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Obesity

Over-the-counter orlistat: early experiences, views and attitudes of community pharmacists in Great Britain

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Abstract

Introduction: Pharmacotherapeutic approaches to weight loss are receiving increased attention. The lipase inhibitor orlistat has recently become available for sale in pharmacies across Europe. This study explored early experiences, views and attitudes of community pharmacists across Great Britain towards aspects of orlistat nine months post legal re-classification.

Methods and Procedures: A postal questionnaire survey of the pharmacist with most responsibility for over-the-counter supply in 13,200 randomly selected community pharmacy premises in Great Britain. Two reminder letters were sent to all participants at two-weekly intervals.

Results: Questionnaires were returned by 4026 (32.4%) pharmacists. Two thousand and ninety one (51.9%) respondents reported no sales of orlistat in the previous four weeks with only two hundred and three reporting a frequent (5.1%) or very frequent supply in the same time frame. Two thousand six hundred and seventy six (66.5%) agreed or strongly agreed that orlistat was a good opportunity to extend their role as health professionals and three thousand seven hundred and twelve (92%) felt confident about product supply. Two thousand three hundred and thirty four respondents (57.9%) agreed or strongly agreed that customers often complained about the cost of the product and one thousand nine hundred and twenty six (47.8%) agreed that it is likely that customers could misuse the product.

Discussion: Despite welcoming the addition of orlistat to the over-the-counter range as an opportunity to extend their role as health

professionals very few sales had been made with the high product cost and potential for misuse identified as areas of concern.

Introduction

Obesity and associated conditions such as type 2 diabetes, cardiovascular disease and cancer, place an enormous burden on the health systems around the world (Pi-Sunyer, 2009). With their prevalence steadily on the increase the World Health Organisation (WHO) now estimates that globally, more than 1 billion people are overweight or obese accounting for up to 7% of the health care cost in most developed countries (Ono *et al.* 2010). The European charter for counteracting obesity published in 2006, sets a target for the obesity prevalence to be reversed before 2015 (WHO, 2006). In light of these growing problems, pharmacotherapeutic approaches to aid weight loss have received increasing attention. In 2008, the European Medicines Association (EMA) approved the lipase inhibitor orlistat to be made available for sale without a prescription (EMA, 2008) making it the only available weight loss medication for sale in Great Britain (GB) and mainland Europe without the supervision of a general practitioner. This reclassification coincided with the suspension of the marketing authorisation of the centrally acting appetite suppressant rimonabant (EMA, 2008) due to the occurrence of psychiatric side effects, and sibutramine due to a rise in cardiovascular events (EMA, 2010). This places orlistat as the sole pharmacological weight loss drug on the international market. It is now marketed as Alli[®] and available in a 60mg dose for sale in pharmacies (GlaxoSmithKline, 2008). Orlistat inhibits gastric and pancreatic lipases thereby preventing the breakdown of dietary fat causing a dose-related decrease in fat absorption (Heck *et al.* 2000). At the licensed dose of 60mg it blocks ~25% of ingested fat and achieves a loss of ~5% body weight over a 16 week period

(Anderson, 2007) claiming to boost weight loss by 50% (GlaxoSmithKline, 2008). The product license restricts sales to individuals over 18 years of age and a BMI of $\geq 28 \text{ kg/m}^2$. Good practice guidance issued by the Royal Pharmaceutical Society of Great Britain dictates that the BMI should always be measured before a sale is made and patients should be advised to take an additional multi-vitamin supplement to counteract the loss of fat-soluble vitamins (RPSGB, 2009). Due to its mechanism of action, orlistat has a considerable list of potential adverse effects patients need to be made aware of, mainly involving the GI system (Filippatos *et al.* 2008). Data from long term randomised trials show that orlistat at a dose of 60mg is both safe and effective for use in a primary care setting (Hauptman *et al.* 2000; Rossner *et al.* 2000; Davidson *et al.* 1999) and a three month, open label naturalistic study carried out in 18 pharmacies across America looking at the compliance and behaviour changes in patients purchasing orlistat from pharmacy concluded that orlistat can be used safely and appropriately with high consumer satisfaction (Schwartz *et al.* 2008). Telephone interviews were used to interview patients 14, 30, 60 and 90 days after first purchase of orlistat which may however have influenced the patients' behaviour throughout the study period. The re-classification has been noted to be an ideal opportunity for pharmacists to promote healthy lifestyle interventions such as regular exercise, diet, smoking cessation and other forms of health screening while supplying orlistat (RPSGB, 2009). The re-classification has however also been heavily criticised by the medical profession as "...an easy pill-popping solution to obesity" which does not consider the holistic approach to adopting a healthy lifestyle (Lancet, 2009; Williams, 2007). Since its re-

classification no follow up studies have been published exploring pharmacist experiences with the sale of 60mg orlistat. This study aims to address this gap by surveying the experiences, views and attitudes of community pharmacists ($n = 13,200$) across GB with 60mg orlistat nine months after its re-classification.

Methods and Procedures

A pilot postal questionnaire was developed from NHS policy documents, professional body communication and the research literature (NICE, 2006; RPSGB, 2008; Edwards *et al.* 2002) and reviewed for face and content validity by five experienced medical and pharmacy practitioners/researchers. A list of all registered community pharmacy premises in GB was obtained from the Royal Pharmaceutical Society of Great Britain. The pilot questionnaire was mailed to 500 randomly selected community pharmacy premises throughout GB. Each questionnaire included a covering letter describing the aim of the study and confidentiality assurance. A request was made that the questionnaire should be completed by the main pharmacist with most responsibility for over-the-counter (OTC) supply. Pilot analysis resulted in minimal changes to the wording of some questions. Results obtained from the pilot study were not included in the final data analysis. The final questionnaire comprised three sections. In section A pharmacists' views and experiences with OTC orlistat were determined, including: frequency of supply, willingness to delegate height and weight measurements, receipt and type of continuing education material (CE), service ambitions of pharmacy, extension of role as health professionals, customer acceptance and complaints, complexity and barriers to supply, potential for misuse and willingness to go off guidelines. The questionnaire was designed in accordance with published best practice applicable to surveys of health service staff (McColl *et al.* 2001) and had a mixture of 5-point Likert scale questions, semantic differential questions and closed questions as response options. Using closed questions, section B collected demographic data including: gender,

age, number of years registered, employment status, type of pharmacy, location of pharmacy, postgraduate qualifications and attitude towards professional practice. The final Section (C) invited pharmacists' to voice their personal opinions and experiences with the supply of orlistat in an open comments section. The final questionnaire was mailed to a randomly selected 13,200 registered community pharmacy premises in GB during November 2009 (excluding the pilot sample). Two reminder questionnaires were sent to all pharmacies (as requested by local ethics) at two-weekly intervals over a four week period. Data were coded and entered into SPSS for Windows version 15 (SPSS Inc.) and analysed using descriptive statistics such as frequencies and crosstabs as well as non-parametric chi square test to identify significant associations in cross tabulation between the willingness of the pharmacist to go off guideline to supply this product, the view of the pharmacist for customers to misuse the product and the type of pharmacy worked in. Content analysis (Hsieh *et al.* 2005) was performed on the responses to the more qualitative answers in section C relating to personal opinion and experiences with the sale of orlistat. All emerging themes and quotes, including any disagreements were discussed and finalised by the research team. Key themes are described using illustrative quotes with each respondent assigned a number. This study was approved by the Ethical Review Panel of the School of Pharmacy and Life Sciences at Robert Gordon University Aberdeen. The North of Scotland Research Ethics Committee advised that this study did not require formal review by an NHS Ethics Committee.

Results

A total of 4026 questionnaires were returned (32.4%) with a near to equal distribution of male (47.1 %) and female respondents (51.3%) (64 missing answers). All demographic data are shown in Table 1.

Frequency of supply

Two thousand and ninety one (51.9%) respondents reported no sale of orlistat in the previous four weeks with only one hundred and seventy two (4.3%) reporting a frequent and thirty one pharmacists' reporting a very frequent (0.8%) supply in the same time frame. Two thousand five hundred and eighty six (62.7%) pharmacists' agreed or strongly agreed that many customers ask for this product by name. Qualitative comments highlighted a rapid decline in sales after initial interest by the general public.

"After the initial hype, interest is now waning" [P-3722]

"Lots of interest/sales initially but has dropped off when patients realise it is not a "quick fix" to weight loss [P-1530].

" People bought it in droves at launch and for a couple of weeks after. Now the sale is not very high" [P-2456]

Pharmacists' attitudes towards product supply

In general, pharmacists' attitudes about the availability of orlistat were positive. Two thousand one hundred and sixty five (53.7%) respondents agreed and five hundred eleven strongly agreed (12.7%) that orlistat was a good opportunity to extend their role as health professionals. One thousand seven hundred and ninety three (44.5%) agreed and six hundred and five respondents strongly agreed (15%) that it is a valuable

addition to the range of pharmacy medicines, which will be effective (56.8%) and lead to patient satisfaction (56.8%).

"Sales of orlistat allows excellent opportunities for giving additional information on lifestyle modifications and weight management services" [P-0105].

"I believe [...] orlistat could be a useful tool in public health and has the potential to be very valuable in community" [P-0094].

Pharmacists' confidence in product supply

Almost all pharmacists felt confident about product supply, three thousand seven hundred and four (92%). The majority, three thousand four hundred and thirty four (85.3%), acknowledged receiving continuing education (CE) material related to OTC orlistat, with drug company training resources being the CE most commonly cited, three thousand two hundred and seventeen (79.9%) (see Table 2). One thousand eighty five respondents (27%) agree that the continuing education materials had met their training needs. Pharmacists were asked if they were comfortable going off guidelines to supply this product, one thousand two hundred and thirty one (59.5%) strongly disagreed and one thousand sixty four (26%) disagreed but acknowledged to delegating height and weight measurements to support staff (49.6%). This occurred most frequently in large multiple pharmacies (chi square test: $p < 0.001$). Responses relating to the frequency of checking customers' BMI before making a supply are given in Table 3.

"Feel very confident to supply, then sell if criteria is met" [P-3083].

"Delegate-depends on staff and level of training" [P-0749]

"I am happy to delegate only for returning customers who I have already advised" [P-1065].

"we don't routinely check weight and height" [P-0101].

Cost as barrier to supply

Two thousand three hundred and thirty four respondents (57.9%) agreed or strongly agreed that many customers often complain about the cost of the product. The location (rural, suburban or urban) of the pharmacy had no bearing on the frequency of the cost complaint (chi square: $p = 0.307$).

"Too expensive. Customers are not prepared to pay that amount of money long term" [P-2778].

Many pharmacists' reported that the customer would rather receive orlistat on prescription to reduce the cost.

"The price and dose make the patients go to the GP to prescribe it. They ask about information but they don't buy it" [P-3609];

"Most people are put off by the cost and say they will ask for a prescription instead" [P 9978].

This was thought to be due to misleading advertising.

"at launch most people thought this was a magic cure for overweight people. The interest has now deteriorated dramatically" [P-0697].

"Mis-advertising of the product in the media (TV news, newspaper etc.), saying that this is a wonder drug to make you loose weight." [P-3169].

Potential for misuse as barrier to supply

Almost half of respondents, one thousand nine hundred and twenty six (47.8%) agreed that it is likely that customers could misuse the product.

This too was irrespective of pharmacy location (chi square test: $p = 0.240$).

"One customer admitted to me that she was taking it because she had a "problem" with food and hoped that getting diarrhoea whenever she ate chocolate would deter her" [P-1114].

In particular concerns around the ease of access through the internet was raised.

"High risk, lots of young girls try to buy it. When they are told of the side effects or dangers they often say they will buy it on the internet as on multiple pharmacy sites it is easy to adjust weight and height to get the right BMI" [P-745].

"No problem in store BUT our company sold it online where people were trusted to give accurate height and weight measurements this was abused" [P-2993].

"Customers that have been refused this product because their BMI is below 28 have been able to obtain this product with no problem at all by ordering online [...] lying about weight" [P-1924].

Suggestions for change

"Would be more beneficial for the supply of this product to be part of a weight management scheme where the patient has 1 to 1 advice with an advisor" [P-0749].

"Would be better if we had a card (like Imigran) that we can use to know if they have been sold it before" [P-0750]

"I've found with no formal monitoring the patients tend to use one box and then not carry on. With no PCT funding for weight loss service, or store programme there is no way to support repeat custom" [P-2120].

Discussion

To our knowledge this is the first large-scale national study to report on community pharmacists' experiences with OTC orlistat since its re-classification in GB. In general community pharmacists' welcomed the addition of orlistat to the product range perceiving it as a good opportunity to extend their role as health professionals and anticipating patient satisfaction. Since the majority of pharmacists had received sufficient continuing education materials on orlistat almost all pharmacists felt confident about supplying the product. Despite the positive attitudes of pharmacists, sales have been very paltry with over fifty percent of pharmacists reporting no sale at all in the previous four weeks mainly citing cost as a barrier for sale.

Despite many studies identifying orlistat as being safe and effective for sale in pharmacies (Hauptman *et al.* 2000; Rossner *et al.* 2000; Davidson *et al.* 1999) there has been a continued debate about the importance of prescribing life-style modification in conjunction with weight loss medication in order to achieve sustainable results (Wadden *et al.* 2005; Schwartz *et al.* 2008). Despite the evidence highlighting the importance of advice and intense follow up for patients receiving orlistat (Feigenbaum *et al.* 2005) pharmacy services do not cater for such a sustained follow up of customers purchasing orlistat. Although pharmacists are ideally placed to provide advice and medicines management as part of the multidisciplinary primary healthcare team (Tinelli *et al.* 2007) funding for this service was not factored into the provision of orlistat OTC. This presents a gap in the continuation of care which patients obtaining orlistat through their family physician would otherwise receive. Our study

highlighted that pharmacists' although enthusiastic about the opportunity to provide customers intending to buy orlistat with much needed lifestyle advice, are frustrated that there is no real opportunity for follow up as customers are not obliged to come back to the same pharmacy. A recent study concluded that opportunities exist for extending weight management services through community pharmacies but it was not clear on the public expectations, awareness and acceptance of these services (Krska *et al.* 2010). Pharmacists reported an initial surge in sales shortly after it became available but interest has since steadily declined with almost half of all respondent reporting no sale at all in the four weeks prior to the study. One of the main barriers to supply emerging from the qualitative comments is product cost. Cost saving as a driver behind many re-classification decision has been insinuated before (Cohen *et al.* 2005) but while these product pose a true cost-saving to customers in countries without the provision of a national health system such as the USA (Editorial, 2004) many of the products available in GB and Europe are still cheaper to the patient when obtained on prescription (Cohen *et al.* 2005). These findings seem to be in line with other studies looking at recently re-classified medicines such as simvastatin and orlistat where cost too has been identified as a barrier (Stewart *et al.* 2007, Hansford *et al.* 2007). *"This item is another example of a potential good POM to P switch which has been ruined by too high a cost- same as omeprazole, simvastatin, orlistat – all too costly"* [P10078]. A second identified barrier to the sale of orlistat is the potential for misuse. Forty seven percent of pharmacists participating in this study agreed (or strongly agreed) that it was likely for customers to abuse orlistat. To date there have been only two published

reports of orlistat misuse in patients with eating disorders (Hagler Robinson, 2009; Malhotra *et al.* 2002) but none since its re-classification. Qualitative quotes pertaining to the ease of online access in particular elude to the seriousness of this problem. Although the accuracy of the online sale of orlistat has not been established, a recent study looking at the accuracy of online forum answers compared to clinicians to questions on orlistat found that both sources provided comparable answers. The overall quality of these answers however was found to be unsatisfactory with emphasis on accuracy and completeness (Nelson *et al.* 2009). The ease of access taken together with poor accuracy of advice online is a grave concern especially for a drug which has such a high adverse drug reaction and drug interaction profile (Filipatos *et al.* 2008) and which seems to be favoured by customers with a BMI < 28m². This may also explain why pharmacists are not prepared to go “off-guideline” to supply this product despite the apparent time-consuming nature of the supply. *“Time consuming process for each supply. With limited staff resources it is stressful” [P-9901].* Many pharmacists have admitted to delegating height and weight measurements to support staff. Although a routine BMI check before each purchase is best practice it is not a licensing requirement for the sale.

This is the first national study of its kind, with a large sample size of 90% of all registered pharmacy premises in GB and a response rate of 32.4% equating to one in three pharmacies across GB. The demographic spread of all respondents is in agreement with the latest workforce consensus of pharmacists in the UK published in 2009 (Seston *et al.* 2010) covering

response from a wide range of pharmacists with varied degrees of experience and background. Limitations of this study which need to be taken into account when interpreting the results include the sampling process which only collected data from one pharmacist per pharmacy and the self-reported nature of the study which did not allow verification of the validity and reliability of the data. In addition, the low response rate limits generalisability of the findings. Responses to the qualitative questions did not allow further exploration of the issues and themes. Future studies should aim to explore the qualitative themes identified a bit more in depth. Exploratory studies collecting the views and experiences of the general public about the access and provision of weight management services through community pharmacies are warranted.

Conclusion

Community pharmacists surveyed welcomed the addition of orlistat to the OTC range, perceiving it as a good opportunity to extend their role as health professionals. They had undertaken an array of continuing education and felt confident to supply this product. However, very few sales were made in the nine months following re-classification with the high product cost and potential for misuse identified as areas of concern.

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Table 1:

Frequencies		n	%
Gender (n=3962)	Male	1897	47.1
	Female	2065	51.3
Age (n= 3986)	29 years and under	985	24.5
	30-39 years	1015	25.2
	40-49 years	908	22.6
	50-59 years	875	21.7
	60 years or above	203	5
Number of years registered as a pharmacist (n= 3980)	5 years and under	1082	26.9
	6 to 10	546	13.6
	11 to 15	452	11.2
	16 to 20	348	8.6
	20 or above	1552	38.5
Type of pharmacy (n=3972)	Independent (1 store)	757	18.8
	Small multiple (2-4 stores)	450	11.2
	Medium sized multiple (5-25 stores)	376	9.3
	Large multiple (over 25 stores)	2325	57.7
	More than one type of pharmacy	64	1.6
Employment Status (n= 4026)	Owner	688	17.1
	Manager	2515	62.5
	Relief	248	6.2
	Second	239	5.9
	Locum	362	9.0
	Non-store	12	0.3
Pharmacy location	Urban	1602	39.8

(n= 4026)	Suburban	1644	40.8
	Rural	706	17.5
Qualification (n= 4026)	Pharmacist prescriber	862	21.4
	Postgraduate qualification	945	75.6

Table 2:

Sources of continuing education (CE) <i>(N = 4026)</i>	N (%)
Have you received CE on OTC orlistat	3435 (85.3)
Drug company training resources	3218 (79.9)
RPSGB	2051 (50.9)
Patient information leaflets	1966 (48.8)
Journals	1402 (34.8)
My pharmacy management	1320 (32.8)
Fellow pharmacists	911 (22.6)
National/Local Pharmacists	619 (15.4)
Professional leaders	260 (6.5)
Senior colleagues	196 (4.9)
Newspaper	71 (1.8)
Television	58 (1.4)
Contract champions	36 (0.9)

Table 3:

<i>Do you always check the customers BMI before making a supply to:</i> <i>(N= 4026)</i>	Yes N (%)
a new customer who <u>has not bought</u> orlistat before.	3847 (95.6)
an existing customer who <u>has bought</u> orlistat before	2813 (69.9)
a new customer who <u>has bought</u> orlistat from another Pharmacy.	3544 (88.0)

Figure legends

Table 1: Demographic data from 4026 respondents

Table 2: Continuing education sources (*N* = 3435)

Table 3: Customers BMI check before making a supply cited by respondents (*N*= 4026)