Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

Mr Peter Stewart,
Committee Member,
Australian Addison's Disease Association Inc.,
PO Box 2436,
Coffs Harbour NSW 2450

Dear Mr Stewart,

Thank you for your letter of 19 September 2008 on the important issue of the safe management of Addison's disease. You requested my response to four questions that you have raised in relation to consumer medicine information (CMI) documents of two oral corticosteroid medications, Hyson and Cortate. I shall answer the questions in the order of your letter.

1) Who is professionally responsible for writing the CMI?

The sponsors of medicinal products are responsible for the contents and format of CMI. The minimal content is prescribed by the Therapeutic Goods Regulations, Schedule 12. For general information on CMI you may wish to visit the following web sites:

http://www.health.gov.au/internet/main/publishing.nsf/Content/nmp-consumers-cmi.htm
http://www.medicinesaustralia.com.au/pages/page52.asp

There is a book on the subject that has been published by the Commonwealth, Writing about medicines for people : usability guidelines for consumer medicine information / David Sless and Robert Wiseman. 2nd ed. Canberra : AGPS, 1997

CMI documents are required for all registered prescription medicines, from oxygen and normal saline to antineoplastic agents as well as for a number of pharmacy supplied medicines.

2) What is the process for reviewing, correcting or updating existing CMI?

New medicinal products have their CMI documents checked by the clinical evaluation units in the TGA. The documents are subsequently deregulated but subject to Schedule 12 of the Therapeutic Goods Regulations. The sponsors have by law an obligation to keep it consistent with the approved product information document.

3) What is the process for disseminating new or updated CMI?

Sponsors have to make CMI documents available at the point of dispensing and many do so from their web sites.

4) Are there any current plans to review CMI for glucocorticoid replacement?

The current CMI documents appear to meet legal requirements. The approved product information upon which they are based neither permits nor precludes self-initiated dose changes. The pharmaceutical companies concerned would be expected to welcome suggestions by the Australian Addison's Disease Association Inc.

It would seem that more specific and tailored educational instruments are needed for patients with Addison's Disease than the CMI documents.

CMI documents are not intended to provide detailed medical advice or detailed information about diseases. For example, the CMI documents for patients with asthma will not include an asthma management plan. Nevertheless, such plans are now regarded as useful and necessary adjuncts to the management of asthma and other chronic diseases. Such plans are developed and maintained by professional and patient organisations.

Your letter may point to an unmet need for an Addison's Disease Management Plan document that could be fine tuned by the treating endocrinologist or other medical practitioner to assist patients and their healthcare professionals in some of the circumstances that you outline in your letter. Such a plan would complement the CMI document. The attachment to your letter suggests that useful work has already been done towards this goal.

Yours sincerely

Dr Rohan Hammett
National Manager
/ October 2008