CASE AUTH/2976/9/17

HOSPITAL CONSULTANT v ASTRAZENECA

Email promotion of Qtern

A consultant in anaesthesia and intensive care medicine alleged that a promotional email for Qtern (saxagliptin and dapagliflozin) from AstraZeneca, via a third party, had been sent to him/her without prior permission. Qtern was indicated for use in adults with type 2 diabetes and the complainant submitted that such medicines were not relevant to his/her practice. Additionally the complainant alleged that the subject line indicated that the email contained important information about Qtern whereas it was just an advertisement.

The detailed response from AstraZeneca is given below.

The Panel noted that the Code required that, *inter alia*, promotional emails must not be sent except with the prior permission of the recipient. Pharmaceutical companies using third parties must be certain that their activities/materials complied with the Code.

The Panel noted AstraZeneca's submission that when the complainant registered on the third party website in 2002 the consent process for agreeing to receive promotional emails from pharmaceutical companies was to opt-in to receive 'external emails'.

The Panel considered that neither the consent process in 2002 nor the 2015 update amounted to the complainant consenting to the receipt of promotional emails from pharmaceutical companies. As AstraZeneca had not obtained prior permission to send the email at issue, the Panel ruled a breach of the Code as acknowledged by the company.

The Panel noted the complainant's concern regarding the relevance of the email which referred to the cost benefit of Qtern, a fixed dose combination, vs its individual components. The Panel noted that the Code required that material should be tailored to the audience. The basis for sending information about diabetes medicines to the complainant had not been made clear in the email; there was no mention that it had been sent to the complainant in relation to his role as a payer/ clinical lead. The Panel considered that although information about diabetes medicines might be of interest to the complainant, his/her need for, or interest in it could not reasonably be assumed. The Panel ruled a breach of the Code.

The Panel considered that given the subject of the email 'AstraZeneca Qtern information' and the sender's name which appeared to include a reference to a clinical alert, it was not unreasonable for the complainant to assume the email was some sort of a clinical alert or contained safety information. Only on opening the email was it obvious that the email was promotional. The Panel considered that, on balance, the nature of the email was misleading and was disguised. The Panel therefore ruled breaches of the Code.

The Panel noted its comments and rulings above and considered that AstraZeneca had failed to maintain high standards and a further breach of the Code was ruled.

A consultant in anaesthesia and intensive care medicine, complained about the email promotion of Qtern (saxagliptin and dapagliflozin) by AstraZeneca UK Ltd. Qtern was indicated for adults aged 18 years and over with type 2 diabetes.

The email referred to the fixed dose combination (saxagliptin/dapagliflozin) which was priced at a 27% discount compared with the individual components. Details of the indications and benefits to health professionals were provided and that a budget impact model was available to demonstrate potential savings.

COMPLAINT

The complainant alleged that the email had been sent without prior permission; he/she already received too much spam and this just added to the list. As an intensive care consultant the information was not relevant to his/her practice and so the consultant queried why he/she received it. The complainant noted that the same message went to all of his colleagues with email addresses with a particular professional network, and junior doctors, and was a waste of time. The complainant submitted that new tablets for diabetes were not relevant to intensive care, and companies should take more care as to whom such information was sent.

The complainant alleged that the subject line of the email [AstraZeneca Qtern information] looked as if the email would have some important information about Qtern – there were some known safety concerns that would have been helpful to detail – but on opening the email it was just an advertisement; that was misleading and very disappointing.

The complainant was appalled to think that the whole of the professional network membership might have received the email at issue, when it was not relevant to most of them.

When writing to AstraZeneca, the Authority asked it to consider the requirements of Clauses 7.2, 9.1, 9.9, 11.1 and 12.1 of the Code. The complainant gave permission for his/her email address to be provided to AstraZeneca.

RESPONSE

AstraZeneca explained that it engaged a third party professional network, to distribute the email campaign in question to a subset of health professionals who had registered on the network website and who had:

- consented to receive promotional material from pharmaceutical companies about prescription only medicines; and
- indicated that they were professionals that fell into the broad category of payer.

AstraZeneca submitted that reasonable steps were taken to ensure that there had not been a breach of the Code in relation to the intended audience or initial impression of the email. However, despite receiving assurances from the professional network that appropriate consent had been obtained from all health professionals registered with it, AstraZeneca discovered that the historical consent process the complainant opted into was not of a standard the company expected, and in this regard it accepted a breach of Clause 9.9. AstraZeneca apologised to the complainant and thanked her for bringing this to its attention. It was now imperative that the third party made appropriate amends so that all health professionals who received information via its services, were appropriately consented to receive that information on behalf of AstraZeneca and the other companies that contracted with the third party.

Prior consent to receive promotional emails

AstraZeneca noted that when the email in question was sent, the complainant was registered with the third party professional network. Following permission granted by the complainant to allow the third party to share details of her opt-ins, including specialities and areas of interest, AstraZeneca ascertained that:

- The current registration process clearly clarified to users that they were opting-in to receive promotional emails from pharmaceutical companies about prescription only medicines. However, AstraZeneca's investigation had highlighted an issue with consent for those, including the complainant, who historically signed up to the third party before the existing registration process was in place.

- It appeared that the complainant registered on the third party website in 2002, and self-declared the specialty of anaesthetics and intensive care (dual accreditation). The consent process then to receive promotional emails from pharmaceutical companies was that users opted-in to receive 'external emails'. Unfortunately, the exact wording that users would have seen at the time had not been retained by the third party. The complainant had provided consent to receive 'external emails'. AstraZeneca provided confirmation of the services the complainant opted-in to receive at the point of, and post-registration in 2002. Examples of the type of material the recipient would have received were not available nor was consent validated annually. However, every email provided an opt-out option and users could proactively update their profiles and alter permissions at any time.

- In 2015, the third party updated its terms and conditions to include, *inter alia*, wording about 'Information from third parties' which was sufficient to obtain consent to send promotional emails from a pharmaceutical company about prescription only medicines. All registered members including the complainant were notified of this change on their logged-in account page and invited to update their profiles and permissions. However, members were not required to take any action to indicate that they agreed to receive such information.

- All emails sent by the third party included information on how to unsubscribe from receiving further emails. Since 2013 the complainant received 4 promotional emails via the third party, although under a different brand name, from different organisations. The complainant had now unsubscribed.

AstraZeneca submitted that the company had engaged the third party in good faith, believing that its opt-in process complied with the Code. However, the third party had not satisfactorily addressed the issue of historical membership. AstraZeneca considered that explicit consent was not specifically provided by the complainant to receive promotional content on products from pharmaceutical companies and thus AstraZeneca accepted a breach of Clause 9.9.

Objective and intended audience

AstraZeneca stated that the Qtern email in question was developed to inform senior NHS payers of relevant Qtern information and details of how to contact AstraZeneca's regional account managers for additional information. The content included the product indication and the cost benefit of the fixed dose combination compared with the mono-components. This information was therefore relevant to payer customers due to their potential impact on budgets and prescribing decisions. The intended audience was 'Managed Markets/Payers'.

AstraZeneca submitted that as the email was intended for payers, it took professional advice as to which of the third party's member specialities would fall in to this definition. Advice was sought indirectly from a primary care doctor and from a secondary care doctor as to which specialties, seniorities, and additional professional roles and organisation types would be appropriate to target as payers. A payers' group was created and agreed by AstraZeneca.

Health professionals registering with the third party professional network self-declared their speciality during the registration process, or could update their profile to include this at any time. All members whose self-declared roles matched those in the agreed payers group were identified. The works agreement was included as a supporting document during the review and certification process for the email to enable the signatories to review and agree the target audience.

The third party membership list numbers were provided and the number of those who had self-declared that they fell into one or more of the specialties included in the works agreement. Individuals with multiple qualifying specialties were eliminated from the list and AstraZeneca was satisfied that the remaining professionals were within the intended target audience and the certified email was sent in September 2017 to around 3,000 health professionals.

In February, 2017 the complainant updated the section 'Additional Professional Roles' in her profile to include 'Clinical Lead'. As a result of this self-declaration, and based on the payer group identified, the complainant was included in the payer group eligible for the email at issue. This was the first and only email that the third party professional network had sent to the complainant on behalf of AstraZeneca.

As the email was tailored to a payer audience and the complainant had self-declared herself into a speciality that was within the defined payer category, AstraZeneca submitted that the email was appropriate for the audience to which it was directed. Payers were often represented across medical specialities and had significant input into budgetary decisions that affected local budgets beyond their primary speciality. The information contained within the email referred to cost savings of Qtern vs its mono-components, thus the content of the email was relevant to payers and AstraZeneca denied a breach of Clause 11.1.

Subject heading

AstraZeneca stated that in 2013, the third party professional network rebranded its service via which promotional emails were sent on behalf of pharmaceutical companies. This service also sent emails in relation to safety, however, since 2013 the complainant had received four emails from this email address, all of which had been promotional. This raised the question as to why the complainant assumed that the email in question was related to safety given that she had never received safety-related emails from the third party and the subject line did not refer to such.

AstraZeneca did not consider the subject of the email 'AstraZeneca Qtern information' or the sender of the email, which appeared to include reference to a clinical alert, were misleading with respect to whether the email included any safety or other important information; the email subject did not contain the words 'urgent', 'important', or 'safety'. In addition, the email title was clear that the information was from AstraZeneca; the company denied a breach of Clauses 7.2 and 12.1.

Whilst AstraZeneca acknowledged that there had been a breach of Clause 9.9 in relation to the historical process used by the third party to gain explicit consent from the complainant to receive promotional emails from a pharmaceutical company, it had engaged the services of the third party in the belief that the current consent process was used to gain the complainant's consent. Given this, and that the company did not consider that there had been a breach of any other clause, AstraZeneca submitted that it had maintained high standards and thus it denied a breach of Clause 9.1. Furthermore, AstraZeneca had reviewed all planned activity with the third party, taken steps to ensure that the third party had identified all individuals who had consented before enactment of the existing consent process and would obtain re-consent accordingly.

Finally AstraZeneca believed that third parties, working on behalf of pharmaceutical companies, should be independently accredited and held to account according to PMCPA standards.

PANEL RULING

The Panel noted that Clause 9.9 required that, *inter alia*, email communications must not be used for promotional purposes, except with the prior permission of the recipient. Pharmaceutical companies were responsible under the Code and they needed to be certain that when using third parties their activities/materials complied with the Code. It was not for the PMCPA to accredit third parties.

The Panel noted AstraZeneca's submission that when the complainant registered on the third party website in January 2002, the consent process for agreeing to receive promotional emails from pharmaceutical companies was that users opted-in to receive 'external emails'. The exact wording that users would have seen at the time was not provided by AstraZeneca as it had not been retained by the third party.

The Panel considered that neither the historical consent process in 2002 nor the 2015 update amounted to the complainant consenting to the receipt of promotional emails from pharmaceutical companies. As AstraZeneca had not obtained prior permission to send the promotional email, the Panel therefore ruled a breach of Clause 9.9 as acknowledged by the company.

The Panel noted the complainant's concern regarding the relevance of the email which referred to the cost benefit of Qtern, a fixed dose combination, vs its individual components. The Panel considered that the email would be relevant to those who worked in the diabetes area and other payers, due to the potential impact on budgets and prescribing decisions. The intended audience was 'Managed Markets/Payers'.

The Panel noted that the complainant updated her details in the 'Additional Professional Roles' profile to include 'Clinical Lead' in February 2017. The Panel queried whether as a clinical lead in anaesthesia and intensive care medicine the complainant would be interested in the cost etc of medicines for diabetes or have any broader role in that regard. In the Panel's view, the email would be more likely to interest clinical leads in other specialities.

The Panel noted the supplementary information to Clause 11.1 that material should be tailored to the audience. The basis for sending information about

diabetes medicines to the complainant had not been made clear in the email in question. There was no mention that it had been sent to the complainant in relation to her role as a payer/clinical lead. The Panel considered that although information about diabetes medicines might be of interest to the complainant, the content of the email did not meet the requirements of Clause 11.1 in that complainant's need for, or interest in it could not reasonably be assumed. The Panel ruled a breach of Clause 11.1.

The Panel considered that given the subject of the email 'AstraZeneca Qtern information' and the sender of the email, which appeared to include a reference to a clinical alert, it was not unreasonable for the complainant to assume the email was some sort of a clinical alert or contained safety information. Only on opening the email was it obvious that the email was not a clinical alert but was promotional. The Panel considered that, on balance, the nature of the email was misleading and was disguised. The Panel therefore ruled breaches of Clauses 12.1 and 7.2 of the Code.

The Panel noted its comments and rulings above and considered that AstraZeneca had failed to maintain high standards and a breach of Clause 9.1 was also ruled.

Complaint received **9 September 2017**

Case completed **20 November 2017**