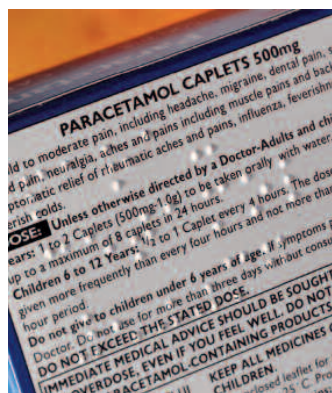


New EU medicines legislation improves patient information

New European medicines legislation states that medicines should be packaged with the name in Braille and that other help for visually impaired patients should be provided. Examples include: leaflets with large print, telephone help lines, audio versions of patient information leaflets (PILs) made available on compact discs and tapes, or leaflets that can be accessed via the internet.

The new legislation, which came into effect on 30 October, introduces wide ranging changes to the regulation of medicines which will give patients access to better information about their medicines. Patients will have direct input into the design and content of the leaflets provided with every medicine. The Medicines and Healthcare products Regulatory Agency (MHRA) will also be publishing public assessment reports and summaries of clinical trial data for newly licensed medicines on the internet.

All medicines which will be handled directly by patients, including herbal medicines, will have to comply with the new provision, and guidance on its application has been published by the European Commission. Medicines such as injectable products which are administered



Packaging labelled in Braille

by health care professionals need not have Braille applied. Other medicines encompassed in this exception includes radiopharmaceuticals, anaesthetics and infusions. However, insulin products and peritoneal dialysis fluids which are handled by the patient will have to comply.

The MHRA says that the name of the medicine in the summary of product characteristics must appear in Braille on the package. Where a medicine is available in more than one strength, these data should also appear in Braille on the label and in some cases where different pharmaceutical forms of a medicine are available, this information should be displayed in Braille on the

label. The MHRA also states that it is not necessary to retain PILs in a variety of formats (eg, Braille, audio and CD-rom) because the marketing authorisation holder can contract out the provision of these documents to third party suppliers.

For products which have already been submitted to the MHRA, are under assessment and not yet authorised, the expectation is that these will comply with the new legislation in relation to Braille. Medicines which were authorised before 30 October 2010 have until 30 October 2010 to comply.

The MHRA says that the legislation strengthens its role of protecting public health by ensuring that a risk profile is drawn up for new products. Companies are required to submit to the MHRA any new information that may affect the risk-benefit balance of products. This will identify areas where more evidence may be needed.

Kent Woods, chief executive of the MHRA, said, "The new EU medicines legislation will improve the protection of public health by enhancing the assessment of risk-benefit during the life-cycle of the product. Patients will be better informed through the improvement of PILs."

brief

■ **Agenda for Change (AfC) may impair the growth in the number hospital pharmacy preregistration placements. This concern was raised at a recent meeting of the Royal Pharmaceutical Society's Hospital Pharmacist Group. Attendees were concerned that trusts are not fully funded for these jobs, which have been allocated to band 5 according to AfC, and therefore are unable to offer preregistration placements to as many students as they would like.**

■ Professional indemnity insurance for hospital pharmacists is a now being offered by Pharmacists' Professional Indemnity Ltd. The policy was introduced in response to a growing number requests from hospital pharmacists. Pharmacists are able to obtain legal cover for any post within the hospital sector.

■ *Hospital Pharmacist* has appointed a new editor. Hannah Pike, MRPharmS, was previously news and features writer for the *Pharmaceutical Journal*. She can be contacted by telephoning on 020 7572 2425 or by e-mail at hannah.pike@pharmj.org.uk

Patients to complete yellow cards

The Medicines and Healthcare products Regulatory Agency (MHRA) has launched a UK-wide pilot to enable patients to directly report their experiences of suspected side effects from medicines through its reporting system — the yellow card scheme.

The pilot follows the success of a smaller pilot, restricted to certain parts of the UK, which ran in January this year and provided a wide range of feedback from patients and carers in the development of

mechanisms for reporting suspected side effects. Patient yellow card reporting forms are available from pharmacies, GP surgeries and other NHS outlets (including hospitals).

Gordon Duff, chairman of the Committee on Safety of Medicines, said, "The benefits of encouraging patients to complete yellow card reports are becoming evident. Patients provide a different and extremely useful insight into suspected side effects that we cannot easily get from yellow

card reports from health professionals. The yellow card scheme is vital in monitoring the safety of medicines in the UK, and the incorporation of patient reporting will have significant benefits, especially as the scheme evolves and patients become familiar with it."

The MHRA says that the pilot will run for as long as necessary to obtain adequate information to implement permanent systems of reporting, which it expects to be in place by the end of 2006.

Submitting articles to *Hospital Pharmacist*

Pharmacists and technicians wishing to submit articles or papers to *Hospital Pharmacist* are invited to contact the editorial office for advice on word counts, style and submission deadlines. Please contact Hannah Pike (e-mail hannah.pike@pharmj.org.uk or telephone 020 7572 2425) or Haley Hill (e-mail Haley.hill@pharmj.org.uk or telephone 020 7572 2419). Advice is also available from the *Hospital Pharmacist* website at www.pjonline.com/about/advicehp.html

Medicine errors still under-reported

Incidents of medication errors in NHS trusts are still seriously under-reported, according to a new report.

“A safer place for patients: learning to improve patient safety,” published by the National Audit Office this month, states that around half of all patient safety incidents in the NHS in which harm was caused to patients could have been avoided if lessons from previous incidents had been learned.

Surveys of 267 NHS acute, ambulance and mental health trusts carried out in 2004–05 found that medication errors accounted for 7.1 per cent of all patient safety incidents reported. This figure is second to patient falls which accounted for 31.5 per cent of reports.

The report points out that the MHRA only receives reports on drug errors that are the result of adverse reactions to the medicines and, because of low reporting rates and the many barriers to reporting medication errors, the true extent of serious errors in the use of prescribed drugs is unknown.

The Chief Medical Officer’s 2000 report “An organisation with a memory” set a target of reducing the number of serious errors in the use of prescribed

drugs by 40 per cent by the end of 2005. The new report says that of those trusts that stated that this target was applicable to them (mainly acute and mental health trusts), only 20 per cent said that they had met it.

Many trusts said that this target was difficult to determine, due to a lack of baseline data. Other common responses were that trusts were currently in the process of putting action plans into place, or that there were few errors in the first place, making a 40 per cent reduction difficult.

The report says that although reporting of patient safety incidents has improved at a local level, at a national level the progress on developing a national reporting and learning system has been slower than envisaged in the Department of Health’s 2001 strategy “Building a safer NHS for patients.” It outlines a need to improve evaluation and sharing of experience by all organisations with a stake in patient safety.

The report concludes that although most trusts have developed a predominantly open and fair reporting culture, largely driven by the Department of Health’s clinical governance initiatives, a blame culture still predominates in some trusts.

MRSA targets — are they down to chance?

Chance makes it impossible to assess reliably whether hospitals are meeting Government targets to reduce methicillin-resistant *Staphylococcus aureus* (MRSA) infections, according to a recent article in the *BMJ* (2005;331:976–77).

David Spiegelhalter, a senior scientist at the Medical Research Council Biostatistics Unit, Cambridge, warns that setting targets for individual hospitals, such as the Government’s national target for reducing the rate of MRSA infection by 50 per cent by 2008, is fraught with difficulties.

He says that the basic problem is that it is unclear whether the targets refer to an observed rate reduction or a true reduction in

underlying risk. He says that this ambiguity is unimportant at a national level but, for individual hospitals, chance variation can make observed rates extremely volatile and make simplistic notions of “hitting targets” unreliable.

According to Mr Spiegelhalter, the Government needs to define the term “target” more precisely in this context.

Looking at data for the financial years 2001–04, he found far more variability in the figures than would be expected by chance alone. He explained that this could be due to the fact that MRSA is infectious and therefore tends to occur in clusters.

Corrections

In the special feature on radiopharmacy in the September issue of *Hospital Pharmacist*, the third sentence of the last paragraph in the second column (p305) should have read: “The whole body dose received after the injection of a technetium-99m (99mTc) radiopharmaceutical is in the order of 1.2 to 5.4mGy.” In Panel 1 (p306), the total dose of radioactivity (mGy) for the whole body entry should have read 1.12 mGy for 80 MBq injected Tc-99m pertechnetate, and 1.78x104 mGy (35% thyroid uptake) for 740 MBq I-131 sodium iodide injected. The reference for these figures is: Valentin DJ. Biokinetic models, absorbed doses, and effective doses for individual radiopharmaceuticals. *Annals of the ICRP* 1998;28(3):116–118.

This error has been taken into account on marking entries for the September Life-long Learning series.

Winners receive technician of the year awards

The eighth annual AAH hospital pharmacy technician of the year awards were presented by Ann Lewis, Secretary and Registrar of the Royal Pharmaceutical Society at a lunch reception at the Park Lane Hotel, London, on 14 October.

The winners, announced in September’s issue of *Hospital Pharmacist* (p294) were Tracy Sedgwick, senior pharmacy technician for medicines management and intermediate care, Darlington Hospital, and Paul Townsend, pharmacy technician, Birmingham

Children’s Hospital. As part of their prize Ms Sedgwick and Mr Townsend will also present their work in a poster session at the annual mid-year clinical meeting of the American Society of Health-System Pharmacists in Las Vegas in December.

Jeff Bulmer, AAH Hospital Service director, said: “I warmly congratulate this year’s winners on their achievements, the remarkable insight they give into the high-level work pharmacy technicians undertake and the inspiration this gives to future pharmacy technicians.”

Also present was Darren Leech, president of the Association of Pharmacy Technicians UK. He stated that the association would be working with AAH Hospital Service in its continuing support of the awards scheme.

The event also saw the launch of next year’s AAH Hospital Service technician of the year awards. Details and entry forms are available now for both the supply chain and the clinical categories. Mr Townsend urged others to enter the competition. “I enjoyed working on this project and am looking forward

to the trip to Las Vegas. Anyone thinking of entering next year’s competition should go for it,” he said.

AAH Hospital Service pharmacy technician of the year awards 2006

Application forms for the 2006 awards can be obtained by contacting Manpreet Chana, AAH Hospital Service, on 02476 432000 or by e-mailing manpreet.chana@aah.co.uk

New job profile announced for pharmacy technicians under Agenda for Change

A new job profile that covers both primary and secondary care roles has been agreed for pharmacy technicians under the Agenda for Change pay system.

“No other profession has ever seen a job profile like this,” Darren Leech, president of the Association of Pharmacy Technicians UK, told *Hospital Pharmacist*. He explained how the new profile, set at band 5, recognises that pharmacy technicians have a role in primary care trusts as well as in secondary care, and follows months of negotiations with trade unions and the Department of Health. “APTUK was aware of

pharmacy technicians working for PCTs who were finding it hard to get their job description matched to previous profiles,” he said.

“We hope that this new profile will avoid the need for pharmacy technicians to fill in long job analysis questionnaires and will cut the administrative burden in PCTs, avoiding the lengthy appeals process. We now have a set of profiles that cover just about all of the pharmacy workforce in the NHS. We are still working on the development of a band 8 profile for senior pharmacy technicians and hope to see a profile released in the coming months.”

Mr Leech added that APTUK is currently performing an audit to assess national consistency of job-matching and hopes to publish the results before the end of the year.

A list of all up-to-date job profiles for pharmacy, including the new band 5 profile, is now available at www.aptuk.org



The new job profile is the first to cover pharmacy technicians working in either primary or secondary care