ANONYMOUS v PIERRE FABRE

Conduct of representative

An anonymous and non contactable complainant alleged that a representative from Pierre Fabre had sent unsolicited emails to NHS colleagues without consent. The complainant alleged that within the emails, of which the complainant did not have copies, the representative discussed and asked to meet to help set up 'oral chemotherapy' clinics for use within clinicians' respective departments.

The complainant considered that the emails were, and could be perceived as, promotional and no prescribing information was attached. The complainant asked if they had been formally certified and whether the representative had obtained permission from oncology pharmacists to communicate with them by email.

The complainant stated that he/she was quite concerned that the pharmaceutical industry, and this representative in particular, appeared not to have been briefed specifically about the use of email; the Code was very clear about the potential issues regarding emailing customers, and stressed that it was completely inappropriate to mention company products in emails of this nature.

The complainant asked if the representative had recently undergone any refresher training on the Code that stressed the importance of certifying all promotional material.

The detailed response from Pierre Fabre is given below.

The Panel considered that the complaint solely concerned emails which referred to oral chemotherapy clinics. The Panel noted Pierre Fabre's submission that such clinics were not a company product or service but part of a re-designed patient treatment pathway which was the responsibility of, and driven by, individual hospital trusts. In that regard the Panel considered that emails which did not refer directly or indirectly to oral chemotherapy clinics were not the subject of complaint.

The Code stated, *inter alia*, that email must not be used for promotional purposes except with the prior permission of the recipient. The Panel noted Pierre Fabre's submission that it did not distribute promotional material by email and so did not subscribe to email directories or otherwise provide representatives with email addresses from proprietary listings. Any email address used had been willingly provided by the recipient to facilitate communication in relation to, *inter alia*, meetings and appointments. The Panel noted that the relevant supplementary information explained that an enquiry received by email could be responded to by email without specific permission; consent to do so being implied.

The Panel examined the two sets of email traffic at issue. In the first series the representative sought a meeting to discuss potential company support for an oral chemotherapy service. There was a general reference to patient support packs. The Panel queried whether it was appropriate to refer, albeit generally, to patient support items in such an email as it might be seen as an inducement to gain an interview contrary to the Code. However, no details were provided about the items and they were not the subject of the complaint. There was no reference direct or indirect to Pierre Fabre's products. The second series of emails discussed a recent meeting where streamlining the patient pathway and best practice had been discussed. Again there was no reference to Pierre Fabre's products.

Whilst the Panel had some concerns about the emails it did not consider that either the first or second series were promotional on the narrow ground alleged. There was no reference direct or implied to Pierre Fabre's products. The recipients' permission as set out in the Code was thus not required and no breach of the Code was ruled. Prescribing information was not required and thus a further ruling of no breach of the Code was ruled. There was no evidence that the representative had failed to maintain high standards and no breach of the Code was ruled.

An anonymous and non contactable complainant was concerned about the conduct of a representative from Pierre Fabre Ltd.

COMPLAINT

The complainant stated that it had been drawn to his/her attention by his/her peers that the representative in question had sent unsolicited emails to NHS colleagues over the last few months and did not have consent, documented or otherwise, to do this.

The emails, of which the complainant did not have copies but was sure that Pierre Fabre's records would validate, showed that the representative had discussed and asked to meet to help set up 'oral chemotherapy' clinics for use within clinicians' respective departments.

The complainant submitted that these emails were, and could be perceived as, promotional and no prescribing information was attached. The complainant asked if they had been formally certified for distribution and whether it could be confirmed that the representative had obtained permission from local oncology pharmacists to communicate with them via email.

The complainant stated that he/she was quite concerned that the pharmaceutical industry, and this representative in particular, appeared not to have been briefed specifically about the use of email; the Code was very clear about the potential issues regarding emailing customers, and stressed that it was completely inappropriate to mention company products in any email of this nature.

The complainant asked if the representative had recently undergone any refresher training on the Code that stressed the importance of certifying all promotional material.

When writing to Pierre Fabre the Authority asked it to consider Clauses 4.1, 9.9 and 15.2 of the Code.

RESPONSE

Pierre Fabre explained that it had investigated this matter and developed a process for the analysis and scrutinised all email traffic from this territory and considered that the allegations were unfounded.

Pierre Fabre did not send promotional material by email and so did not subscribe to any database of email addresses for health professionals. Any email address that the company used had been willingly provided by the recipient. Email communication was only with a very small number of specialised NHS staff.

Pierre Fabre stated that it had discussed this matter with the representative involved and agreed that it would print all email traffic to and from its central email server. This was scrutinised and analysed according to the core function of the primary recipient and with respect to the Code (especially Clauses 9.9, 4.1 and 15.2).

1 Clinical: consultants, specialist registrar (meeting notices from senior medical staff)
2 Pharmacy: specialist oncology pharmacists
3 Nurse: specialist nurses (chemotherapy, disease specialists (lung/breast cancer))
4 Other: managers, primary care trust (PCT) administrators and some representatives from other companies (shared meetings).

The analysis of email traffic could only be that which originated from the Pierre Fabre representative as, along with the complainant, it had little or no access to any subsequent communication cascade.

Six hundred and twenty one emails were reviewed of which 22% were in the relevant territory which was a large geographic area and the majority of the representative's work and email traffic (78%) was elsewhere. A breakdown of regional email traffic was provided.

As the complainant purported to be a pharmacist, Pierre Fabre had concentrated on describing email traffic with pharmacy although similar scrutiny was applied elsewhere. There were 24 emails to and from pharmacists and these were in 4 series. The usual length of each exchange was 5 emails. The long series in one city involved little input from the representative (mainly consultant/pharmacist within the hospital, copying in the representative). A further analysis of email sent to regional pharmacists was provided.

Pierre Fabre's office manager and managing director scrutinised the email content. The first email in each series had been studied for evidence that it might be unsolicited or promotional. A detailed breakdown was provided.

From the 4 email series, the first email referred to a specific earlier meeting and agreed action. The nature, content and duration of each exchange did not suggest that any were unsolicited (Clause 9) or used as promotional material requiring certification (Clause 4).

The representative in question had over 15 years' experience in the pharmaceutical industry spent mostly in a 'top 10' company and in oncology. This experience also included a period with management responsibilities, which included adherence to the Code by colleagues. The representative had passed the ABPI examination, was very familiar with the Code and adherence to both the letter and spirit of the Code was clearly demonstrated in all aspects of his/her work, conduct and communication.

Pierre Fabre's training included sessions on the Code adherence and all representatives received refresher training annually from an external agent. Pierre Fabre had no concerns regarding the awareness and understanding of the Code or the integrity of this very professional representative.

Pierre Fabre considered that it was very unfortunate that the complainant did not have any of the emails at issue and was unable to specify any detail other than help with oral chemotherapy clinics.

The subject of 'oral chemotherapy' was a part of a more general service re-design and modernisation programme and was an area of significant professional interest to the Department of Health (Quality, Innovation, Productivity and Prevention (QIPP), National Chemotherapy Advisory Group (NCAG), hospital trusts, commissioners and all professional bodies involved in the patient pathway (clinicians, nurses, managers and pharmacists)) and the privatisation of hospital outpatient pharmacy services. Other companies had also aligned their activities to support the NHS in this field. Given the opportunities for professional development within pharmacy, nursing and management associated with similar service re-design, Pierre Fabre highlighted that significant email traffic might be initiated and developed by NHS staff within each trust and without Pierre Fabre (or other company) involvement.

In response to a request for further information, Pierre Fabre explained that the matter had been discussed in detail with the representative involved. The analysis of the representative's external email traffic was for the whole territory in 2011 (to the date Pierre Fabre received the complaint) and the

omission of some areas was intended to streamline analysis and aid interpretation. Further details of email traffic in a greater regional area were provided.

Other areas of this territory (43% of email traffic) were outside the regions specified in the complaint. Pierre Fabre did not visit every hospital in the region.

Email was a preferred route of communication for most people in all aspects of business, including the pharmaceutical industry. The Code permitted email to be used for business and it was the responsibility of the industry to ensure that it was used appropriately.

The Code did not define 'non-promotional'. In its analysis, the content of each email was scrutinised to determine if it was 'promotional' to the point where it would require certification according to Clause 4, assessed to determine if the email complied with Clause 9.9 by looking for evidence to establish that there was an existing relationship or dialogue with the representative or company as a direct result of earlier meetings or discussions and compliant with Clauses 15.1 and 15.2 to demonstrate adequate knowledge of product and the standard of ethical conduct.

Pierre Fabre submitted that its representatives were strongly discouraged from using email to refer to any of the company's products by name (proprietary or non-proprietary), indications, dosages, costs, packs sizes or legal status, even when this might be permitted by the supplementary information to Clause 9.9. This fundamentally changed the nature of representative email and reduced the risk of email being used for promotion. With one exception, a clarification of a dose titration within an existing protocol (discussed below), none of the above information appeared in the representative's email and Pierre Fabre did not identify any email that required certification.

The exception mentioned above was one email in a sequence of two that contained a clarification of the recommended dose titration (a copy of the email was provided). This email exchange was with a pharmacist responsible for an established oral treatment service that obviously included, but was not limited to, a Pierre Fabre product. This was not considered to require certification and was considered to be compliant with Clause 15.1.

Two other references were made to 'oral chemotherapy clinics' in other email exchange series. Pierre Fabre highlighted that oral chemotherapy clinics were not a Pierre Fabre 'product' but a contemporary patient treatment pathway that required some re-alignment of medical, pharmacy, nursing and commissioning activity within the outpatient pathology/chemosuite/ pharmacy/hospital management to achieve. It was a management process within the hospital and although representatives from Pierre Fabre and other companies might be involved in some practical details, the responsibility and drive for this was universally down to the professional development of the health professionals and managers within the hospital trust.

Both email series that mentioned 'oral chemotherapy clinics' were included in this clarification submission. None included any product specific information (eg the name of Pierre Fabre's medicine) that would trigger the need for certification.

The first series mentioned an oral chemotherapy service that was already established within the hospital and included the use of several oral medicines (from different manufacturers and generics) and was not exclusive to Pierre Fabre. Pierre Fabre had previously provided patient briefing material to this clinic and this email communication explored the need to re-establish this service to the hospital. The aim of this exchange was to arrange an appointment between consenting adults and was successful.

The second series strongly suggested a pre-existing dialogue. The content did not include any information that would require formal certification as promotional material. The reference to an oral chemotherapy clinic was to highlight opportunities to observe professional developments that had already been made in an adjacent hospital.

As mentioned earlier, oral chemotherapy pathways were a management process and, given the multi-disciplinary nature of cancer treatment (doctor, nurse, pharmacist, manager), they could be hard to establish. When a centre had established this pathway, it was usually very proud of its achievements and often published or presented its experience and hosted visits from other centres. The above email exchange was considered to be the encouragement of inter-professional dialogue and was not considered to require certification.

Pierre Fabre did not distribute approved promotional material by email and did not subscribe to email directories or provide representatives with email addresses from proprietary listings. This removed an important risk of improper use of email. Any email addresses used by company representatives had been offered by the recipient to facilitate communication on matters of mutual interest, most usually relating to meetings, patient support (safety) items and appointments, ie acceptable electronic communication within the Code.

In the analysis conducted for the territory, Pierre Fabre was satisfied that the initial email was a direct result of an earlier meeting, a direct introduction from a hospital colleague and/or contained information that strongly suggested a pre-existing relationship with its representative or with the company (eg a support for an existing treatment service). Pierre Fabre did not find any evidence that any email might be unsolicited or unwelcome.

Cytotoxic chemotherapy for cancer treatment was associated with significant and potentially life threatening toxicity and its use was restricted to specialist centres only. Doses were calculated for each individual and support therapies were required before, during and after use of these products. It was essential that representatives were well trained

and it was satisfied that this individual was competent and proficient.

There was no evidence that email had been misused or abused. The only mention of product specific detail was a clarification of a dose escalation in an established protocol. This was appropriate and Pierre Fabre considered it had complied with Clauses 15.1 and 15.2.

Pierre Fabre stated that in its view it was strange that an 'anonymous' and uninvolved third party observer who did not have access nor was copied in on any of the electronic correspondence, despite the obvious ease with which this could be achieved, had complained. It also seemed strange that the complaint was based on a treatment delivery system that was already established in many NHS hospitals and included many products from different manufacturers and generics. Pierre Fabre noted that the NHS had rapidly privatised hospital outpatient pharmacies. This had created professional tensions between the few remaining NHS pharmacists in some hospitals and between other hospitals that had tried to retain their NHS based pharmacy systems. This tension was unrelated to the activity of a pharmaceutical representative from any company and it would be inappropriate for the industry to be targeted as a distraction from unrelated events. Given the nature of this complaint and the conduct of the complainant, Pierre Fabre considered that this was an important point for the PMCPA to consider.

In conclusion, Pierre Fabre hoped this additional information satisfied the Panel that Pierre Fabre upheld the spirit of the Code in its activities. Pierre Fabre considered that this complaint was not justified, was inappropriate and unfounded.

PANEL RULING

The Panel considered that the complaint solely concerned emails which referred to oral chemotherapy clinics. The Panel noted Pierre Fabre's submission that such clinics were not a company product or service but part of a re-designed patient treatment pathway which was the responsibility of, and driven by, individual hospital trusts. In that regard the Panel considered that the email series from October 2011 which did not refer directly or indirectly to oral chemotherapy clinics were not the subject of complaint.

Clause 9.9 stated, *inter alia*, that email must not be used for promotional purposes except with the prior permission of the recipient. The Panel noted Pierre Fabre's submission that it did not distribute promotional material by email and so did not subscribe to email directories or otherwise provide representatives with email addresses from proprietary listings. Any email address used had been willingly provided by the recipient to facilitate communication in relation to, *inter alia*, meetings and appointments. The Panel noted that the supplementary information to Clause 9.9 explained that an enquiry received by email could be responded to by email without specific permission; consent to do so being implied.

The Panel noted Pierre Fabre's submission that evidence of an existing relationship or dialogue with the representative or company as a direct result of previous meetings or discussion allowed it to assess compliance with Clause 9.9. In the Panel's view such factors did not determine whether the emails were promotional nor whether the requisite permission to send promotional emails was necessary and had been obtained. The Panel was concerned that the criteria used to determine whether representatives' email traffic was promotional were inadequate and lacking in detail.

The Panel examined the two sets of email traffic at issue. In the first series from July 2011 the representative sought a meeting to discuss potential company support for the oral chemotherapy service. There was a general reference to patient support packs. The Panel queried whether it was appropriate to refer albeit generally to patient support items in such an email. Such references might be seen as an inducement to gain an interview contrary to the provisions of Clause 15.3. However, no details were provided about the items and they were not the subject of complaint. There was no reference direct or indirect to Pierre Fabre's products. The second series of emails, dated July and October 2011, discussed a recent meeting where streamlining the patient pathway and best practice had been discussed. Again there was no reference to Pierre Fabre's products.

Whilst the Panel had some concerns about the emails it did not consider that either the first or second series were promotional on the narrow ground alleged. There was no reference direct or implied to Pierre Fabre's products. The recipients' permission as set out in Clause 9.9 was thus not required. No breach of Clause 9.9 was ruled. Prescribing information was not required and thus no breach of Clause 4.1 was ruled. There was no evidence that the representative had failed to maintain high standards. No breach of Clause 15.2 was ruled.

During its consideration of this case, and irrespective of its rulings above, the Panel was concerned about the company's submission on promotional content and representatives' emails. The company should always be mindful of the representative's promotional role and the impression given to health professionals in this regard.

Complaint received **3 November 2011**

Case completed **26 January 2012**