

HEAD OF MEDICINES OPTIMISATION v A MENARINI

Promotion of Adenuric

A head of medicines optimisation complained about an email from A Menarini which was sent to payers, formulary committees, prescribing advisors and medicines management teams. It stated that the recent price increase [29%] for generic allopurinol might be important in relation to the potential increase in the long-term costs of treating hyperuricaemia associated with gout; an attached document which promoted Adenuric (febuxostat) (an alternative to allopurinol marketed by A Menarini) stated that if the current trend continued, the annual allopurinol expenditure would rise by approximately £2.6 million. A graph depicted the rise in allopurinol average unit cost.

The complainant alleged that the letter misrepresented the issues dramatically. To imply that long-term costs could be better planned or managed by using Adenuric (£24.36 for 28) vs allopurinol which had ranged from £1 to £1.40 over the last four years was irresponsible. From the start of the graph in 2011 at £1.20 an annual growth of around 4% meant the price would be, as currently, around £1.40. The complainant noted that the very large scale graph presented the minimal variation in allopurinol costs but not the cost of Adenuric. The complainant further noted that the price of Adenuric, in small type at the bottom of the prescribing information, was a long way from the larger type which highlighted the 29% increase in price for allopurinol.

The complainant provided a summary of prescribing data and costs (December 2014 – February 2015) which he stated showed balanced representation; the 61,242 allopurinol items dispensed, at a cost of £109,951 had increased recently, whereas the 1,320 Adenuric items, at a cost of £34,881 had remained fairly flat. The complainant stated that if A Menarini's advice was followed, and all patients on allopurinol were switched to Adenuric, net NHS expenditure would increase to £2,795,553 per quarter which would increase the category spend to £3million vs the current spend of £205,946. This was not a good use of NHS resources and might divert scarce resources from other conditions and treatments with more effective or efficient treatments.

The complainant also queried whether the email was a data breach to initially share the details with all the people copied in. There was a significant number of broken emails and legacy emails from organisations closed over two years ago.

The detailed response from A Menarini is given below.

The Panel noted the reference to the 29% increase in the average cost of allopurinol and that if the trend continued allopurinol expenditure would rise by approximately £2.6 million. Beneath the

graphical representation of the price increase the text began 'Another ULT [urate lowering therapy] is Adenuric (febuxostat)'. The reader was told that further information about Adenuric could be viewed on the reverse of the item. The reverse featured the prescribing information. The Panel considered that given the emphasis on the financial impact of the recent price increase the material implied that Adenuric would be a suitable and a less expensive alternative. This was not so. The Panel noted that Adenuric (£24.36/28 tablets) was considerably more expensive than allopurinol (£1.43/28 tablets).

The Panel considered that the material was misleading about the relative costs of allopurinol and Adenuric, and the cost advantages that could be achieved by switching to Adenuric. The Panel was concerned that the material referred to a 29% increase in the unit cost of allopurinol without immediately quantifying the unit cost. The Panel was concerned that the reference to future allopurinol expenditure rising by £2.6 million was not robust and noted the complainant's comments in that regard. This misleading impression was compounded by references in the text to planning for long-term expenditure. The Panel did not accept A Menarini's submission that the material provided bald information for the reader to make up their own mind. The cost information for Adenuric was not included other than in the prescribing information. The Panel considered the material including the graph was misleading and did not give a clear, balanced view of the position. Breaches of the Code were ruled as acknowledged by A Menarini.

The Panel noted the email was sent to the company's own mailing list. There was a difference of opinion between the parties as to the accuracy of the list. It was for the complainant to prove his case on the balance of probabilities. The Panel noted that the Code required companies to have prior permission from recipients when using email for promotional purposes. The Panel noted that A Menarini had had developed the email list from names suggested by its staff. The company had not shown it had prior permission to send promotional emails to those health professionals whose email addresses it had acquired. Such permission could not be implied either from possession of the email address or from a health professional not asking to be removed from the mailing list. The Panel did not consider that the requirements of the Code had been satisfied and a breach was ruled.

The email provided by the complainant had been sent to, what appeared to be, a primary care trust; these were replaced by clinical commissioning groups on 1 April 2013. On the material provided, the Panel did not consider that the complainant had demonstrated that the email had been circulated

to those who had no need for or interest in the content. No breach of the Code was ruled. However the Panel ruled a breach of the Code as it considered that the email list was not up-to-date.

The Panel did not consider the promotional nature of the email had been disguised; no breach of the Code was ruled. The Panel also ruled no breach of that part of the Code which referred to studies etc as it was not relevant to the mailing.

The Panel was concerned that the email addresses of all the recipients had been circulated to all on the list. The Panel queried whether permission had been given to pass on these details. The Panel was concerned about the nature of some of A Menarini's submissions including that the material contained bald information for the reader to make up their mind; its comments in relation to permission to receive promotional emails; and that there were no promotional claims or comparisons in the material. The Panel considered that such comments demonstrated a fundamental lack of understanding of the Code. The Panel noted the poor quality of the material and its rulings of breaches of the Code. The potential impact on NHS budgets if the changes were made was of serious concern. It considered that high standards had not been maintained and ruled a breach of the Code.

The Panel noted that Clause 2 was used as a sign of particular censure and reserved for such use. On balance the Panel did not consider that the circumstances warranted such a ruling and thus it ruled no breach of Clause 2.

A head of medicines optimisation complained directly to A Menarini Farmaceutica Internazionale SRL about an email (6 May 2015) he had received from the company. The complaint was copied to the Authority.

The email in question was sent to payers, formulary committees, prescribing advisors and medicines management teams. The email consisted of a covering letter which stated that the attached information about the recent price increase for generic allopurinol might be important in relation to the potential increase in costs for the treatment of hyperuricaemia associated with gout. The attached promotional piece for Adenuric, (ref 5822/ADE/APR/2015/CRJ), headed 'Generic Bulletin – Urate Lowering Therapies [ULTs]', detailed a recent price increase for allopurinol and stated that the average unit cost had increased by 29% and that if the trend continued, the annual allopurinol expenditure would rise by approximately £2.6 million. The attachment stated that these developments had implications for those wishing to plan their long-term expenditure costs for ULTs and featured a graph showing the rise in allopurinol average unit cost. A Menarini marketed an alternative ULT, Adenuric (febuxostat) for the treatment of chronic hyperuricaemia. The attachment stated that Adenuric delivered a continuity of supply, price consistency and a clear level of clinical efficacy. Both allopurinol and Adenuric inhibited uric acid production.

The complaint was considered under the 2015 Code.

COMPLAINT

The complainant stated that he was pretty disgusted with the letter as it misrepresented the issues dramatically. To imply that Adenuric (£24.36 for 28) was a better way to manage or plan the long-term expenditure costs of urate lowering therapies, when allopurinol had ranged from £1 to £1.40 over the last four years was to completely miss the point. From the start of the graph in 2011 at £1.20 an annual growth of around 4% meant the price would be around the current £1.40 level. The complainant noted that the very large scale graph presented the minimal variation in allopurinol costs but not the cost of Adenuric; he assumed that this was because, while having a flat variation, it would be off the top of the page due to the scale used.

The complainant noted that the only reference to the price of Adenuric, in 8 point type at the bottom of the prescribing information, was a long way from the 11 point type which highlighted the 29% increase in price for allopurinol. The complainant stated that he supported the approval, in certain patients, of Adenuric by the National Institute for Health and Care Excellence (NICE), but he considered that to suggest that a product which was currently 1,740% higher than the newly higher price of allopurinol, should help manage 'long-term expenditure costs', was irresponsible.

The complainant provided a summary of the item, cost and cost per item to show a balanced representation. This showed that for December 2014 – February 2015 the 61,242 allopurinol items dispensed, at a cost of £109,951 had increased recently, whereas the 1,320 Adenuric items, at a cost of £34,881 had remained fairly flat. The complainant stated that if, in the unlikely and undesirable event that A Menarini's advice was blindly followed, and all patients on allopurinol were switched to Adenuric, the NHS would see a net increase in expenditure to £2,795,553 per quarter which would increase the category spend to £3million vs the current spend of £205,946. The £12million annual pressure would represent 2.4% of the primary care medicine budget in the complainant's geographical area – equivalent to the entire average uplift. This was not a good use of NHS resources and might divert scarce resources from other conditions and treatments with more effective or efficient treatments. The complainant cited Clauses 7.2, 7.8, 12.1 and 12.2 of the Code and stated that there might be others that applied.

The complainant also queried whether the email was a data breach to initially share the details with all the people copied in – many of whom he knew, others he did not. The complainant noted that there was a significant number of broken emails and legacy emails from organisations closed over two years ago. The complainant also alleged a breach of Clauses 11.1 and 11.3 of the Code.

When writing to A Menarini, the Authority asked it to respond in relation to Clauses 7.2, 7.8, 11.1, 11.3, 12.1 and 12.2 as cited by the complainant. The company was also asked to respond in relation to Clauses 2, 9.1 and 9.9.

RESPONSE

A Menarini noted the complainant's allegation that the email implied that Adenuric might be a better way of managing expenditure costs but submitted that this was, at best, debateable. The letter could as easily have been read as providing bald information for the reader to make up his/her own mind. It was probably a matter of personal interpretation.

A Menarini noted that the graph on page 1 showed that Adenuric was much more expensive than allopurinol. A Menarini acknowledged that it was misleading to show actual costs as there was a vast discrepancy between amounts of actual product sold. However, this was rectified by the cost per item, which redressed this. The graph of allopurinol on page 1 was in reality a flat graph simply showing the recent 29% increase. However, it was true that a 29% increase of not very much was still not very much. The graph itself was factual. The scale might be questionable. There was an implication that this might bring allopurinol closer to Adenuric but it seemed fairly clear that this was not so.

The price of Adenuric was illustrated only at the end of the prescribing information and this was an error and, although not technically misleading, could be interpreted as trying to hide information. A Menarini agreed that, to be fair, it should have been shown in direct comparison.

A Menarini submitted that although the information for the prescriber was there, it was not very clear and while it considered that it was unlikely that any recipient in the target audience would blindly take the action suggested by the complainant, it had to concede that the risk was there, albeit small.

A Menarini regrettably conceded that the email was not unambiguous and not correctly balanced; it was, however, accurate. The recipients could make their own decision, but not without some difficulty. A Menarini conceded breaches of Clauses 7.2 and 7.8.

A Menarini noted the complainant's suggestion that the recipients (which he knew about by open copy) might not have given permission for their names to be used and therefore be inappropriate. The list was taken from a short list held in-house by medical and held names suggested over time by senior field operatives. The names had been used on previous occasions and at every occasion, in upper case, the recipient was given the chance to be taken off the list. None of those circulated in this email had indicated this wish. Finally, it was believed that these recipients were all relevant to the message in the email. Whether the names should have been openly copied was debateable but A Menarini did not consider that to do so was damaging. The company denied a breach of Clause 11.

A Menarini did not agree that the material was disguised promotion. The promotional element seemed completely clear. The primary recipient, and all those by copy, was certainly within the category that was open to promotion (Clause 1.2), the piece was an email but did contain the necessary

prescribing information. As an email it did not have an envelope as with older promotional activities but the header seemed entirely clear. The company denied a breach of Clause 12.

A Menarini noted that Clause 9 referred to taste and suitability. The company did not find anything in the email or its attachment that was distasteful. Furthermore the information contained (even accepting the opening response regarding Clause 7) was suitable for the recipients. A Menarini considered that the use of 'disgusted' was a loose one and depicted the complainant's strong disapproval rather than true 'disgust'.

A Menarini stated that whilst it agreed that it might have breached Clause 7, it did not consider that this had damaged the reputation of the industry as a whole. The email had its failings but was a 'one off' and it was not intended to repeat the exercise.

A Menarini denied a breach of Clauses 9 and 2 and stated that action had been taken to try to prevent a repetition of the accepted breach.

In response to a request for further information, and with regard to Clause 9.9, A Menarini stated that the email list was created by information received from its NHS relationships team using local knowledge and professional contact details. By virtue of having the email address of the recipient NHS customer the company understood that permission to communicate was implied and therefore this was in line with the Code. To support this understanding, this group of NHS customers had been corresponded with on two prior occasions and, as such, had been given the chance to withdraw from receiving such communications from A Menarini. To date, no requests to be removed from this form of communication by any of the customers had been received. A Menarini submitted that information like that in question was valuable for appropriate decision makers and noted that it made no promotional claims or comparisons in the material that was sent.

With regard to Clause 11.1, A Menarini stated that from its response in relation to Clause 9.9 above and in line with its understanding of the Code, the material was only sent to those persons reasonably assumed to be in need of, or interested in, receiving such correspondence. The profile of the recipients were all senior pharmacists or other relevant senior NHS decision makers. As such, the distribution list was appropriate.

With regard to Clause 11.3, A Menarini stated that the mailing list was compiled in June 2014 and as outlined above, this customer group had received two previous emails and had had at least two opportunities to withdraw from receiving such information. For the avoidance of doubt the wording to allow opt-out was:

'Please note, if you do not wish to receive such announcements in the future, please email me and you will be removed from our mailing list.'

To date, A Menarini had received no requests to be removed from this form of communication. The information was sent to 170 individuals with a total of 31 emails that were returned as undelivered. This was not an unexpected percentage.

A Menarini stated that as a result of this case, it had internally investigated its process with a view to refine and adjust as needed.

PANEL RULING

The Panel noted that the email provided by the complainant (dated 6 May 2015 at 10.05) was different to that provided by A Menarini (6 May 10.19) in that they had different circulation lists. The content was otherwise identical. The Panel noted the reference to the 29% increase in the average cost of allopurinol and that if the trend continued allopurinol expenditure would rise by approximately £2.6 million. Beneath the graphical representation of the price increase the text began 'Another ULT is Adenuric (febuxostat)'. The reader was told that further information about Adenuric could be viewed on the reverse of the item. The reverse featured the prescribing information. The Panel noted that the material had to be capable of standing alone in relation to compliance with the Code without reference to or qualification by the prescribing information. The Panel considered that given the emphasis on the financial impact of the recent price increase the material implied that Adenuric would be a suitable and a less expensive alternative. This was not so. The Panel noted that Adenuric at £24.36 for 28 tablets was considerably more expensive than the £1.43 for 28 allopurinol tablets (February 2015, figures provided by A Menarini).

The Panel considered that the material was misleading about the relative costs of allopurinol and Adenuric, and the cost advantages that could be achieved by switching to Adenuric. The Panel was concerned that the material referred to a 29% increase in the unit cost of allopurinol without immediately quantifying the unit cost. The unit cost figures in the graph did not assist as they were not in the same immediate visual field as the increased unit cost claim. The Panel was concerned that the reference to future allopurinol expenditure rising by £2.6 million was not robust and noted the complainant's comments in this regard. This misleading impression was compounded by referring to planning for long-term expenditure in the text. The Panel did not accept A Menarini's submission that the material provided bald information for the reader to make up their own mind. The cost information for Adenuric was not included other than in the prescribing information. The Panel considered the material including the graph was misleading and did not give a clear, balanced view of the position. Breaches of Clauses 7.2 and 7.8 were ruled as acknowledged by A Menarini.

The Panel noted the email was sent to the company's own mailing list. There was a difference of opinion between the complainant and A Menarini in relation to the accuracy of the list. The Panel noted that it was for the complainant to prove their case on the

balance of probabilities. The Panel noted that Clause 9.9 required companies to have prior permission from recipients when using email for promotional purposes. A Menarini had not provided details of such prior permission despite being asked to do so. The Panel did not accept A Menarini's submission that by virtue of having the email address of the recipient NHS customer, permission to communicate was implied and therefore in accordance with the Code. The company had developed the list from names suggested by staff in the field. The company had not shown it had prior permission to send promotional emails to those health professionals whose email addresses it had acquired. Such permission could not be implied either by the fact that the company possessed the email address or that a health professional had not asked to be removed from the mailing list. The Panel did not consider that the requirements of Clause 9.9 had been satisfied and a breach was ruled.

The email provided by the complainant had been sent to, what appeared to be, a primary care trust; these were replaced by clinical commissioning groups on 1 April 2013. On the material provided, the Panel did not consider that the complainant had demonstrated that the email had been circulated to those who had no need for or interest in the content. No breach of Clause 11.1 was ruled. The Panel considered that the email list was not up-to-date and thus a breach of Clause 11.3 was ruled.

The Panel did not consider the email would be seen as anything other than promotional and was not disguised; no breach of Clause 12.1 was ruled. The Panel also ruled no breach of Clause 12.2 as this clause referred to studies etc and was not relevant to the mailing.

The Panel was concerned that the email addresses of all the recipients had been circulated to all on the list. The Panel queried whether permission had been given to pass on these details. The Panel was concerned about the nature of some of A Menarini's submissions including that the material contained bald information for the reader to make up their mind; its comments in relation to permission to receive promotional emails; and that there were no promotional claims or comparisons in the material. The Panel considered that these demonstrated a fundamental lack of understanding of the Code. The Panel noted the poor quality of the material and its rulings of breaches of the Code. The potential impact on NHS budgets if the changes were made was of serious concern. It considered that high standards had not been maintained and ruled a breach of Clause 9.1.

The Panel noted that Clause 2 was used as a sign of particular censure and reserved for such use. On balance the Panel did not consider that the circumstances warranted such a ruling and thus ruled no breach of Clause 2.

Complaint received	6 May 2015
Case completed	15 July 2015