

# THERAPIST v SANOFI

## Provision of information

A clinical hypnotherapist/psychoanalyst/behavioural therapist alleged that Sanofi had been obstructive in that it had refused to provide information about Clexane (enoxaparin) when he had telephoned the company. Clexane was marketed for, *inter alia*, the prophylaxis of thromboembolic disorders of venous origin, in particular those which might be associated with orthopaedic or general surgery, and the prophylaxis of venous thromboembolism in medical patients bedridden due to acute illness.

The complainant, who had previously suffered thromboembolic events, had wanted to know the best time to inject himself with Clexane prior to a nine hour flight. Although the complainant understood that Sanofi had 'lots of data' regarding pre-flight use, it would not pass any on to him; the company asked him to ask his doctor to call but this was somewhat difficult.

The detailed response from Sanofi is given below.

The Panel noted that the complainant had called Sanofi's medical information department in relation to his possible personal use of Clexane prior to a nine hour flight. The complainant had wanted to know how long beforehand he should inject the medicine. There was no relevant information in the SPC and it appeared that Clexane was not indicated for the prevention of venous thromboembolic events in such circumstances. The Panel noted that the complainant did not appear to be a health professional.

The Panel noted Sanofi's submission that the medical information officer concerned had informed the complainant that whilst there was data on the use of Clexane prior to long journeys, the company could not comment on his personal medical situation and he would need to ask his own doctor or pharmacist for advice on what dosing regimen to use. The Panel further noted Sanofi's submission that the medical information officer also stated that if the complainant's doctor or pharmacist required more information Sanofi would be happy to supply it to them if they contacted the company.

Given that the enquiry related to a personal medical matter, the Panel considered that Sanofi had complied with the requirements of the Code; no information was supplied to the complainant with regard to Clexane's use in venous thromboembolism. The Panel ruled no breaches of the Code.

A clinical hypnotherapist/psychoanalyst/behavioural therapist complained about the lack of information he had been given when he had telephoned Sanofi about the use of Clexane (enoxaparin) prior to a long journey.

Clexane was marketed for, *inter alia*, the prophylaxis of thromboembolic disorders of venous origin, in particular those which might be associated with orthopaedic or general surgery, and the prophylaxis of venous thromboembolism in medical patients bedridden due to acute illness.

## COMPLAINT

The complainant stated that he telephoned Sanofi to find out the best time to inject Clexane prior to a nine hour flight. The complainant submitted that he was told that Sanofi had 'lots of data' regarding pre-flight use, however Sanofi had stated that it would not pass this information to him. The complainant stated that his GP and pharmacist had no idea what time parameter to use this medicine. Sanofi told the complainant that he would have to get his doctor to call, which was somewhat difficult.

The complainant submitted that on the Sanofi website there was an abundance of clinical information regarding Clexane, mainly pre- and post-operative care.

The complainant submitted that as he had suffered previous DVTs [deep vein thrombus] and pulmonary embolism, it would be pertinent (considering he was injecting himself) to understand recent relevant data on this subject. He also considered this information should be included for many hundreds of people who had been prescribed this medicine. There seemed to be an obstructive element in providing important information.

When writing to Sanofi, the Authority asked it to respond in relation to Clauses 22.2, 22.3 and 9.1 of the Code.

## RESPONSE

Sanofi confirmed that the complainant had telephoned its medical information department about his treatment with Clexane; he wanted to know the correct time to administer the injection in relation to flights and long car journeys.

Sanofi submitted that whilst Clexane was licensed for the prophylaxis of thromboembolic disorders of venous origin, in particular those associated with orthopaedic or general surgery, the summary of product characteristics (SPC) did not give a specific dosing regimen for the prevention of in-flight thrombosis. The complainant was thus informed that whilst Sanofi knew of data detailing the use of Clexane in this particular indication, it was unable to comment on his personal medical situation and he would need to ask his own doctor or pharmacist for advice on what dosing regimen to use. Sanofi submitted that the medical information officer stated

that if the complainant's doctor or pharmacist required more information, Sanofi would be happy to supply it to them in response to a direct request.

Sanofi submitted that it was unable to comment on the complainant's assertion that its website contained 'an abundance of clinical information regarding Clexane' as the only UK specific website ([www.sanofi.co.uk](http://www.sanofi.co.uk)) did not contain any clinical data regarding Clexane but did include the SPC.

Sanofi stated that as the complainant asked for advice on a personal medical matter, it considered that its medical information officer had acted appropriately.

In summary, Sanofi denied any breach of the Code. Clause 22.3 was clearly adhered to as the patient was referred back to his own health professional for advice. Sanofi could not see the relevance of Clause 22.2 as no information was provided directly to the patient and Sanofi did not make any information available indirectly. Sanofi submitted that high standards had been maintained and therefore there was no breach of Clause 9.1.

#### **PANEL RULING**

The Panel noted that the complainant had called Sanofi's medical information department in relation to his possible personal use of Clexane prior to a nine hour flight. The complainant had wanted to know how long beforehand he should inject the medicine. There was no relevant information in the SPC and it appeared that Clexane was not indicated for the prevention of venous thromboembolic events in such circumstances.

The Panel noted that the complainant was a clinical hypnotherapist/psychoanalyst/behavioural therapist.

On the information provided by the complainant he did not appear to be a health professional. The term 'health professional' in the Code included members of the medical, dental, pharmacy and nursing professions and any other person who in the course of their professional activities might prescribe, supply or administer a medicine.

Clause 23.2 required that requests from individual members of the public on personal medical matters be refused and the enquirer recommended to consult his or her own doctor, other prescriber or other health professional. The Panel noted Sanofi's submission that the medical information officer concerned had informed the complainant that whilst Sanofi was aware of data on the use of Clexane prior to long journeys, it was unable to comment on his personal medical situation and he would need to ask his own doctor or pharmacist for advice on what dosing regimen he should use. The Panel further noted Sanofi's submission that the medical information officer also stated that if the complainant's doctor or pharmacist required more information Sanofi would be happy to supply it to them if they contacted the company.

Given that the enquiry related to a personal medical matter, the Panel considered that Sanofi had complied with the requirements of Clause 22.3 and ruled no breach of that clause. As no information was supplied to the complainant with regard to Clexane's use in venous thromboembolism, the Panel ruled no breach of Clause 22.2. The Panel noted its rulings above and consequently ruled no breach of Clause 9.1.

<b>Complaint received</b>	<b>29 February 2012</b>
<b>Case completed</b>	<b>11 April 2012</b>