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Consumer Medicine Information for glucocorticoid replacement medications 1 year on – a reply to Professor Stockigt and others.

I thank Professor Stockigt and others for raising the issue of consumer medicine information. Consumer medicine information, like any information document, repays careful reading. In summary, there are several areas that are raised in the letter and I respond to them in the order in which they have been raised.

Issue: The Cortate CMI suggests that Cortate be ceased in the event of infection.

This is not accurate in terms of the current CMI. The source cited for the CMI is www.mydr.com.au 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. 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’. This is continued under ‘While you are taking Cortate’, where additional advice includes the need to notify doctors of any serious infections or injury (presumably to allow for dose adjustment) and warnings that dose may be adjusted. In particular there is a special bolded warning to not stop taking Cortate or lower the dose without check with your doctor.

The site, <http://www.appgonline.com.au> does not currently provide CMI texts.

Issue: Is the CMI of Hyson non-compliant with the PI?

The letter notes that the PI has advice to the effect that dose can be temporarily increased in some circumstances (infection, trauma, surgery) but this is not in the CMI. However, the CMI does tell the patient that the dose is variable and that the treating doctor might frequently alter the dose, ‘Your doctor will tell you how many tablets you need to take each day and when to take them. This depends on your condition and whether or not you are taking any other medications’. And that patients should ‘Follow all directions given to you by your doctor and pharmacist carefully’. Subsequently the CMI warns ‘Do not stop taking Hyson or change the dose without checking with your doctor’, and to ‘Visit your doctor regularly so they can check on your progress’. This general advice arguably covers occasional events that require short term dose adjustment and encourages patients to keep in regular contact with the doctor so that such adjustments can be made.

Issue: I believe that the letter may be interpreted as alleging unsafe conduct and/or incompetence on the part of the two sponsors concerned.

In my opinion, this conclusion in both unwarranted and not substantiated on a careful review of the CMI texts.

It is important that prescribers raise the first instance with the sponsor of the medication their concerns about product information and consumer medicine information documents. To this end, the Therapeutic Goods Administration would always be pleased to receive copies of the relevant correspondence. In many cases, sponsors of the medications concerned are able to make improvements in readability and content in product information and consumer medicine information documents. Substantial changes in product information documents may require substantial data and such changes may take more time to effect.

Thank you for your interest in this matter.

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