The interface between self medication and the NHS

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OTC

This is the second of four articles examining the implications of the availability and use of non-prescription medicines for health services in Britain and elsewhere

Cost and convenience seem to be major factors in determining whether, given the choice, patients purchase a medicine over the counter or obtain it on prescription. With current arrangements, exemption from prescription charges provides an incentive to continue to obtain products on NHS prescription even when they are available over the counter. There is therefore no simple relation between the availability of over the counter medicines and the level of prescribing of deregulated products. The appropriate use of over the counter medicines—particularly those that have only recently been deregulated—places a burden of care on community pharmacists and calls for closer working relationships with general practitioners. In particular, systems for referral and for recording details of both prescribed and over the counter medicines need to be developed, and a direct route needs to be established for community pharmacists to report adverse drug reactions to over the counter products.

Reclassification of prescription medicines—by making them available through pharmacies without a prescription—provides the opportunity for consumers to purchase a wider range of medicinal products without making a demand on NHS resources. There is, however, no simple relation between availability of over the counter medicines and demand for NHS prescriptions. Much depends on consumer behaviour, which in turn is influenced by many factors. Thus the interface between self medication and the NHS is complex. To explore the influence of deregulation of medicines on NHS prescribing, this article presents analyses of consumer behaviour in using medicines and prescribers' attitudes to over the counter medication and collates findings from research.

Table 1—*Everyday ailments for which people report treating themselves rather than seeking a consultation with a doctor*[1]

Ailment	% Of people reporting ailment (n=2000)
Headache	80
Athlete's foot	79
Dandruff	73
Heartburn	62
Migraine	62
Period pain	61
Colds	60
Coughs	56
Mouth ulcers	51
Acid stomach	50

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Table 2—*Responses to minor ailments. Values are percentages of 6009 adults and 806 children who reported ailments*[2]

Response	Children	Adults
Saw doctor or dentist	17	13
Used a prescription medicine already in the house	13	13
Used an over the counter medicine	33	24
Used a home remedy	11	9
Did not use anything	28	45

Factors influencing consumer behaviour

Surveys by the British Market Research Bureau, in 1987 and 1994, provide some insight into how people respond to common ailments.[1,2] Table 1 lists the most common conditions that people report treating with over the counter medicines. The 1987 survey covered some 6000 episodes of minor illness experienced in the previous two weeks by adults and over 800 in children; table 2 shows the profile of responses.[2] Self medication with over the counter products was remarkably consistent (26-28%) across the adult age range. The vast majority (89%) of adults who reported minor illnesses had experienced these ailments before, and at some stage a quarter of them had consulted their general practitioner or dentist about them.

Consumers' familiarity with over the counter products varies greatly. Exposure to a drug before deregulation is an important influence. A recent survey found that 74% of consumers purchasing Beconase Hayfever (beclomethasone aqueous nasal spray) had previously used Beconase on prescription; 50% of purchasers of Tagamet 100 had used cimetidine; and 15% of those buying Pepcid AC had used famotidine.[3] Advertising also has a major impact on the uptake of newly deregulated products.

Consumers' willingness to purchase an over the counter product, particularly a newly available one, depends on factors including cost, convenience, and the value of time. In Britain the likelihood of purchasing over the counter medicines is linked with prescription exemption status. Over 80% of NHS prescriptions are exempt from prescription charges, and this is likely to distort consumers' decisions about self medication.[4] A recent study showed that a key factor in whether patients obtained a prescription from their general practitioner for relief of hayfever or purchased an over the counter product was whether they were exempt from prescription charges.[5] Higher prescription charges will therefore encourage self medication among those who pay charges.[6] Pricing of over the counter products and perceived "value for money" are also important. Many packs contain a limited supply of the drug, so for consumers requiring chronic treatment the availability of greater quantities of medicine on prescription encourages consultation with a doctor.

Scepticism from general practitioners

Despite considerable effort by both the Department of Health (in clarifying and giving guidance on general practitioners' terms and conditions of service) and the pharmaceutical industry (through its *OTC Directory*[7]) to facilitate general practitioners' endorsement of over the counter products, British general practitioners have responded slowly. Aspirin and paracetamol preparations still make up half of general practitioners' recommendations for over the counter products,[8] but they are willing to recommend an over the counter medicine when it is cheaper or more convenient for the

patient than a prescription drug[9] or when the patient is already using an over the counter product and is seeking merely to confirm a diagnosis.

One of the factors behind general practitioners' lack of enthusiasm about over the counter products is the belief that the care of patients is a personal responsibility once an individual has decided to consult them.[9] Many patients are likely to have tried self medication before seeing their general practitioner, and they expect that the consultation will result in a prescription; being recommended to buy an over the counter medicine may be perceived as a less than adequate response to their problem. Nevertheless the availability of over the counter drugs does provide the opportunity for some reduction in NHS prescribing.[10] The potential for savings from non-prescribing of a limited range of products available without a prescription, assessed in one general practice, is shown in the box. Out of 1101 items prescribed for the listed products at a cost of £5396 over the quarter, 736 could have appropriately been recommended for over the counter purchase at an average cost per item of £5.22. This would represent a 71% saving to the practice on the prescribing of these products, which over a year would extrapolate to £15 368.

What happens when a drug is deregulated?

When a product is deregulated, demand depends on many factors. The indications for which the deregulated product is licensed in comparison with those for the "parent" prescription product are important, and so is the cost. The market for three products that have been deregulated in Britain in the past four years is shown in figure 1.

CLOTRIMAZOLE (CANESTEN) PRODUCTS

Clotrimazole products for the treatment of vaginal candidiasis were deregulated in July 1992. In the figure the composite demand trend for Canesten topical and vaginal products shows a modest decrease in prescription demand and some increase in supply through pharmacies. The current pricing of these products is unlikely to encourage their purchase over the counter. A single dose treatment costs £5.95, against a prescription charge of £5.25. The NHS list price for the same products is between £3.00 and £3.50.

This product class exemplifies potential problems in consumer education. Canesten was initially launched as an over the counter product without specific advertising or educational support. The company soon received complaints of lack of efficacy, and this was found to be due to inappropriate use: the 2% cream, instead of the 10% cream, was being used intravaginally. An educational campaign mounted by the company was successful in correcting this problem.[11]

ACYCLOVIR (ZOVIRAX) CREAM

Acyclovir cream was made available off prescription for the treatment of cold sores in September 1993.

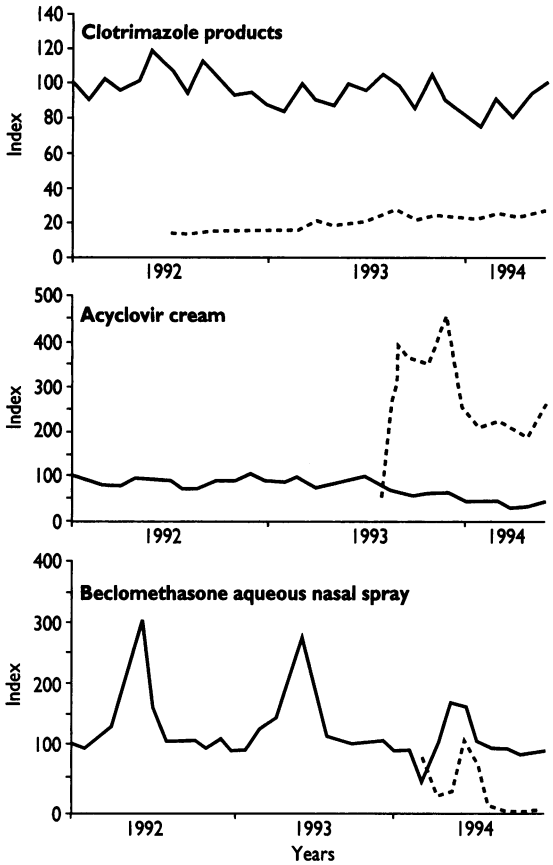


Fig 1—*Demand trends for prescription (——) and over the counter items (– – –) for medicines deregulated from prescription only status to pharmacy status, January 1992 to December 1994. Source: Intercontinental Medical Statistics UK; data derived from a study on the impact of deregulation on NHS prescribing being undertaken by Katherine Payne, Bernadette Ryan-Woolley, and Peter Noyce and sponsored by Department of Health and the European Union*

Consumer awareness of the product was quickly established, and overall demand increased dramatically while NHS prescribing subsided modestly. The over the counter version of the product, Zovirax Cold Sore Cream, is priced at £5.29 per 2 g tube, the same as the prescription version, Zovirax Cream.

BECLOMETHASONE AQUEOUS NASAL SPRAY (BECONASE)

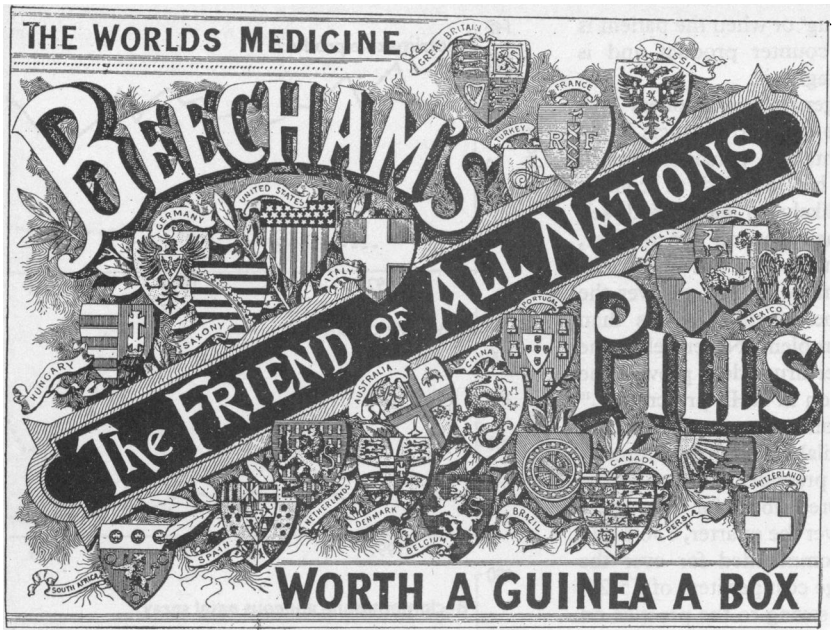
Beclomethasone dipropionate was reclassified for the treatment of seasonal allergic rhinitis in January 1994 and there has been a seasonal shift from NHS prescribing to over the counter purchase. As the over the counter product, Beconase Hayfever, is priced at £7.79 for 180 units (NHS list price for the 200 units is £5.01), a financial incentive remains for patients to obtain the product on prescription, and wider availability seems to have had no effect on prescribing outside the hayfever season.

Assessment of potential savings in a single quarter for non-prescribing of drugs available over the counter, based on St John's Health Centre, Woking, Surrey

No of partners	6
No of patients registered	13 947
Total items prescribed	17 386
Total drug expenditure	£168 456
Average cost per item	£9.69
Products recommended for over the counter purchase	Brufen, Calpol, Pepcid, Tagamet, Zovirax, antiallergic and antifungal products
No of prescription items suitable	736
Average cost	£5.22
Potential saving	£3 842

Safety and appropriate use of OTC medicines

Product safety, and the contribution of packaging and patient information in supporting it, are addressed in the requirements for product licence application for reclassification to pharmacy status. A product is deregulated only after extensive use as a prescription medicine. An appropriately robust safety profile is fundamental to the change of status, with proven efficacy in a specified self limiting and easy to diagnose condition. Safety margins can be reinforced by using lower doses and limited pack sizes with the over the counter version of the product to discourage chronic and inappropriate use. Clinical concerns about the safe



Advertising has a major impact on the uptake of new products

and appropriate use of deregulated products focus on the appropriateness of treatment in acute situations, potential for misdiagnosis, and maintenance of therapeutic control in chronic conditions.

The pharmacist has a key role here, and currently when a medicine with pharmacy status is sold the pharmacist is required to supervise its sale. The movement of more products from prescription only to pharmacy status has heightened the need to put the associated advisory role onto a more structured basis. To counter criticism from the Consumers' Association, which has challenged the quality of the advice available from community pharmacies,[12] the Royal Pharmaceutical Society has (as of 1 January 1995) required all community pharmacies to have established protocols for controlling the sale of pharmacy status medicines.

Preventing problems

Before any drug is prescribed or sold, ideally there should be a brief review of the patient's current medical conditions and medication in order to identify and avoid any potential drug interactions or contraindications. Drug interactions between over the counter and prescribed drugs are possible—the *OTC Directory* provides a comprehensive list.[7]

Consumers need to be educated to recognise that over the counter products can have unwanted side effects similar to those of prescribed drugs. Package inserts highlighting potential interactions of over the counter and prescribed products are an important part of this process.

As part of their contract with family health service authorities, most community pharmacists maintain computerised patient medication record systems. The requirement for remuneration is the maintenance of records on prescribed medicines. In early 1991 only a third of pharmacists using patient medication records had data on over the counter medicines.[13] One study found that less than 10% of pharmacists' interventions involved interactions or contraindications of over the counter medicines.[14]

Outstanding issues

Adverse reactions caused by over the counter drugs are less likely to be reported than those associated with prescription only drugs (which are reported through the yellow card scheme, which currently precludes reporting by pharmacists). To improve the reporting of adverse reactions to over the counter medicines, both consumers and pharmacists must be educated about the importance of monitoring the safety of medicines, particularly of those that have been deregulated recently. Community pharmacists in Britain must have a direct and reliable route for reporting adverse drug reactions, as they do in other countries.

As the scope for self medication increases, so does the potential for medicolegal problems for doctors and pharmacists. Pharmacists need to record the advice they give, which may be difficult in a busy pharmacy. Consumers who have a problem with an over the counter product are perhaps more likely to bring a claim against the pharmacist, but doctors may also be involved: it is only too easy to prescribe without asking the patient which over the counter medicines they are using. General practitioners and community pharmacists must work together to facilitate the appropriate use of over the counter medicines[6,9] and to monitor their use.

Records of patients' medication—held by both prescribers and pharmacists—should include over the counter medicines as well as prescription only medicines.[15] This is important for the safety and benefit of the individual patient and for securing complete information on drug use.[16,17] Formal mechanisms for referring patients between general practitioners and pharmacists need to be introduced.[18]

An interim conclusion

The American experience shows that it takes at least two years, after deregulation, to reach a steady state between levels of prescribing and over the counter purchases of a product.[19] In the United Kingdom, many over the counter medicines have been deregulated only recently, so it is still not clear what overall impact they will have on NHS prescribing. Relief of NHS expenditure is not a foregone conclusion given the inflexible system of prescription charges in Britain. A more rational approach to prescription tax arrangements and the pricing of over the counter medicines is needed. Meanwhile, more work is required to ensure that over the counter medicines are used appropriately and effectively. The development of integrated therapeutic protocols and formal referral systems between general practitioners and pharmacists will do much to reassure general practitioners and consumers. The creation of reliable systems to monitor and report adverse reactions to over the counter medicines is also important, although evidence to date suggests that the risks associated with their use are low.

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For Debate

Setting priorities: can Britain learn from Sweden?

Martin McKee, Josep Figueras

The Swedish government recently published a report on priorities in health care. It was written by a cross party group of politicians and drew extensively on the views of the public, health professionals, experience of earlier local exercises in priority setting, and research based evidence. It laid down an ethical framework for approaching issues of health care rationing. Underpinning the framework are the principles of human dignity, need and solidarity, and cost efficiency. The Swedish approach thus contrasts with the British experience of many local initiatives but an absence of national political guidance. The absence of political consensus on many aspects of social policy in the United Kingdom is a major obstacle to developing an agreed ethical framework within which decision makers in the National Health Service can work.

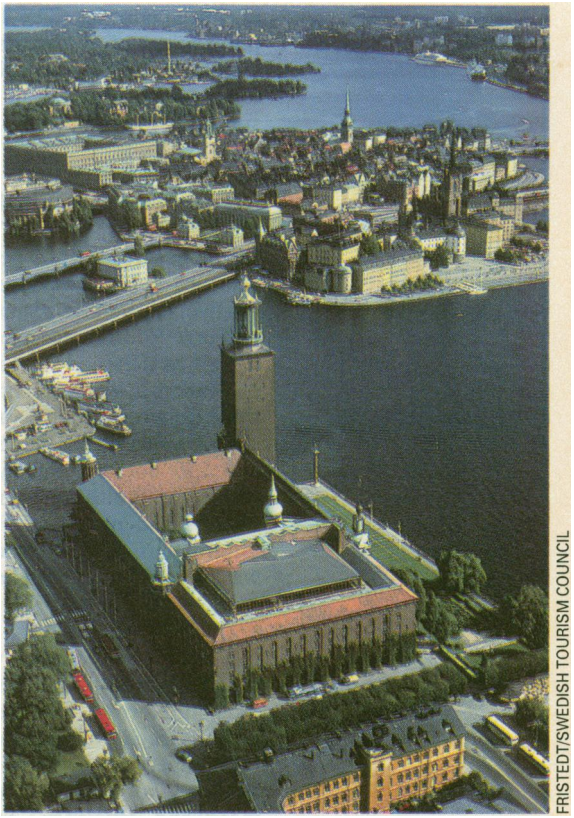
Throughout the industrialised world there is concern about the apparent mismatch between demand for health care and the resources that governments are prepared to commit to meet it. The reasons are complex, the effects vary between nations, and most of the reasons are poorly understood, although they include the effects of aging populations, the introduction of new technology, and rising public expectations. The responses by countries have also varied widely, depending on factors such as the relative power of governments, the medical profession, insurance companies, and national pharmaceutical industries.

Five possible approaches to the mismatch between demands and resources exist: increasing resources either from government revenues or from individuals; controlling either demand (through cost sharing) or supply of services; withdrawing funding from services that are ineffective or where there is a cheaper alternative; increasing the efficiency of service provision; or creating a mechanism explicitly to identify health care priorities.[1] With the possible exception of controls on supply, using capital and manpower ceilings or global budgets, as in the United Kingdom and Germany, there is little evidence that the first four have been successful in controlling the apparently inexorable rise in health care expenditure. Some, however, such as reducing ineffective care, have been difficult to implement. Consequently, there is growing interest in the fifth—explicitly trying to define what types of health care might no longer be provided from public resources. In the United Kingdom this approach has been variously described as rationing or priority setting, the choice of term partially reflecting the speaker's political perspective, with the government favouring the latter but many other commentators the former.[2]

The British experience

The introduction of the purchaser-provider split has stimulated many exercises in explicit priority setting in the United Kingdom.[3] Each has included, to varying degrees, the views of health professionals, the public, and research based evidence. In contrast to most other countries, however, the British experience is characterised by the extent to which these attempts have been undertaken locally, by health authorities. Elsewhere such exercises have been conducted nationally[4-6] or, in the USA, at state level.[7] Indeed, the reluctance of the government to become engaged in a national debate on priority setting and, in particular, the ethical issues that underpin it, has been striking.

A speech by the former Secretary of State for Health that set out the government's views on this issue was noteworthy for the absence of any attempt to provide ethical principles to guide these many decision makers, or even to recognise that such principles might be needed.[8] Furthermore, the Health of the Nation



Sweden has managed to produce an ethical framework for making hard decisions about health care provision because there is broad political support for the exercise

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