



Royal
Pharmaceutical
Society
of Great Britain

Community *Pharmacist*

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FOREWORD

Dear Reader

Just look at what has happened in the past three months. The Royal Pharmaceutical Society has continued with its internal and external reorganisations, the new Chief Executive and Registrar has been announced, and Barry Andrews has chaired his last PSNC meeting and retired from the post, collecting a well deserved CBE on the way out.

The Health Act 2006, which introduced the concept of "the responsible pharmacist", is now in production. This Act will confer on the "responsible pharmacist" many fresh duties and new tasks which were formerly the province of the superintendent pharmacist. The Act is discussed elsewhere in the newsletter, and the CPG committee is on the case, listening, watching the developments as they unfold and making comments as appropriate.

Latterly we have seen the havoc brought about by the weather. The photographs of Martin Bennett's pharmacy in Wicker, Sheffield, awash with water must have affected every community pharmacist. Just how would you cope; where would you start? What about power, or fresh water for making up paediatric antibiotics? How would you send an order in at the end of the day and where is the stock? In the event, the out-turn touched us all. Everyone involved in pharmacy seemed to pull together as a team.

It also demonstrates that that even in national disasters such as flooding, pandemic flu, loss of utilities or even in civil emergencies, community pharmacy just gets on with the job.

Jeremy Clitherow

CPG chairman

How the Health Act 2006 affects community pharmacy practice

David Carter, member of the CPG committee discusses the Health Act 2006 and its importance to community pharmacists



Many community pharmacists are possibly unaware of the major changes to their practice proposed within the Health Act 2006, which could be considered as the most important piece of legislation to hit community pharmacy in recent times.

The Act is actually an enabling Act, which will amend the Medicines Act 1968 in the UK (also the NHS Act 1977 for England and Wales and the NHS Scotland Act 1978 for Scotland) in a number of ways with its Order-making powers and via regulations. The regulations are to be consulted on. The implications of this Act are far reaching and, unfortunately, other topical issues in pharmacy have obscured deliberation on it in many quarters.

The responsible pharmacist

One of the key aspects is that of replacing "personal control" by a pharmacist, with the "responsible pharmacist" concept. The responsible pharmacist will have a statutory duty to secure the safe and effective running of his or her pharmacy. Every pharmacy will have a responsible pharmacist. It is proposed the responsible pharmacist will be able to be absent for given periods of time to fulfil other

professional roles provided certain criteria are met. The Act also makes provisions to enable the delegation of supervision to suitably trained support staff and provision for the supervision by the responsible pharmacist when he or she is not present on the premises (remote supervision). The Act also considers the possibility of a single pharmacist being responsible for more than one pharmacy in exceptional circumstances.

Engage with the debate

As with all proposals, the devil is in the detail, and I would urge pharmacists to engage with this consultation — become involved in the debate — so that the future of community pharmacy is one that the majority of us want. Consideration should be given to the length of time a pharmacist be allowed to be away from the pharmacy, the technology required to enable remote supervision and the interplay between the responsible pharmacist and superintendent pharmacist. Patient safety must be maintained and this is the challenge faced by us all as we move forward. The Act is radical and brings a number of opportunities and challenges for the pharmacy profession. We must get it right.



Getting the right medicine to paediatric patients

Stephen Tomlin, professional secretary to the Neonatal and Paediatric Pharmacists Group, discusses some of the challenges faced when dispensing medicines for children and babies

The changing health care environment and the drive to provide care closer to the patient mean that hospitals will increasingly become responsible only for acute care. It will soon be only the sickest patients who will be seen in secondary care with everything else being dealt with in the community. Although we could discuss this topic at length we have to accept that it is political (and unlikely to move in the opposite direction). From the patient's point of view this has advantages: being attended to closer to home allows some sort of normal life to continue.

Many children (and some adults) must use medicines which are either unlicensed or being used outside their licence (off-label). Although this may not be ideal, it is an essential part of health care practice to ensure that children are treated appropriately — denying use of such medicines may be regarded as being as negligent as not treating children at all.

The shift of health care provision will inevitably mean that the prescribing and dispensing of these medicines will increasingly be required in the community to ensure continuity of care.

The introduction of the BNF for Children has, in part, facilitated this and helped GPs to become more informed about the use of medicines in children. GPs are becoming more comfortable prescribing medication for children that previously they were not so happy to prescribe. The acceptance by GPs that even drugs and doses that are not covered by a manufacturer's licence may best be prescribed in the community brings a range of problems to the community pharmacist.

Although we could debate *ad infinitum* the accountability of all health care professionals for their share of the liability if a prescription is not appropriate for a clinical condition, there is no question that the responsibility for supply of the correct product for that prescription rests with the pharmacist. Not only does it need to be a quality product, fit for its purpose, it also needs to be suitable for the clinical situation and age group for which it is intended.

Purchasing for safety

If there is no licensed product to comply with the prescription then the following options must be considered. There is often more than one option and the urgency of treatment and availability may force the choice of an initial option to enable treatment to begin, which may be followed subsequently by another



more sustainable or appropriate option. The BNF for Children gives many useful solutions to these issues and the following problems and pitfalls are given to raise awareness but, hopefully, not anxiety.

If a licensed product is prescribed the pharmacist should still ensure it is appropriate and can be used in its original formulation. Licensed products often have to be administered in ways other than those intended in the licence to enable a child to be given a suitable dose. If there is no licensed product, an unlicensed option must be considered.

Changing licensed products

Changing licensed products may not always be appropriate as shown by the following examples:

Example 1 Dispersible tablets, are only licensed to give the full tablet dose — they are dispersible to aid administration. Putting a tablet in 5ml of water and giving an aliquot of 2ml to achieve 40 per cent of the full dose to a child may not be appropriate. Dispersible does not mean soluble and studies of some products have shown aliquots such as these can be less than 50 per cent accurate if not adequately dispersed before removing the dose.

Example 2 Even products which seem to be made for purpose need some caution. Phenobarbital Elixir BP is a liquid formulation made to high standards as a medicine

used predominantly in young children. However, since it contains 38 per cent alcohol a 5ml dose given to a newborn baby is the equivalent of an adult having a couple of glasses of wine — alcohol which babies cannot handle as well as adults on account of their immature livers.

Example 3 Before crushing a tablet and mixing it with food or water, there must be some pharmaceutical understanding of the product:

- Does the tablet have some sort of coating that modifies release and therefore makes crushing unsuitable?
- Is the tablet formed of pellets which have protect the drug from stomach acid so that crushing will destroy this and render the drug ineffective?
- Does the tablet crush and quickly fall out of solution once dispersed?

Occasionally the drug may be 100 soluble and aliquots will contain exactly what they would be expected to contain.

Using unlicensed medicines

Make an extemporaneous product

Once a formulation is identified several questions should be posed. How validated are the formulation, stability and storage data that you have? Can the final product be relied on to deliver the appropriate dose accurately? Is the dose reproducible and can the formula-

tion be made to the same standard every time?

Obtaining the raw materials and ensuring the production working environment is fit for purpose is time consuming. However, probably the most problematic part of this process is the fact that the final item is released having only had one or, at most, two people involved in checking all the products and quantities.

Even with multiple checks for “specials” we know that things can go wrong and there are numerous reports of disasters from individually made products.

Maintaining the skills for extemporaneous dispensing is laudable and sometimes necessary but the process should not be taken lightly.

Use of “specials” Specials give us some guarantee that a product has been made to a high quality assured specification. There are, however, important points to consider when purchasing a “special”.

- “Specials” are not made for a particular clinical indication and, although a manufacturer has a responsibility for the quality

of its product, it is the dispensing pharmacist who must ensure it is fit for the intended clinical use.

- Is the concentration suitable for the patient? Consider this: 50ml *tds* for a neonate is unlikely to be taken, but 0.003ml *tds* is not practical to administer.
- Are the excipients appropriate? Forty per cent alcohol is unlikely to be suitable for a neonate. Aspartame would not be appropriate for a phenylketonuria patient.
- Is the product from the specials manufacturer actually made as a batch special or as an extemporaneous product?
- Different manufacturers will use different formulations and manufacturing processes for the same product, thus active excipients and bioavailability will vary. This variance may be critical to patient response with some medication and where possible a patient should be kept on the same manufacturer's medication at all times (where ever they are being seen).

Importing products Although importing products is often the most costly option, it does have distinct advantages. If a product can be obtained by one of the big importation

companies that is licensed in an area with similar regulatory standards to ourselves (eg, US, EU, Australia, Canada) then there are some guarantees on the quality of the product. If it is licensed for the intended use then that is ideal. If it is licensed for another indication, then the same considerations as stated previously must apply.

Supporting information should always be requested in English and evaluation of the delivered product undertaken before dispensing to ensure it is appropriate for use.

Conclusion

All patients (whether adults or children) have the right to expect that the medicine they are being given is appropriate, safe and effective for them to the best of the professional's ability. This is true of all medicines whether licensed or not.

The dispensing of unlicensed and off-label medicines requires some additional thought in terms of their quality assurance for clinical use. This draws on pharmacists' clinical and pharmaceutical skills and the additional effort should have major benefit for the safety and effectiveness of drug treatment for the patient.

Pharmacy has a role in averting abuse of steroids

Jeremy Clitherow, chairman of the CPG, reflects on some of the wider issues of drug misuse that community pharmacists may face

Not many people know about the percentage incidence of hepatitis C among injecting drug users. Latest statistics show a frightening picture, and one which will grow insidiously unless urgent action is taken. The latest Health Protection Agency report states that “approaching one in two injecting drug users have been infected with hepatitis C”, and that is referring to the UK alone, where the infection rates are much lower than elsewhere. For the patient who contracts the infection there is a gloomy outlook. Eighty per cent of such patients will develop a chronic infection and run a high risk contracting cirrhosis and liver cancer.

Growing trend

Given the growing trend of steroid use among the young and the fact that although the oral route is the most convenient and least conspicuous, the formulations of oral products need to be modified to impede or arrest initial metabolism by the liver. In consequence, depot therapy by deep intramuscular injection is going to be the route of choice for most. Therein lies the danger to the community — illicit injections and all that goes with them.

Steroids are big business today. But put aside anti-inflammatory steroids: they may well be what we perceive as the bulk of

steroid usage, but in the illicit market they are not. The real brand leaders are the performance enhancers — the androgenic anabolic steroids. Admittedly, some steroids are taken orally, or even rubbed in as creams and gels, but these are the minority. The overwhelming majority of illegal sales will be in the form of injectable presentations. So what are these users hoping to achieve from using steroids?

Dangers of misuse

Anabolic steroids are synthetically produced variants of the sex hormone testosterone. Body builders and weight lifters will look for the muscle growth function. Gymnasts, long distance runners and athletes will also want stamina. There is a widespread belief among youngsters in the midst of their adolescence or just a little older that anabolic steroids are a harmless route to developing a better looking body. Sadly, the vendors are unlikely to disillusion them, or to advise them of the adverse effects such as acne, development of breast tissue, irritability, aggression, hypertension, liver damage and reduced spermatogenesis.

The illegal marketplace abounds with literature on how to maximise the wanted effects and reduce the side effects of steroids. There is almost another language spoken in that culture. Nicknames for the steroids

themselves include “arnies”, “roids”, “pumpers”, “trainers” and “juice”. For the dosage regimen, the protagonists will refer to “cycling”, “stacking” and “pyramiding”. Cycling involves taking multiple doses of steroids over a specific duration, stopping for a set period and then restarting. Stacking involves using several different types of steroid simultaneously and pyramiding involves escalating the dose administered to a peak, at mid cycle, and then tapering off to zero at the end of the six to 12 week cycle.

In the illegal marketplace, neither the Sale of Goods Act nor the Trades Descriptions Act applies. In consequence, the purchaser is always at risk. The product may be unsuitable and not be what it says on the label, assuming that it is labelled at all. Other risks include the relabelling of animal medicines, chemical substitution, adulteration, and bacterial contamination.

Conclusion

So what can community pharmacists do to help? The answer is to be alert to opportunities to influence the above outcomes via health promotion messages and signposting to more specialist agencies, plus harm reduction schemes such as syringe and needle exchange. Pharmacy has a role to play in averting yet another public health crisis.



New CD regulations will change the way you work

James Murray, CPG committee member, passes on some of his experience of dealing with the new Controlled Drugs regulations

The advent of the new Controlled Drugs regulations and subsequent guidance from the Royal Pharmaceutical Society will not have come as too much of a surprise to us since we knew about the changes in regulations following the Shipman report. However some of the practical problems with running balances may have surprised us, in particular getting to grips with running balances for methadone.

If you have not read it yet, the Society's fact-sheet is certainly a good place to start when you are getting to grips with the new and existing requirements. This can be found at the Society web page dedicated to CDs (www.rpsgb.org/worldofpharmacy/useofmedicines/controlledrugs.html)

There is also plenty of supporting guidance there too, including information on destroying Controlled Drugs, preparing for inspection visits and maintaining running balances.

With running balances in mind, some suggestions that may be of use are listed in the Panel. These have evolved through my own experience — some of it bitter.

CD registers — how to avoid problems with running balances

- Quantities in manufacturers' packs are not exact: sometimes there is not enough, sometimes there is too much. These differences are usually small, but can cause a difference between the register balance and the actual stock amount.
- Reconcile regularly — the minimum should be once a week for most pharmacies, but twice a week (or more) may be appropriate if you have many methadone patients. The more often you reconcile, the easier it is to spot any problems that may have arisen.
- Try to include the process of reconciling liquids balances in your normal working week or, even better, working day. Experience shows that the more often you do it, the less time it takes.
- Involve the whole team — the more people who can do a task, the more people are able to spot and resolve problems and the more frequently the task can be done.
- If you are struggling to reconcile, ask for help and support, speak to a colleague (or someone in your company if you work for a multiple). Just not doing it is not acceptable.
- Ensure you have entered all the supplies you have made and received. It is easy to forget to make an entry, so make sure you have a process in place to ensure all entries have been made. Remember it is a criminal offence not to make the appropriate entries in the CD register — omitted entries often happen during busy periods.
- When you do reconcile the stock, sign your name next to the balance so that subsequent pharmacists know when the balance was last reconciled.
- If you do have a discrepancy in your CD register that you cannot reconcile, you will need to report this to the local accountable officer or your Royal Pharmaceutical Society inspector or appropriate investigating authority. Some companies will have their own process for dealing with discrepancies and you should ensure that you are familiar with this.

Be prepared for an influenza pandemic

The Royal Pharmaceutical Society, along with the other pharmacy bodies, meet regularly with the Department of Health in England to ensure the role of pharmacy is included in pandemic influenza planning at both national and local level.

We have jointly produced service continuity guidance for community pharmacies in a pandemic situation and this can be found at www.rpsgb.org/pdfs/pandemicfluguid.pdf. As major providers of health care, community pharmacies are likely to be in the front line during any pandemic, so it is vital that they have individual plans in place to try to maintain business as usual and enable essential pharmacy services to continue, with the emphasis on ensuring patient safety and the supply of medicines for those with long term conditions.

The DoH is aiming to publish a national framework for responding to an influenza pandemic towards the later part of this year and we have been working with it to ensure the inclusion of pharmacy within this document. There will also be guidance produced on the provision of health care in a community setting and we are putting forward the case on the role community pharmacists in a pandemic situation.

For more information and guidance on pandemic flu please refer to www.dh.gov.uk/en/pandemicflu/index.htm.

Help the committee to help you! Report of July meeting

The CPG committee met in July 2007. The meeting included a presentation from the Association of British Pharmaceutical Industries on its new Code of Practice, which relates to how the pharmaceutical industry can promote its products. The role of CPG in any new professional body was discussed, as well as ways of the current group engaging with the Society's new national pharmacy boards. The group praised the work of the

North West Harmonisation of Accreditation and is to look at ways of spreading this programme across the country. The issue of a lack of bioequivalence among steroid inhalers was also raised. A report was given on the pharmacists role in the upcoming lung cancer awareness week.

The CPG committee wants to ensure the group is serving its members. Please e-mail any suggestions to cpg@rpsgb.org.

New support materials for stop smoking services

The Royal Pharmaceutical Society has developed new practice support materials, "Connect with pharmacy — stop smoking support services for community pharmacists", which provide an overview of stop smoking services with evidence and successful examples of practice. A list of useful resources is also included.

The guidance can be downloaded from the information resources page Society's website at www.rpsgb.org.

The charity PharmacyHealthLink has launched detailed guidance, "Towards a smokefree England — brief interventions for stopping smoking by pharmacists and their staff". The document, which has been produced jointly with the Department of Health, sets out the key distinctions between brief advice and brief interventions and explains how best to use these different approaches when supplying a comprehensive stop smoking service in a pharmacy setting. A summary of recommendations and further sources of information, such as stop smoking websites and the National Institute of Health and Clinical Excellence guidance are also included.

The guidance is available at the charity's website: www.pharmacyhealthlink.org.uk.