



postnote

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CHANGING ROLE OF PHARMACIES

In 2003, the Department of Health (DH) set out its intention to increase the public's choice of when, where and how to get medicines. The introduction of the new community pharmacy contractual framework in April 2005 will help to achieve this. This POSTnote will examine the changing role of pharmacy and the availability of medicines by prescription, over-the-counter and remotely by mail-order or the internet.

Background

Medicines are the most commonly used form of healthcare treatment. They provide relief from everyday ailments to life-saving interventions for acute illness as well as support for people with long term medical conditions such as asthma, or progressive illnesses such as arthritis or multiple sclerosis.

Building on the NHS Plan, in 2003, the Department of Health (DH) set out its intention to increase the public's choice of when, where and how to get medicines by:

- freeing up restrictions in England on locations of new pharmacies in the Government's response to an Office of Fair Trading report¹;
- easing bureaucracy around repeat prescriptions;
- expanding the range of medicines that can be provided without prescription;
- promoting minor ailment schemes in pharmacies;
- increase the range of healthcare professionals who can prescribe².

Many of these changes will be implemented through increasing the contribution that community pharmacists make to primary health care. This note will focus on the changing role of pharmacies.

Classification of medicines

Medicines are classified and made available in three main ways (Box 1): prescription only medicines (POM);

over the counter in a pharmacy without prescription but under the supervision of a pharmacist (P); and available on general sale (GSL). Medicines can also be reclassified. This is usually at the request of the company holding the marketing authorisation, although requests can be initiated by any interested party (see Box 2), such as a professional body, or the Medicines and Healthcare Products Regulatory Agency (MHRA).

Box 1. Medicines legislation

The Medicines Act 1968 and Council Directive 2001/83/EEC control the sale and supply of medicines. The legal status of medicinal products is part of the marketing authorisation. There are three classes of medicine. A new medicine is usually authorised as prescription only (POM). After some years use, if adverse reactions to it are few and minor, it is possible that it may be used safely without a doctor's supervision. If there is sufficient evidence of safety then the medicine may be reclassified for sale or supply under a pharmacist's supervision (P). Similarly, pharmacy medicines which have been safely used for several years may be reclassified for general sale (GSL). Applications to reclassify medicines are evaluated with advice from an expert committee (the Committee on Safety of Medicines) as necessary. Where it is considered that reclassification may safely be made, MHRA consults interested organisations and the public before making a decision.

Pharmacies

Community pharmacies are where most people have access to pharmacy services and where 73% of active pharmacists work. A new contractual framework between community pharmacies and the NHS was introduced in April 2005. While the old system emphasised the volume and throughput of prescriptions, the new framework focuses on the range of services that pharmacists provide for patients. These are divided into three levels – essential, advanced and enhanced (Box 3).

Box. 2 Who's who

- **The Royal Pharmaceutical Society of Great Britain (RPSGB)** is the regulatory and professional body for pharmacists. The primary objective of the Society is to lead, regulate and develop the pharmacy profession.
- **National Pharmaceutical Association (NPA)** is the national body representing Britain's community pharmacy owners.
- **The Royal College of General Practitioners (RCGP)** is the academic organisation in the UK for general practitioners. Its aim is to encourage and maintain the highest standards of general medical practice and act as the 'voice' of general practitioners on education, training and standards issues.
- **The British Medical Association's General Practitioners Committee (BMA GPC)**. The BMA represents doctors from all branches of medicine all over the UK. Its GPC aims to represent all GPs, to promote general practice and to protect its fundamental characteristics and interests.
- **Medicines and Healthcare products Regulatory Agency (MHRA)** is the executive arm of the UK's Drug Licensing Authority and is responsible for all aspects of the regulation of medicines in the UK.
- **The Committee on Safety of Medicines (CSM)** is an expert Committee that advises the Government on the safety, quality and effectiveness of medicines.

Location of pharmacies

Prior to the new community pharmacy contractual framework the granting of contracts to pharmacies to dispense NHS prescriptions was subject to the NHS (Pharmaceutical Services) Regulations 1992. Since the NHS accounts for the vast majority of all prescriptions, it is difficult for a pharmacy to run a viable business without such a contract. This effectively amounted to full regulation of market entry for new pharmacies. The Government wanted to offer patients more choice in where they get their prescriptions dispensed by making it easier to open new pharmacies. In 2004, it announced new rules to introduce criteria of competition and choice to the regulatory test, exempting the following types of pharmacies from the test³:

- those in areas where consumers already go, such as large shopping developments;
- pharmacies intending to open for more than 100 hours a week;
- those in large one stop primary care centres;
- and internet and mail-order pharmacies that allow people to have medicines delivered to their home.

Issues

The Government's commitment to make medicines more readily accessible raises issues including access to medicines, the role of pharmacists, and access to patient information and pharmacies. These are discussed below.

Access to drugs*Reclassification of medicines*

It is widely agreed that there are advantages to making more medicines available without prescription. However, some groups have expressed concern about how far this should be taken. The recent reclassification of a low dose of statin (simvastatin), a medicine that reduces cholesterol levels, is a case in point. Statins, are currently

Box. 3 The new pharmacy contractual framework⁴

Under the new framework there are three tiers of services: nationally set essential and advanced services, and locally set enhanced services.

- *Essential services* are defined as those services that must normally be provided. Essential services include dispensing, repeat dispensing, disposal of medicines, promotion of healthy lifestyles, promotion of self care for patients with minor ailments and signposting for patients to other healthcare provision.
- *Advanced services* are those which require accreditation of the pharmacist providing the service (such as medicine use review) and/ or specific requirements to be met in regard to premises, such as private consultation areas.
- *Enhanced services* are local services such as minor ailment schemes and supplementary prescribing that will be commissioned by Primary Care Trusts, according to the needs of the local population.

Payment will be increasingly directed towards quality, not just dispensing volume, recognising that pharmacies need a fair return for the services they provide.

prescribed to 1.8 million people. In 2004, the Committee on Safety of Medicines (CSM) advised that simvastatin should be available without prescription in a low 10mg dose, but continue to be available as a POM to high-risk patients.

RPSGB welcomed the decision. It believes that there is a clear public health benefit to be gained from making this medicine available without a prescription. However, others including RCGP, BMA GPC and the consumer organisation, Which?, disagree. BMA GPC is against the introduction of statins to the over-the-counter market for a range of reasons, including safety concerns. It suggests that even low doses can cause side effects, such as muscle damage, and thus considers it inappropriate to provide such medicines without a doctor's supervision.

Such safety concerns should be addressed by the CSM when it is considering its advice on an application to reclassify a medicine. While the MHRA consulted the BMA, RCGP and Which? about simvastatin, it is not clear how their concerns were taken into account. Neither MHRA nor the CSM publish a report of the evidence considered and why their decision was reached.

Implications of wider access to medicines

Some have questioned the benefits of wider access to medicines in general and to preventative medicines in particular. While the reclassification of simvastatin has been welcomed by the RPSGB, the medical profession has expressed doubts over the balance between safety and efficacy. For instance, the RCGP points out that the therapeutic benefits of 10 mg of simvastatin (a 27% reduction in risk of heart attack and stroke) only applies to those people at increased risk of heart attack or stroke in the first place. It is concerned that people taking the drug who are not at increased risk of stroke or heart attack may receive no therapeutic benefit while exposing themselves to the risk of side effects.

RCGP is concerned that, in practice, it will be the 'worried well' who take preventative medicines rather than the people who may benefit most from them. It is worried about the psychosocial implications of an ever greater proportion of the population considering themselves to have some sort of health problem. DH argues that by extending access to such medicines it is giving people more choice about how they protect their health. However, RCGP and Which? consider that patients with a clinical need to take medicines such as statins should be able to do so on the NHS.

The role of pharmacists

Pharmacists are experts in the use of medicines and must complete a four year degree and one year's practical training to qualify. It is widely agreed that better use could be made of pharmacists' skills and knowledge; the new pharmacy contractual framework sets out the Government's plans on how to achieve this.

Because community pharmacists operate within a commercial environment, questions have been raised about whether they are best placed to decide if a patient requires a medicine and if so, which one? However, one of the key responsibilities within a pharmacist's code of ethics is to act at all times in the best interests of the patient⁵. Pharmacists are expected to assess whether a prescription or an over-the-counter medicine is appropriate. The public appears comfortable with a pharmacist's dual roles of retailer and healthcare professional. In a survey more than half the respondents disagreed with the assertion that pharmacists sometimes recommend products that are not strictly necessary in order to make a sale⁶.

Pharmacists' skills

Over the past five years a number of schemes have been established to better integrate pharmacists into primary care and the new contractual framework will further encourage this. Examples are described in Box 4. In general these schemes have been considered a success and have been integrated into the new pharmacy contractual framework. They offer easier and faster access to services for people as well as reducing a GP's workload. For example, the *Care at the chemist* scheme in Bootle resulted in a reduction in GPs' minor ailment workload from 8.9% of consultations to 6.6%⁷. Repeat dispensing by pharmacists is also likely to reduce GPs' workloads. Currently about 75% of GPs' prescriptions are for repeat medicines.

Medicines management review

Pharmacists can offer medicines usage review as an advanced service under the new contract. Here, pharmacists undertake a review (of both prescribed and non-prescribed medicines) with patients receiving medicines for long term conditions, to establish a picture of their use of the medicines. It is anticipated that this will help patients to understand why the medicines are prescribed for them, as well as identifying side-effects that they may be exposed to.

Box 4. Better use of pharmacists' skills Minor ailment schemes

Minor ailment schemes have included treatment for conditions such as athlete's foot, earache, constipation, hay fever and cystitis. The interventions available to a pharmacist are usually of three main types: advice only; advice and supply of medicines over-the-counter; or referral to a GP. In the *Care at the chemist* scheme in Bootle patients requesting a GP appointment for minor ailments, such as earache, nasal symptoms, and cough, were offered a consultation at a pharmacy. 38% of patients were happy with this option and thought the arrangement was convenient. Patients who had not had the symptoms before preferred to see a doctor⁷.

Supplementary prescribing

Supplementary prescribing, including repeat prescribing, is a partnership between a:

- GP who establishes a diagnosis and assesses a patient;
- pharmacist or nurse who monitors the patient and prescribes further supplies of medicines within an individual clinical management plan;
- patient who agrees to the supplementary prescribing arrangement.

All pharmacist supplementary prescribers must undergo additional training, including a period of supervised practice. In a diabetes shared care scheme, GPs were able to refer patients with type 2 diabetes back to a pharmacist-led outpatient-clinic if complications developed. The pharmacist reviewed their treatment, altered their medicines according to laboratory results and offered patients advice and information. None of the patients in the shared care scheme were readmitted to hospital with diabetic complications in contrast to 25% of the patients in the control group. In a study of repeat prescribing in Dundee 81% of patients preferred it to the traditional system of requesting a prescription from their GP.⁸

Medication review and management can be complex as many older patients receive treatment for at least four different conditions, leading to concerns about how different drugs interact with each other. RCGP has thus questioned whether pharmacists' training and access to patient records are sufficient to enable a safe review. However, the DH points out that pharmacists training does include drug interactions, and that there is evidence from pilot schemes that pharmacists can carry out medication reviews effectively. Furthermore, to be able to offer this service under the new pharmacy contractual framework, pharmacists must be accredited and will have to provide a report of the review to the patient's GP.

Patient information

Information technology will play a fundamental part in helping pharmacists to provide new services. The NPA and RPSGB consider that expanding pharmacies' healthcare services will require pharmacists to have greater access to a patient's information in order to provide a safe, effective service. The National Programme for IT (see POSTnote 214), including the NHS Care Records Service and electronic prescription service, from GPs to pharmacists, will address this. Over time the benefits of the electronic prescription service will include: increased safety; more choice and convenience for patients; better information for prescribers and dispensers on which to base clinical decisions; and reduced

administrative burden in GP practices and community pharmacies. However, the NHS Care Records Service is not due to be fully implemented until 2010. Therefore, in the meantime, continuity and completeness of patient care will require good communication between GPs, pharmacies and the patient.

Discussions as to what levels of access to patient information a community pharmacist may need are ongoing. The consumer group Which? suggests that patients are likely to be more comfortable with community pharmacists having access to their NHS records where there is an existing patient-pharmacist relationship. Attitudes towards any pharmacist or pharmacy technicians and assistants having access are less certain. The new NHS IT infrastructure makes provision for restricting the information available to a healthcare professional depending on the service that the professional is providing. In addition, pharmacists are bound by their code of ethics to respect patient confidentiality⁵. DH is planning to hold a consultation about pharmacists' access to patient information.

Location of pharmacies

Competition and community pharmacies

In 2003 the Office of Fair Trading (OFT) advised that the pharmacy sector should be deregulated⁹. It suggested that relaxing the rules on where pharmacies can be located, including allowing internet-only and mail-order pharmacies, would save patients and the NHS money. The House of Commons Health Select Committee considered OFT's recommendations but was not in favour of deregulation¹⁰. The Committee considered that the OFT report had failed to take account of the wider role of pharmacies within the NHS. Similarly, the Government did not back a move to a fully deregulated system, but favoured opening up the market in England to more competition and choice. It announced new rules to do this in 2004.

Reform of the NHS (Pharmaceutical Services)

Regulations 1992 will allow market entry exemptions for large shopping developments, pharmacies opening more than 100 hours a week, large one-stop primary care centres and internet and mail-order pharmacies. The National Pharmaceutical Association (NPA) is concerned that some local community pharmacies will not survive such competition. It suggests that this could potentially lead to reduced availability and access to local services. Parliamentarians have also expressed concern that the changes do not fit with the Government's plans to enhance the role of community pharmacies¹¹.

Internet and mail-order pharmacies

Buying medicines online or by mail-order offers potential benefits - for example to house-bound patients or those with an embarrassing health problem - and is likely to become increasingly popular. Internet sales can broadly be divided into legal and illegal. Illegal sites offer POM without a prescription. Predominantly they offer 'lifestyle' drugs such as Viagra (sexual dysfunction) and Xenical (weight loss). The MHRA Enforcement unit attempts to

close down such sites but as many are based outside the UK they fall outside MHRA's jurisdiction.

Distinguishing legal from illegal sites is a major issue for customers. POM and P medicines should only be taken in consultation with a healthcare professional, in order that the appropriate product is prescribed, any side effects are carefully monitored and other medicines and treatments taken into account. As the advent of internet and mail-order pharmacies allows this interaction to take place remotely, the patient needs to be sure they are communicating with a qualified, registered professional. Likewise, the professional needs to be certain that they know the patient they are communicating with. RPSGB has set up a working group that includes government and other interested parties, to consider how the regulatory framework can be enhanced to provide adequate safeguards for people purchasing medicines on-line. The group will consider the need for an information campaign to increase public awareness and is expected to report within the coming year.

Overview

- The Government is committed to expanding the role of pharmacists and making medicines more widely available to the public.
- The medical profession is concerned that increasing access to preventative medicines via reclassification may target the 'worried well' rather than those most likely to benefit.
- It is widely agreed that better use could be made of pharmacists' skills and knowledge. The new pharmacy contractual framework should enable this, leading to easier and faster access to services for patients as well as reducing GPs' workloads.
- Making medicines more readily accessible raises issues about the role of pharmacies, pharmacist's access to patient information, and access to pharmacies.

Endnotes

- 1 *The control of entry regulations and retail pharmacy services in the UK* (2003). Office of Fair Trading
- 2 *Building on the best. Choice, responsiveness and equity in the NHS* (2003). Department of Health
- 3 NHS (Pharmaceutical Services) Regulations 2005, SI 2005/641
- 4 *The new contractual framework for community pharmacy* (2004). Department of Health
- 5 *Code of Ethics and Standards* (December 2004). RPSGB
- 6 *Pharmacies* (October 2003). Which? Online
- 7 *The Pharmaceutical Journal* (2001) Vol. 266 p413
- 8 *Supplementary prescribing by pharmacists* (January 2004). RPSGB
- 9 *The control of entry regulations and retail pharmacy services in the UK* (2003). Office of Fair Trading
- 10 HC 571 of Session 2002-2003
- 11 EDM 1616 of Session 2003-2004

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