4 October 2006

Dr Rohan Hammett
Chair
National Drugs and Poisons Schedule Committee (NDPSC)
PO Box 100
WODEN ACT 2606

Dear Rohan,

Re: Xenical

I am writing to you to express our concerns about Xenical (Orilstat) being available as an S3 drug with advertising approval. We ask that the National Drugs and Poisons Schedule Committee immediately revoke advertising approval and reschedule the drug to S4.

We are aware that Xenical entered the Australian market in 2000 as an S4 drug. The schedule was changed in 2004 to S3, consumers no longer requiring a script to purchase the drug. The National Drugs and Poisons Schedule Committee (the Committee) approved the addition of Xenical to Appendix H in February 2006, allowing the drug to be advertised to consumers.

CHOICE has strong concerns that the drug was rescheduled and given advertising approval. The Committee's initial concerns about rescheduling the drug to S3 included:

(i) that the drug did not meet the safety profile of an S3 drug
(ii) that it needed the assessment of a medical professional to determine the patient's suitability for treatment
(iii) that it would give the wrong public perception that it is the first line of treatment for obesity.

The Committee initially rejected advertising approval on the basis that it was concerned that advertising campaigns would omit information about the "moderate efficacy and reduction of efficacy long term seen in the clinical trail setting and potential side effects" of Xenical. The Committee also expressed the concern that advertising would create "unrealistic expectations of the product's effectiveness" and could "convey an inappropriate public health message that pharmacotheraphy is the first line treatment for obesity".

Given the above concerns, it is surprising that the Committee changed the schedule and then granted advertising approval. The committee's published decision gives no adequate reason why the clearly reasoned previous decisions not to permit advertising were reversed.

Roche began marketing the drug in September 2006. The campaign began with an advertisement during Australian Idol on Channel Ten. The second largest audience for this television program is the 13 to 17 year age group, which twice as many female as male viewers watch. Yet Xenical is not recommended for people under 18 because the safety of the drug has not been established in this population.

The advertisements appear designed to capture a wide audience. There was no mention of the fact that the drug is only suitable for people with a Body Mass Index (BMI) of 30 or 27 if other risk factors are present. Nor did the advertisement place enough emphasis on the need for lifestyle

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changes, such as the adoption of a healthy eating and exercise plan. The advertisement gave the impression that Xenical was an easy solution to losing weight. It did not mention the serious and unpleasant side effects.

We have heard anecdotal evidence from pharmacists that girls as young as 13 with a BMI of less than 25 have already been asking for the drug.

The nature of the advertising campaign and the reported consumer reactions vindicate the Committee's initial concerns about the advertising of Xenical.

CHOICE has made a complaint to the Therapeutic Goods Advertising Code Council (TGACC) Complaints Resolution Panel. The letter and media release are attached. Though we have made a complaint, the matter will take at least 6 weeks to resolve, during which time, Roche can continue to advertise the product.

The TGACC cannot impose a fine. If found in breach of the Therapeutic Goods Advertising Code, Roche may be fined by the Australian Self Medication Industry, of which it is a member. The fine however, usually does not exceed $40 000 and is a drop in the ocean, compared to the amount that Roche spent on marketing the product. It is not likely to deter repeat breaches.

CHOICE is concerned that Roche has set a precedent and that other pharmaceutical companies will apply to change the schedule of their drugs, in order that they may advertise direct to consumers and thus find a loophole through the regulations on direct to consumer advertising.

We ask that the Committee:

- immediately remove Xenical (Oristat) from Schedule H and revoke advertising approval.
- reschedule the drug to S4, for the reasons outlined by the Committee when it twice denied the rescheduling of the drug to S3.

Please do not hesitate to contact me if you have any questions on 02 9577 3374 or 0411 788 076.

Yours Sincerely

Viola Korczak
Health Policy Officer

Attachments

1. Letter the TGACC
2. Choice media release