and contrary to the Code.

The Appeal Board considered that the overall arrangements were such that Galderma had brought discredit upon and reduced confidence in the pharmaceutical industry. The Panel's ruling of a breach of Clause 2 was upheld. The appeal was thus unsuccessful.

In relation to the report from the Panel, the Appeal Board noted the rulings of breaches of the Code. The Appeal Board was appalled and extremely concerned about the materials and arrangements for the meeting; there had been astonishing failures at all levels.

The Appeal Board queried why the submission that a lone KAM, acting contrary to company policy, was responsible for the issues in this case, had only appeared as a brief statement in the appeal and not in the various responses to the Panel, especially considering the number of times the Panel had had to ask Galderma for information. Notwithstanding the KAM's apparent disregard for company policies, Galderma was still responsible for his/her actions under the Code. The Appeal Board questioned Galderma's care and attention taken in its responses to the Panel and its appeal in this case. External confidence in self regulation relied upon a full and frank disclosure at the outset. This and the circumstances of the meeting implied a fundamental lack of understanding of the requirements of the Code and a lack of control exhibited by Galderma. The Appeal Board queried how seriously Galderma took its corporate responsibilities under the Code.

The Appeal Board was extremely concerned about Galderma's conduct, and having considered all the sanctions available under Paragraph 11.3 of the Constitution and Procedure decided that the company should be publicly reprimanded.

The Appeal Board also decided to require an audit of Galderma's procedures in relation to the Code to be carried out as soon as possible and at the same time as that in Case AUTH/2684/12/13. On receipt of the audit report the Appeal Board would consider whether further sanctions were necessary. Following notification of the Appeal Board's consideration, Galderma agreed a date for the audit but after receiving the detailed reasons it then declined to be audited or sign the undertaking and assurance related to the Appeal Board ruling and informed the Authority that it no longer accepted the jurisdiction of the PMCPA. This prompted a second report to the Appeal Board.

The Appeal Board noted that by failing to provide the requisite undertaking and assurance and declining the audit Galderma had failed to comply with the procedures set out in Paragraph 10 of the Constitution and Procedure and thus the Appeal Board decided, in accordance with Paragraph 11.4, to remove Galderma from the list of non member companies which had agreed to comply with the Code. Thus responsibility for Galderma under the Code could no longer be accepted. The Medicines and Healthcare Products Regulatory Agency (MHRA) and the ABPI Board of Management were subsequently advised of the Appeal Board's decision.

An anonymous, non-contactable complainant who described him/herself as a registered nurse complained about arrangements for an aesthetics meeting organised by Galderma (UK) Limited. The meeting in question was an educational day in association with a nurse support group. The complainant provided the agenda which listed four presentations, two of which were particularly relevant to medicines marketed by Galderma; one was about botulinum toxins (Galderma

marketed Azzalure) and the second was about the company's product Pliaglis (tetracaine/lidocaine), a topical anaesthetic for use in dermatological procedures. The covering letter sent with the agenda stated that there was no meeting charge for members of the nurse support group but 'due to the high calibre of the speakers provided by Galderma you are required to have purchased a minimum of Two Emervel Classics from [named pharmacy] between now and the 16th November 2013'.

COMPLAINT

The complainant wrote as he/she was a member of the nurse support group, which recently held an event fully sponsored by Galderma.

The complainant had been in the cosmetic/aesthetic industry for many years and noted that the industry often received bad press, often unfairly. The complainant always looked to raise standards, hence the reason he/she was a member of this group amongst others. One way of raising standards was to increase education and this was something he/she strived to do. The complainant stated that he/she had particularly wanted to go to the meeting and was particularly interested in the presentation on botulinum toxin in aesthetics.

The complainant was disgusted, however, that he/she was forced to buy at least two boxes of Galderma's dermal fillers to be able to attend. The complainant referred to the invitation which stated:

> 'For all current members there is no charge for the conference HOWEVER due to the high calibre of the speakers provided by Galderma you are required to have purchased a minimum of Two Emervel Classics from [named pharmacy] between now and the 16th November 2013.'

The complainant submitted that firstly that was just wrong and, secondly, he/she did not like or use the particular filler, and thirdly was not even trained on it. The complainant noted that the two boxes that he/she had been forced to buy in order to improve his/her education were now sat on a shelf.

The complainant submitted that these types of actions did not do the industry any favours and just lowered standards, which was exactly the opposite of what he/she hoped to achieve.

When writing to Galderma, the Authority asked it to consider the requirements of Clauses 2, 9.1 and 18.1.

RESPONSE

Galderma submitted that Emervel was a medical device. As the complaint concerned the purchase of a medical device in relation to attendance at an educational event related to medical devices the company considered that the arrangements relating to this regional educational meeting fell outside the scope of the Code and trusted that the matter could be closed.

In response to a request from the case preparation manager to respond to the complaint, Galderma submitted that the nurse support group approached a key account manager (KAM) with a proposal to organise and support a regional product educational/training day. The nurse support group negotiated this type of event with manufacturers and suppliers in order to offer its membership on a frequent basis. The subject of the event, Restylane Skin Boosters (a medical device marketed by Galderma), was proposed by the nurse support group together with some suggestions for potential speakers. Galderma agreed to source and fund a suitable venue, contact and fund the speakers, and provide some general support for the organisation of the day. The nurse support group also asked a supplier of medical aesthetic equipment and a wholesaler of aesthetic products to sponsor the event; one of these funded the lunch/refreshments and provided support for the day and the other offered a discount on the supply of product as part of the registration package and provided support for the day including checking the professional status of the attendees.

The KAM considered that the meeting fell outside of the Code as it related to Galderma's medical device products and therefore went ahead with the arrangements. The nurse support group had proposed a number of topics and potential speakers that would benefit its membership. The KAM contacted the two speakers proposed by the nurse support group and a third speaker to cover the other topics proposed by the nurse support group. During the discussions, the nurse support group proposed to additionally include a presentation on Pliaglis on the agenda as it thought it would benefit its membership. The KAM included this in the final agenda and arranged with a Galderma employee to do a short presentation.

The KAM prepared a 'save the date' flyer which was emailed to the nurse support group to distribute to its membership. A final agenda was prepared and emailed to the nurse support group for distribution to its members.

The nurse support group was responsible for drafting the covering letters/emails and distributing these together with the invites to its members.

The named pharmacy monitored the registration desk on the day of the meeting and had since provided a list of 39 attendees. Galderma did not know how many units of Emervel Classic were purchased as this was done directly with the named pharmacy. A list of the items Galderma made available to delegates as part of the meeting were provided.

Galderma stated that it did not have access to any of the presentations other than the one about Pliaglis. Should copies of the other presentations be required, Galderma could request copies from the presenters.

Galderma stated that there was no contract between it and the other co-sponsors or any written agreement between it and the nurse support group. All discussions were done during face-to-face meetings. There were also no written agreements between Galderma and the speakers.

Galderma explained that it was not uncommon within the aesthetics industry for delegates to be

required to purchase product before attending product educational/training sessions. As the complaint specifically concerned the purchase of a medical device in relation to attendance at an event focussed on medical devices, Galderma submitted that the activity neither breached Clauses 2, 18.1 or 19.1 of the Code nor fell within the scope of the Code.

In response to a request from the Panel for further information, Galderma provided copies of the presentations and submitted that all discussions and agreements between the KAM and the speakers were carried out verbally; there was no supporting documentation. Galderma clarified that its general support for the organisation of the day included creating the 'save the date' flyer and the 'final agenda', copies of which had been provided. The artwork for these documents was created internally at the request of the KAM. The documents were provided as PDFs to the nurse support group for approval and subsequent distribution to its members. Additionally, Galderma staff were present at the venue to ensure that delegates were directed to the appropriate rooms.

Galderma submitted that all attendees had to purchase Emervel before the event. The named pharmacy was responsible for this element and for monitoring the registration desk. The named pharmacy was not willing to share the purchasing details of attendees with Galderma and so it could not confirm if anyone attended without having purchased Emervel.

Galderma created the artwork for both the flyer and the agenda and therefore had seen them prior to their distribution. Galderma had not prepared the emails sent by the nurse support group nor did it know how many emails the nurse support group had sent. However, Galderma saw some of the emails that the nurse support group had sent to its membership in connection with this meeting.

Seven Galderma staff were at the meeting including the product manager who presented on Pliaglis, the KAM who coordinated the meeting and five other sales staff. Galderma did not have a stand at the meeting although Restylane and Emervel banners were displayed in the room.

PANEL RULING

The Panel disagreed with Galderma's submission that as the complaint specifically concerned the 'purchase of a medical device' in relation to attendance at an event which focused on medical devices it did not fall within the scope of the Code. The Panel noted that the Code applied, *inter alia*, to the promotion of medicines to health professionals and appropriate administrative staff, Clause 1.1 referred. It did not apply to the promotion of devices *per se* unless such devices could only be used with specific medicines. Galderma marketed Azzalure (botulinum toxin) and Pliaglis (tetracaine/lidocaine). The Panel noted that the agenda included a presentation on botulinum toxins in aesthetics which compared Azzalure, Dysport, Botox, Vistabel, Xeomin and Bocouture and a presentation on Pliaglis by Galderma's product manager. A Pliaglis leavepiece was also available. In addition, the Panel noted that the agenda stated that the meeting provided 'an opportunity to present evidence in your prescribing portfolio relating to Toxin'. The Panel considered that the meeting clearly promoted Galderma's prescription only medicines and in this regard noted that the complainant had attended because he/she was particularly interested in the presentation on botulinum toxins.

The Panel noted the nurse support group's role in relation to the meeting. The Panel noted that Galderma's role included contacting and verbally finalising arrangements and paying the speakers, two of whom were suggested by the nurse support group including a consultant oculoplastic surgeon and a senior aesthetic product developer with Galderma. Galderma provided an additional internal speaker, sourced and funded the venue, drafted and provided the flyer and agenda to the nurse support group for distribution and provided general support. The covering email to the agenda, drafted by the nurse support group described the event as a 'Galderma educational day'. Seven Galderma staff attended including five sales staff. The Panel considered that given Galderma's role and the content of the meeting, the matter of complaint came within the scope of the Code.

Whilst noting that elements of the meeting referred to medical devices, the Panel considered that the content in relation to prescription only medicines and the overall meeting arrangements had to comply with the Code. This would include the requirement for delegates to purchase a product before attending. If the meeting content was only about medical devices then it was likely that the Code would not apply.

The Panel noted that Clause 18.1 stated that no gift, pecuniary advantage or benefit might be supplied, offered or promised to members of the health professions or to administrative staff in connection with the promotion of medicines or as an inducement to prescribe, supply, administer, recommend, buy or sell any medicine, subject to the provisions of Clauses 18.2 and 18.3. Delegates could not be paid to attend meetings unless the arrangements were bona fide fees for services. The Code also prohibited the payment (or offer) of a fee for the grant of an interview (Clause 15.3).

The Panel noted that the email sent with the agenda stated that there was no charge for the meeting for nurse support group members but 'due to the high calibre of the speakers provided by Galderma you are required to have purchased a minimum of Two Emervel Classics from [named pharmacy] between now and the 16th November 2013'. The covering letter further stated that '[named pharmacy] have kindly confirmed a special offer price for us all of £74.34 per box. You will also receive a free Restylane Skin Booster and complimentaries on the day. For a cost of £150 we get a fabulous deal, equivalent to £240 worth of products plus the meeting'. Delegates had to bring their invoices to the conference as proof of purchase to gain entry. Those who were not members of the nurse support group were charged £40 to attend and were also required to purchase 2 packs of Emervel Classic. The Panel noted Galderma's submission that it was not uncommon within the aesthetics industry for there to be a requirement to purchase a product before attending educational or training sessions.

The Panel noted its finding above that the overall arrangements had to comply with the Code. It could also be argued that attendees were paid £90 to listen to talks promoting medicines. The Panel noted the requirements of Clause 18.1. The Panel considered that the discount offered on the obligatory purchase of Emervel together with the items received on the day meant that attendees were given a pecuniary advantage of a minimum of £90 in connection with the promotion of Azzalure and Pliaglis and a breach of Clause 18.1 was ruled. That nurse support group members did not otherwise pay to attend the meeting and non members did was, in the Panel's view, irrelevant.

The Panel noted Galderma's submission that it was not uncommon within the aesthetics industry for there to be a requirement to purchase a product before attending product educational/training sessions. The Panel noted its comments above in this regard. The Panel noted that no training on Emervel Classic was provided at the meeting. The Panel considered that patient safety was extremely important. The Panel considered that requiring a health professional to purchase a product that he/she knew nothing about and upon which he/she was not trained raised possible patient safety concerns. In addition paying health professionals to attend promotional meetings was unacceptable. The Panel considered that overall high standards had not been maintained and a breach of Clause 9.1 was ruled. In addition the Panel considered that the circumstances were such that Galderma had brought discredit upon and reduced confidence in the pharmaceutical industry. A breach of Clause 2 was ruled. This ruling was appealed.

During its consideration of this case the Panel was concerned about a number of matters which, in its view, demonstrated that Galderma had a very poor knowledge of the requirements of the Code and/or a reckless attitude towards its application. The Panel noted its findings and rulings as set out above. In addition, the Panel was very concerned that the presentation on botulinum toxins by Galderma's product developer discussed the use of botulinum toxin in a number of unlicensed indications including depression, rosacea and reduction in sweating. The Panel considered that the promotion of unlicensed indications was a very serious matter contrary to Clause 3.2. To compound matters the presentation did not appear to have been certified by the company contrary to Clause 14.1.

The Panel was also concerned about the lack of formality and clear written agreements in relation to the meeting. The Panel was further concerned that there were no contracts in place between Galderma and its speakers (Clause 20.1) nor were there any briefing documents setting out the requirements of the Code in relation to these speakers.

The Panel was further concerned about the documentation provided to delegates about the meeting. Neither the agenda nor its covering email incorporated the Pliaglis and Azzalure prescribing information (Clause 4.1). Whilst the 'save the date' flyer and the agenda featured Galderma's corporate logo, neither made the extent and nature of the company's involvement sufficiently clear and each was inconsistent with the covering email to the agenda which described the event as Galderma's meeting (Clause 19.4).

The Panel considered Galderma's conduct in this case warranted consideration by the Code of Practice Appeal Board and decided to report the company to the Appeal Board under Paragraph 8.2 of the Constitution and Procedure for it to consider whether further sanctions were warranted.

APPEAL BY GALDERMA

Galderma submitted that a breach of Clause 2 was inappropriate; it strongly refuted the argument that the complainant could be exposed from a safety perspective through not being able to attend the event. The techniques for administering all major hyaluronic acid products were standardised and would be covered in an equivalent way by any company's training. It was therefore inappropriate to suggest that this amounted to 'requiring a health professional to purchase a product he/she knew nothing about'.

Similarly, Galderma noted that its entire role in relation to the meeting was a result of the nurse support group requesting sponsorship/support and due to short time lines on this occasion one KAM acted contrary to company policy. Galderma submitted that these actions did not reflect the attitude or procedures of the company as a whole.

Galderma submitted that if the breach of Clause 2 was ruled on safety grounds this was based on a misunderstanding of the practice of this sector of the medical devices market. If the breach was based on Galderma's procedures it noted that this involvement was unauthorised by the company and once discovered appropriate action was taken. In this regard Galderma further refuted the suggestions that it had 'poor knowledge' of, or a 'reckless attitude' towards the Code and referred to its past unblemished record in relation to the Code and its prompt responses to each of the PMCPA's questions in this matter.

APPEAL BOARD RULING

The Appeal Board noted that contrary to Galderma's appeal submission the Panel's ruling of a breach of Clause 2 was not limited to matters of patient safety. The ruling referred to all the circumstances of the case.

The Appeal Board was not clear what was meant by Galderma's appeal that it refuted the argument that 'the complainant could be exposed from a safety perspective through not being able to attend the [nurse support group] event'. The Galderma representative acknowledged that this was badly worded and in explanation referred to the similarity of the injection technique for all dermal fillers. In Galderma's view as long as a health professional knew the general technique, not being trained to administer a specific dermal filler did not have adverse implications for patient safety and thus the Panel's ruling of a breach of Clause 2 in this regard was based on a misunderstanding.

In response to a question regarding what was meant by Galderma's appeal that '… this involvement was

unauthorized by the company …', the Galderma representative stated that the meeting had been organised by a sole KAM at short notice acting on his/her own without Galderma's knowledge. The Appeal Board was very concerned that this information had not been submitted in any of Galderma's responses to the Panel and that very little detail was provided in Galderma's appeal. The Appeal Board was not convinced that the KAM was the only person who knew about the meeting; it noted Galderma's submission that in addition to the KAM, six other Galderma staff were at the meeting including the product manager who had presented on Pliaglis and five other sales staff. At the very least the product manager would also have been aware of and involved with the meeting. The Appeal Board queried how a single KAM was able to cooperate with a nurse support group, agree a product discount, book national and international speakers, generate meeting materials, source and fund the venue etc without a more senior member of staff having to formally agree and approve the arrangements.

The Appeal Board was extremely concerned about the overall arrangements for the meeting and the lack of control. It noted that the presentation slides had not been certified and there were no speaker agreements or contracts despite the fact that, according to the Galderma representative, the company had previously engaged the speakers and provided them with briefings and contracts. The Appeal Board was extremely concerned that the presentation on botulinum toxins by the person who worked for Galderma, discussed the use of botulinum toxin in a number of unlicensed indications. This was totally unacceptable and contrary to the Code.

The Appeal Board noted that Galderma had accepted the Panel's ruling of a breach of Clause 18.1 in that attendees were given a pecuniary advantage in connection with the promotion of Azzalure and Pliaglis. Galderma had also accepted the Panel's ruling of a breach of Clause 9.1 for failing to maintain high standards.

The Appeal Board noted its comments above and considered that the overall arrangements were such that Galderma had brought discredit upon and reduced confidence in the pharmaceutical industry. Consequently the Appeal Board upheld the Panel's ruling of a breach of Clause 2. The appeal was unsuccessful.

COMMENTS FORM GALDERMA ON THE REPORT

At the consideration of the report, the Galderma representative apologised on behalf of the company for the mistakes it had made. The KAM responsible for the meeting had been reprimanded and training on the Code for all staff was underway.

APPEAL BOARD CONSIDERATION OF THE REPORT FROM THE PANEL

The Appeal Board noted the rulings of breaches of the Code. The Appeal Board was appalled and extremely concerned about the materials and arrangements for the meeting. In its view, there were astonishing failures at all levels.

The Appeal Board queried why the submission that a lone KAM, acting contrary to company policy, was responsible for the issues in this case, had only appeared as a brief statement in the appeal and not in the various responses to the Panel, especially considering the number of times the Panel had had to ask Galderma for information. Notwithstanding the KAM's apparent disregard for company policies, Galderma was still responsible for his/her actions under the Code. The Appeal Board questioned Galderma's care and attention taken in its responses to the Panel and its appeal in this case. External confidence in self regulation relied upon a full and frank disclosure at the outset. This and the circumstances of the meeting implied a fundamental lack of understanding of the requirements of the Code and a lack of control exhibited by Galderma. The Appeal Board queried how seriously Galderma took its corporate responsibilities under the Code.

The Appeal Board was extremely concerned about Galderma's conduct, and having considered all the sanctions available under Paragraph 11.3 of the Constitution and Procedure decided that the company should be publicly reprimanded.

The Appeal Board also decided that an audit of Galderma's procedures in relation to the Code should be carried out as soon as possible and at the same time as the audit required in Case AUTH/2684/12/13. The KAM who Galderma submitted organised the meeting at issue, together with his/her manager should be interviewed during the audit. On receipt of the audit report the Appeal Board would consider whether further sanctions including a report to the ABPI Board of Management were necessary.

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Following notification of the Appeal Board's consideration, Galderma agreed a date for the audit but after receiving the detailed reasons it then in Case AUTH/2684/12/13 declined to be audited or sign the requisite undertaking and assurance related to the Appeal Board rulings and it informed the Authority that it no longer accepted the jurisdiction of the PMCPA. Galderma had also strongly considered that the Panel and the Appeal Board had not given it a fair hearing on this matter.

The Director asked Galderma to clarify its position in relation to Case AUTH/2685/12/13 and to provide further details as to why it considered that the Panel and the Appeal Board had not given it a fair hearing on this matter.

COMMENTS FROM GALDERMA

Galderma submitted that with regard to the fairness of Galderma's hearing, the company did not see any benefit in reiterating its previous arguments in the light of its decision to resign from the jurisdiction of the PMCPA.

Galderma confirmed that as it had resigned from the jurisdiction of the PMCPA, it would not undergo an audit with respect to Case AUTH/2685/12/13. As stated in Case AUTH/2684/12/13 Galderma was fully prepared to undergo an audit by the MHRA as a possible consequence.

In the light of its resignation from the PMCPA's jurisdiction, Galderma knew of, and was comfortable with the Appeal Board's right under the provisions of Paragraph 11.4 of the Constitution and Procedure to remove the company from the list of non member companies which had agreed to comply with the Code and advise the MHRA that responsibility for Galderma under the Code could no longer be accepted. Galderma further noted that such action was required in accordance with the 3 November 2005 Memorandum of Understanding between the ABPI, PMCPA and MHRA. Galderma acknowledged the PMCPA's obligation to notify the ABPI Board of Management that such action had been taken.

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In accordance with Paragraph 11.1 of the Constitution and Procedure the Authority reported Galderma to the Code of Practice Appeal Board for it to decide whether to remove the company from the list of non member companies which had agreed to comply with the Code and advise the Medicines and Healthcare Products Regulatory Agency (MHRA) that responsibility for Galderma under the Code could no longer be accepted. (Paragraph 11.4 of the Constitution and Procedure).

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APPEAL BOARD CONSIDERATION OF THE REPORT FROM THE AUTHORITY

The Appeal Board noted that Galderma had asked to be removed from the list of non member companies that had agreed to comply with the Code.

The Appeal Board noted that the Director had asked Galderma for further details as to why it considered that the '… Panel and Appeal Board have failed to give Galderma a fair hearing on this matter…'. The Appeal Board considered this was a very serious allegation, particularly as the PMCPA had followed its Constitution and Procedure in dealing with these cases. Galderma had not provided further detail.

The Appeal Board noted that by failing to provide the requisite undertaking and assurance and declining the audit Galderma had failed to comply with the procedures set out in Paragraph 10 of the Constitution and Procedure and thus the Appeal Board decided, in accordance with Paragraph 11.4, to remove Galderma from the list of non member companies which had agreed to comply with the Code. Thus responsibility for Galderma under the Code could no longer be accepted. The MHRA and ABPI Board of Management were subsequently advised of the Appeal Board's decision.

Complaint received	**12 December 2013**
Undertaking for matters not appealed	**6 May 2014**
Appeal considered	**15 May 2014**
Report to Appeal Board	**15 May 2014, 24 July 2014**
MHRA informed	**4 August 2014**
ABPI Board informed	**4 August 2014**