



Community *Pharmacist*

July 2005

FOREWORD

Dear Reader

After the gloom of winter, the new pharmacy contract swept in with the April showers, bringing with it fresh green hopes, new visions and aspirations and a real opportunity to begin practising a truly professional role. "Pharmacists are clinicians, not shopkeepers" were the very words spoken by Rosie Winterton. But, as any horticulturist knows, not all spring buds flower as expected. We now find that in addition to some specimens that may well bear superb blossoms and fruit, the hothouse atmosphere of the contract negotiations has left some of our shoots bare and shrivelled.

Nevertheless, we have to grasp any nettles that attempt to choke our seedlings, flawed though some of our plants may be. To quote an often used phrase, the devil is in the detail. Sadly, much of the detail of the contract is lacking. For example, consultation areas are crucial if advanced and enhanced services are to be funded but their specification is still the subject of intense debate.

The uncertainty this causes breeds insecurity. If pharmacists are uncertain, whether proprietor or employee, they cannot perform their professional roles as well as they would like. This is a problem, but let me suggest a solution. The Community Pharmacists Group comprises pharmacists from many areas of community pharmacy practice. At Lambeth, it has the ears of the Council, the Practice Committee and the staff. By informing the CPG of their concerns, members can rest assured that their worries will be understood and will be presented to an appropriate (to use that infamous word from the contract) body. That is guaranteed.

Jeremy Clitherow

CPG chairman

Formalise and publicise services

In this article, pharmacy consultant **Ross Groves** discusses how pharmacists can prove their worth

Pharmacists are familiar with the varying definitions of the word "essential". Essential oils are by no means an absolute necessity, although other liquids produced by distillation might become so, to assist with dealing with the implications of the contract. Essential services are another matter. How can pharmacists make fulfilling their responsibilities as painless as possible?

In fact, many pharmacists will find that they provide most of the essential services already. They all dispense. They dispose of unwanted medicines and are involved in health promotion. They inform the public of other health and social care resources, provide support for self-care and are increasing their services for those with disabilities. In addition, they manage risk continually. Other aspects of clinical governance may be a less obvious part of their working lives but most are there somewhere.

What most pharmacists do not routinely do is demonstrate their involvement in these activities. In future, they will have to, to elicit payments and for continuous professional development purposes. So how can pharmacists continue to prove their worth while negotiations on the contract detail continue? Here are some suggestions.

Make records The Royal Pharmaceutical Society introduced a requirement for standard operating procedures for dispensing to be in place from January 2005. These should cover all aspects of the dispensing process and should be specific to the pharmacy — not generic ones imposed from on high. Those without dispensing SOPs need to get some written, and soon. As of October, primary care trusts will be checking that they are in place

and no SOPs may mean no payment. For those with SOPs, now may be the time to revise them and get some in place for other essential services. For example, the SOPs for repeat dispensing could simply be an extension of current dispensing SOPs. Signposting, disposal of unwanted medicines and enhanced services potentially need SOPs. The list goes on and on.

Documenting what we do already, either in longhand or, preferably, using a computer, is a relatively easy way to demonstrate that we meet many of the requirements thrust upon us. There will be a requirement to document many more of the interventions that are made in community pharmacies. Is there a way to use current technology to capture the information required? Have you asked your software supplier if it has a program that will let you record over-the-counter sales, advice on minor ailments, medication queries and patient group direction supplies etc? Why should pharmacists have to write everything down when a mouse click will do the same job?

Better use of staff Pharmacists need time to prove their worth as well as to provide new services. So they should empower their staff, many of whom feel underused and are capable of more than they are allowed to do. I suggest getting your pharmacy technicians and trained counter staff at least to suggest points for inclusion in SOPs because many of the issues affect them far more than pharmacists. Some could write SOPs for you to approve. Getting staff to write SOPs will also increase their understanding of clinical governance issues.

Make sure that your staff know what to say to people asking about a service. You can train

The eight essential services

- Dispensing** — a continuing role. Pharmacies should have standard operating procedures in place.
- Repeat dispensing** — a new role. A CPPE qualification is required in England and Wales.
- Disposal of unwanted medicines** — a continuing role. Pharmacists should think about SOPs.
- Promoting public health** — a continuing role. Pharmacists should formalise and publicise this service.
- Signposting** — a continuing role. Pharmacists should formalise and publicise this service.
- Supporting self care** — a continuing role. Pharmacists should formalise, publicise and record this service.
- Supporting people with disabilities** — a continuing role which should be formalised and publicised.
- Performing clinical governance** — pharmacists should understand clinical governance and train staff.



them yourself but this can be difficult in the space and under the work pressures of many community pharmacies. Is there someone locally who might be able to train staff in groups? You never know, PCTs might be willing to provide venues, etc, if training can be linked to one of their initiatives. In addition, next time a vacancy arises why not

look for someone with a few extra skills and a willingness to learn?

Formalise and publicise Think laterally. Formalise processes so that PCTs can see exactly what pharmacists contribute. Ring your local public health department and speak to one of its advisers. Surprise them with your

appreciation of how you can help them achieve their targets — reducing accidental poisonings, obesity, coronary heart disease and many more issues link well with public health. Why not ring your PCT and get copies of leaflets with local phone numbers for referrals? See if it is willing to allow pharmacists to be a formal referral point.

How the MHRA regulates the safety of devices

The purchase and maintenance of medical devices makes up a significant percentage of the annual NHS budget, estimated at some £10bn and £1.5m, respectively. In this article, **Sue Ludgate**, clinical director of the devices section at the Medicines and Healthcare products Regulatory Agency, explains some of the agency's functions



A CE mark means that a device meets essential safety and performance requirements

The term “medical device” covers any product, other than medicines, that is used in the health care environment for the diagnosis, treatment, prevention or monitoring of illness or disease. It encompasses a wide variety of products, ranging from blood pressure monitors, aids for the disabled and needles and syringes, to pacemakers, coronary stents, heart valves, joint replacements and equipment used *in vitro* for the examination of specimens, including blood and tissue donations derived from the human body for the purpose of diagnosis or monitoring (eg, blood glucose monitors, cholesterol tests, pregnancy tests).

The Medicines and Healthcare products Regulatory Agency (MHRA) is an executive agency of the Department of Health responsible for both medical devices and pharmaceutical products. In terms of devices, its aim is to safeguard public health by working with

users, manufacturers and regulators to ensure that all medical devices used in the health service meet appropriate standards of safety, quality and performance and comply with the provisions of the European Medical Devices directives. The MHRA is also the primary source of UK information guidance on the safe use of medical devices and second only to the US Food and Drug Administration in terms of its size and field of operation.

Functions of the MHRA

The functions of the MHRA in terms of medical devices are outlined below.

The MHRA acts as the UK regulatory authority for medical devices Acting as the UK regulatory authority for medical devices includes negotiating, implementing and

Adverse incident reporting

The MHRA adverse incident centre currently receives over 9,000 reports of device-related adverse incidents annually, 7 per cent of which involve a fatality or serious injury. Such incidents arise from a wide variety of causes, including:

- Shortcomings in the device itself
- Locally initiated modifications or adjustments
- Inadequate instructions for use
- Inadequate servicing and maintenance
- Inappropriate user practices
- Inappropriate management procedures
- Selection of the incorrect device for the purpose
- Inappropriate conditions of storage

Each report is investigated on a priority scale and action taken as necessary. This includes the issuing of a “device alert” to relevant parts of the health service in order to alert users to real or potential problems, setting out actions necessary to address the issue.

As a result of the adverse incidents reported over the past year:

- Over 50 device alerts were issued to the health service
- 420 product recalls involving supervision or active involvement from the MHRA were undertaken
- 958 improvements in design, manufacturing processes or quality systems were undertaken

Although the MHRA devices sector receives a number of adverse incident reports direct from manufacturers (under the regulatory vigilance system), many important issues have come to light from reports received direct from users, including health care workers, pharmacists and patients. If improvements are to be made in design, function, materials, ergonomics and instructions for use, it is vital that the agency continues to receive reports from these sources. Reports can be made either by telephone (020 7972 8080) or by e-mail (aic@mhra.gsi.gov.uk).

enforcing the European Devices regulations — legislation that has replaced a voluntary system for the control of medical devices within the UK. Under the provision of these regulations, no device may be sold in the EU without a CE mark.

The MHRA oversees CE marking A CE mark means that a device complies with the relevant essential requirements contained in the regulations covering safety and performance aspects. In order to obtain CE marking, the manufacturer must go through a procedure to confirm that the device complies with the relevant essential requirements. With the exception of very low risk devices, such as tongue depressors, these assessment procedures must be checked by a certification organisation known as a “notified body”, of which there are over 60 throughout the EU. This devolved system, therefore, differs from the licensing of drugs, which is carried out centrally in the UK by the MHRA pharmaceuticals division. The MHRA functions also include:

- Establishing systems for the designation and auditing of a number of notified bodies in the UK
- Handling an authorisation system for clinical investigations of non-CE-marked medical devices (ie, medical devices that are still being tested to demonstrate safety and performance)
- Managing a statutory vigilance system whereby all serious device-related adverse

events must be reported by the manufacturer

- Taking action to withdraw a product from the market on grounds of public safety

The MHRA provides a device evaluation service Another major role of the MHRA in terms of medical devices is to manage a programme of evaluation of some medical devices, to inform potential purchasers. This work is commissioned from independent research specialists in the NHS or universities. The devices are tested for performance and safety in both clinical and laboratory settings, with the aim of providing a clear idea of the equipment’s scope, ease of use, suitability for different environments and suitability for different purposes.

Over 100 evaluation reports are published annually and made freely available to the health service. In broad terms these cover:

- Diagnostic radiology equipment
- Power connected devices
- Disability equipment
- *In vitro* diagnostics, including devices available over the counter such as blood glucose monitors

How the MHRA can help pharmacists

The MHRA devices sector has technical and clinical specialists who are able to provide telephone advice on any aspect of devices available over the counter through pharma-

cies. The telephone number for clinical advice is 020 7972 8123.

The MHRA also provides publications such as:

- A device bulletin on “The management and use of *in vitro* diagnostic point-of-care test devices (DB 2002/03)” which gives useful advice for pharmacies providing testing services such as pregnancy tests, cholesterol tests, diabetes screening
- “With your help we can make medical equipment safe” — a simple leaflet to let purchasers of over-the-counter devices know where they can go for advice about devices, or to whom they should report any associated adverse events, so that necessary investigation and action can be taken

How pharmacists can help the MHRA

To assist the MHRA, pharmacists involved in selling over-the-counter devices or in the area of self-testing diagnostic kits, or providing testing services can:

- Disseminate safety information when they receive it
- Promote MHRA information leaflets
- Encourage people to report potential and actual adverse incidents relating to problems with devices
- Regularly visit the MHRA (devices) website for up-to-date news and publications (<http://devices.mhra.gov.uk/>).

Locum’s perspective: few are bothering with enhanced services

Having recently returned to community pharmacy and the occasional locum I heard that the local primary care trust was looking to provide an enhanced service in the form of a patient group direction for the supply of emergency hormonal contraception to teenagers, including those under 16 years of age. This sounded like a good opportunity to get involved a service meeting local needs. Although the area covered by my PCT is not classified as deprived, there are pockets of deprivation and certainly a raised level of teenage pregnancies.

I contacted one of my regular pharmacies only to discover that they would not be providing this service. “We are too busy with dispensing to take on anything else at the moment,” was the reason given. Nevertheless, I decided to get involved and take part in the training.

Training There was no funding for me to attend the training, although sandwiches were provided courtesy of a sponsor. The training involved two, three-hour sessions (evenings) plus the need to redo the “updated” emergency hormonal contraception training pack from the Centre for Pharmacy Postgraduate Education and gain a certificate of completion.

The updated material was only available online and is the same as in the old pack with the relevant bits about taking tablets 12 hours apart being scored out (not deleted). It also started by talking about provision of the service by health authorities — so it was not as updated as it should have been! I completed the assessment questions (which were the same as those in the original package) and gained a certificate, all online. I am in the fortunate position of having internet access which is not the case for all locums.

There was excellent attendance at the first session — about 25 pharmacists. However, there were few pharmacists from multiple contractors. I find this example of a PCT trying to get a service off the ground with little funding, combined with the lack of awareness from several contractors that this might be the way forward for community pharmacy, really worrying for the future.

Provision of the service will only be allowed if a pharmacist who has completed the training is in the pharmacy for four days a week. Incidentally, there are three contractors in the town where I work regularly as a locum. None attended the training.

I hope my experience is an exception.

IN BRIEF

Special interests

Beth Taylor has been appointed by Primary Care Contracting (formerly NatPACT) to lead work to develop a framework for pharmacists with special interests and David Colin-Thomé has agreed to chair the meetings. The first meeting is scheduled for September.

Supplementary prescribing

Some community pharmacies now have electronic links with local surgeries to facilitate supplementary prescribing. Sue Kilby, head of practice at the Society, is keen to hear from them.
E-mail: Sue.Kilby@rpsgb.org

BPC

This year, the CPG will share a stand with the other sector groups at the British Pharmaceutical Conference. Members are invited to meet the CPG committee and staff from the Society’s practice division and to give them their views.



Essential service 3: what do you think of it so far?

Under the third essential service of the new contract, every pharmacy must provide facilities for the disposal of unwanted medicines. So, throw everything into the bins and wait for their suppliers to collect them? Things are not so simple. In this article, **Ross Groves**, pharmacy consultant, looks at the intricacies of rubbish

Eric and Ernie were not averse to the odd catch-phrase and “What do you think of it so far?” has stood the test of time. But rubbish is no laughing matter. Had I wanted to be a waste disposal operative I would have bypassed reading for my degree. However, waste collection and disposal is now a highly complex task and being able to comprehend the complexities requires almost degree level education.

People are getting used to separating out their household waste for recycling and most are aware of the journey that such rubbish will take. Community pharmacists, however, need to know what they can and cannot do with old stock and medicines returned by the public.

A salutary tale

Once upon a time, a box of senna tablets arrived at a pharmacy in a bag of medicines, returned by a patient's relative. Dispensed by the pharmacy, they had been taken home and misplaced, hence they were never taken. All pharmacies need to be registered with the Environment Agency as a “producer of waste”. As the new contract is being introduced so are new regulations on the handling of waste but a pharmacist's duty of care (as defined by the Environmental Protection Act 1990) still exists — the senna tablets would be subject to a duty of care from the time they become waste to the time they are destroyed and they cannot be redispensed.

The moment a medicine officially becomes “waste” is for the civil servants, lawyers and politicians to decide, but the Controlled Waste Regulations 1992 classify medicines from a patient's home as “household waste” and this can legally be stored in a pharmacy. If, however, the waste exceeds 5m³ at any one time or is stored on the premises for more than six months, an exemption from the Waste Management Licensing Regulations 1994 — in the form of a storage licence — must be obtained from the local Environment Agency offices.

Licence to carry On being returned to the pharmacy the tablets find themselves in familiar surroundings. There in the corner is the disposal bin, supplied by a licensed waste carrier. Such firms need a licence to carry waste medicines. So what about other carriers, such as the patient (or relative) returning waste medicines to the pharmacy or the pharmacy staff who collect waste medicines from the patient's home? It transpires that, legally, a pharmacist



cannot pick up our humble senna tablets from a patient's home without a licence, even if he or she has undertaken a medication review and has deemed removal necessary to ensure patient safety. Not only is this activity not part of the essential service, but it counts as “transport of waste” and so requires another licence from the Environment Agency.

Industrial waste On the other hand, if the senna had been dispensed to a patient in a nursing home, the law would classify it as “industrial waste”. Exemptions from the Waste Management Licensing Regulations do not extend to industrial waste so pharmacies cannot accept the senna from any address registered to provide nursing care. Such institutions must make their own arrangements for the disposal of unwanted medicines.

However, the Misuse of Drugs Regulations 2001 permit any person who has lawfully received a Controlled Drug to return it to the person who supplied it. In law, this would apply to nursing home CDs too.

Waste treatment Assuming none of the various collection and storage licences are contravened, could anything else pharmacists might do vis-à-vis unwanted medicines render them in breach of any legislation? First, if the medicine is a CD, another licence (a waste treatment licence) might be needed to denature it. However, fortunately, we now have special kits, which incorporate CDs into resins, and using these to denature CDs is not considered “waste treatment”. The resulting compounds can be put into waste containers.

Second, it seems logical that, if the limit on waste storage is 5m³, means to reduce the volume of waste medicines should be used. Blister strips of senna tablets take up far more space than loose tablets so some might be tempted to push them out of the strips into the waste container. But this is also against the law.

Taking the strip out of the box is fine but deblistering is not. Nor is decanting liquids from bottles. Both count as waste treatment and require that licence. The NHS (Pharmaceutical Services) Regulations 2005 do not require separation of waste into different physical forms unless a PCT or waste collector requires it. If they do then they are responsible for providing the containers necessary.

Hazardous waste Senna tablets are relatively hazard free but that does not apply to all dispensed items. Pharmacists have a duty to store waste but is it dangerous? The answer, of course, requires yet more legislation. This time, the recent changes make the situation a little clearer if still onerous. Sharps are hazardous but classified as clinical waste and cannot be accepted by pharmacies as part of their usual waste disposal service. Patients need to contact their local authority to find out how to dispose of needles, lancets, etc.

The Hazardous Waste Regulations 2005 replace the Special Waste Regulations 1996 and mean that the only medicines classed as hazardous will now be cytotoxic and cytostatic drugs. Although there is no definitive list of such drugs in the UK as yet, pharmacists are responsible for separating unwanted medicines into hazardous and non-hazardous containers. Reasonable (one of those indeterminate words) efforts must be made to separate out cytotoxic and cytostatic waste.

CDs are hazardous but they are not classified as such under the regulations because they are neither cytotoxic nor cytostatic. The limit for storing hazardous waste (which allows exemption from the Environment Agency's notification requirements) is 200kg per year. Paperwork, in the form of special consignment notes, is required when hazardous waste is collected.

A breakdown So, back to the senna tablets. We can accept them from patients or their representatives but not collect them. We must segregate hazardous waste. We can store waste in separate waste containers (eg, tablets separate from aerosols) but not too much of it or for too long. And we cannot push tablets out of their blister strips. Although we need to register with the Environment Agency, we should remain exempt from requiring licences. Our PCTs need to give clear information about their requirements and how they can remove some of the burden from individual pharmacies.

Who would have guessed that 60 senna tablets could cause so much trouble?