



Community Pharmacist

March 2006

FOREWORD

Dear Reader

With the advent of spring it is time to reflect on events since the last CPG newsletter. The transfer of the domiciliary oxygen service to the four new private contractors was a disaster. Pharmacy contractors were rightly dismayed and concerned when they were told that oxygen was to be taken from them. For years community pharmacists had provided a sterling service but this was not taken into account. Nor was the fact that pharmacists were the ones who had to do the explaining to worried patients when things went wrong (but more about this on pS4).

In my personal experience, many out-of-hours supplies were made over Christmas and new year, sometimes without hope of reimbursement. Many would have been without their medicines over that period had it not been for the goodwill of community pharmacists. The influenza pandemic, if it happens, will also require our goodwill. Sufferers will not just need antivirals, but analgesics, antipyretics, linctuses and demulcents as well as the professional advice that goes with them.

Waste is another issue. Over the past few months we have received conflicting guidance from the various agencies on segregation, storage, licensing and eligibility to process cytotoxics, dressings, sharps and aerosols, and much more. Interim guidance on the Hazardous Waste Regulations 2005 is available on the Society website (www.rpsgb.org/members/practice/).

Finally, I am pleased to welcome Sadia Khan as the newly appointed CPG secretary and to congratulate Robert Clayton on his promotion to head of practice at Lambeth.

Jeremy Clitherow

CPG chairman

Changes to NRT licensing and use

In 2005, the Committee on Safety of Medicines (CSM) and the Medicines and Healthcare products Regulatory Agency (MHRA) reviewed indications for all forms of nicotine replacement therapy (NRT) and proposed new circumstances in which they can be used. This was to ensure that the benefits of therapy were maximised and that any risks associated with NRT were seen in the context of the far greater harm of continued smoking.

To further these aims, NRT product information was revised to make it consistent across all products. Some contraindications and restrictions were removed and new indications added.

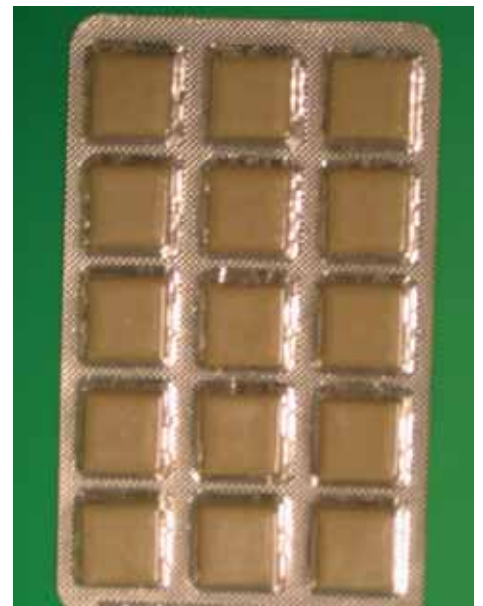
In a letter to health care professionals, Gordon Duff, chairman of the Commission on Human Medicines, advised that patients with diabetes should monitor their blood glucose levels more closely than usual when they started using NRT. In addition, Professor Duff noted that although NRT product information detailed interactions that might occur as a result of stopping smoking, the only significant interaction that might be directly attributable to starting NRT was with adenosine.

The review was welcomed by the Royal Pharmaceutical Society and the other pharmacy organisations. The President of the Society, Hemant Patel, commented that extending access to NRT would enable pharmacists to help more people to give up smoking. He added that for most people the well-established dangers of smoking far outweighed any risk from NRT.

Miriam Armstrong, chief executive of public health charity PharmacyHealthLink, was a key advisor during the consultation. She was asked by ASH (Action on Smoking and Health) to contribute to a guidance document for health professionals on these changes for NRT licensing.

The full guidance document can be found at: www.ash.org.uk. In addition, PharmacyHealthLink has updated its advice on supplying NRT under patient group directions ("Improving local access to smoking cessation therapies by using patient group directions"). This can be found at: www.pharmacyhealthlink.org

For further information please e-mail: info@pharmacyhealthlink.org.uk



Key changes to NRT licensing

- All forms of NRT can now be used by patients with cardiovascular disease. NRT should be offered to patients where the alternative is that they may resume smoking.
- All forms of NRT can be used by smokers aged 12 to 17 years.
- NRT can now be used by pregnant smokers. Those prescribing or supplying NRT should ensure that the potential risks and benefits are understood by the patient. Women should be advised that 24 hour patches need to be removed at night.
- More than one form of NRT can now be used concurrently. Patients with a history of failed attempts to quit using a single form should be offered a prescription for a combination of products (eg, patch plus gum or patch plus inhalator).
- NRT can now be prescribed for up to nine months if patients show evidence of a continued need for NRT beyond the initial eight to 12 week treatment.
- NRT can now be used while still smoking, with a view to reducing the amount smoked, as a prelude to quitting.

Leaflets explaining the new NRT product information are available at www.mhra.gov.uk



£140,000 research project commissioned on the new pharmacy contractual framework

The Pharmacy Practice Research Trust (PPRT) has awarded a team led by Keele University a £140,000 contract to explore the implementation of the contractual framework for community pharmacy in England and Wales, introduced in April 2005. The trust is keen to identify factors that are helping or hindering the implementation of the new framework.

The Keele University researchers will work in collaboration with Webstar Health, an organisation that specialises in providing consulting and project management services within the pharmacy arena and the department of general practice and primary care at Aberdeen University.

The planned evaluation will focus on three areas:

- Implementing enhanced and advanced services
- Outcomes for staff
- Quality issues

Researchers Alison Blenkinsopp, Christine Bond and Gianpiero Celino will use quantitative and qualitative methods to elicit data from key stakeholders, including community pharmacy teams, patients, primary health care professionals (particularly GPs), the NHS (at primary care organisation and strategic health

authority levels) and national organisations. The evaluation will be supported by an external advisory group with representation from the key stakeholders.

Key indicators for community pharmacy contract implementation will be used to evaluate progress with implementation of the contract. Surveys at PCO and individual pharmacy level will be used to quantify service provision and commissioning, and to describe the changes that have taken place since the contract was introduced. The researchers will also gather data on patient perspectives on community pharmacy services introduced as a result of the new contract.

In the first of two phases a community pharmacy survey will investigate what is being done differently at individual pharmacy level, and the effect of these changes on workload, roles and job satisfaction. It will also look at how the clinical governance requirements of the new contract are being put into practice. Keele University and Webstar Health's annual audit survey of all primary care organisations will this year include local health boards in Wales as well as primary care trusts in England. Data will be collected on the extent of commissioning of enhanced services, implementation of advanced services, on the extent of integration of community pharmacy into wider primary care, and

on how monitoring is being conducted. Findings will be fed into the evaluation.

In the second phase the findings of the quantitative work will be used to select five PCO sites for more detailed case studies. Qualitative methods will be used, including focus groups and interviews with community pharmacists, GPs and patients. Documentary analysis of key local implementation papers will be undertaken. Examples of innovative practice will be identified and explored to determine critical success factors.

Feedback on the findings of the evaluation will be obtained from key stakeholders from relevant national professional and patient organisations to collect their experiences and responses to the implementation of the contract, as well as pointers for the future. This feedback will take into account the changes that are occurring in primary care, particularly the developing role of practice-based commissioning and the changing role of PCOs.

The project will start in this year with interim results available by November 2006 and a final report by June 2007. For further details on this project and the work of the PPRT, please contact Beth Allen, acting research manager, Royal Pharmaceutical Society, 1 Lambeth High Street, London SE1 7JN (Tel: 020 7572 2466, e-mail: beth.allen@rpsgb.org).

Community pharmacists invited to share £40,000 invested in research training

The Pharmacy Practice Research Trust is inviting applications from community pharmacists for the 2006 bursary scheme funded by the Leverhulme Trade Charities Trust. The bursary scheme is intended to support community pharmacists who have an interest in developing their skills in conducting research relating to everyday practice.

Applications are invited from community pharmacists who are self-employed (as locums or independent community pharmacists) or employed by a small chain of up to 60 registered premises, and who demonstrate a real need for external support to develop their skills and careers in research.

The Pharmacy Practice Research Trust has £40K to fund a number of projects. The three levels of funding available are:

- **Level 1** Funding to undertake research modules and a small-scale project (supported by a research organisation, for

example, a higher education institute, primary care research network or research and development unit).

- **Level 2** Funding to upgrade a diploma in clinical or community pharmacy to an MSc. This usually involves undertaking a further two modules (one of which is on research methods) and undertaking a project.
- **Level 3** Funding to undertake a non-pharmacy MSc.

The deadline for applications is 9 June and interviews will be held on 19 July 2006 at the Royal Pharmaceutical Society headquarters in London.

Further details, application forms and guidance notes can be obtained by contacting Beth Allen, acting research manager, Royal Pharmaceutical Society, 1 Lambeth High Street, London SE1 7JN (Tel: 020 7572 2466, e-mail: beth.allen@rpsgb.org).

IN BRIEF

Self care challenge document

"The self care challenge: a strategy for pharmacists in England" highlights opportunities for pharmacists to support self care. Various resources accompany this main paper, including "Making the most of pharmacy: six steps to an integrated approach to self care with pharmacy", available at: www.rpsgb.org/members/practice/

Services to drug users guidance

The National Treatment Agency for Substance Misuse, the Royal Pharmaceutical Society and the Pharmaceutical Services Negotiating Committee have published a document entitled "Best practice guidance for commissioners and providers of pharmaceutical services to drug users", available at: www.rpsgb.org/members/practice/

Methadone: are you happy to make it yourself?

In this article, Frances Donachie, a specialist pharmacist in substance misuse for NHS Ayrshire and Arran, discusses some of the implications of preparing methadone mixture extemporaneously

Community pharmacists are an integral part of the care of people who suffer from the effects of opioid addiction and dispensing and supervising the consumption of methadone mixture is the cornerstone of the substitute prescribing programme throughout the UK. However, pharmacists are victims of their own success. They provide the service to so many of these patients, the result is that many pharmacies have problems storing the large volumes of methadone mixture required.

Some time ago manufacturers became aware of the issue of lack of space and began to supply the methadone in powder and diluent form, provided separately. This allowed many high volume pharmacies and those with small Controlled Drug cabinets to continue to provide a methadone service. Adding the powder to the liquid and shaking the bottle seems simple enough but several factors deserve consideration.

The modern community pharmacist is part of a profession that has changed from being seen as being concerned with pills and potions to one centred on patient care and enhanced pharmaceutical services. Nowadays, it is rarely necessary to make a product in the pharmacy and, indeed, other than at university, some community pharmacists may never do so. This is, perhaps, the reason for the lack of clarity around the terms "extemporaneous" and "reconstitution". Extemporaneous is derived from the Latin *ex* (out of) and *tempus* (time), whereas reconstitution is defined as the restoration of a product to its former state. If one accepts these meanings then the debate about whether or preparing methadone mixture from diluent and powder is a reconstitution or extemporaneous preparation is clear, because the required end product never existed in a former state. One must also remember that the final product does not have a marketing authorisation. The use of a licensed product provides the assurance that a product is of a certain standard and that, in the event of a problem, the pharmacist's liability is limited. By choosing to manufacture a product extemporaneously, however, the pharmacist becomes liable for any errors and should ensure that their professional indemnity insurance allows for this.

But, putting semantics aside and accepting the premise that making methadone mixture



from powder and diluent constitutes extemporaneous dispensing, we are required to look at the practical implications.

"Medicines, ethics and practice" details the service specification that any pharmacist undertaking extemporaneous preparation or compounding must follow. In addition, methadone powder and the resulting methadone mixture are both Controlled Drugs, necessitating adherence to legislation and other precautions.

The methadone diluent is supplied generally in 1L bottles and the powder in tubs containing 1, 2 or 5g of methadone. However, the assumption that a tub which states 1g of a Controlled Drug actually contains 1g could lead to it being added to a bottle which states 1L, without any further measurement taking place. This apparently logical thought is fraught with risk. Suppose neither measurement is accurate or the tub is labelled incorrectly, or the incorrect size of tub has been selected? The consequences for all concerned could be dire, especially for the patient.

Pharmacists should never pour the powder into the liquid without measuring it first. And once the powder has been added to the liquid how much mixing is required? Should it be just a quick shoog (a good, old fashioned

Scottish word) or sustained and vigorous shaking? In the absence of any clear instructions from either the manufacturer or a more experienced colleague, many pharmacists have found that the end product has not been exactly what they expected. For example, the dissolution process may be incomplete. In addition, if the resulting mixture is not stored in amber bottles there is a possibility of deterioration because methadone hydrochloride is sensitive to light.

The changes to legislation, regulations and professional scrutiny that followed the Shipman Inquiry have led to all professions, dealing in any capacity with Controlled Drugs, to put in place clear, rigorous protocols and record-keeping that will ensure that all transactions concerning the use and distribution of Controlled Drugs can be traced from manufacture to consumption, or destruction. Any community pharmacist who chooses to prepare methadone mixture must remember this and record all details from purchasing to dispensing, and all steps in between, as is required by regulation and professional guidance.

This is the background to the recent Law and Ethics Bulletin (*PJ*, 25 February, p245) concerning extemporaneous preparation of methadone mixture. Quite rightly, this is an exacting statement of what is required; the responsibilities of any pharmacist undertaking this task are clearly defined as are the pharmacists' responsibilities to patients and prescribers.

Some pharmacists may feel that it is all too much trouble and may revert to using the authorised product, whereas others will wonder what all the fuss is about because they have already been following this procedure. I suspect that many more pharmacists will be delighted to be given such clear guidance (including on insurance) to allow them to safely and legally undertake the task.

The Society is to be congratulated. In taking a pragmatic view of the special circumstances surrounding the use of extemporaneously prepared methadone mixture and by providing clear instruction, it has ensured that the thousands of patients who attend community pharmacy every day for this service can continue to do so safely and with confidence in those who provide their care.



Oxygen shambles cost patients and PCTs

Recently, the Department of Health met pharmacy bodies to discuss problems with the new oxygen services. In this article, CPG committee member Vanessa Taylor gives the committee's view

In January primary care trusts, the Pharmaceutical Services Negotiating Committee and other bodies, having been assured by the new service providers that "all service users' needs would be met" reminded pharmacy contractors that they must not dispense oxygen prescriptions dated after 1 February. Community pharmacists, however, were worried that the patients they had looked after, sometimes for many years, could be disadvantaged. The new service providers were originally due to start providing oxygen on 1 October 2005 but as this date loomed it became apparent that this target would not be met and the date was changed. Meetings were held, helplines developed and leaflets produced. Even more meetings were held. But it was obvious that things were unlikely to go smoothly even with an extended deadline of 1 February.

This proved to be the case and in February shambles prevailed. Helplines were constantly engaged and patients, GPs and other health care workers were unable to get any information. Huge numbers of home oxygen order forms were faxed through to the suppliers,



who could not cope with the demand. Patients suffered and many horror stories were heard, including the death of a patient in Cumbria. It is a good thing that most oxygen-supplying pharmacists agreed to provide the service again, after being told that under no circumstances should they dispense prescriptions dated after January.

So where are we now? The DoH guidelines for oxygen supply have not yet been finalised so community pharmacists can continue to dispense prescriptions for oxygen

until 31 July. However, PCTs will have to foot the bill for both the new suppliers and community pharmacists so let us hope the service level agreements negotiated with the new providers have some penalty clauses attached, to enable the additional expenditure to be reclaimed.

Furthermore, as community pharmacists have stepped in again to provide a professional, efficient service, (even though they were told by the Government that the four new suppliers awarded contracts would provide a better, more cost-effective service using more up-to-date equipment) the CPG hopes that PCTs will remember this goodwill over the coming year, especially when they are negotiating local initiatives.

Summary

Pharmacists can still help patients by filling prescriptions for oxygen until 31 July 2006. They will be paid for providing this service in the same way as in the past. Continuing to provide this service is voluntary.

A comment on "Our health, our care, our say: a new direction for community services"

The White Paper for England and Wales, "Our health, our care, our say: a new direction for community services" was launched in January and has been heralded as the paper that will shift funding from secondary care to primary care. Among the plethora of White Papers this one is truly rare because it supports the wishes of the public as never before. However, at 227 pages long, its implications are wide-ranging, and the real issues are easily lost in an amalgam of unnecessary waffle and the main points of contention are easily missed. The conspiracists, of course, will think this is deliberate because the devil is always in the policy details and funding plans, which are notable by their absence.

While the paper is GP-focused, pharmacy is mentioned in the foreword, in which Tony Blair expresses his desire "to expand the role of practice nurses and local pharmacists" and the Department of Health acknowledges that 94 per cent of the population use a pharmacy at least once a year. The White Paper also recognises that the public hold pharmacists in high regard, citing strengths, such as supporting self-care, and quoting examples of where pharmacists have successfully made a difference in their extended roles (eg, in minor ailments schemes, etc) — which all gives us a white halo!

The four main policy objectives are to:

- Improve services to help prevent diseases and ensure earlier interventions
- Provide more patient choice and involvement
- Reduce health inequalities by improving access to community services
- Increase support for people with long-term conditions

So how could this blue sky thinking affect the way pharmacists work? Possibilities include pharmacies providing more NHS services (eg, anticoagulation or diabetes clinics) and even GPs relocating into pharmacies. In areas under-served by GPs, pharmacy services will become more integrated with social care. Practice-based commissioning will be enhanced and practitioners with special interests will be further developed.

The paper also makes proposals for nursing and mental health services, (mainly to reduce hospital admissions) and there is much rhetoric about bringing specialist services out of hospitals and into the community. This, in principle, sounds eminently sensible although the missing link seems to be a focus on pharmacy and the outline plan to implement the potential new services. But let us look on the

positive side. Perhaps pharmacists should regard the situation as a blank canvas. Instead of saying, "we have not been told what is expected of us", they should get out there and grab the available services before others do. Because, for sure, there will be plenty of competition for those local services.

Whether you want to be a specialist pharmacist or an all-rounder, the world of primary care could be your oyster, it appears. Of course, it will be hard work and pharmacists, in some cases, will need additional training (and accreditation) but the new policy should bring the profession closer to the rest of the primary care team and provide patients with better joined-up local health care. The CPG understands that "Our health, our care, our say" will be followed by action papers, including one on community pharmacy. The CPG will be keeping a keen eye on developments and monitor them as they arise. — Sid Dajani (chairman of the Royal Pharmaceutical Society Practice Committee).

Practice Committee agenda

Community pharmacists are invited to send their views on what they would like to see on the agenda at Practice Committee meetings, to Practice@rpsgb.org