

# VOLUNTARY ADMISSION BY AMDIPHARM MERCURY

## Email sent by representative

Amdipharm Mercury Company (AMCo) voluntarily admitted a breach of the Code in that a representative sent an unapproved email promoting Lutrate (leuprorelin) to a prescribing advisor. Lutrate was indicated in the treatment of advanced prostate cancer.

AMCo stated that the email was discovered as a result of ongoing inter-company dialogue during which it had been brought to the company's attention that a budget impact model relating to cost savings for a specific clinical commissioning group (CCG) contained an error which seemed to have been confined to one territory. AMCo withdrew the model until it could be demonstrated to work in all territories.

The representative concerned had noticed the error and sent revised and correct figures to the customer concerned. On further examination AMCo realised that the revised data itself was marginally incorrect (there was actually an additional cost saving available to the CCG). The inconsistency had since been fully explained to the customer with apologies from the company.

AMCo was disappointed that the representative's email included an unauthorized and unapproved claim which did not appear to be scientifically valid or clear. It was also inconsistent with the training provided to the sales force and fell short of the standards set for AMCo representatives.

The Panel noted AMCo's submission that the voluntary admission related to an email from an AMCo representative which included the claim 'Lutrate is available as a one month and three month formulation providing effective suppression and maintenance of testosterone to castration levels with the tolerability you would expect from each leuprorelin dose'. The Panel noted AMCo's admission that the claim was not scientifically valid and was confusing and ruled a breach of the Code. The claim could not be substantiated as acknowledged by AMCo and a further breach was ruled. Further breaches of the Code were ruled as the email had not been certified and high standards had not been maintained.

The Panel ruled no breach of the Code with regard to the frequency, timing and duration of calls by a representative on health professionals and others.

Amdipharm Mercury Company (AMCo) Limited voluntarily admitted a breach of the Code in that a representative sent an unapproved email promoting Lutrate (leuprorelin) to a prescribing advisor.

Lutrate 1 month depot injection was indicated for palliative treatment of locally advanced or metastatic prostate cancer. Lutrate 3 month depot injection

was indicated for palliative treatment of hormone dependent advanced prostate cancer.

## VOLUNTARY ADMISSION

AMCo stated that it discovered the unapproved email sent by its representative following an internal investigation stemming from ongoing inter-company dialogue. The other pharmaceutical company had drawn AMCo's attention to a budget impact model (BIM) relating to cost savings for a specific clinical commissioning group (CCG) which contained an unaccountable error. The error seemed to have been confined to one territory after prescription cost analysis data was automatically imported in to the BIM. AMCo took a conservative approach to this inaccuracy and voluntarily withdrew the BIM until it could be demonstrated to work in all territories. Additionally, AMCo provided clarification and reassurance to the other company on how the calculations were derived and the assumptions that were made in the model and was awaiting confirmation from it that the matter had been resolved.

AMCo informed the other company that the representative concerned had noticed the error and sent revised and correct figures to the customer in question. On further examination AMCo realised that the revised data itself was marginally incorrect (there was actually an additional £170 cost saving available to the CCG). The customer had since been informed with a full explanation regarding the inconsistency with the company's apologies.

AMCo was disappointed that the representative's email to the prescribing advisor contained an unauthorized and unapproved claim:

'Lutrate is available as a one month and three month formulation providing effective suppression and maintenance of testosterone to castration levels with the tolerability you would expect from each leuprorelin dose.'

This claim did not appear to be scientifically valid or clear and had not been approved for use in this manner. The statement was also inconsistent with the training provided to the sales force and fell short of the standards set for AMCo representatives.

Disciplinary action had been taken and further training had been delivered to the entire sales force. In addition, a formal memo had been sent to the whole UK field force highlighting the importance of ABPI compliant communications to customers and health professionals and clarification on the circumstances when approval/certification was required.

When writing to AMCo, the Authority asked it to respond in relation to Clauses 7.2, 7.4, 9.1 and 15.4 of the Code and in addition Clause 14.1.

## RESPONSE

AMCo reiterated that the email was discovered in connection with on-going inter-company dialogue relating to the provision of inaccurate cost savings data to one customer. The error led to an underestimate of actual savings realisable. The customer had since been provided with the correct savings data and the other pharmaceutical company had been given details of the Lutrate BIM including all of the assumptions and updated information.

With regard to Clause 7.2, AMCo submitted that the unauthorized claim in the email did not specifically distort or mislead the reader as the claim itself did not seem to make sense; 'with the tolerability you would expect from every dose' therefore AMCo submitted that the reader was not misled but more likely confused by the statement, which in itself fell well below the high standards expected in communications with health professionals.

AMCo accepted that there appeared to be a breach of Clause 7.4 as the claim could not be substantiated. The company also accepted that high standards were not maintained in relation to this email in breach of Clause 9.1.

AMCo denied a breach of Clause 15.4 as the request to meet and discuss the budget impact model had been accepted by the customer along with a request for the representative to call back by telephone in two weeks. Other than this, one final email was sent by AMCo to alert the health professional of the error.

Since learning of this mistake, the entire sales force had been retrained and additionally sent a memo which highlighted the importance of ABPI compliant communications to customers and health professionals and clarified the circumstances when approval/certification was required.

AMCo trusted this set out the company's deep regret with respect to this voluntary admission and conveyed the seriousness with which it had taken this incident.

In response to a request for further information from the case preparation manager, AMCo submitted that prescribing information was included in both the email in question and the subsequent two corrective emails sent to the customer. AMCo had no additional comments in relation to Clauses 9.1 or 14.1.

## PANEL RULING

The Panel noted AMCo's submission that the voluntary admission related solely to the email from an AMCo representative which included the claim 'Lutrate is available as a one month and three

month formulation providing effective suppression and maintenance of testosterone to castration levels with the tolerability you would expect from each leuprorelin dose'. The Panel noted AMCo's submission that the claim was not scientifically valid or clear. The Panel found it difficult to understand AMCo's view that the claim in question was not misleading but was likely to confuse readers. The Panel noted that Clause 7.2 required, *inter alia*, that claims be accurate and unambiguous and that material must be sufficiently complete to enable the recipient to form their own opinion of the therapeutic value of the medicine. The Panel noted AMCo's admission that the claim was not scientifically valid and was confusing and ruled a breach of Clause 7.2. The claim could not be substantiated as acknowledged by AMCo and a breach of Clause 7.4 was ruled. The promotional email had not been certified before it was sent to the prescribing advisor and a breach of Clause 14.1 was ruled.

The Panel noted that AMCo had been asked to respond to Clause 15.4 which required that representatives must ensure that the frequency, timing and duration of calls on health professionals, administrative staff in hospitals and NHS and other organisations, together with the manner in which they are made, do not cause inconvenience. The wishes of individuals on whom representatives wished to call and the arrangements in force at any particular establishment, must be observed. The Panel noted AMCo's submission that the request to meet and discuss the budget impact model had been accepted by the customer along with a request for the AMCo representative to call back by telephone in two weeks. The Panel ruled no breach of Clause 15.4; it covered the frequency and manner of calls on doctors and other prescribers which was not the subject of the voluntary admission and therefore not at issue in this case. The company had not been asked to respond in relation to Clause 15.2 and so the Panel could make no ruling in that regard.

The Panel noted that the email in question promoted Lutrate. The representative had created and disseminated his/her own piece of promotional material; it should have been certified in accordance with Clause 14.1. The Panel noted AMCo's submission that the claim was inconsistent with the training provided to the sales force and fell short of the standards set for AMCo representatives. Training provided by AMCo in January 2016 included a slide titled 'Field activities – Representatives' and stated that all emails needed to be certified. The Panel considered that the representative had not maintained high standards and a breach of Clause 9.1 was ruled.

**Complaint received**            **11 May 2016**

**Case completed**                **7 July 2016**