Review Article

Reclassification of omeprazole: a survey of community pharmacists' early experiences and views

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REZUMAT

Obiectiv: Să descrie opiniile şi experinţele recente ale farmaciştilor în legătură cu (OTC) omeprazol.

Metoda: Un chestionar poştal cross-secţional pre-pilotat a fost trimis la 2000 de farmacii selectate întâmplător din Marea Britanie (aprox.15% din totalul de farmacii din această ţară). Chestionarul conţinea articole despre: atitudinea faţă de omeprazolul OTC, educaţia continuă, vânzări şi păreri şi experienţe generale. Datele au fost analizate în mod statistic descriptiv.

Rezultate: Chestionarele din 1156 de farmacii au sosit înapoi completate (57,8% din cele trimise). 68% din cei care au răspuns nu au vândut omeprazol în ultimele 14 zile şi alţi 12% au vândut doar câte un pachet în această perioadă. În total, 920/1147 farmacişti au participat la cursuri de educaţie continuă privind omeprazolul, 73,4% au declarat că sunt de acord să vândă acest produs şi 78% văd omeprazolul ca pe o adiţie binevenită la medicamentele OTC. În jur de 17,6% dintre cei care au răspuns au recomandat cumpărarea omeprazolului în ultimele 14 zile şi mare parte a acestor recomandări (92,8%) au fost acceptate de clienţi. 41 de farmacişti (3,5%) au refuzat să vândă omeprazol în baza faptului că l-au considerat nepotrivit situaţiilor respective, sau din cauza unor potenţiale interacţiuni cu alte medicamente.

Concluzii: Mulţi farmacişti care au răspuns chestionarului cu privire la omeprazolul OTC au întâmpinat pozitiv disponibilitatea acestui medicament ca OTC şi sunt dornici şi capabili să-l furnizeze.

ABSTRACT

Objective: To describe community pharmacists' views and early experiences of over-the-counter (OTC) omeprazole.

Method: A cross-sectional pre-piloted postal questionnaire was sent to 2000 randomly selected community pharmacy premises in Great Britain (approximately 15%). The questionnaire comprised items on: attitudes to OTC omeprazole; continuing education; sales; and general views and experiences. Two reminders were sent. Data were analysed using descriptive statistics.

Results: Questionnaires were returned by 1156 community pharmacists (57.8%). Sixty-eight per cent of respondents had not sold any omeprazole in the previous 14 days and a further 12% had sold only a single pack in this period. In total 920/1147 pharmacists (80.2%) had participated in continuing education on omeprazole, 73.4% agreed or strongly agreed that they were entirely confident in selling it, and 78.0% viewed omeprazole as a welcome addition to OTC medicines. Some 17.6% of respondents had recommended purchase of omeprazole in the last 14 days and the vast majority of these recommendations (92.8%) were accepted by the customer. Forty-one pharmacists (3.5%) had refused sales on the basis that it was inappropriate for the presenting condition, or due to a potential drug interaction.

Conclusion: Many responding community pharmacists welcome omeprazole availability OTC and are willing and able to supply it.

INTRODUCTION

Empowering patients to address their own health needs is a central tenet of the Great Britain (GB) government policies for the NHS and is a core element of service development. (1–3) In the GB, medicines are classified as prescription-only medicines (POMs), pharmacy (P) medicines which are available from a registered pharmacy, by or under the direct supervision of a pharmacist, or as a general sales list (GSL) medicine which may be purchased from any retail outlet. (4) Over-the-counter (OTC) medicines are those that are either P or GSL. Reclassification of medicines from prescription-only to pharmacy-only status has been undertaken in part to reduce NHS costs but also to make medications more accessible to patients, thus promoting self-care. (5) A report published by the Royal Pharmaceutical Society of Great Britain (RPSGB) in 1992 on behalf of the Department of Health actively promoted reclassification from POM medicines to P status. (6) Loperamide was the first medicine reclassified in the GB in 1983, and by 2000 some 69 medicines had been reclassified. (7) In addition to the move to promoting increased self-care, other drivers for reclassification in Europe and the US have been recently identified as being pharmaceutical companies' desire to extend sales of their products and to attempt to decrease healthcare funders' costs. (8) Pharmacists'views on reclassification of medicines have been reported, (9–15) although individual views may differ according to the actual medicine concerned. Evidence on efficacy, potential for misuse, side-effect profile and potential to delay a medical consultation are reasons why pharmacists are less likely to be supportive of declassification from POM status. (9–15) With

regard to the supply of OTC medicines it is important to note that their safe and effective use can be promoted by healthcare professionals and support staff receiving adequate education and training to underpin this service. Community pharmacists have been shown to be willing and able to provide extended services, including provision of OTC medicines for a range of conditions. (13,16)

Omeprazole, a proton pump inhibitor used in the treatment of dyspepsia, was reclassified from 'prescription only' to 'pharmacy' status in summer 2004 and this stimulated the research reported here. Dyspepsia is a common condition, with up to 40% of adults experiencing symptoms at least once a year. Of these, only a quarter consult their general practitioner (GP), while half self-medicate, perhaps seeking a community pharmacist's advice. (17) Evidence-based guidelines for the management of dyspepsia have been published, and indicate that a working diagnosis of 'functional dyspepsia' (i.e. dyspepsia without an identified underlying organic disease) can be arrived at relatively easily and is an appropriate basis for management without detailed investigations. (17,18) These guidelines describe a clear role for the community pharmacist in managing dyspepsia. While lifestyle advice, including smoking cessation and general dietary advice, are advocated as first-line measures, there is no firm evidence base to support this. (17,18) Antacids have been available OTC for many years, yet there is a lack of objective evidence of effectiveness. (17,18) There is some evidence, however, demonstrating the effectiveness of other acid-suppressing drugs, including histamine H2-receptor antagonists (H2RAs) and proton pump inhibitors (PPIs) (17,18) Some H2RAs at certain doses and for restricted indications were reclassified from POM to P medicines in the GB in 1994, and thus have been available to purchase OTC. Community pharmacists have expressed concerns about their OTC availability, (19) however a drug-utilisation evaluation of non-prescription H2RAs in community pharmacies supported their effectiveness with minimal toxicity. (20)

Galpharm Healthcare Ltd requested the reclassification of omeprazole to pharmacy status in May 2003, (21) on the basis that acid regurgitation and heartburn can be self-diagnosed, that H2RAs were already available OTC, that omeprazole was already available OTC in Sweden and the US and that there was low potential for misuse or overdosage. The National Pharmaceutical Association expressed concern at that time that the proposed indication (for the relief of reflux-like symptoms) was too vague, and that omeprazole was not a first-line drug according to national guidelines. (22) However, PPIs are considered usually more effective and often more acceptable to patients and are often used first-line by doctors for empirical management of dyspepsia. (18) Reclassification was subsequently authorised, (22) and a branded version of omeprazole, Zanprol, was launched by GlaxoSmithKline in March 2004, (23) together with supporting educational materials. (24) The RPSGB also provided information directly to pharmacists. (25) Experience in countries including the US and Sweden where omeprazole is already available OTC suggests that it can be used appropriately OTC. (26,27)

It is important to assess community pharmacists' views and attitudes towards the supply of newly reclassified medicines, as others have reported with other reclassified medicines, (7–9) particularly when the medicine being reclassified is the first of a drug class as is the case with omeprazole. Therefore, the aim of the present study was to examine the early experiences of community pharmacists in relation to sales of omeprazole without prescription OTC, and their views on a variety of issues regarding its reclassification, including their confidence in recommending its supply and the adequacy of education and training materials.

METHODS

Setting and sample

A postal questionnaire survey was undertaken using a random sample of 2000 registered pharmacy premises across Great Britain (approximately 15% of registered premises), supplied by the RPSGB. Two reminders were sent at approximately monthly intervals to non-responders (identified from serial numbers on questionnaires, used solely for this purpose).

Questionnaire development and distribution

The questionnaire was developed and assessed for face and content validity by the research team (academic staff with research and community pharmacy practice experience). It comprised four sections. The first section related to the pharmacists' views of their education and training with respect to omeprazole and its reclassification, and these statements were developed from training materials and guidance for omeprazole supply, information in the pharmaceutical press and previous studies on pharmacists' views on reclassification. (9–13,16,19,20,23–25) Pharmacists' confidence in selling it, and whether or not they felt that a non-pharmacist should sell it within the community pharmacy, were assessed by a combination of open and closed questions and Likert-type scales. The

second section sought information about continuing education support, protocols, who actually sells omeprazole and display of the drug and related information, assessed through closed questions. The third section consisted of closed and open questions about the sales of omeprazole in the past 14 days and a final, fourth section comprised closed questions to provide demographic data on the pharmacist and the pharmacy itself.

The questionnaire was piloted in a random sample of 200 community pharmacies, excluded from the main sample, and no modifications were deemed necessary. The questionnaire was sent out in winter 2004/2005, together with a covering letter (inviting participation and providing information on the study) and a stamped-addressed return envelope, to the pharmacist mainly responsible for OTC sales. The study was conducted under the Robert Gordon University research governance and ethics procedures. Grampian Research Ethics Committee was consulted, and indicated that formal ethics approval was not required.

Data analysis

Data were entered into a password-protected database using the SPSS v11 statistical software. Analysis took the form of descriptive statistics in terms of number, frequency or percentage as appropriate.

The responses to the open question relating to views or experiences of OTC omeprazole were collated and independently reviewed by two authors, and then those quotes included were agreed by the research team. A number of themes are described using illustrative quotes; each respondent was assigned a number corresponding to the questionnaire number.

RESULTS

Demographic information

In total, 1156 of 2000 questionnaires were returned, giving a response rate of 57.8%. The sex of responding pharmacists, number of years qualified and the type of pharmacy in which they worked are shown in Table 1. Over half of respondents (574/1128, 50.9%) were involved in developing protocols for sales of OTC medicines by non-pharmacist staff, and more than three-quarters (882/1126, 78.3%) were currently involved in the training of such staff. Most respondents (77.5%) did not have postgraduate qualifications and those who had further qualifications (251/1118, 22.5%) reported a wide range including individual modules, certificate, diploma and masters level courses and some supplementary prescribing.

Table 1 Demographics of respondents

Characteristic	n (%)
Sex (n = 1127)	
male	565 (50.1)
female	562 (49.9)
Number of years registered as a pharmacist (n = 1123)	
0–5	279 (24.8)
6–10	192 (17.1)
11–15	121 (10.8)
16–25	240 (21.4)
>25	291 (25.9)
Type of pharmacy (n = 1128)	
single independent	162 (14.4)
pharmacy company with 2–5 branches	119 (10.5)
pharmacy company with 6–30 branches	121 (10.7)
pharmacy company with >30 branches	726 (64.4)

Pharmacist views on OTC omeprazole supply and education and training provision

Table 2 shows the extent of agreement/disagreement with a number of statements relating to the provision of omeprazole on a five-point Likert scale. Twenty-three per cent of respondents strongly agreed and a further 54.9% agreed that omeprazole is a welcome addition to the OTC treatments available. Some 80.2% of respondents had received continuing education or training on omeprazole. Views were mixed, however, on whether it is

Table 2 Percentage of responding community pharmacists expressing level of agreement to statements relating to omeprazole use (total respondents = 1156)

Statement	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
Well-trained counter staff can sell omeprazole without consultation with a pharmacist (n = 1149)	6.1	33.6	7.3	40.6	12.4
Omeprazole is a welcome addition to the OTC treatments for dyspepsia (n = 1150)	23.1	54.9	13.2	7.1	1.7
Customers should always be referred to the pharmacist for the sale of omeprazole (n = 1149)	20.5	40.0	12.9	25.2	1.4
The education I received regarding omeprazole failed to meet my needs (n = 1137)	2.4	15.5	20.8	50.5	10.9
I feel entirely confident about selling omeprazole (n = 1137)	20.3	53.1	14.2	10.9	1.4
Advertising is the reason for most requests for omeprazole (n = 1110)	12.5	34.6	33.6	16.8	2.5

appropriate for counter staff to supply omeprazole without referral to the pharmacist, and there was some support for the view that advertising prompts requests for the drug.

Education and training materials had been obtained from a variety of sources, with the most common reported as the pharmaceutical company (596/952, 62.6%), journal articles (527/953, 55.3%) and RPSGB practice guidance (398/953, 41.8%). Continuing education meetings (130/953, 13.6%) and drug company representatives (133/953, 14.0%) provided information for fewer respondents. Only 4.0% of respondents (38/953) claimed to have obtained web-based information.

As shown in Table 3, over half of the respondents indicated that their pharmacy had a protocol in place for sales of omeprazole. However, only 36.8% of respondents (414/1124) indicated that non-pharmacist staff had received training on omeprazole. It was reported that only the pharmacist made sales in 55.3% of pharmacies (627/1133), while pre-registration pharmacists did so after consultation with the pharmacist in 15.6% (=177) and without pharmacist consultation in 8.3% of pharmacies (n=94). Medicines counter staff and technicians supplied omeprazole with pharmacist consultation in 45.2% and 28.8% of pharmacies, respectively.

Table 3 Number and percentage of respondents answering yes to specific questions relating to omeprazole use

Question	Yes, n (%)
Have non-pharmacist staff received training on omeprazole? (n = 1124)	414 (36.8)
Is there a protocol for the sale of omeprazole? (n = 1123)	682 (60.7)
Are sales of omeprazole routinely recorded?(n = 1088)	52 (4.8)
Is omeprazole on display in your pharmacy? (n = 1129)	841 (74.5)
Is promotional material on display in your pharmacy? (n = 1110)	457 (41.2)
Is health-promotion material on dyspepsia on display in your pharmacy? (n = 1130)	369 (32.7)

Sales of OTC omeprazole

In relation to sales of omeprazole, more than two-thirds of respondents indicated that they had not sold any OTC omeprazole in the last 14 days (Table 4). Some 17.6% of respondents (n=201) had recommended purchase of omeprazole in the last 14 days. Of those pharmacists who answered the question, the vast majority stated the customer accepted their recommendation (167/180, 92.8%, Table 4). Forty-one pharmacists (3.6%) had refused sales on the basis that it was inappropriate for the presenting condition, or due to a potential drug interaction.

Table 4 Information relating to sales of omeprazole in the 14 days prior to completing the questionnaire

Question	Response, n (%)
Have you personally recommended to a customer that they purchase omeprzole? (n = 1145)	Yes: 201 (17.6)
If yes, did the last customer recommended omeprazole purchase the product? (n = 180)	Yes: 167 (92.8)
Have you personally refused a sale of omeprazole? (n = 1135)	Yes: 41 (3.6)
Approximately how many packs have been sold in your pharmacy? (n = 1097)	
0	784 (71.5)
1	141 (12.9)
2	93 (8.5)
3	32 (2.9)
4	12 (1.1)
5–10	26 (2.4)
11+	9 (0.8)

Responses to open question on omeprazole

An open question was included to give pharmacists the opportunity to express any issues they wished to raise which read: 'Please detail any particular views or experiences you have regarding the OTC sale of omeprazole'. Examples of responses are included to illustrate views put forward by respondents. The opportunity for pharmacists to extend their role was welcomed by some who considered omeprazole supply OTC appropriate, as they felt there was a good evidence base for omeprazole use in dyspepsia and that some H2RAs are already available OTC.

"OTC omeprazole is a good product for managing dyspepsia in certain patients, it has a good evidence base for its use and provided patients receive the appropriate counselling from well-trained staff, I believe the product is a good addition to OTC medication that pharmacists can counter-prescribe." (R319)

"Welcome addition to management of dyspepsia. Am able to step up treatment and advise patient on how to manage condition." (R967)

"Omeprazole is a very valuable treatment for dyspepsia. I recommend [it] regularly to customers with no other risk factors who have had no benefit after taking antacids for their condition." (R151)

Some respondents felt that pharmacist involvement was essential when omeprazole is supplied OTC, whereas others did not share that view necessarily, indicating measures including a sales protocol were required.

"Happy to sell if I have interviewed the person and gathered evidence that they need it and to rule out serious problems." (R1018)

"I think it is reasonable to sell OTC omeprazole with appropriate safeguards and a protocol in place." (R840)

Some pharmacists held a different view and thought a doctor should be involved.

"I don't personally feel it is an appropriate product for OTC purchase – and feel it would be wiser for the patient to consult with the GP." (R587)

There was also concern about potential inappropriate requests for purchases.

"Relies on customers being honest with themselves (and us) regarding severity of symptoms and length of time suffering. Feel that serious problems may be masked and GP intervention delayed as customers will buy product inappropriately." (R484)

Patient barriers to supply were considered to be high cost and lack of patient awareness and education.

"It is not very popular because of the relatively expensive price. There are quite a number of other OTC medicines that work effectively, are more popular and affordable in price." (R728)

The need for improving patient information was also identified.

"Public do not understand that it is not suitable for 'instant' relief of their symptoms. Expense limits its usefulness for OTC sales." (R977)

A number of pharmacists indicated that purchases were often made by customers buying omeprazole who had previously been prescribed the medicine and had run out.

"Sales mainly due to running out of medication on prescription." (R227)

"Most sales I have authorised have been patients currently taking omeprazole or lanzoprazole from their GP who have run out, or those who have been prescribed it in the past and recognise the recurrence of symptoms, in which case I have sold the product until the patient can get to their GP." (R502)

DISCUSSION

The results of this study show that community pharmacists who responded to the questionnaire generally support the reclassification of omeprazole, are confident in recommending it to patients and are satisfied with the training material provided. Over half the respondents indicated that a protocol was used in their pharmacy and that the pharmacist only made sales of omeprazole. Views were mixed on whether counter staff should make sales without reference to the pharmacist, and just over one-third of counter staff had received training. Actual sales of omeprazole were low, with over two-thirds of respondents reporting no sales in the last 14 days. However, patients' acceptance of the pharmacist recommendation of omeprazole was high at over 90%. In addition, a small percentage of respondents (3.6%) had refused sales of omeprazole as inappropriate for the patient requesting it.

A number of limitations mean that the results of this study must be interpreted with caution. The response rate was 57.8% and it is possible that pharmacists who were not in favour of the reclassification may have opted out of the study, although the questionnaire did afford them the opportunity of indicating such views in their responses to questions, such as identifying any concerns. The sampling process only allowed for data collection from one pharmacist per pharmacy. Responses were self-reported by the pharmacists, a limitation common to self-complete postal questionnaires. In future studies the authors recommend that consideration be given to taking additional steps to identify reasons for pharmacists non-responding to surveys and attempts made to identify any differences between respondents and those who do not respond. However, such steps need to be built in to the study design including governance arrangements and will need the necessary increases in study budget and duration. However, this is the first large-scale national study of community pharmacists' views and experiences of OTC omeprazole. Even if the very high level of support is an overestimate of acceptability, our results indicate that a number of pharmacists support the reclassification of omeprazole as a pharmacy medicine and that the public are purchasing this product

Over 70% of respondents felt confident in recommending omeprazole to patients, and the results show a high level of satisfaction with the material provided to community pharmacists by both the pharmaceutical company (24) and the RPSGB. (25) This may reflect the mounting experience with reclassified medicines, (9–15,19,20) and the fact that omeprazole has a clearly defined indication and is an alternative therapy to the H2RAs already available OTC. (17,18) Pharmacists expressed a number of views in relation to the provision of omeprazole; some indicated the need to follow a protocol and/or the need to ensure direct involvement of the pharmacist in sales.

Sales at the time of the study (winter 2004/2005) were low, with over two-thirds of pharmacies reporting no sales in the preceding 14 days; this may

be due to a number of factors including lack of patient awareness of OTC omeprazole. A number of pharmacists felt that cost was a significant barrier to supply. However, where the pharmacist recommended purchase, reported uptake was high.

Responding community pharmacists felt well-placed to assess patients and recommend omeprazole appropriately, which should enable patients to receive effective therapy. It is important to note, however, that non-pharmacist staff have been reportedly making sales of omeprazole in some pharmacies without pharmacist referral. While this may be acceptable, there is a clear need to ensure that the educational provision for non-pharmacist staff is adequate. Promotion of adherence to a protocol derived from the current guidelines and product information would seem to offer the best approach, (17,18,24,25) and it is encouraging that over half of the respondents already had a protocol in place. The need to ensure appropriate training of medicine counter assistants has already been acknowledged. (28) Dyspepsia is likely to be a heterogeneous condition with diverse symptoms and underlying problems, and therefore there is likely to be variation also in patient response to the different classes of medication. (17,18) Making a wider range of potential therapies for dyspepsia available OTC is likely to benefit those who do not respond favourably to either lifestyle advice or intervention with antacids or H2RAs. The increasing availability of medicines such as omeprazole without prescription is also in line with GB government NHS policies regarding an increasing emphasis on self-care. (1–3) Questions do remain, however, as to how other concerns expressed by respondents, including misuse of omeprazole through prolonged use, should be addressed. In addition, some respondents were concerned about masking of underlying progressive pathology although there are recognised alarm signals that should trigger referral to a doctor. (17,18) In a pharmacy-based study of drug utilization in dyspepsia, 162 customers stating one or more criteria requiring referral to a general practitioner claimed that they were not in fact referred. (20)

The findings support the view that reclassification of medicines such as omeprazole is welcomed by pharmacists who feel confident in their role advising patients. Further research is warranted to establish whether the views of community pharmacists change in the longer term, as the benefits and any potential drawbacks of OTC omeprazole come to light. It would be useful to explore any reasons why some pharmacists are not recommending omeprazole. It will also be important to explore patient outcomes and perspectives.

CONCLUSION

Many community pharmacists view the reclassification of omeprazole positively and a number are supplying it to customers with dyspepsia.

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Revista presei

Suplimentele de vitamina B nu ajută la prevenirea cancerului

Suplimentele de vitamina B nu par să ne protejeze împotriva apariţiei cancerului cum păreau să sugereze unele studii anterioare, relevă ultimele cercetări în domeniu din SUA.

Femeile care au luat zilnic suplimente alimentare care includeau vitaminele B6, B12 şi acid folic, cunoscut ca vitamina B9, timp de aproape 7 ani nu au fost mai puţin predispuse la apariţia cancerului, chiar în forme terminale, faţă de cele care au primit placebo în cadrul acestui studiu.

„Aceste cercetări au arătat că suplimentarea dietei zilnice cu vitamine B combinate nu a adus nici efecte benefice, nici negative în sensul cercetat. Astfel că, în termenii de risc de apariţie a cancerului, această cale nu este una eficientă", a declarat Dr. Shumin Zhang de la Brigham and Women's Hospital şi Harvard Medical School din Boston, care a şi condus aceste studii.

Cercetătorii au căutat să vadă dacă un anumit număr de vitamine ne pot proteja împotriva cancerului.

Studiul publicat în The Journal of the American Medical Association a implicat 5442 de femei de pe tot teritoriul Statelor Unite cu vârsta medie de 63 de ani. Acestea prezentau înalţi factori de risc pentru bolile cardiovasculare cum ar fi presiunea sângelui ridicată sau nivel ridicat de colesterol. Unii experţi erau încrezători că vitaminele din grupul B le vor proteja de apariţia cancerului, cum reieşea din unele studii anterioare, mai ales referitor la cancerul de colon.

Dar în cadrul acestui studiu, numărul de femei la care au apărut forme de cancer a fost aproape identic în grupul celor care luau suplimentele de vitamine B(187) faţă de cele care primeau placebo (192). Cele două grupuri au prezentat riscuri similare de apariţie a cancerului în diferite forme, inclusiv în faze terminale.

Totuşi, există beneficii ale consumului vitaminelor de tip B şi acidului folic, mai ales din vegetalele verzi sau din cereale, dar şi din suplimente. Este important ca populaţia să consume cantitatea necesară de vitamine B care sunt implicate direct în creşterea, dezvoltarea organismului şi buna lui funcţionare. De exemplu, acidul folic este direct implicat în producţia de celule roşii şi este important pentru femei să prevină anumite defecte congenitale ale creierului şi coloanei nou-născuţilor prin consumul de acid folic în doze suficiente.

Există voci, cum ar fi Dr. JoAnn Manson of Brigham and Women's Hospital, care susţin că populaţia care mănâncă alimente bogate în acid folic au totuşi un risc mai scăzut de apariţie a cancerului.

Există alţi cercetători care studiază efectul suplimentelor de vitamine B6, B12 şi acid folic asupra bolnavilor de Alzheimer şi speră ca acestea să încetinească avansarea bolii.