CASE AUTH/2102/3/08

ANONYMOUS REPRESENTATIVE v MEDA

Promotion of Aldara and activities of representatives

An anonymous representative alleged that he was being encouraged to promote Aldara (iniquimod cream) off license to maxillofacial and plastic surgeons. The complainant was also concerned about the call rates Meda had recently introduced and a letter that representatives gave to doctors.

In relation to call rates, the Panel noted that the supplementary information to the Code stated that the number of calls made on a doctor or other prescriber by a representative each year should normally not exceed three on average excluding attendance at group meetings and the like, a visit requested by the doctor or other prescriber or a visit to follow up a report of an adverse reaction. Thus although a representative might speculatively call upon or proactively make an appointment to see a doctor or other prescriber three times in a year, the number of contacts with that health professional in the year might be more than that. In the Panel's view briefing material should clearly distinguish between expected call rates and expected contact rates.

The Panel noted the January regional meetings included slides about customer targets. One slide stated that call frequency was to be within ABPI guidelines. The expectations for 2008 were set out on the same slide. These being of 100 target GPs the minimum requirement was 1:1 contacts. In quarter 1, 25% were to be seen twice, the equivalent figures for quarters 2, 3 and 4 were 50%, 75% and 90% respectively. In addition in quarter 2, 30% were to be seen 3 times with 60% and 90% in quarters 3 and 4 respectively. Targets were only given for primary care.

One of the slides used on the initial training course (ITC) referred to calls but no details were given regarding call frequency. One of the questions in the test on the Code also referred to calls.

The Panel noted an email from the commercial manager provided by the complainant. This reproduced the second part of the slide ie that relating to the quarterly requirements for coverage and frequency. The email included '… however we need to be seeing more of them and more frequently. We have minimum expectations around customer contacts in particular GP activity which as a minimum we must be achieving'.

The Panel was concerned that it appeared that the representatives had not been provided with the details of the requirements of the Code and clear definitions of 'contact rate' and 'call rate' and why the differences were important. The Panel noted Meda's response but considered that the slide regarding customer targets used at the January salesforce meetings could have been more explicit. It did not state that the rates were cumulative. Although it stated the call frequency had to be within ABPI guidelines it did not appear that these had been explained to the salesforce. It was also concerned that the contact rates were described as minimum when the Code did not permit more than three unsolicited calls in a year. On balance the Panel considered that the slide presentation and other instructions advocated a course of action which was likely to lead to a breach of the Code. A breach of the Code was ruled.

The Panel considered that there was no evidence that over calling had occurred and thus no breach was ruled in that regard.

In relation to the letter sent to doctors by representatives, the Panel noted Meda's submission that this letter had been certified and prescribing information had been provided on the reverse. The complainant had not been entirely clear as to what his complaint was about the letter. It was not necessarily unacceptable to use a letter to try to gain an appointment with a health professional and no breach was ruled.

In relation to the alleged off licence promotion, the Panel was concerned that original minutes (undated) of a 10 March regional salesforce teleconference stated that a representative had had success with plastic surgery in that he was '…successfully promoting to plastics, and they tend to be using Aldara for shrinking of lesions, prior to surgical excision. There was concern expressed by [a named representative] that this could be an off label promotion, but as we would only be talking about [certain] lesions, this should not be too much of a problem ...' The amended copy of the minutes (also undated) for the same teleconference included additional information 'I just want to confirm what I said on the TC and that is we should never promote Aldara off-licence, and if other specialties have expressed an interest then we can follow up to find out what their interest in Aldara is? We should not be contacting this specialty directly, only following up requests'.

The Panel noted the submission that two specialist account managers had made specific contact with maxillofacial customers as a direct result of a referral from a dermatologist who worked closely with the maxillofacial surgeons for managing small, superficial basal cell carcinomas (sBCCs).

The Panel was concerned that Meda was promoting Aldara to plastic surgeons to shrink lesions prior to surgery. This was inconsistent with the summary of product characteristics which stated, *inter alia*, that Aldara was indicated for the topical treatment of sBCCs. The Panel ruled a breach of the Code.

An anonymous company representative complained about the promotion of Aldara (iniquimod cream) by Meda Pharmaceuticals Limited and about the activities of its representatives.

Aldara had three indications: external genital and perianal warts (condylomata acuminate) in adults; small superficial basal cell carcinomas (sBCCs) in adults; and clinically typical, nonhyperkeratotic, nonhypertrophic actinic keratoses (AKs) on the face or scalp in immunocompetent adult patients when size or number of lesions limited the efficacy and/or acceptability of cryotherapy and other topical treatment options were contraindicated or less appropriate.

COMPLAINT

The complainant stated that he was concerned about the total lack of knowledge within the company around ABPI and it was only due to representatives showing concern that some actions had been changed. However the company still behaved in an unethical manner and examples were cited.

1 Call rates were only introduced in January 2008, however representatives were concerned there was a breach here. (Copy email provided).

2 Representatives were encouraged to write to doctors using 'the GPwSI letter' which was self written' by an ex-representative, not the company; this had a reply slip on the bottom to gain an appointment from the clinician. (Copy provided).

3 Representatives were also encouraged to promote Aldara off licence into maxillofacial units and plastic surgeons to obtain business. Others had raised this as a breach, but whilst on a recent teleconference, one representative claimed he got a lot of response from this focus, one other person raised concerns, and the manager replied: 'well it is off licence, but just do it, but be careful'. This was totally wrong and it was the complainant's job and ABPI qualification too! (It had also been seen on business plans where people had written they would promote off licence).

There was a lot of concern around the conduct of Meda in general, and the complainant had also witnessed clinicians' complaints.

When writing to Meda, the Authority asked it to respond in relation to Clauses 2, 3, 9.1, 14.1, 15.4 and 15.9 of the Code.

1 Call rates

RESPONSE

Meda explained that it had a salesforce of 41 specialist account managers, four commercial managers and one head of sales. Each specialist account manager worked a defined geography and took responsibility for the customers within the NHS for their promoted products. The company's salesforce was divided into two teams, one of which promoted Aldara. The Aldara salesforce was divided into two regions (northern and southern) of ten specialist account managers, each region was managed by one commercial manager.

As the complaint referred to Aldara, then the response below was based specifically on communications to the Aldara salesforce.

Meda stated that regional salesforce meetings were held on Tuesday, 8 January and Wednesday. The agenda for these meetings was provided.

There was a session relating to Salesforce Expectations that was part of the session 'Setting the Pace'. This was a joint session between the senior product manager for Aldara, medical advisor and the respective commercial manager for that region.

This session positioned the Aldara campaign for both primary and secondary care in 2008 and gave an overview of what the salesforce could expect in terms of promotional materials, meetings support and mailings. Then each commercial manager set out the expectations of the Aldara salesforce for quarter 1, 2008. This was the same presentation for both meetings.

The presentation covered all aspects of the Aldara salesforce. Call rates were discussed and outlined in a slide which focussed on what needed to be delivered for quarter 1, 2008 to enable a good start to the year. The communication plan for 2008 was that at the end of each quarter the salesforce would be given an updated set of expectations for the forthcoming quarter and these were called operational plans. This allowed the sales management team the flexibility to adapt the implementation of the Aldara campaign and provide the necessary focus for each given quarter and follow the same timelines as the business planning process which was quarterly. Details about each representative's customer activity was provided.

Coverage and frequency were discussed and outlined in another slide. The coverage and frequency expectations were only given with reference to the primary care campaign and not hospital contacts. This slide covered the whole of

2008 because the main focus of the salesforce activity was in primary care and the commercial managers wanted to provide the context to the salesforce to demonstrate how this would evolve over 2008 across all quarters. Hence reference to the coverage and frequency expectation being in line with the Code was clearly stated on the slide and verbalised. The content of this slide was also repeated in subsequent emails from the commercial manager to the southern region. No commercial manager had requested additional contacts outside of the Code in either primary care or secondary care.

In response to a request for further information Meda stated that the salesforce had been briefed on the Code in February 2007 using the same materials that were used on the initial training course (ITC). All new starters to Meda undertook an ITC which included a specific session that covered the Code. This session was an interactive session with supporting PowerPoint slides (copies provided) and specifically covered the Code from a salesforce perspective. Within this presentation one slide covered the aspects of call frequency which was verbalised and expanded upon by the presenter. The slide stated:

'Calls (Clause 15)
- No inducement for an interview
- Clarity regarding your identification
- No fee for an interview
- Convenience of calls
- Call Frequency
- Delivery of 'endurance items'

- **Members of the MEDA salesforce must at all times maintain a high standard of ethical behaviour.'**

In addition each delegate received a hard copy of the Code as well as a copy of the Code in the Field book. Specific instructions were given to each ITC delegate that they needed to have read and understood the Code. As from January 2008, each ITC delegate's knowledge and understanding of the Code was tested the day after the Code training session. A written test devised by an external medical consultant was used with a pass mark of 80%. The test included a specific question relating to contact rates and call frequency. The tests were marked and returned to the delegates and any incorrect answers were clarified to ensure understanding. Any advice required by specialist account managers relating to contact rates, call rates and the Code were discussed with individuals on the telephone, field visits or one to one meetings with their commercial manager.

With regard to customer targets the slide used at the January salesforce meetings stated:

'Customer Targets

- Pathfinder to be set up to track coverage and frequency
- Call frequency to be within ABPI guidelines.

Of 100 Target GP's (minimum requirements – 1:1 Contacts)
Q1 – 40% coverage – 25% seen twice
Q2 – 80% coverage – 50% seen twice – 30% seen 3 times
Q3 – 90% coverage – 75% seen twice – 60% seen 3 times
Q4 – 95% coverage – 90% seen twice – 90% seen 3 times

275 contacts needed – 23 per month – 1 per day'

Meda stated that the figures for customer targets, coverage and frequency demonstrated the expectations of the salesforce through each quarter of 2008. The figures for each quarter related to the cumulative perspective for 2008 and this was clarified in the briefing. The GPs to be seen three times were all a subset of those to be seen twice and this was explicit in the briefing. Each commercial manager undertaking the presentation verbally clarified and illustrated the figures eg 'If you have 100 target customers by the end of 2008 you will need to have seen 95 of them once, of which a subset of 90 needs to have been seen twice, of which a subset of 90 needs to have been seen three times.'

PANEL RULING

The Panel noted that the supplementary information to Clause 15.4 stated that the number of calls made on a doctor or other prescriber by a representative each year should normally not exceed three on average excluding attendance at group meetings and the like, a visit requested by the doctor or other prescriber or a visit to follow up a report of an adverse reaction. Thus although a representative might speculatively call upon or proactively make an appointment to see a doctor or other prescriber three times in a year, the number of contacts with that health professional in the year might be more than that. In the Panel's view briefing material should clearly distinguish between expected call rates and expected contact rates.

The Panel noted that at the January regional meetings the presentations included slides about customer targets. One slide stated that call frequency was to be within ABPI guidelines. The expectations for 2008 were set out on the same slide. These being of 100 target GPs the minimum requirement was 1:1 contacts. In quarter 1, 25% were to be seen twice, the equivalent figures for quarters 2, 3 and 4 were 50%, 75% and 90% respectively. In addition in quarter 2, 30% were to be seen 3 times with 60% and 90% in quarters 3 and 4 respectively. Targets were only given for primary care.

One of the slides used on the ITC referred to calls but no details were given regarding call frequency. One of the questions in the test on the Code also referred to calls.

The Panel noted an email from the commercial manager provided by the complainant. This reproduced the second part of the slide ie that relating to the quarterly requirements for coverage and frequency. The email included '… however we need to be seeing more of them and more frequently. We have minimum expectations around customer contacts in particular GP activity which as a minimum we must be achieving'.

The Panel was concerned that it appeared that the representatives had not been provided with the details of the requirements of the Code and clear definitions of 'contact rate' and 'call rate' and why the differences were important. The Panel noted Meda's response but considered that the slide regarding customer targets used at the January salesforce meetings could have been more explicit. It did not state that the rates were cumulative. Although it stated the call frequency had to be within ABPI guidelines it did not appear that these had been explained to the salesforce. It was also concerned that the contact rates were described as minimum when the Code did not permit more than 3 unsolicited calls in a year. On balance the Panel considered that the slide presentation and other instructions advocated a course of action which was likely to lead to a breach of the Code. A breach of Clause 15.9 was ruled.

The Panel considered that there was no evidence that over calling had occurred and thus no breach of Clause 15.4 was ruled.

The Panel did not consider the circumstances warranted a ruling of a breach of Clause 9.1 nor Clause 2 which was used as a sign of particular censure and reserved for such use.

2 Letter about Aldara sent to doctors

RESPONSE

Meda stated that the primary care campaign for Aldara focussed on accessing a key group of approximately 800 GPs who had a registered interest in dermatology and were called GPs with special interests (GPwSI). In terms of the dermatology indications these were a key group of customers to contact.

The letter in question introduced the specialist account manager to this specific customer group. This letter was previously created by another company through the product development team and was reintroduced by a commercial manager within Meda to help specialist account managers access this group. The letter was re-approved for use by the Meda salesforce using the Meda promotional material approval process and signed off by all relevant ABPI signatories in July 2007. This letter was then given to the representatives for them to use with their customers.

PANEL RULING

The Panel noted Meda's submission that this letter had been certified and prescribing information had been provided on the reverse. Prescribing information did not appear on the version supplied by the complainant. It was not clear how the letter had been made available to the sales force. It should have been such that it was not possible for it to be used without the requisite prescribing information. The complainant had not been entirely clear as to what his complaint was about the letter. It was not necessarily unacceptable to use a letter to try to gain an appointment with a health professional. In the circumstances the Panel decided there was no breach of Clause 14.1 of the Code and ruled accordingly.

3 Alleged promotion outside the marketing authorization

RESPONSE

Meda explained that Aldara was launched in the UK in 1997 for the treatment of external genital and perianal warts in adults. Following that it was licensed in 2005 for small superficial basal cell carcinomas (sBCCs) in adults and finally in 2007 it was licensed for clinically typical, nonhyperkeratotic, nonhypertrophic actinic kertoses (AKs) on the face or scalp in immunocompetent adult patients when size or number of lesions limited the efficacy and/or acceptability of crytherapy and other topical treatment options were contraindicated or less appropriate.

Due to the mode of action of Aldara this had stimulated other customers' potential use. Representatives were briefed on the ITC about dealing with specific queries on the use of Aldara for indications outside of the licence and what they needed to do in terms of passing the lead/contact onto the medical advisor via email or telephone. At all briefings any specific enquiries outside of the licence raised by a member of the salesforce were clarified by a member of the Meda management team and passed on to the medical advisor.

Meda had two specialist account managers who had made specific contact with maxillofacial customers as a direct result of a referral from a dermatologist who worked closely with the maxillofacial surgeons for managing sBCCs in adults.

With specific reference to a teleconference mentioned, there had been two teleconferences, one in January and the other in March for one of the Aldara teams. The minutes of the teleconferences and the amendments by the commercial manager were provided. The minutes of the teleconference on 14 March clearly showed that off-licence use was raised by the specialist account managers themselves, and on that teleconference the commercial manager restated

that they should never promote Aldara outside of the licence.

In addition the amendments of the minutes of the teleconference by the commercial manager stated 'I just want to confirm what I said on the [teleconference] and that is we should never promote Aldara off-licence, and if other specialties have expressed an interest then we can follow up to find out what their interest in Aldara is? We should not be contacting this specialty directly, only following up requests'.

Meda submitted that there was one specialist account manager who had a task relating to maxillofacial but this was in reference to a specific customer follow-up from a dermatologist in line with Aldara licensed use.

PANEL RULING

The Panel was concerned that the original minutes (undated) of the 10 March teleconference stated that a representative had had success with plastic surgery in that he was '…successfully promoting to plastics, and they tend to be using Aldara for shrinking of lesions, prior to surgical excision. There was concern expressed by [a named representative] that this could be an off label promotion, but as we would only be talking about AK/SCC lesions, this should not be too much of a problem ...'. The amended copy of the minutes (also undated) for the same teleconference included additional information '**I just want to confirm what I said on the TC and that is we should never promote Aldara off-licence**, and if other specialties have expressed an interest then we can follow up to find out what their interest in Aldara is? We should not be contacting this specialty directly, only following up requests'.

The Panel noted the submission that two specialist account managers had made specific contact with maxillofacial customers as a direct result of a referral from a dermatologist who worked closely with the maxillofacial surgeons for managing sBCCs.

The Panel was concerned that Meda was promoting Aldara to plastic surgeons to shrink lesions prior to surgery. This was inconsistent with the summary of product characteristics (SPC) which stated, *inter alia*, that Aldara was indicated for the topical treatment of sBCCs. The Panel ruled a breach of Clause 3.2 of the Code.

The Panel did not consider the circumstances warranted a ruling of a breach of Clause 9.1 nor Clause 2 which was used as a sign of censure and reserved for such use.

Complaint received **7 March 2008**

Case completed **22 April 2008**