

# GENERAL PRACTITIONER AND PHARMACIST v STIEFEL

## Sponsored journal insert

A general practitioner and a pharmacist jointly complained about an insert on the management of mild and moderate acne vulgaris which had been published in GP journal. Stiefel marketed Duac Once Daily Gel (clindamycin 1% and benzoyl peroxide 5%) which was indicated for the treatment of mild to moderate acne vulgaris, particularly inflammatory lesions.

The complainants had previously alleged, *inter alia*, that the GP insert was disguised promotion for Duac (Case AUTH/2244/6/09). When the Authority had informed Stiefel of that complaint the company was not asked to consider the requirements of Clause 2; the complainants had not implicitly or explicitly alleged a breach of Clause 2. Due to a procedural error, the Panel nonetheless ruled a breach of Clause 2 which was consistent with other recent cases regarding sponsored inserts. The parties were informed of the initial ruling of a breach of Clause 2 and then the following day when the error was discovered by the Authority, immediately informed of the error and told that the ruling was null and void.

The complainants stated that whilst they did not specifically require Clause 2 to be considered in Case AUTH/2244/6/09, it did not negate its relevance. Indeed, as noted by the Authority there were recent precedents for this regarding company sponsored inserts purporting to be independent. Disguised promotion warranted a Clause 2 ruling. The complainants requested that the GP journal insert be subject to a complaint with regard to a breach of Clause 2 of the Code.

The detailed response from Stiefel is given below.

The Panel noted that the procedural error made in Case AUTH/2244/6/09 was unacceptable and should not have occurred. The procedural error had been discovered by the Authority, the ruling amended and the parties informed.

The Panel noted Stiefel's submission that Case AUTH/2255/8/09 had been pre-judged to be in breach; this was not so. Stiefel had not previously had the opportunity to make a detailed submission on the alleged breach of Clause 2. Any comments by Stiefel could now be considered by the Panel.

The Panel noted Stiefel's submission and its amended ruling in Case AUTH/2244/6/09. The Panel considered that the presentation of the insert was such as to reduce confidence in, and bring discredit upon the pharmaceutical industry. A breach of Clause 2 was ruled.

A general practitioner and a pharmacist jointly complained about an insert on the management of mild and moderate acne vulgaris which had been published in GP journal and provided as a service to medicine by Stiefel Laboratories. Stiefel's product Duac Once Daily Gel (clindamycin 1% and benzoyl peroxide 5%) was indicated for the treatment of mild to moderate acne vulgaris, particularly inflammatory lesions.

The complainants had previously alleged, *inter alia*, that the GP insert was disguised promotion for Duac (Point 9 in Case AUTH/2244/6/09). When the Authority had informed Stiefel of that complaint it had asked the company to consider the requirements of a number of clauses but had not cited Clause 2; the complainants had not implicitly or explicitly alleged a breach of Clause 2. Due to a procedural error, the Panel nonetheless ruled a breach of Clause 2 which was consistent with other recent cases regarding sponsored inserts. The parties were informed of the initial ruling of a breach of Clause 2 and then the following day when the error was discovered by the Authority they were immediately informed of the procedural error and told that ruling was null and void.

### COMPLAINT

The complainants stated that whilst they might not have specifically required Clause 2 to be considered in Case AUTH/2244/6/09, it did not negate its relevance and the Panel was at liberty to require Stiefel to also consider the breach of this clause of the Code in respect of the GP insert. Indeed, as the Authority had noted in its explanatory letter, there were recent precedents for this regarding company sponsored inserts purporting to be independent. Disguised promotion warranted a Clause 2 ruling. The complainants requested that the GP journal insert be subject to a complaint with regard to a breach of Clause 2 of the Code.

### RESPONSE

Stiefel noted that it had accepted the Panel's ruling in Case AUTH/2244/6/09 in which the GP journal insert was ruled in breach of Clauses 9.10 and 12.1 but not Clause 2.

Stiefel submitted that it concurred with the Panel's ruling because although the company was motivated to sponsor the Acne Working Group to meet a genuine need for a set of UK guidelines for the management of acne in general practice (and the opinions expressed in it were those of the experts not the company's) the printing of the company logo with the statement 'Provided as a service to medicine

by Stiefel' did not describe the full extent of the company's involvement. All materials mentioned in the complaint and all other materials related to the subject of the complaint were immediately withdrawn. Stiefel submitted that it had reviewed its processes and implemented further training to ensure its materials complied with the Code.

Stiefel believed that this case, Case AUTH/2255/8/09, and Case AUTH/2244/6/09, were one and the same as the initial ruling included a breach of Clause 2. This breach was subsequently withdrawn by the Authority as it was not part of the original complaint. The complainants were so informed and this prompted them to formally allege a breach of Clause 2.

Stiefel believed that Case AUTH/2255/8/09 had been already been pre-judged to be in breach of Clause 2. Therefore as the company had no additional points to make in submission to this fresh complaint, and in order to dispose of this case expeditiously, it considered that it had no option but to accept a breach of Clause 2.

#### **PANEL RULING**

The Panel noted that the procedural error made in Case AUTH/2244/6/09 was unacceptable and should not have occurred.

The Panel noted that in complaints from outwith the industry, or in cases arising from published criticism of the industry, the Director could ask the respondent company to consider the requirements of those clauses of the Code which were considered relevant to the matters raised (Paragraphs 5.1 and 6 of the Constitution and Procedure). The Panel could subsequently only make rulings under those clauses identified to the respondent company.

The Panel noted that the complainants had not alleged a breach of Clause 2 in Case AUTH/2244/6/09 and although a ruling of a breach of that clause might be consistent with other recent cases

regarding sponsored inserts, Clause 2 was not raised in the initial correspondence with Stiefel and so the Panel could not make a ruling under that clause. In the absence of a specific allegation, the only action available to the Panel was to draw Stiefel's attention to its concerns in that regard. The procedural error had been discovered by the Authority. Action was taken to correct the procedural error and the parties were informed. The Panel had amended its ruling such that its raised concerns about Clause 2. The relevant paragraph was as follows: 'During the consideration of this matter the Panel was concerned to note that sponsored journal supplements which had similarly been ruled in breach of the Code because they were considered to be disguised promotion had also been ruled in breach of Clause 2. The Panel could not consider such a ruling in this case because the complainants had not explicitly or implicitly alleged that the supplement reduced confidence in or brought discredit upon the industry and so Stiefel had not been asked to consider the requirements of Clause 2. Nonetheless, the Panel requested that Stiefel be advised of its concerns in this regard.'

#### **Case AUTH/2255/8/09**

The Panel noted Stiefel's submission that Case AUTH/2255/8/09 had been pre-judged to be in breach; this was not so. Stiefel had not previously had the opportunity to make a detailed submission on the alleged breach of Clause 2. Any comments by Stiefel could now be considered by the Panel.

The Panel noted Stiefel's submission and its amended ruling in Case AUTH/2244/6/09. The Panel considered that the presentation of the insert was such as to reduce confidence in, and bring discredit upon the pharmaceutical industry. A breach of Clause 2 was ruled.

**Complaint received**                      **4 August 2009**

**Case completed**                              **18 September 2009**

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