

Consumer Medicine Information for Cortate – the continuing saga!

It has been quite some time now since we started reporting to you the deficiencies in the consumer medicine information (CMI) that is supplied when you first receive Cortate or Hysone. Fortunately the TGA, although not conceding that changes are required, have stated they are willing to review changes if supplied by the drug companies. Alphapharm, the makers of Hysone have been very accommodating and have accepted changes and recommendations made by the Endocrine Society of Australia (ESA). These changes have been submitted to the TGA for review, so let's keep our fingers crossed.

Unfortunately, Aspen Pharmacare, the makers of Cortate have not accepted all of the proposed changes and are only willing to consider limited changes to the precautions section of the CMI. How extensive these changes will be is not known at this stage as they are requesting clinical data to support the ESA's recommendations. In an email, their scientific affairs manager, Evelyn Anderson, tells us "*Changes to other sections will require a full evaluation by the TGA which will cost the company \$111,700 and requires full clinical data, eg. changes to the indications, dosage and administration sections. Aspen is not willing to do this.*" The AADAI believes that many of these recommended changes are correcting inaccurate information and hopes the TGA will look favourably on a submission by Aspen without seeing the company incur any, or minimal costs. It will be interesting to see whether the changes already submitted by Alphapharm will attract the costs quoted by Aspen. If not, hopefully it will be a stimulus for Aspen to consider similar changes. If such high costs are involved in correcting inaccurate information, what effect on timely change with this have on all CMI?

The national manager of the Therapeutic Goods Administration, Dr Rohan Hammett, states in a letter to Professor Jim Stockigt that "*CMIs were originally envisaged as aids to the appropriate use of prescription medicines so that patients could be well-informed.*" The AADAI and ESA feel the CMI for Cortate is inaccurate and potentially dangerous. Surely it is the responsibility of both Aspen Pharmacare and the TGA to ensure this information "*aids to the appropriate use of prescription medicines*" and ensure that patients are "*well-informed*".

In a mostly two horse race, it will soon become interesting which drug will be the one of choice for endocrinologists and doctors when prescribing for Addison's patients. In the coming years a new drug named DuoCort, a once a day medication specifically designed for Addison's disease will be released giving doctors and patients an even greater choice.

We must commend the ESA and the group of Endocrinologists who have continued in their attempts to remove dangerous inaccuracies in the Consumer Medicines Information.

Peter Stewart
AADAI