

End of CD hand-writing requirement?

COMPUTER-GENERATED prescriptions and registers for Controlled Drugs (CDs) should be permitted, according to Government proposals.

The suggested changes to the Misuse of Drugs Regulations 2001 are outlined in a consultation document that has been produced by the Home Office.

The first proposal is that the current requirement that certain details of prescriptions for CDs to be hand-written should be removed. "In view of the developments in information technology, the Government now considers that the hand-writing requirement should be relaxed and an amendment made to the 2001 regulations to permit prescriptions for Schedule 2 and 3 drugs to be hand-written or computer-generated," the consultation letter says.

However, it adds that no other part of the regulation should be relaxed so prescribers would still need to state the quantity of drugs in both words and figures, and sign the prescription by hand. Advantages of the change include saving time, reducing the number of errors in reading prescriptions and avoiding the need for them to be reissued.

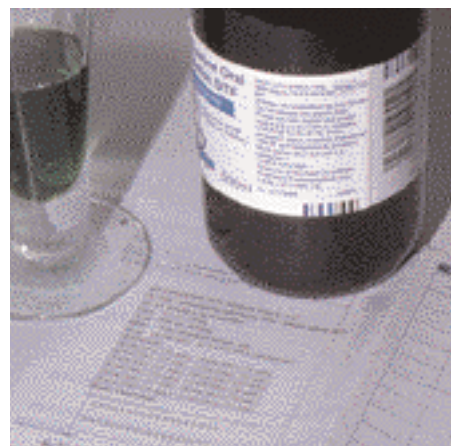
The second proposal is to allow registers for Schedule 1 and 2 CDs to be maintained on a computer. This would be subject to safeguards being incorporated into the software to ensure that entries could not be

altered at a later date. The author of each entry would also have to be identifiable. This change would be optional and pharmacists (and other professionals required to keep registers) would still be able to retain records in a bound register.

Further to this, the Government proposes that copies of information from requisitions, orders and private prescriptions required for certain CDs could be kept on computer as an alternative to preserving the original form. It also proposes that the regulations should be amended to allow requisitions for Schedule 2 and 3 CDs to be computer-generated.

The Government does not consider that these changes will result in an additional resource burden on the public or private sector. "The changes are of an optional nature and those affected will be able to decide the extent to which they wish to take advantage of them. Whether they do so will depend on whether it makes good business sense for them. In most cases it will because, in practice, most manual records are backed by computerised stock systems," the consultation document states.

The proposals are aimed at easing the burden on doctors, pharmacists and businesses in the pharmaceutical sector. They have been considered and approved by the Advisory Council on the Misuse of Drugs.



Computer-generated prescriptions for Controlled Drugs look set to become the norm

A copy of the document can be found at the Home Office website (www.homeoffice.gov.uk). Comments should be made to Naim Siddiqui, Drugs Unit, the Home Office (tel 020 7273 3474, e-mail Naim.Siddiqui@homeoffice.gsi.gov.uk). The consultation period runs until 22 August.

The proposed changes would affect England, Wales and Scotland. The Government plans to implement the proposed changes during 2003, subject to consideration of comments received in the consultation period.

European Court stops EC fining Bayer on parallel imports

THE European Commission is likely to lose its appeal against an order of the European Court quashing a euro3m fine on Bayer for trying to prevent parallel imports of Adalat (nifedipine) to Britain from Spain and France (*P7*, January 27, 1996, p121).

The court's advocate general has recommended rejection of the appeal in a case which has been running since 1996. The opinions of advocates general are usually accepted by the European Court.

Quashing the fine in 2000, the court ruled that the commission had failed to establish a case against Bayer, because its action was based on competition law, rather than single market rules. Because of this, the

commission would have had to prove that there had been an agreement between Bayer and wholesalers to restrict the imports. This had not been the case (*P7*, 11 November 2000, p706).

Instead, Bayer had limited Adalat sales to Spanish and French wholesalers to their national requirements. This had led to complaints being made to the commission by the wholesalers, which had launched a competition case and fined Bayer. Although the wholesalers still worked with Bayer, this was hardly an anti-competitive agreement, particularly when it was the wholesalers' complaints that led to the legal action being launched, the court ruled.

Parallel imports save the NHS £228m

PARALLEL imports saved patients and the National Health Service over £228m (euro342m) in 2002, according to the York Health Economics Consortium, a health economics consultancy. In the European Union, parallel trading in medicines saved euro635m (£423m).

Overall, the saving is much greater, says the YHEC, because of the effect of parallel trade on price competition. Parallel trade represents the only form of price competition in the market for patent-protected

medicines. The consortium warns that the savings could be at risk if manufacturers are allowed to restrict sales to wholesalers in countries where medicines cost less and from which parallel imports originate.

Taking a different view on parallel trade, the Association of the British Pharmaceutical Industry said last year that parallel trading cost the pharmaceutical industry in Britain £1bn a year in lost revenues (*P7*, 19 October 2002, p556).

New campaign against drug misuse

A NEW Government drugs campaign called "Talk to Frank" has been launched this week. The campaign aims to offer "an anonymous, discreet but well-informed friend" who can offer advice, information and support about recreational drugs. Frank can be accessed by telephone on 0800 77 66 00 or on the internet (www.talktofrank.com). The helpline is staffed by trained specialists who will answer questions or refer callers to treatment and support organisations.

ROYAL PHARMACEUTICAL SOCIETY NEWS

Society complaints procedure

The Society is launching a formal complaints procedure to deal with issues concerning standards of service delivery, failure of processes or quality of staff performance (p771).

New directorate structure

The Society is changing its directorate structure with the aim of taking the organisation forward and strengthening its integrated roles as a modern regulatory body and professional organisation for pharmacy (p772).

Unlicensed ephedra under review in UK

THE Medicines and Healthcare products Regulatory Agency is reviewing the use of *Ephedra* species in unlicensed herbal remedies.

It is taking this step in the light of US Food and Drug Administration plans to restrict the permitted dose and duration of use of ephedra in supplements and to introduce warning labelling. In Canada, ephedra products with doses equivalent to 8mg ephedrine and daily doses of 32mg ephedrine have been withdrawn, as have unlicensed ephedra products combined with other stimulants.

Current controls over ephedra in the United Kingdom restrict doses of more than 600mg herb (equivalent to 12mg

ephedrine alkaloids) and daily doses of more than 1,800mg herb to pharmacy supply. Below these doses, ephedra products can only be supplied following a one-to-one consultation with a herbalist.

The MHRA wants more information on the nature and extent of usage of ephedra in unlicensed herbal remedies and details of the information and advice given to patients prescribed ephedra by herbalists. It also wants to collect views on the current regulatory position. Information can be sent to Alexandra Williamson, 16-131 Market Towers, 1 Nine Elms Lane, London SW8 5NQ (tel 020 7273 0970, e-mail alex.williamson@MHRA.gsi.gov.uk) until 20 June.

Call to integrate complementary health care into health service

PATIENTS are being denied safe access to the benefits of complementary medicine because such therapies are not fully integrated into the health service, according to the Prince of Wales's Foundation for Integrated Health.

This view is set out in the organisation's five-year plan, published shortly before the World Health Organization was to consider a resolution calling, among other things, for the integration of traditional medicine into mainstream care in all WHO member states. The foundation takes the view that everyone

should have access to the treatment approach of their choice, safe in the knowledge that it is effective and well regulated. It says that many of these therapies remain outside mainstream services, beyond the reach of many patients and health professionals, and beyond the scrutiny of National Health Service audit and inspection.

Key elements of the five-year plan are:

- Giving guidance to NHS trusts on how to provide complementary health care
- Encouraging the development of integrated health care schemes
- Providing seed funding for research into integrated and complementary health care
- Encouraging all medical schools to teach complementary medicine modules

The report can be accessed via *Pfj Online* (www.pjonline.com/links/pj).

MHRA alert: Pan Pharmaceuticals

THE Medicines and Healthcare products Regulatory Agency has issued a warning that Pan Pharmaceuticals Pty Ltd, Australia, has had its manufacturing authorisation suspended by the Australian Therapeutic Goods Administration because of serious safety and quality breaches. These include substitution of ingredients, manipulation of test results and substandard manufacturing processes.

Pan Pharmaceuticals produced a wide range of medicines, herbal products and nutritional and vitamin supplements marketed under its own name and on behalf of other companies. Nearly 2,000 products, mostly intended for export, are affected. British companies known to have imported products manufactured by Pan include Health Imports, Illingworth & Illingworth Health Foods, Health Perceptions and Synpharma. Details of products known to have been affected are available via the *Pfj Online* links page (www.pjonline.com/links/pj).

Drivers warned over OTC medicines

OVER-THE-COUNTER medicines have inconsistent and inaccurate labels that pose a danger to drivers, the Department of Transport says.

The Department commissioned research from Loughborough University as part of a programme of research into the effects of drugs on driving. It found that British National Formulary recommended labelling is not always followed by manufacturers and that different manufacturers give differing advice regarding the potential for drowsiness of the same active ingredients.

Some medicines even include different advice on their packaging and information leaflets and few products have well-presented labels, the researchers say. They add that manufacturers should be given better guidelines on these issues and that a standard warning symbol should be considered.

Road safety minister David Jamieson said: "Labelling must be clear and understandable. I understand that the Medicines and Healthcare products Regulatory Agency is examining the issue." He added that people should ask a pharmacist if they are in any doubt about medicines and should stop if they feel drowsy when driving.

PJ Online

Pfj Online contains the editorial contents of *Pfj* publications.

Carers

Links to websites for carers, the Carers' awareness week (June 9–15) plus a recent continuing professional development article on how pharmacists can support carers. www.pjonline.com/links/carers

Credit for learning

Questions, answers and associated articles from the *Hospital Pharmacist* series. www.pjonline.com/noticeboard/credit

Enteral nutrition

Related links and guidance on administering drugs from the British Association for Parental and Enteral Nutrition. www.pjonline.com/links/enteralfeds

Children/babies

Links on breastfeeding, stillbirth and cot deaths, accident prevention plus a recent continuing professional development series on pregnancy. www.pjonline.com/links/children

Council reports

Links to reports of Council meetings, Statutory Committee and other meetings. Part of the Society section of the Noticeboard. www.pjonline.com/noticeboard

Photocopies/reprints

The Society's library offers a photocopy service, for which there is a charge. Colour reprints are available from the *Pfj* advertisement department. www.pjonline.com/about

BRIEFLY

BMJ looks at industry relations

"Doctors, drug companies and, most importantly, patients would all benefit from greater distance between doctors and drug companies," argues Dr Richard Smith, editor of the *BMJ*. The 31 May issue of the *BMJ* focuses on the relationship between doctors and drug companies and explores its effects on research, its influence on prescribing, and the consequences for patients.

Pain common in addiction

Chronic severe pain is experienced by 37 per cent of patients on methadone maintenance treatment programmes and 24 per cent of patients on inpatient addiction programmes, a study has found. Pain was given as one of the reasons for using drugs. Substance abuse treatment programmes need to develop comprehensive and structured pain management protocols, the study concludes (*JAMA* 2003;289:2370).

Treating alcoholism with topiramate

Topiramate (Topamax) could be used to treat alcohol dependence, research suggests. A 12-week study involving 150 people found that those taking topiramate had 2.9 fewer drinks per day than those taking placebo. In addition, the topiramate group had 28 per cent fewer heavy drinking days and 26 per cent more abstinent days (*Lancet* 2003;361:1677). An accompanying editorial notes that the study contrasts with most alcoholism studies, which tend to measure persistence in abstinent patients. The results suggest that different therapies could be targeted at different stages of treatment (*ibid*, p1666).

Smoking mothers should breast feed

Breastfeeding may counteract some of the harmful effects of maternal smoking during pregnancy, say Dutch researchers. They looked at the results of school tests taken by 570 children at the age of nine years and recorded details of their mothers' smoking habits and how the mothers chose to feed their children. Only those children whose mothers had smoked during pregnancy and who had been bottle fed performed poorly on the school tests (*Journal of Epidemiology and Community Health* 2003;57:403).

Do one in 10 men have chlamydia?

Up to 10 per cent of young men could be infected with chlamydia, new data suggest. This is substantially higher than previous estimates. Researchers tested 798 male military recruits for chlamydia and found that 78 (9.8 per cent, 95 per cent confidence interval 7.8–12.04) were positive for *Chlamydia trachomatis*. Of the 78 chlamydia-positive men, 69 (88 per cent) were asymptomatic. The authors say there was no evidence that the group of men were especially sexually active (*Lancet* 2003;361:1792).

NICE issues guidance for breast and colon cancer

THE National Institute for Clinical Excellence has issued further guidance on the use of drug treatments in breast and colorectal cancer.

NICE's latest recommendations, published earlier this week, mean that patients with locally advanced or metastatic breast cancer should be offered capecitabine (Xeloda) in combination with docetaxel (Taxotere) rather than docetaxel on its own when anthracycline-containing treatment has failed or is unsuitable. Capecitabine is also recommended as monotherapy when anthracycline and taxane-containing treatment have failed. For patients with metastatic bowel cancer, NICE recommends that capecitabine or tegafur with uracil (Uftoral) should be options for first-line treatment.

Both sets of guidance stress the importance of patient involvement in decisions about treatments. "The patient should be informed about the options and the differences between the medicines so that he or she can be fully involved," NICE says.

In the guidance on use of capecitabine in breast cancer, NICE says evidence suggests that capecitabine combination therapy is likely to be more effective than docetaxel monotherapy for several outcomes. "However, the side effects of combination therapy may be less acceptable, and the final choice of therapy may be influenced by factors such



Xeloda has been endorsed by NICE for both colorectal and breast cancer

as contraindications and the health and preference of individuals," NICE says.

The guidance for colorectal cancer states that both capecitabine and tegafur with uracil are likely to have clinical effectiveness similar to that of standard chemotherapy (intravenous fluorouracil/folinic acid). It adds that because intravenous regimens may be preferable under certain circumstances, capecitabine and tegafur with uracil should be available as options for treatment rather than as the preferred choices.

The full guidance is available online at www.nice.org.uk.

Iron supplements could reduce fatigue in non-anaemic women

IRON supplements could solve the problem of unexplained fatigue in women even if they are not anaemic, new research suggests. However, the effect may be restricted to women with a low blood ferritin level.

Swiss researchers examined the effect of iron therapy in 136 women aged 18 to 55 years who had consulted their general practitioners primarily with symptoms of tiredness. The women were assigned to either oral ferrous sulphate (80mg/day elemental iron) or placebo and were asked not to take over-the-counter vitamins or additional iron supplements during the study. The level of fatigue perceived by patients was measured at baseline and after one month using a visual analogue scale and questionnaire.

The researchers found that women who received iron supplements reported a larger decrease in their level of fatigue than did those given placebo (29 per cent decrease compared with 13 per cent). Only women with low serum ferritin concentrations improved with iron supplementation. However, low serum ferritin concentrations were common, with 85 per cent of women taking part in the study having a ferritin level of 50µg/L or lower.

"Identifying iron deficiency without

anaemia as a potential cause of fatigue is important," the researchers say. They suggest that this may avoid inappropriately attributing symptoms of tiredness to emotional causes. "Instituting iron therapy early may also improve quality of life," they suggest (*BMJ* 2003;326:1124).

Osteoporosis drive launched in Scotland

A DRIVE to improve osteoporosis treatment and awareness of the condition has been launched this week by the Scottish Intercollegiate Guidelines Network, NHS Health Scotland and the National Osteoporosis Society.

As part of the campaign SIGN launched a new clinical guideline on the management of osteoporosis on 28 May. This includes a summary of the evidence supporting treatments for osteoporosis. The guideline can be found at the SIGN website (www.sign.ac.uk). The organisations are also calling for an end to restricted availability of scanning devices, saying that they should be provided in all health boards.

Improved control and compliance with compound inhaler for asthma patients

USING an inhaler containing fluticasone propionate and salmeterol (Seretide) results in better control of asthma than using separate inhalers, countering scepticism over the place of compound inhalers in asthma therapy. Two 12-week double blind studies ($n=705$), presented this week at the American Thoracic Society conference, compared the effects of fluticasone propionate and salmeterol in one inhaler with equal doses of the two drugs in separate inhalers. They show that use of the compound inhaler produced a morning peak expiratory flow (PEF) rate of 13L/min above the value expected from adding the improvement seen with salmeterol alone to that seen with fluticasone alone.

Dr Sanjay Aggarwal, clinical development physician for GlaxoSmithKline, told *The Journal* that although a 15L/min increase in PEF is usually accepted as the threshold over which patients perceive benefit, 13L/min was a good improvement and

higher than in previous studies. "A combination inhaler allows both drugs to be deposited in the same place rather than one at the top and the other at the bottom of the lungs," Dr Aggarwal said.

Other studies presented at the conference indicate that use of the compound inhaler improved both control and compliance. Control was gauged using the number of short-acting β_2 -agonist inhalers prescribed. Prescribing data for 6,346 patients were analysed. Patients prescribed an inhaler containing fluticasone and salmeterol together were prescribed a mean of 4.5 (SD=5.5) short-acting bronchodilators in one year compared with 6.1 (SD=6.4) prescribed in the group prescribed separate salmeterol and fluticasone inhalers ($P=0.0001$).

Using a similar technique, another study looked at compliance with asthma therapy in 3,094 children. Compliance was measured on the premise that if the patient

collected prescriptions for all the asthma therapy he or she was expected to use in a year, compliance would be 100 per cent. Researchers reported that patients prescribed the compound inhaler ($n=94$) were 72.5 per cent compliant compared with those who were prescribed two separate inhalers or fluticasone only (55.8 and 55.0 per cent, respectively, $P=0.0005$ and <0.0001 , respectively).

Dr Paul McCarthy, associate medical director for GSK told *The Journal* "By the next revision of the asthma guidelines, this evidence will be published and hopefully it will be taken into account. If I had to make a bet, in the future, combination inhalers will be first-line therapy."

Bosentan improves survival in pulmonary hypertension patients

FIRST-LINE treatment with bosentan (Tracleer), a dual endothelin receptor antagonist, significantly improves three-year survival in patients with primary pulmonary hypertension (PPH), according to the first study to assess long-term survival with this drug.

The study was presented at the American Thoracic Society conference. Survival in patients treated with bosentan was higher (86 per cent) after three years follow-up than a predicted survival rate of 48 per cent from a United States registry of patients before specific treatments for PPH were developed.

The study showed that survival increased earlier in the bosentan group than in control patients (96 vs 69 per cent at one year) and was then maintained to three years. The differences between observed

and predicted survival rates at six, 12, 24 and 36 months were all in favour of bosentan ($P<0.001$).

The results came from a retrospective analysis of 169 patients with PPH who took part in two randomised, double-blind, placebo-controlled trials, followed by open label extensions. All patients had severe PPH. Lead investigator Dr Vallerie McLaughlin, Rush-Presbyterian Medical Centre, Illinois, US, said: "Previous studies showed that treatment with bosentan improves symptoms and decreases the rate of clinical worsening. Now we have new evidence suggesting that first-line treatment with bosentan is associated with improved survival." She added: "Based on these findings, bosentan should be considered first-line therapy for most patients with PPH."

First year of life critical in asthma

INCREASED risk of asthma is associated with environmental exposure to asthma triggers in the first year of life, but not at older ages, according to findings from the Children's Health Study presented at the American Thoracic Society conference.

The parents of over 700 children were interviewed and researchers found that exposure to herbicides during infancy was associated with a 4.6-fold increased risk in asthma and exposure to pesticides with a 2.4-fold increase. Exposure to cockroaches, wood or oil smoke, farm crops and animals was also implicated. According to Dr Frank

Gilliland, University of Southern California, Los Angeles, in the first year of life, children are particularly likely to become sensitised to asthma triggers. "Infants are different from older children or adults . . . their respiratory rates are higher, and their ability to metabolise and excrete materials from the environment is different," he explained.

The Journal attended the American Thoracic Society's 99th international conference in Seattle, Washington, courtesy of GlaxoSmithKline

CONFERENCE BRIEFS

Moxifloxacin better than standard

A five-day course of oral moxifloxacin (Avelox) 400mg daily produces a higher clinical cure rate for acute exacerbations of chronic bronchitis than a seven-day course of a standard antibiotic (70.9 per cent vs 62.8 per cent, $P=0.05$). In addition, the time until the next exacerbation was found to be longer in the moxifloxacin group than in the comparator group (131.0–132.8 days vs 103.5–118.0 days, $P=0.03$) and this is consistent with superior eradication of bacteria, researchers say.

Texting compliance in asthma

Texting teenagers to ask them if they have used their inhalers and using electronic devices to measure peak flow and relay readings to the GP are the future for compliance in asthma. Dr Mark Britton, consultant physician at St Peter's Hospital, Chertsey and chairman of the British Lung Foundation, told *The Journal*: "I see technology as a way forward for patient self-management. Investigative projects are being funded by the telephone companies, but the ultimate aim would be a degree of investment from primary care trusts to allow monitoring at home."

Linezolid for resistant TB

Five patients with tuberculosis resistant to between eight and 14 therapies benefited from receiving linezolid (Zyvox). Addition of linezolid to their failing drug therapy led to sustained negative conversion of sputum cultures in all patients. "This certainly seems like a promising medication for drug-resistant TB," said Dr Timothy Harkin, assistant director of Bellevue Hospital's chest service, New York. Dr Harkin hopes that linezolid will be the subject of clinical trials sponsored by the World Health Organization.

Correction

Pan Pharmaceuticals

The Medicines and Healthcare products Regulatory Agency stated that Health Perception had bought products from suspended Australian manufacturer Pan Pharmaceuticals (p740). The MHRA subsequently said that this was not correct for the period affected by the global product recall.