

# Submission to the National Drugs and Poisons Schedule Committee (NDPSC) on rescheduling Orlistat (Xenical)

Wednesday, January 24, 2007



#### **About CHOICE**

CHOICE is a not-for-profit, non-government, non-party-political organisation established in 1959. CHOICE works to improve the lives of consumers by taking on the issues that matter to them. We arm consumers with the information to make confident choices and campaign for change when markets or regulation fails consumers.

CHOICE is independent: we do not receive ongoing funding or advertising revenue from any commercial, government or other organisation. With over 200,000 subscribers to our information products, we are the largest consumer organisation in Australia. We earn the money to buy all the products we test and support our campaigns through the sale of our own products and services.

Our policy voice is widely recognised. We campaign without fear or favour on key consumer issues based on research into consumers' experiences and opinions and the benefit or detriment they face. Our current campaigns cover food, health, financial services, product safety, communications and consumer protection law.

CHOICE conducts research, publishes policy reports and online information, gives presentations and keeps the media informed of our policy views. We provide representatives for many industry and government committees and independent bodies considering matters of concern to consumers.

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#### Introduction

Orlistat is a pharmaceutical designed to aid weight loss. It is effective for people who are obese with a BMI (body mass index) over 30 and for some who are overweight with a BMI of 27 or more with certain co-morbidities. It has an important place in helping people who are obese or who are overweight with co-morbidities.

After much consideration, the NDPSC granted Orlistat an S3 (schedule three) 'pharmacist only' listing in October 2003 and subsequently in June 2006 added it to Appendix H thus allowing it to be advertised to consumers using its brand name (Xenical).

However, there is evidence that, due to the nature of the drug and its indication, an S3 listing is not appropriate for Orlistat. This evidence is further supported by the way in which the drug has been marketed and dispensed since advertising approval was granted.

In our opinion Orlistat should be rescheduled to its original S4 (schedule four) 'prescription only' status. This submission provides evidence of detriment to the public of Orlistat being an S3 drug. It presents the results of a shadow shop of pharmacies dispensing Orlistat, reports on CHOICE's complaint about inappropriate marketing and refers to community concern about the current scheduling.

# **Background**

CHOICE started a campaign to reschedule Orlistat in October 2006. We have undertaken this campaign because there is persuasive evidence of potential detriment to consumers if this product retains its S3 status.

The consumer in the shadow shop we conducted asked for the two week pack of Xencial when it was available but bought the four week pack if it was not available. The price for the two week pack varied between \$59.95 and \$79.95. The average price was \$67.89. The price for the four week pack ranged from \$114.95 to \$130.00. The average price for the four week pack was \$122.97. If consumers are sold a product that is not appropriate to their needs or medical condition they will be wasting a significant amount of money. There are also health implications of consumers taking drugs they do not need.

This campaign has broad based consumer support. Among other indications, consumers have sent a number of emails to the NDPSC calling for the drug to be scheduled to S4.



# **CHOICE Shadow Shop**

In late 2006 CHOICE heard anecdotal evidence from pharmacists that girls as young as 13 in the healthy weight range were asking for Orlistat. This was the trigger which led us to conduct a shadow shop to determine:

- if people with a BMI of less than 30 with no risk factors were sold Xenical by pharmacies, and
- if pharmacies were following the procedures developed by the PSA (Pharmaceutical Society of Australia).

CHOICE found that 80% of the pharmacies sold the product to our shadow shopper, even though she did not meet the criteria for the drug. We also found that few pharmacies were following the guidelines developed by the PSA.

The PSA Guidelines require pharmacists to perform two main functions when dispensing Orlistat. First, they should confirm if Orlistat is appropriate for the customer. Second they should counsel consumers on lifestyle changes. The CHOICE shadow shop found that pharmacists were not following the guidelines and were dispensing the drug inappropriately.

We refer to 'pharmacists' selling the product but it must be noted that the product was sold by a pharmacy assistant on at least once occasion. The shadow shopper could not always determine if the drug was sold to her by the pharmacist on all occasions as the person selling the drug did not always wear a badge. In one particular pharmacy, she was told that "whilst the pharmacist would and is supposed to run through the product with me —he was too busy".

#### **PSA Guidelines**

The PSA has developed guidelines for pharmacists when dispensing Orlistat. They include the following<sup>1</sup>:

- 1. receive the request,
- 2. clarify patient's needs,
  - a. ensure consultation is private,
  - b. consider: BMI and waist circumference, co-morbid conditions, age, factors contributing to excess weight,
- 3. confirm Orlistat is appropriate
  - a. consider: efficacy of Orlistat and alternatives
  - b. contraindications and precautions,
- 4. supply Orlistat if appropriate, counsel on the following points:
  - a. action and dosage,
  - b. vitamin supplements,
  - c. drug interactions,
  - d. side effects,
  - e. lifestyle modifications,
  - f. realistic goals.
  - g. referral regarding co-morbid conditions, and
- 5. review progress: follow-up advice.

<sup>&</sup>lt;sup>1</sup> Pharmaceutical Society of Australia; Provision of Orlistat as a Pharmacist Only Drug.



#### Research methodology

A shadow shopper visited 30 different pharmacies in the Sydney metropolitan area. She visited the pharmacies over four days in December 2006. We consider this to be a robust sample because of the broad range of areas of metropolitan Sydney which were included in the sample.

The shopper completed a questionnaire which consisted of 24 questions at the end of each transaction. The purpose was to record in detail, her experience at each pharmacy so we could collate data about how the drug was dispensed and if pharmacists were following the PSA guidlines. She filled in a questionnaire immediately after leaving each pharmacy.

The shadow shopper was a 19 year old female full time student with a BMI of 25 and no co-morbiities. She is employed part time as a lifeguard at her local swimming centre. She has a healthy diet of meat, fruit and vegetables and rarely eats takeaway food. She walks three to four hours a week and swims regularly. She has never used Orlistat.

Her BMI was verified by CHOICE laboratory staff on the first day of her shadow shop in December 2006.

### Key findings from the shadow shop

Twenty four of the 30 pharmacies visited (80%) sold our shadow shopper the drug even though she did not meet the guidelines set out in the consumer medicine information for Orlistat. Indeed, we found that the PSA guidelines were not being following as:

- none of the pharmacies asked our shopper for ID (even though the safety and efficacy of this drug has not been tested for people under 18 years),
- one of the pharmacies that sold her the product measured her weight,
- none of the pharmacies that sold her the product measured her height,
- only five of the 30 asked her weight and only 6 asked her height,
- only 3 of the 24 pharmacies (8%) that sold her the product calculated her BMI. This
  calculation was based on what she told them (which was accurate). These
  pharmacies did not measure her weight and height themselves,
- none of the 24 pharmacies that sold her the product asked about her exercise regime,
- only 1 of the 24 pharmacies that sold her the drug asked about her current diet,
- none of the pharmacies conducted the consultation in a private area, and
- only 16 of the 24 pharmacies (67%) that sold the product advised her of some of the side effects.

The PSA guidelines were not even substantially complied with in any case. In many cases the pharmacies departed from the Guidelines in many different ways. Orlistat was dispensed to a consumer who does not meet the clinical criteria for the drug by 4 out of 5 pharmacies.

#### **Examples of inappropriate dispensing**

It is clear that pharmacists are not following the guidelines for dispensing Orlistat. The product in one case was sold even though our shopper commented "she [the pharmacist] told me that although she doubted I was obese that it's good to set a target weight goal to aim for". And again at another pharmacy, "he said that I didn't really look like I needed to lose weight, so I could probably use it for around two months".



In sum, there were three cases where the pharmacist stated that the shopper did not need the drug but sold it to her regardless. One pharmacist who did calculate her BMI (based on figures which she provided) verified that it was 25. This is 5 points below what is recommended for Orlistat (absent co-morbidities). Yet that pharmacist sold her the product with the full knowledge that the drug was not appropriate for her.

Some pharmacies had promotional material in their store for Orlistat to help pharmacists determine the consumers' BMI. However, as our shopper commented, "I found it funny that on the counter they actually had a 'Xenical Mat' to measure BMI- not that I got to use it". Only 8% of the pharmacies that sold her the drug calculated her BMI.

Some pharmacists went so far as to personally endorse the product. Our shadow shopper stated that "she [the pharmacist] said that she had used it herself and [it] was the only thing that worked". A drug would not be personally endorsed by the pharmacist if it was an S4 drug because the consumer could only purchase it with a prescription, not on the recommendation of the pharmacist.

### No time for advice in a busy retail environment

In a busy retail environment, the pharmacist may not always have time to undertake a proper consultation. Indeed, the average consultation time was 6.2 minutes, which sometimes included waiting time.

As a result, pharmacists may not always have time to counsel the shopper. At one pharmacy, our shopper was told "that whilst the pharmacist would and is supposed to run through the product with me— he was busy".

The busy retail environment may have been responsible for no information exchange in some cases. For example, at one pharmacy "she handed me the product, didn't say anything to me at all, only told me the price". In another pharmacy, "no information was exchanged at all. He told me the price of the product and gave it to me".

Furthermore, not once was our shopper taken to a private area, even though it is one of the requirements in the PSA Guidelines.

Because Xenical is an S3 drug, it is up to the ethics of the individual pharmacist to determine whether or not to sell the drug to a consumer who does not meet the clinical criteria. While some pharmacists will not sell the drug if it is not appropriate, the shadow shop revealed that a significant majority dispensed the drug even though the consumer did not meet the guidelines for the drug.

#### **Buying drugs online**

The results from our shadow shop are from visits to pharmacies. We hypothesize that it would be even easier to purchase the drug online. Consumers are now able to buy Orlistat on the internet without even seeing a pharmacist. While the consumer must talk to the pharmacists over the phone, the pharmacist does not see the consumer, and can therefore not measure their BMI.

If Orlistat becomes an S4 drug, this will solve this problem because the consumer will need a prescription and thus will need to see a GP in person.



# Advertisements for Xenical encourage excessive use

The marketing strategies employed by Roche to market Orlistat encouraged excessive use of the drug. CHOICE made a complaint to the CRP about advertisements which were broadcast on television stations across Australia in September 2006. The CRP determined that the advertisements were in breach of section 4(2)f of the Therapeutic Goods Advertising Code which found the advertisements to "encourage[s] inappropriate or excessive use".

The CRP also found the advertisements in breach of section 22(5) of the Therapeutic Goods Act which states:

A person being the sponsor of therapeutic goods that are included in the register, must not, by any means, advertise the goods for any indication other than those accepted in relation to the inclusion of the goods in the register.

CHOICE argued that the advertisements aimed to increase demand for Orlistat. In finding that it encourages inappropriate or excessive use, the CRP in effect agreed with CHOICE's argument. The drug is only suitable for consumers with a BMI over 30, or over 27 if the person has other risk factors such as high blood pressure or cholesterol. Yet the advertisements did not mention BMI. Indeed, the advertisements gave the impression that Orlistat is suitable for people who wanted to 'lose a few kilos'.

While the advertisements had to be withdrawn from further broadcast as a result of our complaint, the fact that Orlistat is on Appendix H means that Roche can advertise the drug in the future. While the advertisements used in 2006 may not be used, there is no guarantee that future advertising will not inadvertently stimulate demand in consumers who do not have the appropriate indication; indeed it is hard to imagine an advertising campaign which did not do so.

This raises an important conceptual issue that the NDPSC will need to seriously consider. What is the purpose of advertising a product, if not to encourage use? Is there public detriment simply from this product being available over the counter as an S3 drug?

#### Marketing strategies

Pharmaceutical companies see targeting life style drugs as the growth area for future revenues. The obesity pandemic represents an opportunity for the pharmaceutical industry. It is a significant untapped market. In 2000 alone, antiobesity drugs accounted for sales of nearly half a billion US dollars in the seven largest global markets, and this is set to triple by 2010.<sup>2</sup>

Roche has adopted a novel marketing strategy by seeking to schedule Orlistat to S3. By doing so they are circumventing the prohibitions against direct to consumer advertising and are thus able to reach a much larger audience. This can be viewed as a test case for other pharmaceutical companies.

It makes sense from a marketing point of view that Roche would prefer Orilstat to remain S3 because it ensures that they can continue to market the drug directly to consumers.

<sup>&</sup>lt;sup>2</sup> Padwal, R. Majumdar, S. (2007) 'Drug treatments for Obesity: Orlistat, Sibutramine, and Rimonabant', The Lancet, V369



The marketing strategies employed for this campaign have been very clever. The 'X Plan' (a telephone advice line for consumers who purchase the drug) gives the impression that the questions that call centre workers ask are for the benefit of the consumer, when in fact the answers provide Roche with marketing data, and this appears to be their primary purpose.

There is information on the packaging of Xenical which encourages users to join the X plan. We have been told by consumers who have used this line that they are bombarded with 10 minutes of questions. Our shadow shopper was recommended by pharmacy staff "to register with the Xenical membership promotion a number of times". We understand that consumers who call the telephone line are asked some of the following questions when they ring the 'X plan':

- where they bought Xenical,
- what their doctor's name is (even if their doctor never recommended Xenical).
- whether their doctor recommended it or not.
- whether they have a health care card,
- whether they bought the 2 or 4 week pack,
- what their current weight is,
- how much they expect to lose, and
- how many times they have tried to lose weight in the past.

These questions appear to be included to aid the Roche marketing department and not primarily or at all to benefit consumers. If the drug is scheduled up to S4, Roche will no longer be able to use its customers to gather marketing information.

#### Why Orlistat needs to be rescheduled

The NDPSC'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, and
- (iii) that it would give the wrong public perception that it is the first line of treatment for obesity.

Subsequent events suggest that the NDPSC was right to be concerned about rescheduling Orlistat to S3. First, when Roche aired inappropriate advertisements which encouraged excessive use. The advertisements did indeed give the impression that the drug was the first line treatment for obesity. Second, when our shadow shop revealed that the drug was being dispensed inappropriately. A medical professional such as a GP is best able to determine a person's suitability for the drug. The decision to reschedule back to S4 should be considered in light of the evidence that is presented in this submission.

One of the reasons the NDPSC rescheduled Orlistat was because of the belief that pharmacists could provide good advice to consumers, identify co-morbidities and monitor the misuse of Orlistat. The CHOICE shadow shop has found however, that pharmacists are generally not following the guidelines and indeed, that the majority are dispensing the drug inappropriately.

The scheduling of the drug overseas should also be considered. Orlistat is a 'prescription only' drug in the US and UK.



# Other weightloss products on the market

While the safety and efficacy of complementary weightloss products is not the central issue relevant to the committee's current review, these issues are worth bearing in mind. The argument put by the PSA among others is that making Orlistat more widely available will reduce the harm caused to consumers through purchasing ineffective alternative weightloss treatments.

CHOICE found that several pharmacists in the shadow shop were suggesting complementary weightloss products for which there is no efficacy data. The products recommended to our shopper included:

- Fatblaster,
- Blackmores metabolism advantage,
- Blackmores weightloss accelerator,
- Optifast
- Cardio weightloss scheme for winter (soup), and
- Detox.

CHOICE looked at the evidence for efficacy of two of the above products in the January 2006 issue of CHOICE. We specifically looked at Fatblaster and Optislim. We found that there was no persuasive evidence for weightloss through use of these products.

The National Health Research Council advises that "there is no evidence of significant long term weightloss from any of these [weightloss products]. Patients should be advised about the lack of evidence for using over the counter weightloss medications and in some cases, the dangers of using them".

We are concerned that pharmacists are promoting products for which there is no efficacy data. Pharmacists are conflicted between their role as 'community pharmacists' and their desire to operate profitable businesses.

Orlistat is the only weightloss product on the market with efficacy data. It should be made available to consumers in Australia. However, it should not be marketed as the first line treatment for obesity, as the advertisements in September 2006 attempted. It should be an S4 drug so that consumers can benefit from a consultation from their GP.

#### NDPSC submission criteria

Orlistat should be rescheduled to S4 because there is detriment to the public if it remains an S3 drug. The Roche advertisements for Orlistat aired in September 2006 and the CHOICE shadow shop in December 2006 provide evidence why Orlistat should be rescheduled to S4.



We individually address each of the criteria the NDPSC must consider in making a determination. Section 52E of the Therapeutic Goods Act 1989 provides that:

- (1) In exercising its powers under subsection 52D(2), the Committee must take the following matters into account (where relevant):
- (a) the toxicity and safety of a substance;

The long term safety of the drug has not been established. Research by Padwal and Majumdar found that "all antiobesity drugs drug trials have been limited by their high attrition rates and lack of long term morbidity and mortality data".<sup>3</sup>

Orlistat works for a small proportion of the population, but is marketed in a way that seeks to encourage widespread use. It is not to be used as a first line treatment for obesity. There are several risks in using Orlistat including:

- (i) in long term use, it may reduce the absorption of fat-soluble vitamins including vitamin A, betacarotene, viatmain D, 25 hydroxyvitamin D, vitamin E and vitamin K<sup>4</sup>, though still within the normal range;
- (ii) a low but possible increased risk of age related macular degeneration (ARMD) due to impaired absorption of lutein and Zeaxanthin has been proposed with Orlistat<sup>5</sup>;
- (iii) it may decrease cyclosporine. The NPS (National Prescribing Service) recommends monitoring plasma cyclosporine concentration<sup>6</sup>;
- (iv) hypertension and pedal edema have been reported with Orlistat use<sup>7</sup>;
- (v) a case of hepatic failure was reported. "There was a clear temporal association between Orlistat therapy and the patient's development of liver failure"<sup>8</sup>; and
- (vi) depression has also been reported with the use of Orlistat<sup>9</sup>.

The above is by no means an exhaustive list. The risks listed above illustrate why this drug should only be available to those who meet the clinical profile for this drug, which is currently not the case.

- (b) the risks and benefits associated with the use of a substance; Subject to the lack of information about long term safety (see 1a) there is evidence of benefits through use of Orlistat. However these benefits only accrue to consumers with particular characteristics (who meet the clinical profile). Evidence including that set out above suggests that it is not possible to limit distribution of Orlistat to the appropriate target group while it is listed as a Schedule 3 drug. The following factors lead us towards this conclusion.
- (i) Weight loss and body image are matters of considerable concern to many people in the community including many for whom Orlistat is inappropriate. Some of those people have very strong motivations to obtain a drug based solution to what they perceive as a significant problem in their life.
- (ii) Brand name marketing of Orlistat encourages consumers for whom the product is not appropriate to seek it out; while the sponsor's September 2006 marketing campaign

<sup>&</sup>lt;sup>3</sup> Padwal, R. Majumdar, S. (2007) 'Drug treatments for Obesity: Orlistat, Sibutramine, and Rimonabant', The Lancet, V369

<sup>&</sup>lt;sup>4</sup> NPS Radar (Rational Assessment of Drugs and Research), December 2004

<sup>&</sup>lt;sup>5</sup> NPS Radar (Rational Assessment of Drugs and Research), December 2004

<sup>&</sup>lt;sup>6</sup> NPS Radar (Rational Assessment of Drugs and Research), December 2004

<sup>&</sup>lt;sup>7</sup> DRUGDEX Evaluation, Orlistat

<sup>&</sup>lt;sup>8</sup> DRUGDEX Evaluation, Orlistat

<sup>&</sup>lt;sup>9</sup> DRUGDEX Evaluation, Orlistat



was particularly vulnerable to this charge, this will almost certainly be the effect if not in fact the object of any marketing campaign for a product such as this;

- (iii) It is extremely unlikely that pharmacists as they operate in Australia will be able to limit supply to those consumers who will benefit in the face of S3 availability and any kind of marketing campaign. Relevant factors include likely consumer persistence, lack of separate consulting areas, lack of time in busy pharmacies and the conflict of interest with the sales motives. Our shadow shop demonstrated that pharmacists are not able to limit the supply of Orlistat to the intended consumers.
- (c) the potential hazards associated with the use of a substance; The side effects of the drug include: diarrhoea, abdominal pain, flatulence, nausea and rectal discharge. These mainly gastrointestinal side effects are unpleasant and could potentially lead to more serious conditions if intake of the drug is not ceased. It is desirable for these reasons, that the use of the drug be monitored. A GP who has to write a prescription for the drug is better able to monitor usage of the drug, then a pharmacist in a busy retail environment, who may never see the customer again.
- (d) the extent and patterns of use of a substance;
  Data on all obesity drugs including Orlistat is "limited by modest efficacy and low rates of persistence with treatment". 11

Indeed, the NPS notes that "there is no single, effective treatment for weight reduction and a multifaceted approach is the key to successful long-term weight loss". The NPS notes further that Orlistat will not help all patients achieve weightloss, especially if there are no accompanied lifestyle changes.

- (e) the dosage and formulation of a substance; We do not have expertise to comment on the dosage or formulation of the substance.
- (f) the need for access to a substance, taking into account its toxicity compared with other substances available for a similar purpose;
  Orlistat should be available to consumers in Australia. We have read the XENDOS study which Roche often cites to support its case. The study found that "compared with lifestyle changes alone, Orlistat plus lifestyle changes resulted in greater ...weightloss". However, Xenical should not be used as a first line treatment for Obesity. Diet, exercise and behavioural therapy should be used in the first instance.
- (g) the potential for abuse of a substance; Some young women may be particularly vulnerable to manipulation based on concerns about body image. This is no doubt why the initial advertisements for Xenical, using the female torso, targeted women. Our shadow shop revealed that this drug is widely available to women who are not obese, and do not meet the clinical criteria for the drug. There is

<sup>&</sup>lt;sup>10</sup> Acharya, N. Wilton, L. Shakir, S. (2006) 'Safety Profile of Orlistat: Results of a Prescription –Event Monitoring Study', International Journal of Obesity, V30

<sup>&</sup>lt;sup>11</sup> Padwal, R. Majumdar, S. (2007) 'Drug treatments for Obesity: Orlistat, Sibutramine, and Rimonabant', The Lancet, V369

<sup>&</sup>lt;sup>12</sup> NPS Radar (Rational Assessment of Drugs and Research), December 2004

<sup>&</sup>lt;sup>13</sup> Togerson, J. Hauptman, J. Boldrin, M. Sjostrom, L. (2004) 'XENical in the Prevention of Diabetes in Obese Subjects (XENDOS) Study', Diabetes Care, V 27, N 1

<sup>&</sup>lt;sup>14</sup> NPS Radar (Rational Assessment of Drugs and Research), December 2004



therefore, great potential for the substance to be abused. This threat would be markedly reduced if it was scheduled to S4.

- (h) the purposes for which a substance is to be used; The substance is only suitable for consumers with a BMI over 30 or 27 if there are comorbidities. However, it is being sought by and made available to people in the healthy weight range.
- (i) any other matters that the Committee considers necessary to protect public health, including the risks (whether imminent or long-term) of death, illness or injury resulting from its use:

Our concerns about Orlistat being available as an S3 drug are made clear in this submission.

#### Conclusion

Evidence in this submission shows that Orlistat is being dispensed to consumers for whom the drug is not appropriate. Marketing messages have been addressed to consumers for whom the drug is not indicated. We are aware that demand for the drug by those consumers has been created, and many of them have requested the drug from pharmacies. Pharmacies are not in a position to ensure that those consumers are not dispensed the drug. The realities of the service environment in pharmacies, the significance of weight loss and body image in our society and the conflict of interest inherent in declining a sale to a consumer who does not have the relevant indication make it difficult to see how pharmacies could effectively play this role. In any case evidence obtained by CHOICE suggests that a large majority of pharmacies have not been able to resist the inappropriate demand for the product created by the sponsors' marketing.

If Orlistat was scheduled up to an S4 drug, it would only be dispensed to consumers who have been counselled by their GP and who meet the clinical criteria. It would only be issued with a prescription. Pharmacists would not be able to sell the drug to consumers who did not meet the clinical profile for the drug. This would relieve pharmacists of the temptation to sell the drug to consumers with a BMI under 30.