

Submission on Consumer Medicine Information on Adrenal Replacement Medications: Summary of interaction with *Australian Prescriber*

A paper on the persistence of inconsistent, incomplete and unsafe Consumer Medicine Information for glucocorticoid replacement medications was submitted to the *Australian Prescriber* journal in May 2008. The authors withdrew the submission in August 2008 after a series of unusual editorial strategies to avoid publication. The following is a summary of the interactions with the editorial committee of the *Australian Prescriber*:

22 May 2008 - Concerns about failure to correct deficiencies in consumer medicine information for glucocorticoid replacement medications were detailed in a communication to Australian Prescriber, published by the National Prescribing Service, committed to “quality use of medicines”.

23 June - The editor responds:

“As your letter raised matters of drug regulation, the Therapeutic Goods Administration has been invited to respond. The Editorial Executive Committee will consider the matter again once it has this response”.

09 July - Response to editor, copied to editorial chairman, pointing out that distribution to the TGA, before a decision on publication of the communication, is in breach of editorial confidentiality. The authors confirmed support for any response, sought after a decision to publish.

15 July - Letter received from editor, affirming previous actions without acknowledging any issue of editorial confidentiality, stating:

“The Editorial Executive Committee will probably decide whether or not to publish the correspondence and the response at its next meeting. If they are accepted for publication, some editing is likely to be required. I shall write to you again after the Editorial Executive Committee has reached a decision.”

25 July - Letter from first author to editorial chairman requesting a face-to-face meeting with the authors, to clarify the status of the submission, in particular agreement on review procedure and editorial confidentiality.

28 July - Letter from editorial chairman affirming current editorial procedure, with the assertion that “all material is subject to peer review”. No acknowledgement of request for a face-to-face meeting.

5 August - Opinion received from chair of the UK-based Committee on Publication Ethics, commenting on the editorial sequence – document available. (Australian Prescriber is not a signatory to the COPE conventions).

5 August - Letter of July 28 from editor, refusing the submission because of “concerns about some of the statements”. The editor states: “It is important that consumer medicine information is useful, however corticosteroids may not be the best example of a problem.” Enclosed was a response from TGA, dated June 2008 (i.e. at least 5 weeks previously). The TGA response, initially sought for publication, is now presented as “external review” – document available.

8-11 August - Further requests to AP editor and chairman in an effort to achieve authentic review of the submission.

18 August - Phone discussion with editor; no progress, submission withdrawn.

23 August - Report in *The Australian*: documents and responses on their website

URL: www.theaustralian.news.com.au/story/0,,24226761-23289,00.html

See also:

1. The paper submitted to *Australian Prescriber*:
Consumer Medicine Information (CMI) for glucocorticoid replacement medications one year on: unsafe errors persist. Stockigt JR, Torpy DJ, Fuller PJ, Colman PG, Topliss DJ.
Available on the Endocrine Society of Australia (ESA) website as a position statement:
URL: www.endocrinesociety.org.au/Glucocorticoids_unsafe_CMI_paper.pdf (PDF file, 37KB)
2. *Summary of On-line Consumer Medicine Information for the Glucocorticoid Replacement Medications, Cortate and Hysone.* Stockigt JR.
URL: www.endocrinesociety.org.au/Glucocorticoids_online_CMI_sources.pdf (PDF file, 21KB)

Additional documents available: COPE opinion, TGA response.

JR Stockigt, 11 Sept 2008