

HEALTH PROFESSIONAL v GALDERMA

Unsolicited emails

A health professional complained about two unsolicited emails sent by Galderma (UK) on 2 April and 3 December 2013. The first email was an invitation to a symposium which was to be broadcast on 4 April as part of the Anti-aging Medicine World Congress (AMWC). The invitation referred to 'Advanced anatomy to relax, fill and care'. The second email stated that the festive season was a busy time of year for aesthetic clinics and that it was not too late to take advantage of special offers with regard to the purchase of Galderma's dermal fillers. The complainant alleged that the unsubscribe link did not work.

The complainant alleged that the reference to 'relax' in the April email clearly referred to Azzalure (botulinum toxin), used to relax muscles in the treatment of wrinkles. None of Galderma's other products had a mechanism of action which 'relaxed' anything. The complainant surmised that if mailing lists of this type were bought by Galderma, there might be recipients who were outside the licensed customer group who would be led to the company's medicines.

The detailed response from Galderma is given below.

The Panel noted that the April email was an invitation sent by a third party on behalf of the company to attend an educational symposium organised by Galderma International. The Panel noted Galderma's submission that its products, including its medicines, were mentioned throughout the session and that brand names were visible on the screen and referred to outside the auditorium.

The symposium booklet, which featured the statement 'Relax, fill and care' on the front cover, showed that one section of the symposium was entitled 'Relax and fill the upper face'. Four of the five speaker introductions referred to the use of botulinum toxin.

The Panel noted that although the symposium *per se* was not the subject of the complaint, given its content, the April email was an invitation to an event which promoted the use of Galderma's medicines. The invitation had been sent to UK health professionals and so in that regard the Panel considered that it came within the scope of the Code.

The invitation featured the statement 'Advanced anatomy to relax, fill and care' and the Panel noted Galderma's submission that 'relax' referred to the use of botulinum toxins. The Panel considered that the email, given its link to a promotional symposium and the use of the word 'relax', promoted, *inter alia*, Azzalure.

The Panel noted that Galderma was unable to provide any evidence that recipients of the email would be aware that they would be sent promotional material. The Panel was extremely concerned by Galderma's submission that neither it nor Galderma International (based in France) had taken steps to ensure that the invitation complied with the UK Code. The Panel considered that, on the balance of probabilities, Galderma had not obtained prior permission to email the invitation to those who received it and a breach was ruled. High standards had not been maintained and a further breach was ruled. These rulings were upheld on appeal.

The Panel noted that although 92% of those expected to attend the AMWC were expected to be health professionals, 8% would be others, which included, *inter alia*, distributors. The Panel queried whether distributors should have received the email given that they would not be qualified to prescribe medicines but, nonetheless, noted that there was no information before it to show that UK distributors had received the invitation. On that basis, the Panel ruled no breach of the Code.

The Panel did not consider that the use of 'relax' in association with the botulinum toxins was misleading. No breach was ruled.

The Panel noted that the December email reminded readers that special offers on the purchase of dermal fillers were available. The email referred to 'exclusive offers on the Galderma aesthetic portfolio' and so in that regard included more than just Galderma's medical devices. The end of the email stated that Galderma was the maker of, *inter alia*, Azzalure and Pliaglis (lidocaine/tetracaine). In the Panel's view the general reference to a portfolio of products and the use of the brand names of medicines meant that the email promoted medicines and so fell within the scope of the Code.

The Panel noted that prior permission was required to send emails which promoted medicines. The consent form which recipients had completed in order to receive the December email was from Q-Med, a division of Galderma, and referred to both the Q-Med range of products and products within the Galderma group. Running along the top of the form were three 'buttons' to click for more information on, *inter alia*, aesthetic medical devices; there were no buttons which related to medicines. In the Panel's view, the form did not make it abundantly clear that completion of it amounted to granting permission for promotional material about medicines to be emailed and a breach was ruled. High standards had not been maintained and a breach was ruled.

The Panel considered that, apart from the complainant's allegation, there was no information before it to show that the unsubscribe function did not work or to suggest that the email had gone to those who should not have received it. Thus no breach was ruled.

The Panel noted its rulings above with regard to both emails and considered that the matters were not such as to bring discredit upon or reduce confidence in the pharmaceutical industry. No breach of Clause 2 was ruled.

During its consideration of this case, the Panel noted that each email should have incorporated relevant prescribing information. The Panel requested that Galderma bore this in mind for future emails. The Panel also noted its concern that neither Galderma UK nor Galderma International had taken any steps to ensure the invitation to UK health professionals to attend the Galderma symposium complied with the UK Code. In the Panel's view this showed a serious lack of understanding of the application of the Code. The Panel was also concerned that Galderma had had to be contacted a number of times before it had provided all of the relevant information. Galderma's first response was that as the complaint was about activities associated with its medical devices, it was not covered by the Code and should be closed. This was not helpful and again showed a general lack of understanding of the applicability of the Code. Self regulation relied upon full and frank disclosure at the outset.

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.

The Appeal Board was very concerned about the number of times Galderma had had to be asked for further information; in its view there had been significant obfuscation. External confidence in self regulation relied upon companies providing a full and frank disclosure at the outset. The company's first response that the matter did not fall within the scope of the Code was incorrect and demonstrated a fundamental lack of understanding.

Overall, the Appeal Board was appalled at Galderma's general lack of knowledge of the requirements of the Code and was concerned to note that both the international and UK companies had appeared to transfer responsibility for compliance with regard to the April email to the AMWC organisers. In this regard the Appeal Board questioned how seriously Galderma UK took its own responsibilities under the Code. Galderma UK needed to be extremely diligent regarding future activities.

The Appeal Board considered that given the outcome and Galderma's conduct in relation to this case, the company should be publicly reprimanded and that its procedures in relation to the Code should be audited forthwith. 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 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. 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. 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.

A health professional, complained about two emails sent by Galderma (UK) Limited on 2 April and 3 December 2013. The email of 2 April was an invitation to a live triplex symposium which was to be broadcast on 4 April as part of the Anti-aging Medicine World Congress (AMWC). The invitation referred to 'Advanced anatomy to relax, fill and care'. The email of 3 December stated that the festive season was a busy time of year for aesthetic clinics and reminded readers that it was not too late to take advantage of special offers with regard to the purchase of Galderma's dermal fillers.

In addition to dermal fillers, Galderma marketed Azzalure (botulinum toxin) and Pliaglis (lidocaine/tetracaine) both of which were medicines.

COMPLAINT

The complainant explained that he had received a number of unsolicited emails from Galderma over the course of the past year. He submitted that he had never given the company permission to email him directly. He did not believe his details should be bought by a pharmaceutical company in order to proactively contact him. The complainant considered that this type of contact was inappropriate.

The complainant alleged that the unsubscribe link did not work as he had unsubscribed and still received emails. The emails also appeared to emanate from different email addresses.

The complainant was most concerned about the reference to 'relax' in the email of 2 April and alleged that this clearly referred to Azzalure, used to relax muscles in the treatment of wrinkles. None of Galderma's other products could be described as having a mechanism of action which 'relaxed' anything. The complainant surmised that if mailing lists of this type were bought by Galderma, there might be recipients who were outside the licensed customer group who would be led to the company's medicines.

When writing to Galderma, the Authority asked it to respond in relation to Clauses 2, 3.2, 7.2, 9.1 and 9.9.

RESPONSE

Galderma stated that the email of 3 December 2013 related to the company's medical devices [Restylane and Emervel fillers] and therefore fell outside the scope of the Code. Galderma was satisfied that appropriate consent was obtained to send the email and there was a system to monitor and action requests to unsubscribe from the mailing list. After the email was sent seven recipients asked to be unsubscribed and all of them had been removed from the mailing list.

The email of 2 April 2013 was not sent by Galderma but by the organisers of the AMWC which was held in Monaco, 4-6 April 2013. Forty eight satellite symposia were held during this world congress. Galderma believed the symposium referred to on the invitation, as well as invitations for many of the other symposia held during the congress, were sent to all those registered to attend the world congress.

Galderma submitted that as the complaint related to activities associated with its medical devices which fell outside the scope of Code, it trusted that the matter could be closed. If the complainant wished to raise his concerns directly with the company it would be happy to explain what measures it had to keep its mailing list up-to-date.

In response to the case preparation manager's request for more information, Galderma stated that the email of 2 April 2013 was sent on behalf of Galderma. The company noted that this was an international meeting, the organisation and arrangement for which was carried out by its head office, Galderma International. Galderma UK was not involved in the meeting arrangements, organisation, invitations etc.

As part of the sponsorship package, sponsors were given the opportunity to send mailings to attendees. The invitation to the Galderma symposium, which was held during the world congress, was sent by the AMWC organisers to all registered attendees. Galderma had no access to the AMWC database of registered attendees and had no control over the addition or removal of recipients included in this database. The invitation was an electronic copy of an invitation distributed from the Galderma stand at the congress.

Galderma explained that the AMWC was an international meeting held in Monaco and neither Galderma International nor Galderma UK took any steps to ensure that the invitation complied with the Code as the ABPI Code was not applicable. Galderma International, however, reviewed the material to ensure that it complied with the appropriate regulations in Monaco.

Galderma submitted that unsubscribing from the AMWC mailing list would not automatically result in unsubscribing from the mailing lists of all the companies which exhibited at the AMWC. The complaint related to receipt of unsolicited emails

from Galderma. As stated above, the symposium invitation (email dated 2 April) was not sent by Galderma UK, the other email of 3 December related to information about medical devices and therefore fell outside the scope of the Code. Nevertheless, Galderma was satisfied that it had obtained appropriate consent to send the email of 3 December and it had a system in place to monitor and action requests to unsubscribe from its mailing list. As stated above following the email sent on 3 December, seven requests to unsubscribe were received and had all been actioned.

In response to another request from the case preparation manager for further information, Galderma stated the email of 2 April was sent on behalf of Galderma International. As stated above, the email was an electronic copy of a paper invitation distributed from the Galderma stand at the congress. The electronic copy was provided to the AMWC organisers by Galderma International and had been approved by Galderma International. Information from the AMWC organisers described the profile of attending delegates as dermatologists (30%), plastic and cosmetic surgeons (20%), anti-aging doctors and other specialities (gynaecologists, endocrinologists etc) (30%), aesthetic and general practitioners (12%), and others such as medical allied health, nurses, clinic managers, distributors etc (8%). Galderma International was therefore satisfied that delegates to the AMWC were of an appropriate professional status to receive such mailings.

Galderma International's sponsorship package included three emailings. Thirty four Galderma UK sponsored health professionals attended the congress. Galderma UK did not know how many UK delegates attended the congress but information from the AMWC organisers showed that 7,369 delegates attended the 2012 AMWC. Attendance was expected to exceed 8,000 in 2013, 45% of which were expected from western Europe. The symposium was organised by Galderma International, however, Galderma UK sponsored thirty four delegates to attend the congress, although it did not know how many, if any of these, attended the symposium. Attendance at the Galderma International symposium was not a condition of sponsorship to attend the congress. Five Galderma UK staff attended the AMWC congress and were present on the Galderma exhibition stand at various times during the congress.

Galderma International confirmed to Galderma that it was satisfied that appropriate consent was obtained by the AMWC organisers (as part of the registration process) to send such emails and the emails were sent to appropriate recipients. Galderma denied any breach of the Code.

In response to a request from the Panel for more information and its observation that a statement at the end of the email of 3 December referred to Galderma, the makers of, *inter alia*, Azzalure and Pliaglis, Galderma maintained that the email related to its medical devices. 'Galderma, the makers of, *inter alia*, Azzalure and Pliaglis', was a statement of fact that appeared outside the main body of the text. The sentence listed all of Galderma's

aesthetic product range irrespective of legal status. Galderma failed to see how this could be considered promotional or in breach of the Code. That said, the company had a robust system in place to collect consent and to manage requests to unsubscribe. Galderma provided a screen shot from its website for those who wanted to sign up to receive product news and information on promotional offers by post, email and text.

With regard to the email of 2 April, Galderma reiterated that it was sent by the AMWC organisers; it was not sent by Galderma or using the Galderma database. Therefore, a request to unsubscribe from this email would not automatically unsubscribe the recipient from all other company mailing lists. Whilst Galderma had complete confidence in its system, following the complaint it checked that the unsubscribe function operated effectively. The test indicated no problems and that, together with the fact that no recipients had reported any problems with the unsubscribe function, further supported its confidence in the system.

Galderma stated that it did not have access to the registration paperwork used by the AMWC organisers. However, it had been advised that registration included access to sessions, workshops, exhibition, certificates of attendance, congress bag and all congress documents/material. Galderma noted the following legal information from the AMWC organisers:

'PERSONAL DATA

The website [web address given] is declared to the National Commission of Information and Liberties, under the number 1375031. Your data subscribed on our website are aimed to be used by our Administrative Secretariat only. This data will of course not be given up or sold to any external company or person. In compliance with the French internal legislation, you could modify, suppress or change any of your data (art.34 of the law – informatique et Libertes – dated 06.01.1978). To exercise this right, contact: [email address given].'

Galderma submitted that the AMWC organisers arranged many congresses throughout the world. Exhibiting at the congress and utilising the congress resources was a service that pharmaceutical companies paid for. There was no reason to believe that the organisers had not fulfilled their professional duty to keep mailing lists up-to-date by acting upon requests to unsubscribe.

Galderma stated that the objective of its symposium was to provide training on the anatomical structures involved in various facial aesthetic procedures with particular reference to its products. Galderma provided details of the two hour session. Live procedures were carried out in the auditorium which was televised on a large screen. On a parallel screen, a surgeon showed the anatomical features (fat tissue, skin layers, nerves, blood vessels etc) involved in the procedure using a cadaver broadcast live from France. The symposium was organised by Galderma International and Galderma products (medical devices and medicines) were mentioned

throughout the session. The brand names of Galderma products were also visible on the screen as well as outside the auditorium. Galderma UK did not have a copy of the symposium. Galderma noted that the content of the symposium was not the subject of the complaint and so it queried why the Panel had requested a recorded copy.

Galderma referred to the symposium objective as stated above and the reference to Galderma products and stated that within that context 'relax' in the statement 'Advanced anatomy to relax, fill and care' referred to the effects of botulinum toxins, 'fill' referred to the effects of dermal filler as did 'care'.

Galderma noted that the complaint related to the failure to action a request to unsubscribe, receipt of the unsolicited emails and use of the word 'relax', all of which it considered had been addressed. The company repeated that, in its view, the activities at issue did not fall within the scope of the Code and even if they did there was no breach.

In response to a further request from the Panel for more information, Galderma submitted that Galderma International was based in France.

With regard to Q-Med, Galderma explained that it acquired the company and its full range of aesthetic medical devices in 2011. The Q-Med product range which consisted of Restylane and Macrolane (medical devices) and Restylane SkinCare (cosmetic) was integrated into the Galderma aesthetic portfolio which consisted of Emervel (medical device) and Azzalure and Pliaglis (prescription only medicines). The reference to the Galderma group of products, on the health professionals' consent to receive emails form, referred to all of these products and any future additions to the aesthetic portfolio.

PANEL RULING

With regard to Galderma's concern that it had been asked for information which went beyond the scope of the complaint, the Panel noted that the details requested had not been sought in order to widen the scope of the complaint but to ensure that the Panel fully understood the context in which the two emails had been sent.

The Panel noted that the email of 2 April 2013 was an invitation to attend an educational symposium organised by Galderma International. The email had been sent by a third party on behalf of the company. The Panel noted Galderma's submission that during the symposium, Galderma products, including its medicines, were mentioned throughout the session and that brand names were visible on the screen and referred to outside the auditorium.

The symposium booklet, which featured the statement 'Relax, fill and care' on the front cover, showed that one section of the symposium was entitled 'Relax and fill the upper face'. In four of the five speaker introductions, the use of botulinum toxin was referred to.

The Panel noted that although the symposium *per se* was not the subject of the complaint, given its

content the email of 2 April 2013 was an invitation to an event which promoted the use of Galderma's medicines. The invitation had been sent to UK health professionals and so in that regard the Panel considered that it came within the scope of the Code.

The Panel noted Galderma's submission that the UK company was not involved with the meeting arrangements, organisation, invitations etc. Nonetheless, it was a well-established principle under the Code that UK companies were responsible for the acts or omissions of overseas parent companies or affiliates that came within the scope of the Code.

The invitation featured the statement 'Advanced anatomy to relax, fill and care' and the Panel noted Galderma's submission that 'relax' referred to the use of botulinum toxins. Galderma marketed Azzalure, a botulinum toxin. The Panel considered that the email, given its link to a promotional symposium and the use of the word 'relax', promoted, *inter alia*, Azzalure.

The Panel noted that the Code prohibited the use of emails to promote medicines, except with the prior permission of the recipient. Previous cases had established that text or dialogue requesting permission to send promotional material had to make it abundantly clear that the intention was to send promotional material from pharmaceutical companies about medicines.

The Panel noted, as stated above, Galderma's responsibility for the UK use of the email. The company was unable to provide any evidence that recipients of the email would be aware that they would be sent promotional material. The Panel was extremely concerned by Galderma's submission that neither it nor Galderma International (based in France) had taken steps to ensure that the invitation complied with the UK Code. The Panel considered that, on the balance of probabilities, Galderma had not obtained prior permission to email the invitation to those who received it. A breach of Clause 9.9 was ruled. High standards had not been maintained. A breach of Clause 9.1 was ruled. These rulings were appealed.

The Panel noted the demographics of those expected to attend the AMWC and that although 92% were expected to be health professionals, 8% would be others, which although they included nurses, also included medical allied health, clinical managers, distributors etc. Galderma International was satisfied that the all delegates were of an appropriate professional status to receive the emailed invitation. The Panel queried whether, in particular, distributors should have received the email given that they would not be qualified to prescribe medicines but, nonetheless, noted that there was no information before it to show that UK distributors had received the invitation. On that basis, the Panel ruled no breach of Clause 3.2.

The Panel noted that 'relax' had been used in association with the botulinum toxins and in that

regard did not consider that its use was misleading. No breach of Clause 7.2 was ruled.

The Panel noted its rulings above with regard to the email of 2 April and considered that the matter was not such as to bring discredit upon or reduce confidence in the pharmaceutical industry. No breach of Clause 2 was ruled.

Turning to the email of 3 December, the Panel noted that it was sent to remind readers that special offers on the purchase of dermal fillers were available. The email referred to 'exclusive offers on the Galderma aesthetic portfolio' and so in that regard included more than just Galderma's medical devices. A statement at the end of the email stated that Galderma was the maker of, *inter alia*, Azzalure and Pliaglis. In the Panel's view the general reference to a portfolio of products and the use of the brand names of medicines meant that the email was not limited to medical devices; it promoted medicines and so fell within the scope of the Code.

The Panel noted its comments above regarding the prior permission required to send emails which promoted medicines. The consent form which recipients had completed in order to receive the email at issue was from Q-Med, a division of Galderma. The form referred to both the Q-Med range of products and products within the Galderma group. Running along the top of the form were three 'buttons' to click for more information on, *inter alia*, Restylane, Emervel and Macrolane; there were no buttons which related to medicines. In the Panel's view, the form did not make it abundantly clear that completion of it amounted to granting permission for promotional material about medicines to be emailed. A breach of Clause 9.9 was ruled. High standards had not been maintained. A breach of Clause 9.1 was ruled.

The Panel noted the complainant's allegations that the unsubscribe link did not work. Galderma had stated, however, that after the email had been sent, seven recipients asked to be unsubscribed from the mailing list and this had been actioned. The Panel considered that, apart from the complainant's allegation, there was no information before it to show that, on the balance of probabilities, the unsubscribe function did not work. No breach of Clause 9.9 was ruled.

The complainant had made a general allegation, based on Galderma's purchase of mailing lists, (which the Panel assumed applied to both emails at issue) that some recipients of the email of 3 December might have been outwith the licensed customer group, but had produced no evidence to show that this was so. A complainant had the burden of proving his/her complaint on the balance of probabilities. The Panel considered that no evidence had been provided to suggest that the December email had gone to those who should not have received it. No breach of Clause 3.2 was ruled.

The Panel noted its rulings above with regard to the email of 3 December and considered that the matter

was not such as to bring discredit upon or reduce confidence in the pharmaceutical industry. No breach of Clause 2 was ruled.

During its consideration of this case, the Panel noted that given its view that both emails were promotional, each should have incorporated relevant prescribing information. The Panel requested that Galderma bore this in mind for future emails. The Panel also noted its concern that neither Galderma UK nor Galderma International had taken any steps to ensure the invitation to UK health professionals to attend the Galderma symposium complied with the UK Code. In the Panel's view this showed a serious lack of understanding of the application of the Code. The Panel was also concerned that the case preparation manager and the Panel had had to contact Galderma a number of times before the company had provided all of the relevant information. Galderma's first response was that as the complaint was about activities associated with its medical devices, it was not covered by the Code and should be closed. This was not helpful and again showed a general lack of understanding of the applicability of the Code. Self regulation relied upon full and frank disclosure at the outset.

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 appealed the Panel's ruling of breaches of Clauses 9.1 and 9.9 in relation to the email invitation of 2 April 2013.

Galderma submitted that the Panel had operated under a misapprehension with regard to the email from the AMWC organisers. Whilst Galderma had previously acknowledged that Galderma International approved the email, that document was not itself at issue.

Galderma submitted that what was at issue was who controlled the mailing. The AMWC was a large and long-running (13 years) international event with a high ethical and scientific reputation with delegates from some 40 nations. As was normally the case with such conferences, the organisers would have invited every delegate to every session. Galderma was not allowed to know, under data privacy law, the identity of the recipients; it thus had no control over the mailing or the selection of recipients.

Galderma submitted that the Panel's potential misunderstanding was evidenced in its ruling and its statement that 'Galderma had not obtained prior permission to email the invitation to those who received it'. As stated above, Galderma was not allowed to access the mailing list in any way.

Galderma submitted that it was unrealistic to suggest that it should have second-guessed the AMWC organisers about their data protection consent forms. Galderma referred to the AMWC

notice quoted above and like every other company involved, Galderma considered that it had conducted due diligence and was entitled to rely on the adequacy of the consent procedures of the AMWC organisers. The content and procedures of AMWC communications were approved under applicable French law and codes (which reflected the EFPIA Code).

Galderma noted that under Clause 23.6 of the Code, 'Companies are responsible for information about their products which is issued by their public relations agencies' and queried whether the Panel had drawn an analogy to this sort of situation. If so, this was not an analogous situation as the AMWC, unlike a public relations agency, did not do Galderma's bidding, and as noted above, it had operated in this regard, totally at arm's length from Galderma and other participating companies.

Galderma submitted that it was important to analyse what a ruling of a breach of Clause 9.9 meant and whether undertakings to this effect could be observed in practice. Galderma understood and agreed that it was a well established principle under the Code that a UK company was responsible for the acts and omissions of overseas parent companies of affiliates. However, as noted above, this could only be the case where the company had control or transparency of the situation.

Galderma submitted that for example, if UK physicians decided to attend an international conference held outside the UK, with no direct involvement of the UK company, (the company being represented by either the non UK head office or a local affiliate by way of a stand and/or symposium), it would seem absurd for the UK company to be responsible for activities related to those attendees. If this were so then documentation and proceedings for all meetings held anywhere in the world, where UK physicians could potentially attend, would need to be certified in the UK to ensure that all activities complied with the UK Code, just in case a UK physician decided to attend the meeting.

In summary Galderma submitted that what the Panel appeared to be asking of it in the AMWC situation was unachievable in practical terms. Galderma could not therefore be considered to be in breach of Clause 9.9 nor, accordingly, in breach of Clause 9.1.

COMMENTS FROM THE COMPLAINANT

The complainant had no comment on Galderma's appeal.

APPEAL BOARD RULING

The Appeal Board noted that Galderma International had sponsored the AMWC and that, as part of the sponsorship package, the organisers would send three emails on behalf of the company to congress attendees. The email at issue, dated 2 April 2013, was one of those emails and was an invitation to a Galderma promotional symposium. The email had been paid for and approved by Galderma International and so in that regard the Appeal Board

considered that the company was inextricably linked to it and thus responsible for controlling it and ensuring that it met the requirements of the codes in every country to which it was sent. The company could not transfer responsibility for compliance to the conference organisers. In sending the email, the AMWC organisers had not operated at arm's length from Galderma as submitted.

The Appeal Board noted that as the meeting at issue was a major international congress held in Europe, attendance of UK health professionals (even in addition to the thirty four sponsored to attend by Galderma UK) was to be expected. In that regard Galderma International should have consulted its UK colleagues to ensure that when the congress organisers sent the email to invite UK health professionals to a Galderma symposium, it met the requirements of the UK Code. The Appeal Board was extremely concerned to note that neither Galderma International nor Galderma UK had taken any steps to ensure that the email at issue, when sent to UK health professionals, complied with the UK Code. The Appeal Board considered that although Galderma International should have consulted its UK company with regard to compliance with the UK Code, Galderma UK for its part had sponsored UK health professionals to attend the congress and so it should have been more proactive and worked with its international colleagues to ensure that where applicable, materials and activities complied with the UK Code.

The Appeal Board noted that it was a well established principle under the Code that UK companies were responsible for the acts or omissions of overseas parent companies or affiliates that came within the scope of the Code. The email at issue, sent to UK health professionals, came within the scope of the Code. Galderma had provided no additional evidence in its appeal to show that those who had received the email had given prior permission for the email to be sent. The Appeal Board upheld the Panel's ruling of a breach of Clause 9.9. High standards had not been maintained and the Appeal Board upheld the Panel's ruling of a breach of Clause 9.1. The appeal was unsuccessful.

COMMENTS FROM GALDERMA ON THE REPORT

At the consideration of the report, the Galderma representative submitted that the company had made a number of mistakes and it apologised. The Galderma representative stated that this was the first complaint about Galderma for ten years. Thus the company had not been through the process for a long time. Lessons had been learnt and changes had and would be made to address the issues raised.

[Post meeting note: The last complaint about Galderma was in 2007 (Case AUTH/2019/7/07). The last report about Galderma was considered by the Appeal Board in 2003 (Case AUTH/1281/2/02)]

APPEAL BOARD CONSIDERATION OF THE REPORT FROM THE PANEL

The Appeal Board was very concerned about the number of times the case preparation manager

and the Panel had had to ask Galderma for further information. In the Appeal Board's view there had been significant obfuscation. External confidence in self regulation relied upon companies providing a full and frank disclosure at the outset. The company's original response that the matter related only to medical devices and did not fall within the scope of the Code was incorrect and demonstrated a fundamental lack of understanding.

The Appeal Board was extremely concerned to note from questioning the Galderma representative that the company did not have a key standard operating procedure (SOP) relating to a matter in question. The Appeal Board considered that, as a matter of urgency, the company must put in place procedures so that it was confident that, where applicable, future arrangements complied with the UK Code.

Overall, the Appeal Board was appalled at Galderma's general lack of knowledge of the requirements of the Code and was concerned to note that both the international and UK companies had appeared to transfer responsibility for compliance with regard to the email of 2 April, 2013, to the AMWC organisers. In this regard the Appeal Board questioned how seriously Galderma UK took its own responsibilities under the Code. Galderma UK needed to be extremely diligent regarding future activities.

The Appeal Board considered that the outcome and Galderma's conduct in relation to this case warranted the imposition of further sanctions. The Appeal Board decided that the company should be publicly reprimanded and that its procedures in relation to the Code should be audited as soon as was practically possible. On receipt of the audit report the Appeal Board would consider whether further sanctions were necessary.

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Following notification of the Appeal Board's consideration, Galderma agreed a date for the audit.

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COMMENTS FROM GALDERMA

Following receipt of the details of the Appeal Board's consideration, Galderma reiterated that it was one of 34 sponsors of the AMWC. The process of obtaining consent adopted by the AMWC organisers would have been the same in relation to all mailings to all the AMWC delegates and accordingly any sponsor whose products included medicinal products would be as guilty as Galderma of the breaches of the Code ruled by the Panel and the Appeal Board. Moreover Galderma understood that all the attending delegates had indicated to the AMWC that they were prepared to receive information and emails from the AMWC about the congress events.

Moreover Galderma disagreed that using the symposium title in an invitation to a sponsored symposium itself promoted a specific prescription medicine. All sponsored symposia required a title. This title was used in the official agenda programme

books. Delegates used this title to determine their attendance or not. Congress organisers relied on companies to sponsor symposia at their congresses to help fund the scientific content of the congress.

Galderma considered that the intent of a public reprimand for this alleged infringement was excessive.

Galderma extremely strongly considered that the Panel and the Appeal Board had not given it a fair hearing on this matter and thus it gave notice that it would no longer submit to the jurisdiction of the PMCPA and would not undergo the audit.

Galderma fully anticipated that once the PMCPA had advised the MHRA of the company's decision to withdraw from the PMCPA's jurisdiction, the MHRA might wish to conduct an audit of a similar nature and/or take other measures and it was quite prepared to undergo this.

Under the MHRA Galderma submitted that it could continue to observe the provisions of the Code so far as they reflected advertising regulations and the MHRA Blue Guide.

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.

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 this case. 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. 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	11 December 2013
Undertaking received for matters not appealed	15 April 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