

CONSULTANT IN RESPIRATORY MEDICINE v ALK-ABELLÓ

Unsolicited emails

A consultant in respiratory medicine complained that he had received several unsolicited emails, which he understood were unacceptable under the Code, from ALK-Abelló about Grazax (SQ-T oral lyophilisate). He had also received an absolute barrage of information through more conventional means. The complainant did not believe that he had given blanket approval to be contacted by email.

The Panel noted that the covering letter sent by an agency to health professionals about its specialist database stated that the main aim of its website was to give GPs a wider knowledge of consultants' special interests, clinic times, waiting times etc. Reference was made to its use by primary and secondary care staff as well as, *inter alia*, pharmaceutical and insurance companies. The use to which the data would be put by pharmaceutical companies was not stated.

The Panel noted that an email from the agency to ALK-Abelló explained that 'The consultants are sent entry forms via mail/post or they give their details over the phone to our editorial team. The editors explain to the doctors where the data will be displayed and what types of user will have access to it. They are given the choice of whether they want to submit an email address for our users to be able to contact them on'. There did not appear to be a conversation between the consultant and the editorial team other than if they amended their details by phone. The Panel had no evidence to show whether such conversations expressly covered the receipt of promotional as opposed to other material from a pharmaceutical company. In any event the Panel noted that the complainant had updated a hard copy of his form in manuscript. The form included his email address. The Panel noted the respondent's submission that the agency guaranteed in writing that it had permission of all physicians on the database for them to be contacted via email.

The Panel considered that the Code required companies to be able to demonstrate that health professionals had agreed to receive promotional material by email. The Panel considered that ALK-Abelló did not have explicit consent to send physicians on the database promotional material. Whilst it was implicit that users might email a consultant, the Code required such consent to be explicit and the nature of the material to be sent electronically to be made clear. ALK-Abelló had not demonstrated that the complainant had given express consent to receive promotional material by email. The emailed material was clearly

promotional. The Panel ruled a breach of the Code.

The Panel noted the limitation on the number of promotional mailings sent by a company following the launch of a new medicine set out in the supplementary information to the Code; it was not clear whether the term mailing referred to post, email or both. Four mailings had been sent to the complainant between 2 January and 26 February. In addition invitations to three meetings had been sent. The Panel considered that an invitation to a meeting in Manchester on 20 April was a promotional mailing. It included product claims. Thus the company had not complied with the Code and a breach was ruled.

A consultant in respiratory medicine complained about unsolicited emails received from ALK-Abelló (UK) Limited about Grazax (SQ-T oral lyophilisate).

COMPLAINT

The complainant stated that he had received several unsolicited emails about Grazax. He had also received an absolute barrage of information through more conventional means. The complainant understood that unsolicited emails were not acceptable under the Code.

The complainant did not believe that he had given blanket approval to be contacted by email and his secretary knew that he did not wish to be contacted thus.

When writing to ALK-Abelló, the Authority asked it to respond in relation to Clauses 9.1, 9.9 and 12.2 of the Code.

RESPONSE

ALK-Abelló strongly refuted the allegation that it had breached Clause 9.1 as it had always maintained high standards of ethical promotion of Grazax; all materials had been prevetted by the Medicines and Healthcare products Regulatory Agency (MHRA), the launch meetings were CPD accredited and it had adhered to the Code at all times.

In relation to Clause 9.9, ALK-Abelló had used an agency to obtain the complainant's email address from a third party agency which guaranteed in writing to ALK-Abelló (email provided) that it had the permissions of all physicians on its database for a third party to contact them through email.

ALK-Abelló obtained the complainant's email address in good faith and had only used it to invite him to educational meetings with continuing professional development (CPD) accreditation. Therefore ALK-Abelló refuted the alleged breach of Clause 9.9 as it had prior permission of the recipient. Further, the emails were not promotional in nature, only containing invitations and logistical information relating to CPD accredited educational meetings.

The supplementary information to Clause 12.2 stated that 'In the first six months following the launch of a new medicine, a health professional may be sent an initial mailing and no more than three other mailings about the medicine'.

ALK-Abelló launched Grazax on 2 January 2007. An initial mailing containing a 'Dear Dr' letter and summary of product characteristics (SPC) was sent to hospital physicians, including the complainant, who routinely treated allergic rhinitis ie specialist in allergy/immunology, ENT and respiratory medicine. A further three promotional mailings for Grazax were sent to the same doctors on 22 January, 5 February and 26 February. All of these mailings were prevetted and approved by the MHRA.

Invitations to CPD accredited educational meetings (these were not promotional mailings) were also sent to hospital doctors on:

- 11 January – invitations to CPD accredited educational meetings being held at London, Birmingham, Manchester;
- 5 March – update to original invitation to inform of date change to Manchester meeting;
- 8 March – update to London meeting to inform of additional date due to extreme weather conditions affecting delegates during first London meeting.

The meeting invitation and agenda were both prevetted and approved by the MHRA and the educational meetings had received CPD accreditation. Speakers at the meetings were recognised experts in treating allergic rhinitis.

ALK-Abelló submitted that it had fully complied with the requirements of Clause 12.2 and therefore refuted the allegation of any breach.

In response to a request for further information, ALK-Abelló provided a copy of the covering letter and the database form sent to consultants by the third party agency and the form that was amended and returned by the complainant. The covering letter clearly stated that this information might be provided to pharmaceutical companies. In a personal communication, the third party agency confirmed that its database was used by a large number of pharmaceutical companies for a similar use with no previous alleged breach of Clause 9.9.

The invitation, agenda and delegate pack for the 'Novel Therapy for Allergic Rhinitis' meeting that was held in Manchester on 20 April were also

provided. As previously stated, all these materials were prevetted and approved by the MHRA as was standard for a new chemical entity. Prescribing information was included on the invitation and agenda following a request from the MHRA through the prevetting process.

PANEL RULING

The Panel noted that the covering letter sent by the third party agency to health professionals about the specialist database stated that the main aim of the website was to give GPs a wider knowledge of consultants' special interests, clinic times, waiting times etc. Reference was made to its use by primary and secondary care staff as well as, *inter alia*, pharmaceutical and insurance companies. The use to which the data would be put by pharmaceutical companies was not stated.

The Panel noted an email to ALK-Abelló explained that 'The consultants are sent entry forms via mail/post or they give their details over the phone to our editorial team. The editors explain to the doctors where the data will be displayed and what types of user will have access to it. They are given the choice of whether they want to submit an email address for our users to be able to contact them on'. There did not appear to be a conversation between the consultant and the editorial team other than if they amended their details by phone. There was no evidence before the Panel to indicate whether such conversations expressly covered the receipt of promotional as opposed to other material from a pharmaceutical company. In any event the Panel noted that the complainant had updated a hard copy of his form in manuscript. The form included his email address. The Panel noted the respondent's submission that the third party agency guaranteed in writing that it had the permission of all physicians on the database for other parties to contact them via email.

The Panel considered that Clause 9.9 required companies to be able to demonstrate that health professionals had agreed to receive promotional material by email. The Panel considered that ALK-Abelló did not have explicit consent to send physicians on the third party agency database promotional material. Whilst it was implicit that users might contact a consultant by email Clause 9.9 required such consent to be explicit and the nature of the material to be sent electronically to be made clear. ALK-Abelló had not been able to demonstrate that the complainant had given express consent to receive promotional material by email. The emailed material was clearly promotional. The Panel ruled a breach of Clause 9.9.

The Panel noted the limitation on the number of promotional mailings sent by a company following launch of a new medicine set out in the supplementary information to Clause 12.2. It noted that the Code did not make it clear whether the term mailing referred to post, email or both. Four mailings

had been sent to the complainant between 2 January and 26 February. In addition invitations to three meetings had been sent. The Panel considered that the invitation to the meeting in Manchester on 20 April was a promotional mailing. It included product claims. Thus the company had not complied with Clause 12.2 and a breach was ruled.

The Panel did not consider that the circumstances warranted a ruling of a breach of Clause 9.1.

Complaint received	27 March 2007
Case completed	3 July 2007