

Fat chance?

In April 2009 Alli, the over-the-counter dosage of orlistat, was launched in a huge push to consumers who might benefit from its fat uptake-limiting properties. Six months on, **Pharmacy Professional** writers ask – what has been the impact?

YOU CAN probably blame the Press. In the same way that papers will add ‘-gate’ to any scandal in a vain attempt to imbue their story with the impact and importance of Watergate, so the ‘War on...’ headline has been reliably rolled out – especially with reference to any of society’s many ills.

Indeed, “war on obesity” was used more than 220 times in UK national newspapers in the last three years. But the shouty headline could, this time, be justified. Figures out just before Pharmacy Professional went to press indicated that primary care trusts might have to allocate as much as £6.3bn a year to battle obesity by 2015, while a government Foresight report in 2007 put the broader economic impact of 50% of the population being obese in less than a decade at a further £38.5bn a year.

It’s not surprising that the big pharmaceutical companies have been targeting weight-loss drugs. First, consumers want science, as opposed to the dubious merits of wonder-berries and crushed shell fat absorbers. ➡





Second, the market is growing. A July 2009 report by Datamonitor estimates that in the seven most developed consumer markets there are 125m obese adults, and the prospect of serving those adults with a regular or repeated treatment opens up the possibility of blockbuster drugs that will dramatically affect corporates' bottom lines. Datamonitor puts the annual market value for an effective anti-obesity drug, in these key markets, at \$10bn and extrapolating to the overweight (as opposed to clinically obese) as well as moving the geographical limits would easily double, and could quadruple, this estimate.

But prescription anti-obesity drugs have had a chequered history at best, with a series of highly publicised scares followed by product withdrawals. Alli is the first OTC medication but is itself a smaller dose of a prescription medication, orlistat, that has been available for years.

Orlistat was developed by Roche but when prescription sales failed to set the world on fire GlaxoSmithKline stepped in and acquired the rights to market the OTC version, which was launched in the US in the summer of 2007. It was one of the first 'switch' drugs to be allowed by the US Food & Drug Administration, and the basis of their approval was that orlistat acts

At the time, market analysts forecast annual sales of as much as \$500m in the US market

in the intestine, inhibiting the uptake of dietary fats, rather than in more complex organs where side-effects might occur. At the time, market analysts forecast annual sales of as much as \$500m in the US market.

Fast forward to August, 2009. Alli has been launched in the UK, with a massive education and marketing push that saw thousands of pharmacists receive briefings from GSK, not to mention flashy display stands and heavy support from print



and TV advertising. It should have been a significant money earner for pharmacists, who had all the tools and support to help clients understand and use the drug appropriately.

However, damage from the bulletin board rumour mills, which had always focused on the side effects of Alli, including wind and rather more embarrassing issues, were compounded by an FDA announcement that it was reviewing complaints that orlistat had caused liver damage in patients, citing 32 cases between 1999 and 2008.

GSK says Alli has been rigorously tested and is safe. And, it has always been completely open and honest about the effects that social media sites, bloggers and board posters were commenting on – if you 'bust' the diet by eating a fatty meal, there is the possibility of diarrhoea. The solution is – don't bust the diet. If you're having a celebration meal or just have to have that tub of ice-cream, lay off the Alli.

But whatever the problems, it looks like Alli, as with its prescription precursor, is not going to sell anywhere near the analyst predictions. US sales according to trade magazine Ad Age in 2008 were \$131m, while the company spent \$96m on ads. Revenues from WeightWatchers Inc. in the same year were \$1.54bn. European sales have kicked in now, however, and GSK reported £82m worth of global sales in the second quarter of 2009 with more than half attributable to Europe. Again – to put it in perspective, they sold £109m worth of Lucozade...

Pharmacy Professional has surveyed a range of pharmacists and other healthcare professionals for their views.

There was a rush of interest at first...

Richard Evans
Locum pharmacist, West Wales
"From what I'm seeing, it's just not hitting targets."

"Alli is not the answer on its own, you have to do the full package. It's not the be all and end all – it's part of a lifestyle change and it won't do the job all on its own. It's like nicotine patches – if you're not willing or ready to give up the fags, don't bother to start

"People are asking for the pill who don't hit the criteria, who have a BMI of much lower than 28, in many cases you simply have to look at them to know that they're nowhere near the criteria BMI."

Another issue, said Evans, is price. Although GSK is at pains to point out that there is a network of support, a booklet and other material that comes with the medication to help with weight loss above and beyond the drug itself, the practical cost of a course of Alli is £2 per day. "There was a rush of interest at first, but a lot of people did say 'oh, that's expensive'."

You really have to see what makes people tick
Shahrad Taheri, consultant endocrinologist at Birmingham Heartlands Hospital and clinical director of its obesity clinic

“Anything a patient does is positive. If they can independently access a medication, and follow the lifestyle changes, that’s positive. But if they don’t, and it’s yet another thing that doesn’t work, then that can be a big disappointment.

“There really is no silver bullet and the problem is that patients have very big expectations, but you’ve got to be up for it. Expectations are too high, people look at celebrities who have been successful but they HAVE changed their mentality and the tablet is a springboard.

“Pharmacists have a really important role to play but the problem is that weight management is very time-intensive and you really have to see what makes people tick before you can help them.

“A lot of people have not got the message that it’s the same drug – orlistat – and when you tell them what it is, they say ‘oh, no, I tried that and didn’t like it’.

“The message that drug companies have to learn is that this isn’t a treatment you can get into the water system – you have to have the right treatment for the right patient at the right time. The issue with orlistat is that it’s not like a blood pressure tablet, which you take and blood pressure goes down, simple: there’s more to it.”

Alli is a real opportunity – not a magic bullet

James Hallatt, General Manager GSK Consumer Healthcare UK:

“Obesity and overweight are a major concern of our society and people need help. Alli offers a clinically proven way to help people lose weight. It is not a magic bullet – users must be committed to weight loss; Alli, when added to a reduced calorie, lower-fat diet, can help people lose 50% more weight than dieting alone.

“Alli represents a real opportunity for overweight and obese people to benefit significantly from professional pharmacy intervention. GSK is committed to ensuring pharmacy staff not only feel comfortable and confident helping



people lose weight with Alli, but also that pharmacists can make the most of the exciting business opportunity the launch of Alli presents.”

Alli allows you to build the relationship

Marc Donovan, pharmacist at Boots in Cardiff

“We see it as a great opportunity to provide enhanced advice around weight loss. As a pharmacist I’ve been involved in weight management advice for years, and I have noticed a whole lot of improvement and engagement within the profession. With Alli, I’ve undergone training, but it’s not just the medication itself – it’s around weight loss and an awful lot of people who have tried to access the drug, and not been eligible for whatever reason, we’ve been able to counsel them about other ideas, such as healthy eating.

“My advice has been to suggest people adopt a low-fat diet, then start on the product, I think it’s significant to give lifestyle advice, rather than here’s the product, go away.

“It’s difficult because people do have the right to self-diagnose and ask for certain products off the back shelf but, especially with Alli, we have to ask ourselves is it suitable for them? If you don’t have engagement on the possible side effects, it’s likely they won’t continue, and the side effects get the better of them. You need to build a relationship and Alli allows that – there’s not many products that do. But it allows us to help patients make the choice – pharmacists need to meet the challenge, and patients appreciate that pharmacists have a role to play.”

People were intrigued, but things have levelled out

Mitesh Soma, founder, Chemist-Direct.co.uk

“We sell a range of products targeted at weight management, most of which are supplements, and Alli is the most popular. At launch we did see a surge in sales, when it was marketed heavily, I think people were intrigued to try it, but things have levelled out and now it’s a small percentage of our sales.

What about those who use internet

pharmacies to bypass pharmacist-checked criteria?

“RPS registered pharmacists look at every order. We ask the right questions, we look at things like previous purchases, and if we have any reason to suspect someone is buying who shouldn’t be, we can and do decline the sale. We contact them to say why and suggest that they see their doctor to get further help.

The only real issue is the BMI confusion

Locum pharmacist, West London (name withheld by request)

“When it first came out, and I talked to customers about it, the only issue was urgent rushes to the loo – but then after a week, maybe they got used to the routine, and they were fine, no problems and there were lots of repeat sales.

“The only real issue was a confusion over the BMI required to be eligible for the drug. Many said ‘Look, 25 is overweight,’ but I was always very strict that the minimum BMI had to be 28 – and that’s the RPS guideline, and that’s the limit that was set under the licence. But customers said ‘Oh, other pharmacies give it to me.’ I think that this has been an issue – if the BMI hurdle was 25, an awful lot more would be sold.

“When it first was made available as an OTC drug, I was working in Kensington and the first week was amazing. People queued out the door, buying three or four big packs at a time and the price was not an issue.

“But I really don’t see many people buying it now – I think the last time I did a consultation and someone bought it was two weeks ago.” ■

More information

The Royal Pharmaceutical Society of Great Britain provides clear guidance to pharmacists for the OTC orlistat treatment on <http://www.rpsgb.org/pdfs/otcorlistatguid.pdf>. The issues surrounding a change of diet, managing weightloss expectations, side effects and how to limit them, and also guidance on who is included in the marketing authorisation are all covered.