

■ ADHERENCE

## Do we listen to patients?

From Mr K. A. T. Ramsden, MRPharms

Rob Horne's comments regarding non-adherence with drugs and patient beliefs (*PJ*, 9 October, p525) may seem, to many, like a statement of the obvious. And, of course, that is what makes his remarks so brilliant. It is so obvious that few see it and as a result many professionals fail to address what is, in my view, the most important single issue facing the future management of health.

In order to understand a patient's beliefs, we must first listen. If we are then to change their beliefs then we must be prepared, among other things, to fail gracefully. Surely it is better for a patient to decide not to use an intervention than it is for them (and us) to pretend they will. Anyone who monitors waste medicines will already know how big (and costly) this problem already is.

In short, we need to treat our patients as adults and allow them to make their own choices. This is obvious, I know, but in the culture of health management do we really allow ourselves to do this?

**Kurt Ramsden**  
*Guisborough, Cleveland*

■ MEDICINES WASTE

## The root of the problem is in prescribing

From Mr J. Phillips, MRPharmS

The root of the problem with returned medicines is in the initial prescribing, and successive governments have continually avoided the issue. The figure of £500m worth of returned and incinerated medicines is indicative that something is wrong with the system that allows such enormous waste.

Several factors are involved, apart from the carte blanche to prescribe unlimited quantities. The plethora of pack sizes of solid dose medicines presents a nightmare to the average pharmacy: calendar packs, non-calendar packs, pack sizes of almost every whole positive integer, blister packs, caplets, melts, fastabs, soluble, dispersible. One has to ask if there is any necessity for such a range.

Four groups share joint responsibility for the waste:

- The Government for not limiting prescribing quantities to the minimum necessary for adequate treatment
- Prescribers for failing to implement the above (with the advent of the repeat prescription service there is no need for more than 28 days' supply of even the most regular medication)
- Pharmacists for having failed, over many years, to present a united front to the other parties when faced with decisions affecting their future, such as demanding equal representation within the NHS
- Manufacturers for failing to consider the needs, as regards packaging at least, of patients, prescribers and pharmacists

Finally, patients must be made aware of their responsibilities as consumers. The prescription charge is a disgrace and should be replaced by a different system by which some cash is returned to the NHS. In addition, all consultations should attract a fee that could be reclaimed in suitable cases.

**J. Phillips**  
*Colchester, Essex*

■ COMMUNITY PHARMACY

## Staff are overwhelmed by new "opportunities"

From Miss C. M. Watson, MRPharmS

I would like to comment on letters from Ken Sagar and Mitul Patel (*PJ*, 2 October, p465 and p467)

because they eloquently express concerns that I also have.

I do not think what Mr Sagar experienced is acceptable dispensing practice. Unfortunately his experience is being repeated by thousands of patients the length and breadth of Britain. Patients are being confronted with a "dolly mixture" assortment of medicines when they receive their repeat prescriptions. There is no continuity of packaging and the size, colour and shape of tablets and capsules can vary depending on source.

I note that patient representative groups are beginning to take issue with this problem. We are being encouraged to take on new roles but in my opinion we are not even performing our core role properly. All the counselling in the world will not convince a worried elderly patient with perhaps four or more repeat medicines that a pink and white capsule one month is the same as a purple and grey one the next. We have no idea if the lack of continuity in appearance of medicines is affecting compliance.

The argument that our skilled buying is keeping the drugs bill down is a red herring. (Generic manufacturers are being investigated for price fixing.) The issue of parallel imports being cheaper than UK-sourced drugs has not been tackled either. Counterfeit drugs are already in the supply chain. How can this be described as a professional service?

Mr Patel has described a typical scenario in many community pharmacies. Staff are overwhelmed by new "opportunities", increased volume of dispensing, model schemes, patient group directives, standard operating procedures, grandparent clauses, staff training, audit, increased demand for

information on medicines, alternative therapies, health promotion etc. The list is endless. I find I now dread hearing the words "a customer would like a word with you" because I know if I spend 10 minutes with them there will be a build up of tasks waiting for my attention. This saddens me because this used to be my favourite part of my practice. I think I must be burnt out.

**Catherine Watson**  
*Tain, Ross-shire*

■ BRAND NAMES

## What is the point of the MHRA guidance?

From Mr R. Lowe, MRPharmS

In June of last year I was moved to write to *The Journal* about my professional dislike of an "umbrella" brand name being used for over-the-counter medicines containing completely different active ingredients (*PJ*, 7 June 2003, p792). I was much heartened, therefore when the Medicines and Healthcare products Regulatory Agency addressed this issue in December 2003 when it published the "MHRA naming policy guideline with respect to umbrella segments of product names" (MHRA guidance note number 29).

To quote two of the general principles of this document (points 6 and 8, respectively): "Directive 2001/83/EC requires that an invented name should not be liable to confusion with the common name. In addition product names, including umbrella segments, should not be misleading with respect to the following:

1. Therapeutic effects of the product
2. Composition of the product
3. Safety of the product
4. Confusion of the product with other products with similar names

In the MHRA view any of the above could raise concerns about the safety of the product." And: "Industry is encouraged to give less prominence to the umbrella segment and greater prominence to the active ingredient(s)."

Imagine my surprise, then, to discover that Reckitt Benckiser had rebranded the over-the-counter pack sizes of Fybogel as Senokot Hi Fibre in mid August. There has certainly been no reformulation of the old Fybogel

## Letters to the editor

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product to include any senna. In search of an answer as to how this could be sanctioned by the licensing authority I again consulted guidance note number 29. Under the "Specific circumstances" section of the guidance, the MHRA provides some useful examples of its thinking as to the use of umbrella brand names and the following example (point 11) seems to fit the bill: "The proposed product for which an umbrella segment will be used in the name contains different active ingredients and is for use in the same therapeutic area as the existing product". The guidance states that in such a circumstance: "If in the opinion of the licensing authority the existing original product name is associated with a particular active ingredient, the licensing authority will need to be convinced that the use of the umbrella segment will not give rise to safety issues or efficacy issues due to differential efficacy and speed of onset of effect. This scenario is likely to be the most difficult one for which to obtain approval."

I would therefore like to congratulate Reckitt Benckiser in convincing the MHRA that there is no association between Senokot and senna and achieving what the MHRA has set as the most unlikely of goals in gaining its approval. Perhaps I am a grumpy old pharmacist in need of the benefits of a stimulant or bulk-forming laxative to improve my outlook on life. Perhaps this is of trivial importance, but it does leave me wondering what is the point of the MHRA guidance.

**Robert Lowe**  
Wymondham, Norfolk

## TUBERCULOSIS

### Many opportunities for pharmacists

From Mr T. W. Rennie, MRPharmS

I would like to express great satisfaction and commend the authors of the recent series of extensive articles relating to

tuberculosis (TB). I would, however, like to emphasise a number of points which I believe are pertinent.

The economic aspect of treating multidrug-resistant TB (MDR-TB) is highly significant. Treatment for MDR-TB has been estimated to be about 10 times more expensive (£54,000–£60,000) than treating fully sensitive TB (£6,040).<sup>1</sup>

DOTS (directly observed treatment, short course) is a comprehensive five-point policy promoted by the World Health Organization and not implemented in the UK due to the low incidence rate.<sup>2</sup> A three-month alternative chemoprophylaxis regimen, rifampicin plus isoniazid, recommended in British Thoracic Society guidelines<sup>3</sup> may be preferred to six-months of isoniazid because of its shorter duration. Either regimen is suitable.

Finally, with the notable exception of streptomycin, most first-line antituberculous drugs are considered safe for use in pregnancy and breastfeeding for treatment of TB, and even chemoprophylaxis of TB infection using isoniazid.<sup>4</sup>

A fifth article in the series could have described future roles for pharmacists, such as adherence counselling, or various research activities relating to TB. There are many opportunities for pharmacists to be directly involved in TB care.

**Tim Rennie**  
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## CPD

### Missing the point of CPD completely

From Mr P. J. Curphey,  
FRPharmS

I was astonished (not really, just incredulous) at the letter from Sultan Dajani, an elected member of the Royal Pharmaceutical Society's Council (*PJ*, 9 October, p516).

To suggest that the complexity of one's job dictates the complexity of one's continuing professional development misses the point completely. Certainly keeping up to date is demanding and more continuing education may be required, but in terms of personal professional development the process is exactly the same. Has Mr Dajani learnt nothing from his time on the Council?

The process requires a reflective period to search out ways of self-development and an audit process to ensure that it is working and that you have correctly identified the shortfall. None of that negates the need to keep up to date in CE terms, which is an ethical requirement anyway.

My real concern is that there may be those who are beguiled by this lack of understanding and who believe that it is possible to have part-time pharmacists with part-time competence.

There may be those who believe that a locum pharmacist working one day a week can be different from a full-time pharmacist. Can you imagine patients being happy with that thought?

What an insult, too, to locums, to suggest that they only have to "dispense within standard operating procedures". Where are these dangerous pharmacists? Help us all to steer clear of them!

I despair that people should think this way. No wonder the Pharmaceutical Services Negotiating Committee and others find it so hard to negotiate with our paymasters. Our own Council members are prepared to minimise the pharmacist's key role.

If this is an attempt to engage those who are concerned about the recent rise in fees then I hope it has failed.

I have some sympathy with those for whom the increases are large, but their CPD identification, monitoring and support is the same for everyone, part-time or full-time, overseas or based in Britain.

Maybe in Mr Dajani's part of the world locums are simply warm and breathing — there to satisfy the law. But in the real world top class locums are working their socks off and certainly my locums keep me on the straight and narrow both in professional and best practice terms.

They would be the last people to suggest that their CPD needs are any different from mine although they might both agree my CE needs brushing up.

How demoralising to realise that there are Council members who really do not understand their profession or who, after all the wrangling, have no concept of the new regulation agenda nor how times have changed.

**Peter Curphey**  
Ballagh Glen,  
Isle of Man

### Off the record

Our new occasional series is open to any writer. Readers are invited to send either 400- or 600-word items about some anecdotal aspect of pharmacy practice that they think is worth sharing. Items are published anonymously but contributors must supply their full name and address. Items should be sent to [graeme.smith@pharmj.org.uk](mailto:graeme.smith@pharmj.org.uk) for consideration

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## ■ COUNTERFEIT MEDICINES

**An excuse to smear parallel trade, with no evidence**

From Mr R. Freudenberg

As worrying as the two recent cases of counterfeits detected in the UK are (*PJ*, 11 September, p335), the reaction to these events is also of concern. The Patients' Association "summit" to address the issue — remarkably arranged and publicised in less than three days after the Reductil recall was announced — seemed just an excuse to smear parallel trade, without a shred of connecting evidence. In fact there has never been a single confirmed case of a counterfeit medicine reaching a patient as parallel trade, ever.

If Roger Odd knows of parallel trade being wrongly labelled or offered when date expired, he should report these instances to the regulatory authority and the traders concerned. As for patients being worried by foreign language on the packs, this situation is mainly the consequence of pharmaceutical companies using their trademark rights to block repackaging.

As for recalls, parallel traders can, and have, performed these just as efficiently, promptly and comprehensively as any other pharmaceutical distributor.

It is also disingenuous of Pfizer to claim that repackaging by parallel traders is the "weakest point of the European supply chain". All overlabelling or repackaging plus insertion of an English language version of the patient package insert, measures that are required by law, are carried out by trained operators under strict GMP conditions by parallel traders in possession of a manufacturer's (assembly only) licence. They employ an EU Qualified Person — invariably a pharmacist with industry experience — and operate to standard operating procedures agreed with the Medicines and Healthcare products Regulatory Agency, which also performs regular inspections.

The tight, regulated European environment for parallel trade should not be confused with the chaotic situation that prevails in the US. In the absence of patient packs, multiple intermediaries (not just pharmacies) repack from bulk there. Why does Pfizer not address this problem? Indeed, its fears are ironic having just announced to UK wholesalers that it will apply a rigid quota on

supplies to them. Artificially restricting stock in this way is known to create shortages — one of the factors that attracts counterfeiters in the first place.

Counterfeit medicines in Europe remain remarkably rare. But if pharmacists are worried about them they should specifically order parallel trade, as these are the only products professionally examined as a matter of routine after they leave the manufacturer.

**Richard Freudenberg**  
*Secretary-General*  
*British Association of European*  
*Pharmaceutical Distributors*

OLIVIER BRANDICOURT, managing director, Pfizer Ltd, replies: As Richard Freudenberg points out, there have been two recent instances of counterfeit medicines entering the legitimate UK supply chain. In August, the Medicines and Healthcare products Regulatory Agency issued an alert recalling two batches of Lilly's Cialis. In September, the MHRA issued a second alert recalling a batch of Abbott's Reductil.

Pfizer recently became aware of an internet pharmacy called Paypill which supplied counterfeit Viagra to patients via the internet. Paypill stated that it used the same parallel traders for supply as the NHS.<sup>1</sup> Pfizer is therefore deeply concerned that the legitimate supply chain is at risk.

The World Health Organization estimates that 8–10 per cent of medicines in the global supply chain are counterfeit.<sup>2</sup> In Russia, for example, it is estimated that 8–12 per cent of the medicines are counterfeit.<sup>3</sup> Recent expansion of the EU has brought it closer to Russia. Pfizer has found counterfeit medicines across the globe and in every EU market. A WHO expert has stated that risks of counterfeits entering the EU are "obvious".<sup>4</sup>

A recent report by the Social Market Foundation stated that parallel trade "offers a vehicle by which to introduce counterfeit products into the supply chain".<sup>5</sup>

Each year, more than 140 million medicine packs are parallel traded in the EU. A direct consequence of parallel trade is the repackaging of medicines. Pfizer is concerned that repackaging provides an opportunity for counterfeit medicines to enter the legitimate supply chain and jeopardise patient safety. In 2003, the US Food and Drug Administration identified repackaging of medicines as a weakness in the supply chain.

Last year, 18 million Lipitor

tablets were recalled when counterfeit Lipitor entered the US supply chain in Florida through third-party repackagers.<sup>6</sup> The counterfeits were subsequently found in 15 states and suspected in six others. In June this year, the FDA announced that counterfeit Viagra had been sold in two Californian pharmacies.<sup>7</sup>

Mr Freudenberg also refers to incorrectly labelled and out of date parallel imports. In addition to the issue of counterfeits, the Social Market Foundation report highlighted the possibility of human error during the repackaging process.

In audits of sample parallel import Pfizer medicines destined for the UK, Pfizer identified a number of regulatory compliance issues with the potential to jeopardise patient safety. Examples include:

- Different dosage strengths of medicines inside the pack to the strengths stated on the outside
- A pack referring to tablets but containing capsules
- Discrepancies between the expiry date and batch number on the pack and the expiry date and batch number on the medicines inside

The evidence described and Pfizer's experience across the world demonstrates that the integrity of the supply chain is at risk. Pfizer is duty bound to highlight these concerns and the potential for them to jeopardise patient safety.

Finally, Pfizer wishes to make the following comments in relation to the supply policy identified in Mr Freudenberg's letter. The policy, which operates in many European markets, has been implemented in the UK in the context of concerns about the security of an increasingly fragmented supply chain. The primary objective of our supply policy, however, is to enable Pfizer to meet its duty to ensure the continued supply of medicines to patients in the countries in which it operates. By allocating quotas commensurate with UK national demand, Pfizer is able to manage the supply of its medicines in the UK more efficiently and reduce the risk of supply shortages that have become an increasing concern.

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## ■ GEOGRAPHY

**Fuzzy borders!**

From Mrs A. S. England, MRPharmS

Now I know why the map of Britain on the front cover of the *PJ* (9 October) has fuzzy borders between England and Scotland. It was drawn by the same journalist who reported on Andrew Gray's robots located in Berwick-upon-Tweed, Northumberland (ibid, p534).

The last time I checked Northumberland (including Berwick-upon-Tweed) was in England, not Scotland, as stated later in the article.

**Angela England***Morpeth, Northumberland***Contact us**

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