CASE AUTH/2244/6/09

GENERAL PRACTITIONER AND PHARMACIST v STIEFEL

Promotion of Duac

A general practitioner and a pharmacist jointly complained about the promotion of Duac Once Daily Gel (clindamycin 1% and benzoyl peroxide 5%) by Stiefel. The materials at issue were a GP leavepiece; a pharmacist leavepiece; two journal advertisements; two abbreviated advertisements and a GP Review, January 2008, Management of mild and moderate acne vulgaris. Duac was indicated for the treatment of mild to moderate acne vulgaris, particularly inflammatory lesions.

The detailed response from Stiefel is given below.

One of the complainants telephoned Stiefel's medical information department on 29 May to ask for copies of references cited in the Duac promotional materials: The company was not cooperative: The medical information person could not give an assurance that she could provide the cited data-on-file as it might not be available. After much insistence and reference to the Code, the complainant was finally assured that the request would be treated as urgent. Over two weeks later the information had not been received.

The Panel noted that there was disagreement as to what had been requested. It was impossible to know what exactly transpired between the parties. Nonetheless two cited references had been posted one week after the initial request for papers. Unfortunately the house number recorded on the telephone enquiry report was wrong by one digit and thus the package was returned to Stiefel marked 'addressee unknown'. It was unfortunate that the wrong address had been recorded however, in the Panel's view, such an error did not constitute a breach of the Code. References had been posted in a timely manner and so no breach of the Code was ruled. This was upheld by the Appeal Board following an appeal by the complainants.

The complainants alleged that the GP leavepiece was inconsistent with the indication of Duac Once Daily Gel, in that it depicted an acne grading chart which featured not only inflammatory lesions but also, non-inflammatory and nodulocystic lesions. That the chart featured severe lesions misleadingly implied that Duac could be used for other than mild to moderate acne.

The Panel considered that Duac an acne grading chart showing all the grades of acne was useful so that a prescriber could tell when the condition was too severe to be treated with Duac. Nonetheless, if all grades of acne were to be shown, prescribers must be very clearly informed of when to use Duac; in that regard the Panel considered that a double-headed arrow spanning the pictures of mild to moderate acne and the statement in the prescribing information that Duac was for mild to moderate acne were insufficient. Some readers might assume that Duac could be used for severe acne. The Panel considered that the leavepiece was inconsistent with the particulars listed in the Duac summary of product characteristics (SPC). A breach of the Code was ruled. The Panel further considered that the leavepiece was misleading about the product's licensed indication and in that regard did not encourage the rational use of Duac. Breaches of the Code were ruled.

The complainants alleged that the claim in the leavepieces, referenced to Langner *et al* (2007), that 'Duac Once Daily Gel works fast' was misleading, exaggerated, could not be substantiated and was inconsistent with the SPC. The SPC stated that patients should be advised that in some cases 4-6 weeks of treatment might be required before the full therapeutic effect was observed. Langner *et al* (2007) did not substantiate the claim.

The Panel noted that Langner *et al* (2007) was a comparison of Duac and Zineryt in the treatment of mild to moderate facial acne. The claim at issue, however, was not comparative and did not compare Duac's efficacy or time to onset of action with that of Zineryt. Langner *et al* (2007) showed that from week 0 to week 1, the total number of non-inflammatory lesions in patients treated with Duac (n=73) fell from a mean of 53.4 to 41.8, similarly the mean total number of inflammatory lesions fell from 34.3 to 27.9 and the mean total number of lesions fell from 87.7 to 69.7. Over 20% of patients treated with Duac showed at least a 30% reduction in total lesion counts at week 1 and over 60% showed at least a 30% reduction in total lesion counts at week 2. The Panel considered that the claim 'Duac Once Daily Gel works fast' was not misleading or exaggerated as alleged. No breach of the Code was ruled. The claim had been substantiated and so no breach of the Code was ruled. The Panel did not consider that the claim was inconsistent with the SPC as alleged. No breach of the Code was ruled.

Upon appeal by the complainants the Appeal Board noted that the audience (GPs and pharmacists) would be familiar with the treatment of acne, and would consider that a topical treatment which showed results after one to two weeks would be considered as acting 'fast'. The Appeal Board noted that Luckey *et al* (2007) concluded that an acne treatment acted fast because a significant effect was observed at week 4. Teenagers would want to know that they could expect to see a positive

response to therapy after a week or so. In this regard the Appeal Board noted that it would take much longer before oral therapies were seen to have an effect. The Appeal Board did not consider that health professionals would be misled as to assume that the claim implied that the full therapeutic effect of Duac would be achieved 'fast'.

The Appeal Board considered that the claim 'Duac Once Daily Gel works fast' was not misleading or exaggerated as alleged, it had been substantiated and was not inconsistent with the SPC as alleged. The Appeal Board upheld all of the Panel's rulings of no breach of the Code.

The claim that Duac was 'cosmetically acceptable' appeared in the leavepieces and was referenced to data on file (2001). The complainants alleged that the data on file was not in the public domain and had not been provided on request. It was not up-to-date and one could reasonably surmise that it was unlikely to substantiate the claims of cosmetic acceptability for the modern teenagers depicted in the leaflets. It was also very likely that today's teenagers had a very different perspective compared with the prevalent view in 2001. The claim of cosmetic acceptability focused entirely on the teenagers' need to look good and not silly. However, the latter ignored the occurrence of important side-effects which also needed to be balanced whilst pursuing aesthetics. The emphasis on cosmetic acceptability, particularly with regard to the face as opposed to other equally important parts of the body was not only inconsistent with the SPC but also tantamount to suggesting that Duac was used as a cosmetic.

The Panel noted that the data on file compared the consumer acceptability of Clindoxyl Gel [similar to Duac] and Benzamycin gel on the basis of immediate perception of aesthetic attributes and after one week's use. Patients (n=51) were asked to rate smell, colour and feel on the skin in terms of greasiness, granularity, spreadability, and whether a residue/film was left; they were also asked if they had experienced stinging and to rate the ease of applying make-up after applying the product to their skin. Subjects preferred Clindoxyl Gel over Benzamycin on virtually each attribute and on an overall basis.

The Panel noted that the complainants had not seen the data on file and had complained that, *inter alia*, results from 2001 would not be relevant to teenagers in 2009. No rationale was provided for this argument. The Panel did not consider that the claim was misleading in that regard and no breach of the Code was ruled. The Panel considered that on the basis of the results of the consumer acceptability study, it was not unreasonable to claim that Duac Once Daily Gel was cosmetically acceptable. The claim was not misleading and had been substantiated. No breaches of the Code were ruled. The Panel did not consider that the claim was tantamount to suggesting that the product was a cosmetic. In that regard the claim encouraged the rational use of the medicine. No breach of the Code was ruled.

The complainants noted that the GP leavepiece claimed that Duac Gel got on with teenagers. This claim of efficacy appeared to be unsubstantiated. Langer *et al* (2007) did not substantiate the claim as the mean age was 21.2 years in the Duac arm of the study.

The Panel noted that in Langner *et al* (2007) patients in the Duac group were aged 12-38, mean age of 21.2 years. There was no data before the Panel which suggested that efficacy differed according to the age of the patient.

In the GP leavepiece the headline 'Duac Once Daily Gel gets on with teenagers' was followed by a number of claims regarding the ease of use/acceptability of Duac eg once daily application, odour free etc. The Panel further noted, from above, that the majority of patients had at least a 30% decrease in total lesion count at two weeks. In the Panel's view this onset of action time would encourage compliance in a group where compliance was likely to be difficult. On balance the Panel considered that the claim 'Duac Once Daily Gel gets on with teenagers' had been substantiated. No breach of the Code was ruled.

The claim 'Teenagers are "busy" Duac is a once daily gel' appeared in both leavepieces. One advertisement stated 'Once a day is good, because they're, like, so busy'. The advertisement and the pharmacist leavepiece also featured the claim 'can be worn under make-up'. The complainants alleged that the issue of convenience was overstated given that the SPC clearly stated that the gel should be applied once daily in the evening to affected areas after the skin had been thoroughly washed, rinsed with warm water and gently patted dry. The complainants were not sure that this strict regimen was consistent with the ease of use implied by the unqualified once daily application claim in support of the use of Duac for teenagers who were impatient and busy. The claim that Duac could be used under make-up might be of relevant to young teenagers, however in the early phase of treating moderate acne it was generally accepted that cosmetics should be avoided in order to detect side effects and particular cosmetic products should be avoided all together. The focus on an early response aligned with less than helpful and unqualified generalisations regarding the use of cosmetics was misleading.

The Panel noted that Duac should be applied once daily in the evening, to affected areas after the skin had been thoroughly washed, rinsed with warm water and gently patted dry. The Panel did not consider that this was a strict regime as alleged or that it imposed restrictions on 'busy' teenagers. No breach of the Code was ruled.

With regard to wearing make-up, the Panel noted that the Duac SPC stated that cosmetics that had a

strong drying effect, and products with high concentrations of alcohol and/or astringents, should be used with caution as a cumulative, irritant effect might occur. There was no clinical data before the Panel to support the concomitant use of make-up. The Panel considered that the claim 'can be worn under make-up' did not reflect the evidence and was misleading in that regard. A breach of the Code was ruled.

The complainants alleged that the claim 'No need to keep it in the fridge' in the GP leavepiece was incomplete and therefore misleading. The storage of conditions prior to dispensing [store in a refrigerator at 2-8ºC] were important and had been omitted; this information was relevant to both pharmacists and dispensing GPs.

The Panel noted that the leavepiece at issue was specifically for non-dispensing prescribers. The claim 'No need to keep it in the fridge' appeared as the fourth bullet point on a page headed 'Duac Once Daily Gel gets on with teenagers'. In the context in which it appeared the Panel considered that the claim was about the patient's use of Duac, not the dispenser's storage of the product and so no breach of the Code was ruled.

The complainants alleged that the claim in the advertisement that 'Duac … starts working within a week' was misleading and unsubstantiated. Langner *et al* (2008) cited in support was a small, single-blind study which did not represent the balance of evidence in respect of the speed of onset of action of Duac. Specifically the comparison was with Differin Gel and in that regard the claim should be qualified as it might not be relevant with other topical treatments.

The Panel considered data to substantiate the claim that Duac 'starts working within a week' would have to show that the product was effective in less than seven days. The Panel had no such data before it. Both Langner *et al* (2007) and (2008) reported efficacy at week one but not before then. The Panel thus considered that the claim was misleading and had not been substantiated; breaches of the Code were ruled. The Panel considered that the claim was about Duac alone; it was not a comparison with Differin Gel or any other product. In that regard the Panel did not consider that the claim was a misleading comparison as alleged and no breach of the Code was ruled.

The complainants alleged that the advertisement also appeared to imply that the speed of onset of action and effectiveness of Duac improved teenagers' confidence with particular reference to facial acne rather than lesions on other parts of the body to such an extent that patients could stop hiding under their hoodies within one week. The latter was clearly a generalisation and inconsistent with the SPC which did not indicate that Duac was specifically effective in the management of facial acne over and above lesions on other parts of the body. The promotion of this aspect of the benefits of Duac was exaggerated and distorted the premise for rational prescribing.

The Panel did not consider that the advertisements implied that Duac was particularly effective for facial acne as opposed to acne on any other part of the body. In the Panel's view the advertisements depicted a typical acne patient. The Panel did not consider that the advertisements inappropriately exaggerated or distorted the premise of rational prescribing as alleged. No breach of the Code was ruled.

The Acne Working Group GP Review January 2008 was cited in support of general claims about acne in the pharmacist leavepiece. The complainants stated that it was evident that the Acne Working Group was convened at the behest of Stiefel which was close to the discussions and in control of the outputs. The cover of the article looked like the independent parent journal, GP, and this in conjunction with the statement that the review was provided as a service to medicine by Stiefel misled because it implied that it was not promotional. Promotional claims for Duac were principally about the importance of benzoyl peroxide and the issue of antibiotic resistance and this was reflected often in review. The review was disguised promotion. Indeed the mention of Duac and certain of its benefits appeared in a discussion of benzoyl peroxide combination therapies and selectively in the conclusion. Prescribing information should have been provided. A cost comparison of topical treatments, including Duac, appeared simply to be based on medicine acquisition cost and did not allow for varying treatment durations, indications, pack sizes and importantly, cost efficacy. This was misleading and unbalanced. The complainants alleged that reprints of the review had been used promotionally.

The Panel noted that the supplement in question had been sponsored and facilitated by Stiefel. An agency working on behalf of the company had identified experts to be part of the Acne Working Group. Invitations sent by Stiefel stated that Stiefel would like the group to develop rigorous and robust guidance, including a treatment algorithm, to help inform clinicians on the management of mild and moderate facial acne and the relative position of topical combinations vs oral antibiotics and retinoids. Stiefel had thus, at the outset, defined the scope of the Acne Working Group. The chair had been briefed by a senior brand manager. At the groups first meeting Stiefel had given a short presentation on the role for topical combination treatments and provided factual information on its products. Stiefel had reviewed the supplement before it was released and had subsequently given its representatives copies to give to GPs and had referred to the guidance in its promotional material for Duac.

The Panel considered that Stiefel was wholly responsible for the Acne Working Group and thus for any output from it. The group was formed at

Stiefel's behest and the company had defined the scope of its work in the invitation it had issued and had briefed the chairman. There was no strictly arm's length arrangement.

The Panel considered that the material at issue was not a supplement 'Provided as a service to medicine by Stiefel' as stated on the front cover, but a paid for insert reporting the outcome of a group which had been charged, *inter alia*, with informing clinicians about the relative position of topical combination products in the treatment of mild to moderate facial acne. The group concluded that combination therapies involving benzoyl peroxide might assist in patient concordance and the minimization of antibiotic resistance. The Panel did not consider that the statement 'Provided as a service to medicine by Stiefel' accurately reflected the nature of the company's involvement. A breach of the Code was ruled. It was not stated that the Acne Working Group had been formed by Stiefel. The Panel considered that the material was disguised promotion as alleged. A breach of the Code was ruled.

The Panel noted that the supplement contained a table of data headed 'Cost comparison for acne treatments'. Readers were directed to a footnote which stated that costs had been taken from MIMS January 2008. In that regard the Panel considered that the table listed acquisition costs only; there was no implication that the table detailed cost efficacy of the medicines. The Panel did not consider that the table was unbalanced or misleading as alleged. No breach of the Code was ruled.

The Panel considered that presenting the output of the Acne Working Group as an independent supplement to a journal demonstrated apparent poor knowledge of the requirements of the Code. Health professionals generally looked to medical journals as a source of independent information; where authors wrote on behalf of companies or as a result of the activities of pharmaceutical companies this must be made clear. In the Panel's view the majority of readers would have viewed the material at issue quite differently if they had known the relationship between the Acne Working Group and Stiefel. High standards had not been maintained. A breach of the Code was ruled.

A general practitioner and a pharmacist jointly complained about the promotion of Duac Once Daily Gel (clindamycin 1% and benzoyl peroxide 5%) by Stiefel Laboratories Ltd. The materials at issue were a GP leavepiece (ref DU:7076UK); a pharmacist leavepiece (ref DU:E7156UK); two journal advertisements (refs DU:E7121UK and DU:E7232UK); two abbreviated advertisements (refs DU:E7233UK and DU:E7168UK) and a GP Review, January 2008, Management of mild and moderate acne vulgaris (ref DU:E7120UK). Duac was indicated for the treatment of mild to moderate acne vulgaris, particularly inflammatory lesions.

When writing to Stiefel the Authority asked it to respond in relation to Clauses 3.2, 7.2, 7.4, 7.5, 7.7, 7.10, 9.1, 9.10 and 12.1 of the Code.

1 Provision of references

COMPLAINT

The complainants noted that whilst developing a review article on the management of acne in primary care, one of them telephoned Stiefel's medical information department on 29 May to ask for copies of references cited in the Duac promotional materials; Langner *et al*, (2007); patient preference study, data on file, Stiefel Laboratories (2001); Acne Working Group GP Review January 2008 and Langner *et al* (2008).

The company was not cooperative; its response bordered on being initially uninterested and then belligerent. The medical information person stated that she could not give an assurance that she could provide the data-on-file as it might not be available. After much insistence and reference to the Code, the complainants were finally assured that their request would be treated as urgent. Unfortunately, over two weeks later the information had not been received. This was disappointing and of concern to the complainants. In the meantime the complainants had independently sourced three references which were in the public domain.

RESPONSE

Stiefel submitted that its recollection of the telephone call differed from the complainants; principally in that it was explained that all documentation would be provided, but it might take up to 10 working days to arrive. The caller would not provide an email or telephone details and asked for the documents to be posted to a personal address.

Stiefel submitted that its records showed that only two references were requested, not three or four as suggested. These references were posted to the given address on 9 June 2009, but were returned on 22 June as 'addressee unknown'. Since the complaint had been anonymised Stiefel was unable to guarantee that the telephone call was actually the one referred to in the complaint, however, given the subject matter and timing this seemed rather likely.

PANEL RULING

The Panel noted that the complainants and respondent did not agree on what the complainants had requested. It was impossible to know what exactly transpired between the parties. Nonetheless the Panel noted the submission that references (Langner *et al* 2007 and data on file 2001) had been posted to one of the complainants on Tuesday, 9 June, seven working days after the initial request for papers. Unfortunately the house number recorded on the telephone enquiry report was wrong by one digit and thus some days later, the

package was returned to Stiefel marked 'addressee unknown'. It was unfortunate that the wrong address had been recorded however, in the Panel's view, such an error did not constitute a breach of the Code. References had been posted in a timely manner and so no breach of Clause 7.7 of the Code was ruled.

APPEAL FROM THE COMPLAINANTS

The complainants submitted that the company's response was inconsistent with the need for the medical information department to maintain high standards. It was incredible that the company cited the minutiae of its records as a reliable/flawless record of what was discussed and simultaneously expected the complainants to believe that this record of events somehow and crucially allowed the erroneous recording of key information such as the first line of the complainant's address. This called into question the veracity of the company response. The Panel seemed to suggest that as long as a company could demonstrate it sent the information requested in a timely manner it did not ultimately matter where any response was sent, even when the correct information was provided. This effectively absolved companies from the need to demonstrably maintain high standards and simply ensured that they only needed to tick the necessary boxes. This was very convenient for a company which might be unable or unwilling to respond to requests for certain information. Ultimately the ruling meant that it was for the busy health professional to be encumbered and pursue the company for undelivered information and given the ruling, it was not to say that the second time around it would be sent to the correct address … as long it was sent somewhere!!

COMMENTS FROM STIEFEL

Stiefel submitted that the call was answered by a highly experienced medical information officer. During the call the enquirer was asked if he would email the exact details of his request as she was unfamiliar with the material he was requesting, but the caller declined. The medical information officer also offered to let the caller know when he would receive the material, but he refused to provide his email and telephone details. The caller provided his name, a personal address and his Royal Pharmaceutical Society of Great Britain (RPSGB) registration number. These details were read back to him and he confirmed that they were correct. It was explained to the caller that all documentation would be provided, but because it had to be sourced via Stiefel's information services department it might take up to 10 working days to arrive. A request for the two references asked for by the caller was emailed to Stiefel's information department on the same day and the urgency of the request was also stated in this email. The references were then sent out to the address Stiefel had documented for the caller.

Stiefel regretted that the information was then sent to what turned out to be an incorrect address and that this had inconvenienced the complainant. However, Stiefel believed that it had responded in a timely and appropriate manner and tried to ensure that it had as much information as possible to ensure the request was addressed in full. Stiefel's records demonstrated its intent to fulfil the caller's request and that it was given priority. Stiefel believed that every effort was made to comply with the customer's request and the requirements of the Code and therefore it supported the Panel's ruling that it was not in breach of Clause 7.7 of the Code.

FINAL COMMENTS FROM THE COMPLAINANTS

There were no further comments from the complainants.

APPEAL BOARD RULING

The Appeal Board noted that, at the outset, the caller had been advised that it might take up to ten working days for him to receive the requested references. On the same day that it was received, the request for the papers was emailed to Stiefel's information department and marked urgent.

The references (Langner *et al* 2007 and data on file 2001) were posted to the enquirer on Tuesday 9 June, seven working days after his initial request. Unfortunately due to an error in the house number recorded on the telephone enquiry form, the package was returned to Stiefel marked 'addressee unknown'. At this point Stiefel had not been able to contact the enquirer by any other means as he had refused to provide any alternative contact details when asked by Stiefel. The Appeal Board considered that although there had been a genuine error in the recording of the house number the complainant's request had, nonetheless, been dealt with in a timely manner. The Appeal Board upheld the Panel's ruling of no breach of Clause 7.7. The appeal on this point was thus unsuccessful.

2 Use of an acne grading chart

An acne grading chart depicting mild, moderate and severe acne appeared in the GP leavepiece.

COMPLAINT

The complainants alleged that the leaflet was inconsistent with the therapeutic indication of Duac Once Daily Gel which was to treat mild to moderate acne vulgaris, particularly inflammatory lesions. The leaflet depicted an acne grading chart which featured not only inflammatory lesions but also, non-inflammatory and nodulocystic lesions. The chart featured severe lesions and thus misleadingly implied that Duac could be used for lesions other than those that were mild to moderate.

RESPONSE

Stiefel submitted that the leavepiece clearly stated the therapeutic indication of Duac Once Daily Gel. The use of the acne grading chart was intended to provide an overview of the scale of acne disease and demonstrated where Duac Once Daily Gel could be used. Duac Once Daily Gel was written underneath the mild and moderate section with an arrow spanning the two categories. The severe acne section was separated from the mild and moderate sections. As it stood, it was clear that there were patients on the grading scale for whom Duac Once Daily Gel would not be suitable. Stiefel submitted that the chart was not misleading.

PANEL RULING

The Panel noted that page 1 of the leavepiece showed a photograph of three teenage boys and referred to 'An acne treatment for their world'. Inside the leavepiece an acne grading chart showed photographic examples of mild acne on the left-hand side of the page through to moderate and then severe acne on the right-hand side of the page. Below the pictures of mild and moderate acne was the Duac product logo and a horizontal double-headed arrow marked 'An acne treatment for their world'. The pictures of severe acne on the right-hand side of the leavepiece were slightly separate from the other pictures. The Panel noted that it was only in the prescribing information where it was explicitly stated that Duac was for mild to moderate acne.

The Panel considered that an acne grading chart showing all the grades of acne was useful so that a prescriber could tell when the condition was too severe to be treated with Duac. Nonetheless, if all grades of acne were to be shown, prescribers must be very clearly informed of when to use Duac; in that regard the Panel considered that a double-headed arrow spanning the pictures of mild to moderate acne and the statement in the prescribing information were insufficient. Some readers might assume that Duac could be used for severe acne. The Panel considered that the leavepiece was inconsistent with the particulars listed in the Duac summary of product characteristics (SPC). A breach of Clause 3.2 was ruled. The Panel further considered that the leavepiece was misleading about the product's licensed indication and in that regard did not encourage the rational use of Duac. Breaches of Clauses 7.2 and 7.10 were ruled.

3 Claim 'Duac Once Daily Gel works fast'

This claim appeared in the GP and pharmacist' leavepieces referenced to Langner *et al* (2007).

COMPLAINT

The complainants alleged that the unqualified and generalised claim that Duac worked fast was misleading, exaggerated the facts, could not be substantiated and was inconsistent with the SPC. The SPC stated that patients should be advised that in some cases 4-6 weeks of treatment might be required before the full therapeutic effect was observed. A clinical study, Langner *et al* (2007), was cited in support of this unqualified claim to suggest that the data were not only clinically significant but also statistically significant. However, the study did not substantiate the claim. The primary efficacy variable of the study was to assess the proportion of patients showing at least a 30% improvement from baseline of non-inflammatory and inflammatory lesion count at weeks 1 and 2. The secondary endpoints were the proportion of patients showing a 30% improvement or greater from baseline at weeks 4, 8 and 12 and in total lesion counts at all post-baseline assessments. The results showed that for both treatment groups, a progressive decline was observed in the number of inflammatory and non-inflammatory lesions. The improvement was, with only one exception, greater in the group treated with Duac than in the comparator group; the difference was close to/approached significance at week 1 for inflammatory lesions but was only statistically significant for inflammatory and for total lesions at week 2. With the exception of week 2, the difference in inflammatory lesion counts was not statistically significant. The unqualified use of 'fast' could imply an earlier response than supported by these data.

RESPONSE

Stiefel submitted that the claim that Duac Once Daily Gel worked fast was supported by Langner *et al* (2007). The study showed that inflammatory and total lesions were statistically significantly reduced compared with the comparator, Zineryt, by week 2, with the difference approaching significance at week 1. Zineryt, was the most widely prescribed topical product for mild to moderate acne. Stiefel understood that acne patients wanted a rapid response from their treatment and it believed that a response within two weeks qualified as fast in this therapeutic category, especially when compared with competitor products. Stiefel submitted that more recent data had been generated which demonstrated that Duac Once Daily Gel started to work within one week.

Stiefel submitted that the claim that Duac Once Daily Gel worked fast was not inconsistent with the SPC, as it was well known and accepted that the full therapeutic effect of a product would be progressive. The data showed that Duac Once Daily Gel worked within two weeks and the SPC and prescribing information confirmed that the full effect might not be seen until after 4-6 weeks of treatment. The claim did not imply complete efficacy.

PANEL RULING

The Panel noted that the study cited in support of the claim (Langner *et al* 2007) was a comparison of Duac and Zineryt in the treatment of mild to

moderate facial acne. The claim at issue, however, was not comparative and did not compare Duac's efficacy or time to onset of action with that of Zineryt.

Langner *et al* (2007) showed that from week 0 to week 1, the total number of non-inflammatory lesions in patients treated with Duac (n=73) fell from a mean of 53.4 to 41.8, similarly the mean total number of inflammatory lesions fell from 34.3 to 27.9 and the mean total number of lesions fell from 87.7 to 69.7. Over 20% of patients treated with Duac showed at least a 30% reduction in total lesion counts at week 1 and over 60% showed at least a 30% reduction in total lesion counts at week 2. The Panel considered that the claim 'Duac Once Daily Gel works fast' was not misleading or exaggerated as alleged. No breach of Clauses 7.2 and 7.10 were ruled. The claim had been substantiated and so no breach of Clause 7.4 was ruled. The Panel did not consider that the claim was inconsistent with the SPC as alleged. No breach of Clause 3.2 was ruled.

APPEAL FROM THE COMPLAINANTS

Whilst the complainants welcomed the ruling of breaches of Clauses 7.2 and 7.3 of the Code regarding the claim that Duac worked within one week (Point 8 below) they would like the Panel to qualify its ruling with regard to the claim that Duac 'works fast'. The latter claim was unqualified with regard to defining a specific time period for the term 'fast'. The substantiation for this term was pegged to 7-14 days after treatment. As such, this unqualified claim could still mislead by implying that Duac was effective within seven days. The complainants alleged that appropriate qualification of the claim was necessary without which it was in breach of the Code.

COMMENTS FROM STIEFEL

Stiefel submitted that the items in question were clear in that Duac was indicated for the treatment of mild to moderate acne. The additional information relating to the speed of action of Duac was substantiated by the clinical data and was not inconsistent with the terms of its marketing authorization. The SPC stated that 'Patients should be advised that, in some cases, 4-6 weeks of treatment may be required before the full therapeutic effect is observed', but this was not in contradiction with the fact that approximately 20% of patients experienced a 30% improvement within a week. Therefore, Stiefel supported the Panel's ruling and denied a breach of Clause 3.2 of the Code.

Stiefel submitted that health professionals and chronic acne sufferers were aware that most treatments took several weeks to have a noticeable effect and therefore any treatment that worked within a week or two was generally regarded as fast-acting. Stiefel noted that Luckey *et al* (2007) concluded that Dapsone gel acted fast in acne vulgaris because a significant effect was observed at week 4.

Stiefel submitted that Langer *et al* (2007), a comparison between Duac and Zineryt, and Langer *et al* (2008), a comparison between Duac and Adapalene, showed that Duac worked within a week and acted faster than either comparator. To date, Stiefel was not aware of any published head-to-head comparisons which showed any alternative topical mild to moderate acne treatment had a faster onset of action than Duac Once Daily Gel.

Given that physicians understood that a 'fast' treatment for acne worked within 4 weeks, and the enclosed Duac information, Stiefel submitted that its statement, based on an even faster effect, was accurate, fair and capable of substantiation and promoted the rational use of its medicine. Therefore, Stiefel supported the Panel's ruling and continued to deny a breach of Clauses 7.2, 7.4 and 7.10 of the Code.

FINAL COMMENTS FROM THE COMPLAINANTS

The complainants reiterated that they welcomed the ruling regarding the claim that Duac worked within one week particularly as it was inconsistent with the Duac SPC and that approximately 20% of patients on Duac experiencing any improvement in any time period hardly constituted the balance of evidence or probability of what might reasonably be expected by the other 80%!

The complainants wanted the Panel to qualify its ruling with regard to the claim that Duac worked fast for the reasons stated above.

APPEAL BOARD RULING

The Appeal Board noted that the study cited in support of the claim (Langner *et al* 2007) showed that from week 0 to week 1, the total number of non-inflammatory lesions in patients treated with Duac (n=73) fell from a mean of 53.4 to 41.8, similarly the mean total number of inflammatory lesions fell from 34.3 to 27.9 and the mean total number of lesions fell from 87.7 to 69.7. Over 20% of patients treated with Duac showed at least a 30% reduction in total lesion counts at week 1 and over 60% showed at least a 30% reduction in total lesion counts at week 2.

The Appeal Board noted that the audience (GPs and pharmacists) would be familiar with the treatment of acne, and would consider that a topical treatment which showed results after one to two weeks would be considered as acting 'fast'. The Appeal Board noted that Luckey *et al* concluded that an acne treatment acted fast because a significant effect was observed at week 4. Teenagers would want to know that they could expect to see a positive response to therapy after a week or so. In this regard the Appeal Board noted that it would take much longer before oral therapies were seen to have an effect. The Appeal Board did not consider that health professionals would be misled as to assume that the claim implied that the full therapeutic effect of Duac would be achieved 'fast'.

The Appeal Board considered that the claim 'Duac Once Daily Gel works fast' was not misleading or exaggerated as alleged, and it thus upheld the Panel's ruling of no breach of Clauses 7.2 and 7.10. The claim had been substantiated and so the Panel's ruling of no breach of Clause 7.4 was also upheld. The Appeal Board did not consider that the claim was inconsistent with the SPC as alleged and upheld the Panel's ruling of no breach of Clause 3.2. The appeal on this point was thus unsuccessful.

4 Claim that Duac is 'cosmetically acceptable'

This claim appeared in the GP and pharmacist leavepieces and was referenced to data on file (2001).

COMPLAINT

The complainants alleged that the data on file cited to support the claim of cosmetic acceptability was not in the public domain and had not been provided as per their request. However, it was clearly not up-to-date and one could reasonably surmise that the data was unlikely to substantiate the claims of cosmetic acceptability with particular reference to the modern contemporary teenagers depicted in the leaflets. It was also very likely that today's teenagers had a very different perspective on what was cosmetically acceptable compared with the prevalent view of their peers in 2001. The claim of cosmetic acceptability focused entirely on the teenagers' need to look good and not silly. However, the latter ignored the occurrence of important side-effects which commonly included erythema, peeling, dryness, burning and pruritis which also needed to be balanced whilst pursuing aesthetics. This was not responsible promotion. The emphasis on cosmetic acceptability, particularly with regard to the face as opposed to other equally important parts of the body was not only inconsistent with the SPC but also tantamount to suggesting that this product was to be used as a cosmetic.

RESPONSE

Stiefel submitted that the data on file referred to was posted to the complainants on 9 June 2009 but returned on 22 June as 'addressee unknown'. There was no substantiation to the claim that this data was no longer relevant to teenagers today, nor was it known on what basis the complainants could determine that the data was unlikely to substantiate the claims made, as the data on file had not been reviewed by them.

In the data on file Stiefel believed that the parameters assessed (smell, colour, feel of the product etc) were as relevant today as they were in 2001 when the study was conducted. Stiefel submitted that there was no suggestion that Duac Once Daily Gel could be used as a cosmetic and it did not believe there was any way in which this inference could be made. The term 'cosmetic acceptability' was well known and understood to mean how acceptable the physical characteristics of the product were to the patient.

In response to a request for further information, Stiefel explained that the Clindoxyl formulation used in the sensory comparison, which was marketed in Canada and the US, contained methyl parabens as a preservative, whilst the Duac formulation marketed in the EU did not. There was also a difference in the grade of carbomer used in order to meet the requirements of the European Pharmacopoeia. In all other respects the formulations were the same and there were no differences that would affect the aesthetic and sensory qualities of the product.

PANEL RULING

The Panel noted that the data on file cited in support of the claim was a study which had compared the consumer acceptability of Clindoxyl Gel and Benzamycin gel on the basis of immediate perception of aesthetic attributes and after one week's use. Patients (n=51) were asked to rate the smell of the products, their colour and their feel on the skin in terms of greasiness, granularity, spreadability, and whether they left a residue/film. Patients were also asked if they had experienced stinging and to rate the ease of applying make-up after applying the product to their skin. Subjects preferred Clindoxyl Gel over Benzamycin on virtually each attribute and on an overall basis.

The Panel noted that the complainants had not seen the data on file and had complained that, *inter alia*, results from 2001 would not be relevant to teenagers in 2009. No rationale was provided for this argument. The Panel did not consider that the claim was misleading in that regard. No breach of Clause 7.2 was ruled. The Panel considered that on the basis of the results of the consumer acceptability study, it was not unreasonable to claim that Duac Once Daily Gel was cosmetically acceptable. The claim was not misleading as alleged and had been substantiated. No breach of Clauses 7.2 and 7.4 were ruled. The Panel did not consider that the claim was tantamount to suggesting that the product was a cosmetic. In that regard the claim encouraged the rational use of the medicine. No breach of Clause 7.10 was ruled.

During the consideration of this point, the Panel noted that the complainants had referred to the side effects of Duac Once Daily Gel ie erythema, peeling, dryness, burning and pruritis. In the Panel's view the cosmetic acceptability of a product was different to its side-effect profile. In each leavepiece, under the claim of cosmetic acceptability, was the stabpoint 'non-drying'. The SPC, however, in Section 4.8, Undesirable effects, listed dryness as a very common (> 1/10) side effect. The Panel was thus concerned that the claim 'non-drying' was inconsistent with the particulars listed in the SPC and requested that Stiefel be advised of its views in that regard.

5 Claim 'Duac Once Daily Gel gets on with teenagers'

This claim appeared in the GP leavepiece.

COMPLAINT

The complainants noted that the leavepiece claimed that Duac Gel got on with teenagers. This was a claim of efficacy in this particular patient group which appeared to be unsubstantiated. Indeed the cited reference, Langer *et al* (2007), did not substantiate the claim as the mean age of the subjects was 21.2 years in the Duac arm of the study.

RESPONSE

Stiefel submitted that Duac Once Daily Gel was licensed for the treatment of mild to moderate acne vulgaris in all age groups (except children under 12 years of age). The claim that Duac Once Daily Gel 'gets on' with teenagers was intended to reflect the characteristics of the product that would make its use as convenient as possible to teenagers. These characteristics were listed below the statement, giving it clear context.

PANEL RULING

The Panel noted that Langner *et al* (2007) set out to treat patients aged 12-39 years who had mild to moderate facial acne. Patients in the Duac group were aged 12-38 and had a mean age of 21.2 years. There was no data before the Panel which suggested that the efficacy of Duac differed according to the age of the patient.

In the GP leavepiece the headline 'Duac Once Daily Gel gets on with teenagers' was followed by a number of claims regarding the ease of use/acceptability of Duac eg once daily application, odour free etc. The Panel further noted, from point 3 above, that the majority of patients had at least a 30% decrease in total lesion count at two weeks. In the Panel's view this onset of action time would encourage compliance in a group where compliance was likely to be difficult.

On balance the Panel considered that the claim 'Duac Once Daily Gel gets on with teenagers' had been substantiated. No breach of Clause 7.4 was ruled.

6 Claims 'Teenagers are "busy" Duac is a once daily gel' and 'can be worn under make-up'

The 'busy' claims appeared in the GP and pharmacists' leavepieces. One advertisement (ref DU: E7232UK) stated 'Once a day is good, because they're, like, so busy'. The advertisement and the pharmacist leavepiece also featured the 'make-up' claim.

COMPLAINT

The complainants alleged that the issue of convenience was overstated particularly given that the SPC clearly suggested certain restrictions which might be important to teenagers with regard to the administration of Duac. The SPC stated that the gel should be applied once daily in the evening to affected areas after the skin had been thoroughly washed, rinsed with warm water and gently patted dry. The complainants were not sure that this strict regimen was consistent with the ease of use implied by the unqualified once daily application claim in support of the use of Duac for teenagers who were impatient and busy. Also the claim that Duac could be used under make-up might be relevant to young teenagers, however in the early phase of the treatment of moderate acne it was generally accepted that cosmetics should be avoided in order to detect side effects and indeed some products should be avoided all together. The focus on an early response aligned with less than helpful and unqualified generalisations regarding the use of cosmetics was misleading and irresponsible.

RESPONSE

Stiefel submitted that a basic hygiene regimen was a standard aspect of topical acne treatments. It was unlikely that washing and drying the skin before use would be considered a 'strict regimen' by patients. The claim of a once daily application for Duac Once Daily Gel was qualified by the SPC which stated that Duac Once Daily Gel should be applied once per day. This was in line with the clinical evaluations conducted prior to product registration. A once daily application was preferential to a twice daily application, as evidenced by data on file.

Stiefel submitted that Duac Once Daily Gel could be worn under make-up and it was generally accepted that people would wish to continue to use make-up during treatment. Additionally, there were many make-up products available to camouflage acne. It was, of course, at the discretion of the prescriber to suggest whether make-up was worn; the claim was simply that Duac Once Daily Gel could be worn under make-up.

PANEL RULING

The Panel noted that Duac should be applied once daily in the evening, to affected areas after the skin had been thoroughly washed, rinsed with warm water and gently patted dry. The Panel did not consider that this was a strict regime as alleged or that it imposed restrictions on 'busy' teenagers. No breach of Clause 7.2 was ruled.

With regard to wearing make-up, the Panel noted that the Duac SPC stated in Section 4.5 (interaction with other medicinal products and other forms of interaction) that, *inter alia*, cosmetics that had a strong drying effect, and products with high concentrations of alcohol and/or astringents, should

be used with caution as a cumulative, irritant effect might occur. There was no clinical data before the Panel to support the concomitant use of make-up. The Panel considered that the claim 'can be worn under make-up' did not reflect the evidence and was misleading in that regard. A breach of Clause 7.2 was ruled.

7 Claim 'No need to keep it in the fridge'

This claim appeared in the GP leavepiece.

COMPLAINT

The complainants noted that the leavepiece was aimed at health professionals and alleged that the claim that there was no need to keep Duac in the fridge was incomplete and therefore misleading. The storage of conditions prior to dispensing [store in a refrigerator at 2-8°C] were important and had been omitted; this information was relevant to both pharmacists and dispensing GPs.

RESPONSE

Stiefel noted that the claim 'No need to keep it in the fridge' was listed within a section of claims regarding the suitability of Duac Once Daily Gel to patients, in particular teenagers. It was clear that the statement referred to use by patients.

Stiefel submitted that the leavepiece in question was designed specifically for non-dispensing prescribers. A separate leavepiece for dispensing prescribers and pharmacists (DU:E7156UK) clearly stated the storage conditions before and after dispensing.

PANEL RULING

The Panel noted that the leavepiece at issue (ref DU:7076UK) was specifically for non-dispensing prescribers ie those who would not need to store Duac prior to dispensing. The claim 'No need to keep it in the fridge' appeared as the fourth bullet point on a page headed 'Duac Once Daily Gel gets on with teenagers'. In the context in which it appeared the Panel considered that the claim was about the patient's use of Duac, not the dispenser's storage of the product. In that regard the Panel did not consider that the claim was misleading as alleged and so no breach of Clause 7.2 was ruled.

8 Claim 'Duac … starts working within a week'

This claim appeared on an advertisement (ref DU:E7233UK) and an abbreviated advertisement (ref DU:E7121UK). The claims were unreferenced. Both advertisements showed a picture of a young man sitting in a doctor's waiting room with his head down and hidden in the hood of his jacket.

COMPLAINT

The complainants alleged that the claim that Duac Once Daily Gel started working within a week was misleading and unsubstantiated. Langner *et al* (2008) was cited in support of this claim. This was a small, single-blind study which did not represent the balance of evidence in respect of the speed of onset of action of Duac. The primary efficacy variable was the absolute values and the percentage change from baseline in inflammatory lesion counts at week 2. There was no mention of this in the advertisements. The claim misleadingly only referred to data relating to the secondary endpoints which were the absolute values and the percentage change from baseline in inflammatory lesion counts at weeks 1, 4, 8 and 12 and in non-inflammatory and total lesion counts at all post-baseline assessments. The results indicated that the difference between groups for the percentage change from baseline was statistically significant, but only from/at week 1 onwards. This latter was clearly not consistent with the wording 'within a week'. Specifically the comparison was with Differin Gel and any claim of fast onset of action should be qualified to clarify the comparison as it might not be relevant when compared with other topical treatments.

The complainants alleged that the advertisement also appeared to imply that the speed of onset of action and effectiveness of Duac somehow improved teenagers' confidence with particular reference to facial acne rather than lesions on other parts of the body to such an extent that patients could stop hiding under their hoodies within one week. The latter was clearly a generalisation which was inconsistent with the SPC. The latter did not make any specific recommendations or indicate that Duac was specifically indicated and effective in the management of facial acne over and above lesions on other parts of the body. After all the confidence of teenagers who enjoyed swimming, for example, would not necessarily be enhanced if the rapid effectiveness of Duac did not extend to the legs and arms. The promotion of this aspect of the benefits of Duac was inappropriately exaggerated and distorted the premise for rational prescribing.

RESPONSE

Stiefel submitted that Langner *et al* (2008) stated that Duac showed an earlier onset of action with a faster significant reduction in inflammatory and total lesion counts than Differin Gel. A between-group comparison of the percentage change from baseline showed that Duac was statistically significantly superior to Differin Gel from week 1 onwards both for inflammatory lesions ($p \leq 0.001$) and for total lesions ($p \leq 0.004$). The authors concluded that Duac had a significantly earlier onset of action, was significantly more effective against inflamed and total lesions and was better tolerated, which should improve patient compliance.

Langner *et al* (2008) also assessed clinical acne grade and demonstrated that 'acne grade decreased in both treatment groups; however, this decrease was more significant with Duac, with statistical

significance (p = 0.013) being achieved as early as week 1'. Given that a statistically significant reduction in clinical acne grade was seen by week 1 with Duac Once Daily Gel, Stiefel submitted that it was appropriate to claim a fast onset of action.

Stiefel submitted that it did not know of any published head-to-head comparisons which showed that any alternative topical mild to moderate acne treatment had a faster onset of action than Duac Once Daily Gel.

The advertisements did not imply efficacy in any one part of the body over another and Stiefel could not understand how the advertisement could be inconsistent with the SPC in this regard.

PANEL RULING

The Panel considered data to substantiate the claim that Duac 'starts working within a week' would have to show that the product was effective in less than seven days. The Panel had no such data before it. Both Langner *et al* (2007) and Langner *et al* (2008) reported efficacy at week one but not before then. The Panel thus considered that the claim was misleading and had not been substantiated; breaches of Clauses 7.2 and 7.4 were ruled. The Panel considered that the claim was about Duac alone; it was not a comparison with Differin Gel or any other product. In that regard the Panel did not consider that the claim was a misleading comparison as alleged and no breach of Clause 7.3 was ruled.

The Panel did not consider that the advertisements implied that Duac was particularly effective for facial acne as opposed to acne on any other part of the body. In the Panel's view the advertisements depicted a typical acne patient. The Panel did not consider that the advertisements inappropriately exaggerated or distorted the premise of rational prescribing as alleged. No breach of Clause 7.10 was ruled.

9 Acne Working Group GP Review January 2008

This review was cited in support of general claims about acne in the pharmacist leavepiece.

COMPLAINT

The complainants stated that it was evident that the Acne Working Group was convened at the behest of Stiefel which was close to the discussions and in control of the outputs from this working group. The cover of the article looked like the independent parent journal, GP, and this in conjunction with the statement that the review was provided as a service to medicine by Stiefel misled the reader because it implied that it was not promotional. Promotional claims for Duac were principally about the importance of benzoyl peroxide and the issue of antibiotic resistance and this was reflected often in the article. The review was disguised promotion for Duac. Indeed the mention of Duac and certain of its benefits appeared in a discussion of benzoyl peroxide combination therapies and selectively in the conclusion. Given the latter and the clearly promotional nature of the article, prescribing information should have been provided. The article also invited a cost comparison of topical treatments including Duac. Unfortunately it appeared simply to be based on medicine acquisition cost and did not allow for varying treatment durations, indications, pack sizes and importantly, cost efficacy. This was misleading and unbalanced. The complainants also alleged that reprints of the review had been used promotionally.

RESPONSE

Stiefel submitted that the reference code was to allow easy identification of the piece in circumstances such as these. It did not mean that the piece had undergone full editorial review by Stiefel nor did it mean that it was a promotional item.

Stiefel had appointed an external, independent medical education company to organise a working group to produce a primary care treatment algorithm for acne, as there was no other relevant guidance available. The review also looked at the psychological impact of acne. Stiefel did not control the output from this group nor did it have editorial control over the article. Stiefel considered that the article was balanced and fair.

Stiefel submitted that the article provided a balanced overview of acne management and recommended benzoyl peroxide or topical retinoid as first line treatment in mild acne and a combination of either an antibiotic or retinoid with benzoyl peroxide for moderate acne. Products were not mentioned by brand name in the article.

The article referred to antibiotic resistance and the use of benzoyl peroxide to prevent, eliminate or reduce the generation of resistant bacteria. This was an important topic in the treatment of acne with topical antibiotics and it was therefore appropriate to the article. Although the article mentioned the use of clindamycin plus benzoyl peroxide combinations, it also discussed the use of benzoyl peroxide monotherapy and the use of separate benzoyl peroxide and antibiotic products.

Stiefel submitted that the article provided a cost comparison based on acquisition costs as per MIMS. Duac Once Daily Gel was mentioned, along with all other acne products listed. It was difficult, and seemed to require a biased point of view, to see this as a cost comparison of Duac Once Daily Gel against other products, rather than an overview of all products. Stiefel noted that a direct comparison of unit acquisition costs was not favourable for Duac Once Daily Gel.

In conclusion, Stiefel submitted that none of the complainant's comments were justified, it had acted

in accordance with the Code and maintained a high standard throughout.

In response to a request for further information Stiefel explained that the review was a Stiefel sponsored initiative, to address the need for guidance in primary care with regard to the management of acne as there was no other relevant guidance available. The review would also look at the psychological impact on acne sufferers. At no point did Stiefel control the output from the group or have editorial control over the article.

The opinions reflected those of the authors. However, Stiefel acknowledged that, by sponsoring and facilitating the review, the acne working group was not fully independent, and so in the original publication of the review and the subsequent reprints, Stiefel's sponsorship was clearly highlighted.

Stiefel explained that potential members of the Acute Working Group had been proposed by the medical communications agency appointed to co-ordinate the work. Stiefel had agreed to the list of potential members but had not suggested who any of the working group should be.

What was required of the members was clearly outlined in the invitation from Stiefel ie:

- to join the Acne Working Group to develop rigorous and robust guidance for the treatment of mild and moderate facial acne, including a treatment algorithm and the relative position of topical combinations vs oral antibiotics and retinoids
- to attend two meetings in 2007 in central London
- to receive an honorarium plus reasonable travel expenses
- to complete an acceptance and availability form and return to the agency.

The chair was briefed by a senior brand manager with regard to the requirement as the chair of the group. This meeting was followed up with a confirmation letter (a copy was provided).

The first of the two meetings took place in September 2007 in London. In attendance were the Acne Working Group, a senior manager from Stiefel and a medical writer, organised by the medical communications agency to take notes and prepare the manuscript for circulation after the two meetings. There were no other attendees from Stiefel or the agency.

The second meeting took place on Thursday, 22 November 2007 in London from 10am - 4pm. The attendees at this meeting were the Acne Working Group and the medical writer. There were no attendees from Stiefel or the agency. Again the group had a working lunch and details of refreshments could be provided.

An initial draft of the content of the supplement at issue was developed from the outcome of the two meetings and this was circulated to the Acne Working Group for comment. This process was repeated until the group agreed on the content.

The final version was put through the Stiefel approval system to proof read for accuracy and to ensure that no comments were misleading, before being released to GP for publication as a supplement with the statement 'Provided as a service to medicine by Stiefel' on the front page.

Stiefel noted that none of the Acne Working Group were involved in any of its advisory boards. Two members had been involved in research projects over a number of years. No other member of the group was involved in any other paid projects with Stiefel.

Stiefel submitted that it did not influence the scope and content of the GP review in any way and had no control over the output or the conclusions of the publication. Its only involvement was in the first meeting, in September 2007, where a senior manger attended to meet and greet the experts and provide factual information on Stiefel products.

Stiefel submitted that the supplement was produced as an independent review conducted by experts. Stiefel representatives were given reprints of the supplement to give to GPs and subsequent promotional materials referred to the guidance.

Stiefel noted that the guidance clearly stated on the front page 'Provided as a service to medicine by Stiefel' with the Stiefel logo next to it.

In conclusion, Stiefel considered that it had acted in accordance with the Code with regards to its involvement in the Acne Working Group GP Review and in the way that the ensuing documents had been used in subsequent promotional activities. The company believed that by including its logo in bold at the top of the document with the statement 'Provided as service to medicine by Stiefel', the declaration of sponsorship was sufficiently prominent to ensure that readers were aware of it at the outset, thereby complying with Clauses 9.10 and 12.1 of the Code.

PANEL RULING

The Panel noted that it was acceptable for companies to sponsor material. It had previously been decided, in relation to material aimed at health professionals, that the content would be subject to the Code if it was promotional in nature or if the company had used the material for a promotional purpose. Even if neither of these applied, the company would be liable if it had been able to influence the content of the material in a manner favorable to its own interests. It was possible for a company to sponsor material which mentioned its own products and not be liable under the Code for its contents, but only if it had been a strictly arm's length arrangement with no input by the company

and no use by the company of the material for promotional purposes.

The supplement in question had been sponsored and facilitated by Stiefel. A medical communications agency working on behalf of the company had identified experts to be part of the Acne Working Group. Invitations to be part of the group had been sent by Stiefel. The invitations had stated that Stiefel would like the group to develop rigorous and robust guidance, including a treatment algorithm, to help inform clinicians on the management of mild and moderate facial acne and the relative position of topical combinations vs oral antibiotics and retinoids. Stiefel had thus, at the outset, defined the scope of the Acne Working Group. The chair had been briefed by a senior brand manager. At the first meeting of the working group Stiefel had given a short presentation on the role for topical combination treatments. Stiefel had submitted that its senior manager had provided factual information on its products at the meeting. Stiefel had reviewed the supplement before it was released to GP. Stiefel had subsequently given copies of the supplement to its representatives to give to GPs and had referred to the guidance in its promotional material for Duac.

The Panel considered that Stiefel was wholly responsible for the Acne Working Group and thus for any output from it. The group was formed at Stiefel's behest and the company had defined the scope of its work in the invitation it had issued and had briefed the chairman. There was no strictly arm's length arrangement.

The Panel considered that the material at issue was not a supplement 'Provided as a service to medicine by Stiefel' as stated on the front cover, but a paid for insert reporting the outcome of a group which had been charged, *inter alia*, with informing clinicians about the relative position of topical combination products in the treatment of mild to moderate facial acne. The group concluded that combination therapies involving benzoyl peroxide might assist in patient concordance and the minimization of antibiotic resistance. The Panel did not consider that the statement 'Provided as a service to medicine by Stiefel' accurately reflected the nature of the company's involvement. A breach of Clause 9.10 was ruled. It was not stated that the Acne Working Group had been formed by Stiefel. The Panel considered that the material was disguised promotion as alleged. A breach of Clause 12.1 was ruled.

The Panel noted that the supplement contained a table of data headed 'Cost comparison for acne treatments'. Readers were directed to a footnote which stated that costs had been taken from MIMS January 2008. In that regard the Panel considered that the table listed acquisition costs only; there was no implication that the table detailed cost efficacy of the medicines. The Panel did not consider that the table was unbalanced or misleading as alleged. No breach of Clause 7.2 was ruled.

The Panel considered that presenting the output of the Acne Working Group as an independent supplement to a journal demonstrated apparent poor knowledge of the requirements of the Code. Health professionals generally looked to medical journals as a source of independent information; where authors wrote on behalf of companies or as a result of the activities of pharmaceutical companies this must be made clear. In the Panel's view the majority of readers would have viewed the material at issue quite differently if they had known the relationship between the Acne Working Group and Stiefel. High standards had not been maintained. A breach of Clause 9.1 was ruled.

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.

Complaint received **17 June 2009**

Case completed **17 September 2009**