

Case AUTH/3816/7/23

COMPLAINANT v STIRLING ANGLIAN

Omission of adverse event statement within an Acepiro advertisement

CASE SUMMARY

This case related to an Acepiro (acetylcysteine) promotional advertisement on a learned society's homepage which did not contain the adverse event reporting statement within the advertisement itself.

The outcome under the 2021 Code was:

Breach of Clause 12.9	Failing to include the prominent adverse event reporting statement
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**This summary is not intended to be read in isolation.
For full details, please see the full case report below.**

FULL CASE REPORT

A complaint was received from an anonymous, non-contactable complainant about Stirling Anglian.

COMPLAINT

The complaint wording is reproduced below:

'I'm not sure if this a complaint but my understanding is that Pharma companies have to now include a safety statement in the banner advertisement, I've seen it with other products recently but not on this one so I thought I would bring it to your attention in case it is incorrect.'

When writing to Stirling Anglian, the PMCPA asked it to consider the requirements of Clause 12.9 of the 2021 Code.

STIRLING ANGLIAN'S RESPONSE

The response from Stirling Anglian is reproduced below:

'A hard copy version of the advertisement is included with this response but since it is a digital advert, I include the URL to the website page where it is currently being hosted [web link provided].

We are a little uncertain regarding the nature of the complaint. Is the complainant asking about the absence of adverse event reporting details? Or asking about the absence of adverse events typically summarised in the Prescribing Information? Or both?

The advertisement can be seen exclusively to [learned society] members (healthcare professionals with an interest in respiratory medicine) once they login with their credentials to the [learned society] website. The digital advert is hosted on the electronic Home page once logged in. No access to this Home page with the advert is granted without logging in. No hard copy version of this advert has been distributed. As such we would consider that the advertisement is subject to:

Section 12.4 (4.4) In digital material such as advertisements in electronic journals, emails, electronic detail aids and suchlike, the prescribing information as required by Clause 12.1 may be provided either:

- *by inclusion in the digital material itself, or*
- *by way of a clear, and prominent, direct, single click link.*

In this case, the digital advertisement in question includes a prominent direct single click link to the Acepiro Prescribing Information which we have included with this response. Please can you confirm that this is satisfactory?'

FURTHER INFORMATION

In response to a request for further information from the case preparation manager to respond to Clause 12.9 instead of Clause 12.4, Stirling Anglian's response is reproduced below:

'Stirling Anglian would like to sincerely apologise for this confusion and as stated in an earlier e-mail on 11th September, this advertisement has been withdrawn. A copy of the withdrawal certificate has been included with this letter which I have also included in hard copy. Once, again, I would like to take this opportunity to apologise for this error on Stirling Anglian's part, As a consequence, other digital adverts have been reviewed for any absence of Adverse Event reporting statement.'

PANEL RULING

This case related to an Acepiro (acetylcysteine) promotional advertisement on a learned society's homepage.

The Panel noted with concern that Stirling Anglian had not responded to the substance of Clause 12.9 and queried why it considered the complaint was unclear given it referred to the omission of a safety statement in the banner advertisement rather than in the linked prescribing information and the explicit request to respond to Clause 12.9 of the 2021 Code.

According to Stirling Anglian the advertisement in question was seen exclusively by the learned society's members once they logged in to the learned society's website where it was hosted on the home page. The Panel noted the advertisement at issue featured the claims 'Simple', 'Effective' and 'Economical' which sat above an image of a glass of water and the claim 'Just one tablet daily'. There was also the statement 'Prescribe Acepiro by brand' beneath which was a pack shot and a prominent link to prescribing information in the bottom right-hand corner.

Clause 12.9 required that all promotional material include the prominent adverse event reporting statement as referred to in the Code. The Panel noted that, in this instance, the adverse event reporting statement could be found by following the link labelled 'Prescribing Information here'. In the Panel's view, the provision of the adverse event reporting statement, via a hyperlink

which directed users to prescribing information, did not meet the requirements of Clause 12.9 under the 2021 Code; the adverse event reporting statement should have appeared as an integral part of promotional material. The Panel considered that the requirements of Clause 12.9 had not been met and ruled a **breach of Clause 12.9** accordingly.

Complaint received **31 August 2023**

Case completed **23 September 2024**