Switching prescription drugs to over the counter

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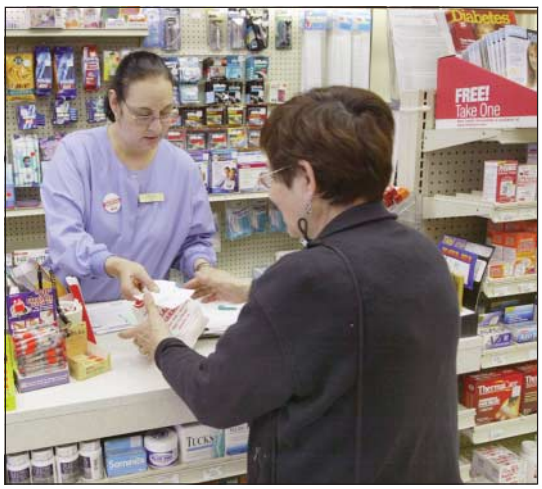
Appropriate self treatment is an important aspect of both the European and American healthcare systems, but what is really driving increased over the counter availability?

Increased numbers of prescription drugs are being made available over the counter worldwide. Recent high profile switches have included drugs in classes previously not eligible, such as omeprazole in Sweden and simvastatin in the United Kingdom. Switches are motivated mainly by three factors: pharmaceutical firms' desire to extend the viability of brand names; attempts by healthcare funders to contain costs; and the self care movement. Making drugs available over the counter affects a large number of stakeholders, including patients, pharmaceutical firms, physicians, pharmacists, drug regulatory agencies, and private and public health funding organisations. In this article, we illustrate the roles that pharmaceutical firms, healthcare organisations, and government regulatory agencies played in three recent switches that have fuelled global debate: simvastatin in the United Kingdom, omeprazole in Sweden, and loratadine in the United States.



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More prescription drugs are likely to become available over the counter

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Simvastatin

Generally, a prescription drug becomes a candidate for over the counter availability if it is used for a non-chronic condition that is relatively easy to self diagnose and has low potential for harm from abuse under conditions of widespread availability. Statins do not fit this description. Much has been said about the UK Medicines and Healthcare Products Regulatory Agency's controversial decision in May 2004 to reclassify simvastatin 10 mg as an over the counter medicine. In a best case scenario, the switch will increase use of simvastatin by people at moderate risk of developing coronary heart disease, resulting in reduced risk. However, there have been no clinical trials of over the counter statins for primary prevention of heart disease.

Concern has been raised that the main motive behind the government's decision to allow simvastatin to be sold directly to the public is the potential reduction in NHS expenditure.[1] Although it is conceivable that the agency expedited the switch to save NHS costs, this is unlikely to have been the main motive. Firstly, the drug sponsor, and not the agency, initiated the switch,[2] suggesting a profit motive. Secondly, NHS cost savings will be limited because high risk patients will still be eligible for statins on prescription; the target market for over the counter simvastatin is people at moderate and low risk, who are currently ineligible for NHS prescription (A Lawrence, MHRA, personal communication).

Omeprazole

In November 1999, the Swedish Medical Products Agency approved the switch of omeprazole 10 mg to over the counter sales with a label caveat that warns patients not to take more than two pills daily (20 mg) and limits use to 14 days. Higher doses of omeprazole remain available as prescription only. In this case, the move was made well before the patent was due to expire, and cost was the underlying motive.[3] The Swedish Federation of County Councils, the agency directly responsible for Sweden's pharmaceutical reimbursement, petitioned the Medical Products Agency to switch omeprazole because of prescribing costs. The omeprazole switch in Sweden is unusual because it was forced on the manufacturer before the patent expired and was for a class of drug that doesn't easily fit the usual requirements for over the counter status. Historically, Sweden has been reluctant to switch drugs and has the lowest number of switches among 15 European Union countries.[4] Sweden is the only country apart from the United States that has deregulated omeprazole.

Loratadine

Cost was also the main motive behind the switching of the antihistamine loratadine to over the counter status in the United States. In an unprecedented move, WellPoint, a US health insurer, petitioned the Food and Drug Administration to switch three antihistamines: loratadine, cetirizine, and fexofenadine while they were well within patent.[5–7] On review, the FDA recommended the switch in 1998. However, the FDA's recommendations are not binding; each manufacturer has to voluntarily initiate a switch of its drug. So far, only loratadine has been made available over the counter, and this was done in response to expiry of its patent. After losing a protracted patent litigation in spring 2002, Schering-Plough expected generic loratadine to enter the market later that year. To expand the brand name's viability, the company applied to switch loratadine at its original prescription strength of 10 mg, which the FDA approved in November 2002.

As a parallel strategy, drug firms often launch follow-on drugs to replace an innovator drug whose patent is expiring. Schering-Plough received US approval for loratadine's follow-on (desloratadine) in 2001 and launched it in 2002, near the end of loratadine's patent. A similar pattern was seen with omeprazole and the follow-on esomeprazole. Esomeprazole was launched in 2001, and the manufacturer successfully applied for omeprazole's switch to over the counter availability in 2003.[8] The FDA approved a 20 mg dose for over the counter omeprazole (double that in Sweden). Omeprazole 20 mg also remains available as a prescription drug for treatment of diseases that require diagnosis and supervision by a healthcare provider.

Effect of over the counter availability

How health funding organisations respond to switches of drugs such as loratadine and omeprazole is especially important in the United States, where cost sharing between insurers and patients is common. In making reimbursement decisions, insurers first decide whether to include particular classes of drugs on the formulary. Subsequently, they select drugs within each class and assign copayment tiers (high, medium, or low).

We conducted a survey of 12 leading managed care organisations regarding their responses to switches. We found a strong tendency to remove switched drugs from the formulary and raise copayments of prescription drugs in the same class. Increasing the copayments of prescription drugs in the same class gives patients further financial incentive to take the over the counter drug. All 12 organisations removed loratadine from their formularies and raised copayments for prescription antihistamines. One third are taking all second generation antihistamines off their formulary. Eight removed omeprazole from the formulary, and seven raised the copayments for prescription proton pump inhibitors. None of the respondents are eliminating this class from their formularies.

Switching drugs to over the counter availability reduces insurers' prescription drug costs but increases the costs for most patients. However, some benefit, particularly uninsured patients, who previously had to pay the full retail prescription price and the cost of physicians' visits. Insured patients faced with high copayments on their prescriptions may also benefit financially from over the counter availability.

US regulatory change

The FDA has been reluctant to allow switches of certain classes of drugs, such as corticosteroids, that have passed through regulatory hurdles in the European Union and elsewhere. One reason for this may be that, in contrast to most European regulatory agencies, the FDA requires studies of patients' understanding of labelling for each drug switched. Another reason may be that drugs in the United States are available only on prescription or over the counter. In many other countries, including Sweden and the United Kingdom, some drugs are classified as behind the counter—that is, available only with the authorisation of a pharmacist. The lack of a behind the counter option in the United States may heighten safety concerns because over the counter drugs are available to the public without any kind of professional intermediary.

Regulatory changes are underway in the United States. The FDA is currently considering over the counter status for certain drugs for chronic conditions, such as statins. The agency hopes to increase annual switches by about 50%.[9] Moreover, the FDA is exploring its legal authority to initiate switches of drugs it deems suitable, specifically targeting 5-10 unspecified drugs that are available over the counter in other countries but not the United States. It will rely partly on foreign data to support claims that patients understand the labelling.

As a sign of a regulatory shift, the FDA has withdrawn its officially stated objection to switching lipid lowering drugs.[10] It is currently reviewing two rejected switch applications for the statins lovastatin and pravastatin. It may be looking at data from the United Kingdom on over the counter simvastatin to evaluate these applications. If one or more statins were to be made available over the counter, copayments of prescription alternatives would probably rise, as has happened with second generation antihistamines and proton pump inhibitors.

Future implications

The number of drugs being switched from prescription to over the counter availability is likely to continue to rise. Six widely prescribed drugs that are candidates for switching will lose patent protection between 2005 and 2008 (cetirizine, esomeprazole, lansoprazole, pravastatin, simvastatin, and zolpidem). The manufacturers are likely to apply for switching before the patents expire so that they can gain a foothold in an expanding over the counter market ahead of generic competition.

Forced switches of drugs within patent threaten the pharmaceutical industry's earning capacity. The only instance of this is omeprazole in Sweden, and it is not likely to be repeated in the near future. However, healthcare funders are likely to support manufacturers' applications to switch some drugs in an effort to curb the growth of prescription costs. For patients, the trend towards more switches will take self care to a new level, focused increasingly on chronic prevention of serious illnesses.

Summary points

Switching of prescription drugs to over the counter availability is increasingly common

The classes of drug available over the counter are expanding to include those used for prevention of serious illness

The main motives are pharmaceutical firms' desire to expand their market, attempts to reduce drug bills, and the self care movement

Contributors and sources: All authors conduct research into how drugs are developed. JPC's main area of interest is pharmaceutical reimbursement and he is senior research associate at Erasmus University, Rotterdam. JPC was responsible for article content, survey design, acquisition of sources and data, analysis and interpretation of sources and data, drafting of the manuscript, and critical revision of the manuscript. CP participated in writing the article, acquisition of sources and data, analysis and interpretation of sources and data, and critical revision of the manuscript. CPC participated in writing the article, analysis and interpretation of sources and data, and critical revision of the manuscript. JPC is guarantor.

Competing interests: None declared.

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Corrections and clarifications

Supporting surgery for obstetric fistula
In this news article (*BMJ* 2004;329:1125, 13 Nov) we mistakenly said that Dr Shereen Bhutta was chief of obstetrics at the Jinnah Postgraduate Medical Centre, whereas in fact Professor Khurshid Jehan Noorani is the centre's head of the department of obstetrics and gynaecology; Dr Bhutta is associate professor in the department.

MMR: What they didn't tell you
In the review of this *Dispatches* television programme, the author, Abi Berger, stated that the results of a study conducted by Dr Nick Chadwick "were not made public" (*BMJ* 2004;329:1293, 27 Nov). She meant that the results were not presented at the press conference held in 1998 that effectively sparked off the health scare about the measles, mumps, and rubella (MMR) vaccine—not that the results were not in the public domain at all. The results had been published in the *Journal of Medical Virology* (1998;55:305-11).

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Learning as a team

Since we launched BMJ Learning we have received a lot of feedback that members of primary care teams in Britain are starting to learn together. Traditionally, general practitioners have gone to meetings for doctors to do their learning, and similarly with practice nurses and practice managers. However, many of our users have told us that this has changed in the past year: now they close their practice for half a day a month, and all staff attend learning meetings together. Many of them have asked that BMJ Learning supports them in this practice.

To do so, BMJ Learning has become more interdisciplinary. We have added new features to the site to support practice nurses, receptionists, and practice managers in their learning. You can use the site as an individual, or you can use it as a team so you can learn together. For example, you could use our modules on audit and preventing complaints as a foundation for half a day's teaching on clinical governance. Learning together has many advantages, not least, the chance to share different insights and perspectives on clinical and ethical dilemmas.

Our latest interactive case history is on avoiding drug error in primary care. There are many causes of drug error, but the most common one is breakdown in communication between doctors and patients and other members of the primary care team.[1] Our learning module explains why this happens and how to put in place procedures to stop it happening. It is not just about learning communication skills: the module also points out recent changes to prescribing information in Britain, such as the new advice that risperidone and olanzapine should be avoided in patients with dementia as they increase the risk of stroke in such patients.[2] To find out more about avoiding drug error in primary care, try our new learning module on bmjlearning.com.

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1 Sandars J, Esmail A. *Threats to patient safety in primary care: a review of the research into the frequency and nature of error in primary care.* London: Department of Health, 2002.
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