



# AUSTRALIAN ADDISON'S DISEASE ASSOCIATION INC

Raising awareness of Addison's disease and supplying a caring network for members and their families

President: ph (02) 6652 4761 Fax (02) 66524861  
Secretary: ph (02) 6657 2571 Fax: (02) 66571025  
P.O. Box 2436, Coffs Harbour, N.S.W. 2450

e-mail: [info@addisons.org.au](mailto:info@addisons.org.au)  
Web site: [www.addisons.org.au](http://www.addisons.org.au)  
ABN: 60 466 289 835

To: Dr Rohan Hammett, National Manager, TGA  
CC: Dr Lynn Weekes, Chief Executive, NPS  
CC: Patricia Lai Kwon, Scientific Affairs Director, Alphapharm, Pty Ltd  
CC: Greg Lan, Managing Director, Aspen Pharmacare Aust, Pty Ltd  
CC: Dr Jim Stockigt and co-authors  
CC: Ms Siobhan Murphy, Country Manager, MIMS  
CC: Dr Martin Van Der Weyden, Editor, Medical Journal of Australia  
CC: Dr Mark Mclean, President, Endocrine Society of Australia

19 September 2008

Dr Hammett

I am writing this letter to raise our committee's concerns following recent media publicity about inadequate and potentially harmful information published in the Consumer Medicines Information for glucocorticoids, in particular Cortate and Hysone.

As a support group for people with Addison's disease, we understand just how important it is to have accurate and clear information on the treatment of this condition. In situations of serious illness or infection, it can be life threatening to an Addisonian if they do not receive increased medication. The difficulty in having emergency rooms and treating doctors realise the importance of increasing a patient's medication has been an ongoing issue for us, to a point where we have produced our own emergency treatment letter and emergency ID card for members (included).

We come into contact with many newly diagnosed Addisonians who are confused regarding their medication, even after consulting their doctor or specialist. This confusion is exacerbated by the fact that for most, diagnosis of Addison's disease comes after a long and debilitating illness which leaves many with a lack of concentration, or what many describe as being "foggy". Most who contact us recall very little of what their doctor has discussed with them, so the reliance on information printed in a CMI may become, for some, the only patient information they have.

It appears that most information in the CMI pertains to glucocorticoids in the more commonly known role as an anti-inflammatory drug; however to the estimated 3,000 or more people with Addison's disease in Australia it is a life saving replacement therapy. Any publication that gives advice to stop this medication must also clearly differentiate the advice to those using it as a replacement therapy and include clear instructions, including the importance of increasing medication during illness, otherwise lives may be placed at risk. These issues have been raised by a number of senior endocrinologists whose professional expertise should not be ignored, and yet some of this confusing information still exists even after repeated attempts to seek change.

Although the CMI for Hysone has removed the wording "*Do not take Hysone if you have any infections that are not being treated or are not responding to treatment*", it still does not adequately address the area of replacement therapy and the importance of increasing the medication when required. As of the time of writing this letter, the CMI for Cortate has not been updated.

We have seen the response from your department to the communication that was sent to Australian Prescriber by Professor Stockigt and four senior endocrinologist colleagues. We wish to convey our disappointment at the

conclusions and opinions in that response. We endorse the claims that the CMI for these drugs are dangerously incorrect. In your response, you state *“This source includes the text, ‘Do not take CORTATE if you have an uncontrolled infection.’ The authors may have failed to read the subheading that clearly shows that the advice pertains to commencing Cortate (Before you take Cortate), not ceasing it while on treatment.”* Not all information listed below that subheading appears to be aimed at patients who are yet to start taking this medication. Regardless of whether a patient has started this medication or not, if it has been prescribed as a replacement therapy the information is clearly incorrect, misleading and dangerous.

You also state *“There is subsequent repeated advice to patients under ‘How to take Cortate’ to not alter their dose without professional advice, to indicate that dose may be adjusted, doses should not be missed, that treatment should not be unilaterally ceased and that ‘Your doctor will check your progress at regular intervals’”*. We disagree with the suggestion that Addisonians (who may have a serious infection or illness) should wait until they seek professional advice or visit their doctor before altering their medication. That contradicts standard practice for an Addisonian to self-initiate short term increases in dosage at times of illness, without which carries the risk of an Addisonian Crisis, a condition that MUST be treated immediately and often requires urgent hospitalisation.

I also wish to comment on a letter to the editor of the Australian newspaper by Dr Lynn Weekes of the NPS 29/08/2008. I particularly refer to the statement *“National Prescribing Service has issued a fact sheet about using corticosteroid medicines safely...”* Although this fact sheet does state *“Sometimes you may need to increase the dose of your medicines, for example if you are ill, injured or stressed”* it then refers readers to *“Ask your doctor or pharmacist for a copy of the Consumer Medicines Information leaflet for your medicine”*, the very document under question. Except for the above inclusion, the document seems to have little content of value and the time may have been better spent reviewing the CMI. It is unlikely that many people diagnosed with Addison’s will find or get to read this fact sheet as, unlike the CMI, it is not routinely provided by the pharmacist when dispensing medication, so I am unsure what benefit to Addisonians Dr Weekes hoped to gain. I must however thank the NPS for including a link to the Australian Addison’s Disease Association’s website.

Your department has made a negative response to genuine professional concerns and at this stage appears to be unwilling to take responsibility for improving the CMI. We therefore seek your specific answers to the following questions:

- 1) Who is professionally responsible for writing the CMI?
- 2) What is the process for reviewing, correcting or updating existing CMI?
- 3) What is the process for disseminating new or updated CMI?
- 4) Are there any current plans to review CMI for glucocorticoid replacement?

The Australian Addison’s Disease Association committee believes the CMI for Cortate and Hysone should be reviewed and revised. More specifically, those responsible for writing the CMI seek expert advice about including an appropriate statement on self initiated dose change. Additionally we would like to see the CMI reviewed by a qualified independent group, such as the Endocrine Society of Australia. We would also like to see all CMI clearly note any changes since last publication, so readers can easily see the relevant updated information.

We invite all parties involved to respond to our comments and questions, as well as keep our Association up to date on any decisions or changes on this issue.

Sincerely,



Peter Stewart  
AADA Committee Member  
webmaster@addisons.org.au