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UK COMMUNITY PHARMACISTS EXPERIENCES ON OVER-THE-COUNTER TAMSULOSIN

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ABSTRACT

BACKGROUND: In the UK, government policy toward self-care now supports the management of some long-term conditions. In 2004, simvastatin was switched to P access for people who have a moderate risk of coronary heart disease. This deregulation met with opposition from pharmacists due to concern over patient management and the increased workload burden envisaged around training and record keeping. In 2010, tamsulosin was reclassified for the treatment of urinary symptoms of benign prostatic hyperplasia (BPH); the first medicine since simvastatin to be marketed for a non self-limiting condition. This study aimed to explore community pharmacist's early experiences with the supply of non-prescription tamsulosin.

OBJECTIVES: To determine community pharmacists' views toward the recent deregulation of tamsulosin.

METHODS: Self-completed postal survey.

RESULTS: A response rate of 36% was achieved (n=108/301). Pharmacists found company and professional body training materials met their needs and provided sufficient support to enable them to sell tamsulosin. Protocols for sale were followed by the majority of respondents (81%) and nobody delegated the selling of tamsulosin to non-pharmacist staff. Pharmacist recommendations were low, although specific patient requests were higher, and 70% of all patient requests were referred on to the doctor. For those patients started on tamsulosin only a small minority returned to the pharmacy at the 14-day check-up.

CONCLUSIONS: Pharmacists felt prepared to sell tamsulosin although the majority of consumer requests were inappropriate and triggered referral.

Key words: Tamsulosin, non-prescription, over-the-counter, community pharmacy.

INTRODUCTION

Government policy throughout the Western world has seen a greater emphasis on empowering patients to manage their own health. In the UK, the government agenda to modernise the National Health Service (NHS) was spelt out in the White Paper: The NHS Plan[1]. Within this document the government made clear its intention to make self-care an important part of NHS healthcare. It stated that the frontline for healthcare was in the home. Since that time the government has published numerous papers detailing how maximising self-care can be achieved[2-6]. Conversion of policy to practice has been evidenced by the formation of nurse-led services such as NHS walk-in centres and NHS Direct (a telephone help-line) and making more medicines available without the need for a prescription. In the UK, non-prescription medicines are classified as either Pharmacy medicines (P) or General Sales List medicines

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(GSL). P medicines must be sold under the supervision of a pharmacist and GSL medicines are products that can be sold without the supervision of a pharmacist and purchased from any retail outlet. Since the first medicine (in 1983) to transfer from prescription status, over 80 medicines have become P, and 50 P medicines have gained GSL status. More recent switches to P status have come from new therapeutic classes (e.g. proton pump inhibitors, antibiotics and triptans) and also included in 2004 the POM to P switch of simvastatin for people who have a moderate risk of coronary heart disease.

The greater availability of medicines undoubtedly has contributed to patients exercising higher levels of self-care and can be illustrated by the year-on-year growth in the non-prescription medicine market[7]. Healthcare inequalities however, exist in the UK whereby individuals or groups have poor uptake of, or limited access to, healthcare services[6]. One such group who tend to be reluctant in accessing healthcare services are middle aged men[8,9]. However, it has been reported that a substantial minority (25%) of men would rather speak to a pharmacist than any other type of healthcare professional about a minor ailment, and as many as 83% of men would be more likely to address minor health complaints if they could seek treatment directly from a pharmacist[10].

Tamsulosin was reclassified from POM to P in the UK in Spring 2010 and thus became available for purchase over-the-counter (OTC) from pharmacies. (Figure 1 highlights when and how it can be sold). This represents the first UK medicine to treat a chronic condition available

Figure 1. Conditions in which tamsulosin can be sold OTC

Product License

To whom:	Men aged 45 to 75 years
For what:	Treatment of functional symptoms of benign prostatic hyperplasia (BPH)
Dose:	400 micrograms daily (1 tablet)
Duration of treatment:	Maximum treatment period of 6 weeks without clinical assessment by a doctor
Contra-indications/precautions:	Symptoms are < 3 months duration Prostate surgery Unstable or undiagnosed diabetes Problems with liver, kidney or heart Fainting dizziness or weakness when standing (postural hypotension) Eye operation of cataract planned Recent blurred or cloudy vision that has not been investigated
	Not be given to any man who reports dysuria, haematuria, or cloudy urine, in the past 3 months, or who is suffering from a fever that might be related to a urinary tract infection
	Allergy / hypersensitivity to tamsulosin

Practice Guidance

Supply:	Initial treatment: 14-day pack (followed by a further 28-day pack if appropriate) whilst the physician confirms diagnosis and suitability for long-term OTC treatment. Following initial treatment, pharmacists should establish that the physician has carried out a clinical assessment within the 6 week timeframe and confirmed suitability for further supply.
	Every 12 months, pharmacists should advise patients to consult a physician for a clinical review.
	If symptoms have not improved within 14 days of starting treatment, or are getting worse, the patient should stop taking tamsulosin and be referred to the physician.

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without a prescription. This deregulation is also notable for the fact that it may encourage men to take more of an interest in their welfare through community pharmacies, especially as the majority of men with benign prostatic hypertrophy (BPH) do not consult their doctor when experiencing symptoms[11].

Tamsulosin is marketed as a P medicine in the UK under the brand name Flomax Relief®. This is the first time that a treatment for BPH, a chronic, progressive symptomatic condition, has been available for self-care. The aim of this project was to gauge the opinion of community pharmacists on the sale of tamsulosin, based on early experiences.

METHOD

A piloted self-administered survey was mailed to all community pharmacies (n=301) from three primary care trusts (PCTs) in the West Midlands, UK. A single mailing was sent to pharmacies addressed to the 'pharmacist in charge' in early January 2010. Returns were included for analysis up until the middle of February (which gave potential respondents six weeks to complete the survey).

The survey consisted of five sections. Section A asked for demographic information; Section B assessed the extent of pharmacist agreement to various statements about the deregulation of tamsulosin; Section C looked at training materials on tamsulosin for community pharmacists; Section D explored the protocols for sale of tamsulosin; and, Section E enquired into the level of sales of tamsulosin. Questions consisted of five point Likert rating scales, closed questions and a number of open-ended questions. The Likert scales used combinations of positive and negative statements to avoid acquiescence bias i.e. to stop the respondent from agreeing with each question. The survey data was transferred and analysed using Statistical Package for the Social Sciences (SPSS) software. Descriptive analysis along with chi-squared tests were used as the data was non-parametric and categorical. Z scores of proportions were used to analyse Likert scales (comparison of agree/strongly agree vs. uncertain/disagree/strongly disagree).

Ethics committee approval was granted by the Behavioural Science Committee at University of Wolverhampton.

RESULTS

From the 301 pharmacists contacted, 108 usable surveys were returned, giving a response rate of 36%. Response rates from each PCT were not significantly different ($p=0.167$). Table 1 illustrates the demographic details of respondents. The gender profile was equally split and not significantly different from national pharmacy workforce statistics ($p=0.145$)[12]. However, age (greater proportion of respondents under the age of 30 and fewer respondents over the age of 60: ($p<0.001$) did differ. Most pharmacists had been qualified for less than 20 years (42%, less than 10 years; 24% between 10 and 20 years). Job roles differed significantly from the latest pharmacy workforce census, with an under-representation of locum pharmacists and an over representation of branch managers. ($p<0.001$) The majority (69%) of respondents worked for multiple chain pharmacies and mirrors national statistics ($p=0.128$)[13].

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Table 1. Demographic data of respondents

Demographic variable	Numbers (%)	p*
Returns from each PCT (n=108)		
PCT 1	42 (38.9)	
PCT 2	29 (26.9)	NS
PCT 3	37 (34.3)	
Sex (n=108)		
Female	52 (48.1)	NS
Male	56 (51.9)	
Age (n=108)		
Below 25 years	13 (12)	
26-35 years	45 (41.6)	
36-45 years	23 (21.3)	<.001
46-55 years	23 (21.3)	
56-60 years	4 (3.8)	
Current work situation (n=108)		
Pharmacist branch manager	46 (42.6)	
Locum pharmacist	19 (17.6)	
Independent pharmacist owner	19 (17.6)	<.001
Relief pharmacist	11 (10.2)	
Second pharmacist	13 (12)	
Type of pharmacy? (n=108)		
Independently owned (single pharmacy)	17 (15.7)	
Independent chain (2-5 branches)	17 (15.7)	
Member of a medium chain (6-50 branches)	21 (19.4)	NS
Member of a large chain (over 50 branches)	53 (49.1)	

X^2 test where $p < 0.05$ deemed significant. NS = not significant.
Comparison of sample with national pharmacy workforce statistics.

Pharmacists' opinion was sought on how the deregulation of tamsulosin had affected their practice (Table 2). Respondents had conflicting opinions on whether tamsulosin should have become a non-prescription medicine. However, a significant number thought its deregulation afforded them better opportunities develop patient rapport ($p < 0.001$) and would help them have a more active role in treating future chronic conditions. Despite the re-classification, almost twice as many pharmacists felt that the initial diagnosis should still be made by a physician. Since the availability of tamsulosin, pharmacists had not identified more patients with BPH symptoms ($p < 0.001$) nor had they seen the level of patient enquiry increase. No significant differences in responses were seen for gender, age or job role.

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Table 2. Pharmacist views on the deregulation of tamsulosin

Statement		Agree or strongly agree	No opinion	Disgree or strongly disagree	
	n	%	%	%	p*
Since the deregulation of tamsulosin I have not identified more patients with benign prostate hypertrophy (BPH)	108	34%	25%	41%	<.001
The deregulation of tamsulosin will help pharmacists to have a more active role in the future management of chronic conditions that were traditionally the GPs remit	108	48%	21%	31%	ns
I believe that tamsulosin being deregulated was the correct decision	108	44%	15%	42%	ns
I think that patients should continue to be initially diagnosed through their GP rather than by a pharmacist	108	55%	12%	33%	ns
The deregulation of tamsulosin provides pharmacists the opportunity to build better rapport with male patients	108	69%	17%	15%	<.001
Since the deregulation of tamsulosin, I have noticed an increase in patients coming into the pharmacy for advice on benign prostate hypertrophy (BPH)	108	49%	14%	37%	ns

* *z-score of proportions: comparison of agree/strongly agree vs. uncertain/disagree/strongly disagree; analysis z-score converted to p value.*

Pharmacists had very positive views on the training materials provided by both the company marketing tamsulosin ($p<0.001$) and the professional body ($p<0.001$). (Table 3). The provision of the company's 'symptom checker' (a structured survey to determine patient suitability for the product) was felt to be appropriate ($p<0.001$) and preferred to the pharmacists asking their own questions to determine tamsulosin's appropriateness for patients ($p<0.001$).

With regard to how tamsulosin was sold, most pharmacists adhered to a pre-written protocol (81%, n=75), and every pharmacist stated that the sale of tamsulosin could not be made solely by a non-pharmacist; just 32% (n=34) of pharmacists made any record of sales on a patient medical record held within the pharmacy. Pharmacists were asked to state how many requests, sales and referrals to the physician they had made over the previous 3 months. Respondents had seen a relatively low level of enquiry from patients, with 75% dealing with five or fewer requests. In fact, the modal number of requests over this period was just one, and 18% reported no enquiries. To open-ended questions, pharmacists frequently reported that patient requests were triggered by company advertising campaigns. Sales initiated by pharmacists were equally low; over 85% had sold four or less packets of tamsulosin and almost half (46%) had not sold

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Table 3. Pharmacist views on the deregulation of tamsulosin

Statement		Agree or strongly agree	No opinion	Disgree or strongly disagree	
	n	%	%	%	p*
The company training pack gave enough resources to train me on the deregulation of tamsulosin	102	85%	12%	3%	<0.001
After using the company training pack only, I was confident enough to go onto sell tamsulosin over-the-counter without the need to refer to additional resources	102	81%	11%	8%	<0.001
I find that the 'symptoms checker' questionnaire asks all the appropriate questions	102	87%	8%	5%	<0.001
When making my decision on whether tamsulosin is suitable for my patient I prefer to use the company 'symptoms checker' questionnaire compared to asking my own questions	102	83%	11%	6%	<0.001
The professional body guidance is useful in supplementing the company training pack	97	84%	11%	5%	<0.001
The professional body guidance answered my queries better than the company training pack	97	52%	33%	15%	na

** z-score of proportions: comparison of agree/strongly agree vs. uncertain/disagree/strongly disagree; analysis z-score converted to p value.*

any. Pharmacists cited the high price point as a deterrent to sale, misunderstanding of patients in relation to whom was suitable for OTC supply (which led to physician referral) and their own misgivings toward mis-diagnosis. For those patients that were sold tamsulosin, half (52%) never returned for a further supply after 14 days, and just 13% of pharmacists said that all their patients returned. Referrals on to a physician were, however, higher, with 70% of pharmacists referring one or more patients; the modal number of referrals being two. The majority of these referrals were for patients that fell outside the licensed usage of OTC tamsulosin, for example those aged over 75, those with other co-morbidities or those already taking a medicine for BPH but were unaware (e.g. finasteride). Some pharmacists did comment that their referrals had led to the patient re-presenting to the pharmacy for a medicine to treat BPH.

DISCUSSION

This small study is the first to evaluate the views of UK community pharmacists on the deregulation of tamsulosin. Views were sought from pharmacists 9 months after the launch of tamsulosin on the UK market. Pharmacists appeared ambivalent toward the deregulation

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even though they were positive about the training put in place for them to sell tamsulosin. Many thought initial diagnosis should remain with the physician, and this may suggest a lack of confidence in their own ability. Furthermore, pharmacists highlighted tamsulosin's high cost, restrictive license and concern over mis-diagnosis as barriers to sale; misdiagnosis was something medical colleagues also raised during the public consultation exercise prior to tamsulosin's deregulation. High unit cost is an issue of practical importance, as in the UK, all patients over the age of 60 receive free prescription medicines. This is an additional question for pharmacists to consider when assessing patient suitability for tamsulosin – should I sell to someone over 60 or refer them for a free prescription?

The restrictive OTC licence of tamsulosin appears, from this study, to be the major factor in the low number of sales (whether patient-led or pharmacist initiated). Pharmacists reported, in open questions, that many men were referred on to the physician. Consequently, the number of referrals to a physician was, by comparison with other switches, high. Findings from this study suggest that tamsulosin is facing the same problems associated with simvastatin when introduced in to the UK market[14,15]. Given the pattern of poor sales and high physician referrals, coupled with the fact that there is little current support and acceptance by healthcare staff for chronic conditions to be managed through pharmacies[16-18], the viability of tamsulosin as an OTC medicine could be in doubt and it may follow the same path as simvastatin (the original product, Zocor HeartPro® was discontinued in 2010).

Although the number of men presenting in pharmacies was not high, this is understandable given tamsulosin's relative newness on the market and its target patient population. However, was it not for OTC tamsulosin (promoted by media advertising) then these men may have either delayed seeking advice or not done so at all, and this lends some support to the rationale for the deregulation.

We acknowledge that this was a small study with a relatively low response rate. The failure to send a second mailing may well have contributed to the response rate, but due to financial constraints this could not be undertaken. Despite this, the majority of participants worked for multiple chain pharmacies, and the proportion mirrors national statistics. In addition, the survey did not document whether pharmacist referrals of men asking about tamsulosin to physicians were actually completed. This, however, was not the focus of the survey, which sought to evaluate pharmacists' attitudes. Furthermore, documentation of pharmacists' consultation was done in only a minority of pharmacists' encounters with men asking about tamsulosin. While these limitations potentially affect the degree to which inferences can be made from this study, the survey is a viable global impression from a cross-sectional sample of pharmacists, and identifies key learnings about the reticence of the profession to embrace certain types of switches.

Conflict of Interests: None

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