ANONYMOUS v FLYNN PHARMA

Promotion of Medikinet

An anonymous complainant stated that he had received some inappropriate mailings from Flynn Pharma regarding Medikinet, a product for attention deficit hyperactivity disorder (ADHD). The complainant did not and had never treated ADHD. He had also received a reply paid card (RPC) and a representative had telephoned him requesting an appointment. It did not state on the RPC anything about having to grant a representative an appointment. A colleague had been given a drug and therapeutics committee application form by a representative; the complainant understood that these should not be handed out by representatives. The colleague was also provided with a clinical paper in German, and was told that there was no English translation.

The complainant had also been invited to a meeting and considered this was inappropriate as he did not treat ADHD. The complainant requested that the company be more specific with its targeting.

The Panel noted that the Code required promotional material to be sent or distributed to those people whose need for, or interest in, the particular information could reasonably be assumed; it should be tailored to the audience to whom it was directed. Medikinet XL treatment had to be supervised by a specialist in childhood behavioural disorders. The introductory mailing was sent to doctors whose names were on a commercial database of child psychiatrists and paediatricians. The Panel considered that although the first group were likely to initiate treatment, general paediatricians were likely to be responsible for maintaining treatment under the supervision of such a specialist. In the Panel's view, although the mailing was mainly aimed at the primary prescriber the distribution of the mailing was not unreasonable. Both psychiatrists and paediatricians would become involved in treatment. It was not in the interests of a company to promote a product other than to those who would need to be familiar with it. No breach of the Code was ruled.

The Panel noted that it knew neither the identity nor the professional status of the complainant. The complainant had stated that (s)he did not and had never treated ADHD. The Panel did not know, however, if the complainant was such that (s)he might reasonably be assumed to be responsible for some patients with ADHD who stayed under the supervision of a specialist. The Panel did not think it was unreasonable for a representative to seek an appointment with such individuals; such requests should comply with the Code. The complainant had provided a copy of a completed RPC from which it appeared that (s)he had requested a memory stick and reprints of key papers. There was no evidence that the representative had subsequently attempted to use the materials as an inducement to gain an interview. The complainant was anonymous and had provided no contact details and so it was impossible to seek further information from him/her, or from the representative, about what was said during the telephone call. There was no evidence that the representative had repeatedly tried to see the complainant or that any inducement or subterfuge had been employed. No breach of the Code was ruled.

The complainant referred to a drug and therapeutics application form provided to a colleague by a representative. This application form gave a detailed profile of Medikinet. The company stated that this form was normally provided on request. No information about the circumstances of its provision was provided by the complainant. No breach of the Code was accordingly ruled.

The Panel noted Flynn's explanation that as the drug and therapeutic application form cited a paper published in German the original reference was included to substantiate the point made. In the Panel's view this was not helpful and an English translation should have been provided. There was no information about whether the complainant's colleague had requested substantiation for a claim etc. It appeared from Flynn's submission that the German reference was always supplied with the drug and therapeutics document. The Panel did not consider there had been a breach of the Code in this regard. If a request for substantiation had been made then the company would have had to supply substantiation in English.

An anonymous complainant complained about material he and his colleagues had received from Flynn Pharma Ltd about Medikinet (controlled release methylphenidate) and telephone calls made by one of the company's representatives. Copies of a mailing which included a reply paid card (RPC) and a document entitled 'New Medicines Profile D&T Application – Medikinet XL' were provided together with a clinical paper published in German, Döpfner *et al*.

COMPLAINT

The complainant explained that he had recently received some inappropriate mailings from Flynn Pharma regarding Medikinet, a product for attention deficit hyperactivity disorder (ADHD). The complainant did not and had never treated ADHD. He also received an RPC and a representative had

telephoned him requesting an appointment. It did not state on the RPC anything about having to grant a representative an appointment. This had also happened to a colleague who had also been given a drug and therapeutics committee application form from a representative. He understood that this was considered a piece of medical information and should not be handed out by representatives. The complainant's colleague had also been given a clinical paper in German, and was told that there was no English translation. The complainant was unsure how this stood with the Code, but observed that it was of no use whatsoever.

The complainant had also been invited to a meeting on 4 June. Again this was totally inappropriate as he did not treat ADHD.

The complainant requested that the company be more specific with its targeting as this was becoming a hassle and a waste of his time.

Flynn was asked to respond to Clauses 12.1 and 15.3 of the Code.

RESPONSE

Flynn explained that Medikinet XL was launched in the UK in March 2007. An introductory mailing was sent to child psychiatrists and paediatricians, these being the prescribing groups that might initiate and manage treatment of ADHD. Flynn noted that Clause 12.1 required promotional material only to be sent to those categories of persons whose need for, or interest in, the particular information could be reasonably assumed (emphasis added). Doctors' names were taken from a commercial database of such professionals. Unfortunately there was no precise way of targeting health professionals, particularly those within a sub-speciality, but the company considered its approach to be sensible and reasonable. It would, of course, remove any health professionals from such mailing lists if it knew this was not a relevant interest area, or upon their request. An RPC attached to the mailing stated 'Please complete the reply-paid card if you would like to receive this valuable source of information' (ie further information on Medikinet XL provided on a memory stick). There was no requirement to complete or return the RPC. It was unclear from the complaint whether the complainant had done so, but a returned RPC would have indicated interest. Equally, the company hoped that a health professional who was targeted in an area outside their professional interest would not return the RPC and/or advise the company that they were not a relevant contact.

In relation to Clause 15.3 the company submitted that it did not believe the complainant had made any assertions that this was the case and respectfully submitted that there was no case to answer. The company categorically stated that, with regard to its promotional activities, there was no instruction to provide any inducements to grant or attend a meeting, prescribe a particular product or take any action in regard to Flynn, its products, services or employees.

Flynn explained that the drug and therapeutics document referred to certain data published in German and consistent with good practice, the original reference was included to substantiate the particular point made. Flynn's policy was that these were normally only issued on request. It was not, to Flynn's knowledge, an issue per se, that representatives passed or communicated medical information, which was one of the points raised by the complainant.

The complainant did not describe the circumstances leading up to the provision of the drug and therapeutics paper, but as previously stated, such items were normally provided upon request. Also Flynn did not consider it improper or inconsistent with the Code for a representative to issue 'medical information' materials. Indeed Flynn thought a situation where a representative did not or could not, would more readily provide grounds for complaint.

Given the anonymity of the complainant, the company was unable to remove their name from a contact or mailing list, but would be happy to do so. It was not in the company's interests to contact health professionals outside the field of interest and it had no wish to cause unnecessary inconvenience through such contact. Flynn had already discussed the case in general terms with the representatives to remind them of the need to ensure targeted doctors and health professionals were relevant and working within ADHD. This was simply good professional business sense.

In summary, Flynn respectfully submitted there was no case to answer with regard to a breach of the Code. This did not detract however from the fact that a health professional had complained to the Authority. Flynn apologised to the complainant for the inconvenience caused; if (s)he disclosed their identity, then the company would remove their name from its contacts database.

PANEL RULING

The Panel noted that Clause 12.1 and its supplementary information required promotional material to be sent or distributed to those categories of persons whose need for, or interest in, the particular information could reasonably be assumed. Promotional material should be tailored to the audience to whom it was directed. The Panel noted from the drug and therapeutics application form that Medikinet XL treatment had to be supervised by a specialist in childhood behavioural disorders. The introductory mailing was sent to doctors whose names were on a commercial database of child psychiatrists and paediatricians. The Panel considered that although the first group were likely to initiate treatment, general paediatricians were likely to be responsible for maintaining treatment under the supervision of such a specialist. In the Panel's view, however, the mailing at issue was mainly aimed at the primary prescriber – it was an introductory mailing. Nonetheless, the Panel did not consider that the distribution of the mailing was unreasonable. It had been sent to child psychiatrists and paediatricians – classes of health professionals who would become involved in

treatment. It was not in the interests of a company to promote a product other than to those who would need to be familiar with it. No breach of Clause 12.1 was ruled.

The Panel noted that it knew neither the identity nor the professional status of the complainant. The complainant had stated that (s)he did not and had never treated ADHD. The Panel did not know, however, if the complainant was such that (s)he might reasonably be assumed to be responsible for some patients with ADHD who stayed under the supervision of a specialist. Any material directed at such groups of people must be tailored to their needs. The Panel did not think it was unreasonable for a representative to seek an appointment with such individuals. Any such requests should comply with the Code. The complainant had provided a copy of a completed RPC from which it appeared that (s)he had requested a memory stick and reprints of key papers. There was no evidence that the representative had subsequently attempted to use the materials as an inducement to gain an interview. The complainant was anonymous and had provided no contact details and thus it was not possible to seek further information from him/her, or from the representative, about what was said during the telephone call. There was no evidence that the representative had repeatedly tried to see the complainant nor that any inducement or subterfuge had been employed. No breach of Clause 15.3 was ruled.

The complainant referred to a drug and therapeutics application form provided to a colleague by a representative. This application form detailed Medikinet, its formulation, indications, formulary implications, dose/administration, efficacy, safety, treatment alternatives including cost and its place in therapy. The company stated that this form was normally provided on request. No information about the circumstances of its provision was provided by the complainant. The company had been asked only to respond to Clauses 12.1 and 15.3. No breach of these clauses was accordingly ruled.

The Panel noted Flynn's explanation that as the drug and therapeutic application form cited a paper published in German the original reference was included to substantiate the point made. In the Panel's view this was not helpful and an English translation should have been provided. There was no information about whether the complainant's colleague had requested substantiation for a claim etc. It appeared from Flynn's submission that the German reference was always supplied with the drug and therapeutics document. The Panel did not consider there had been a breach of the Code in this regard. If a request for substantiation of a claim etc had been made then Clause 7.5 would apply and the company would have had to supply substantiation in English. The Panel asked that Flynn be advised of its concerns in this regard.

Complaint received	**7 June 2007**
Case completed	**4 July 2007**