

Guidance published on safer CD management in secondary care

Guidance to promote the safe and effective use of Controlled Drugs in secondary care in England is published this week by the Department of Health and the Royal Pharmaceutical Society.

The guidance aims to support health care professionals and organisations in implementing new governance arrangements and legislative changes — in particular, the role of the accountable officer — following the Government's response to the fourth report of the Shipman Inquiry.

It brings secondary care into line with primary care, for which guidance has already been issued by the National Prescribing Centre. Systems for procuring, storing, supplying, transporting, prescribing, administering, recording and disposing safely of CDs are set out in the guidance; it does not provide advice on the clinical choice or use of CDs.

Chapters cover the new legislation and governance arrangements as well as the management of CDs in pharmacy departments, wards, operating theatres and in specific circumstances, such as use of patients' own drugs, out-of-hours supply and temporary closure of wards. There is also a chapter on staff training for managing CDs.

The guidance incorporates recent changes to working practices, specifically the contribution of pharmacy technicians and other health care professionals, and explains how these fit into the existing legal framework.



Secondary care CD management will be brought into line with that in primary care

The Society was commissioned by the DoH to produce the guidance following consultation with a multidisciplinary stakeholder group. Robert Clayton, the Society's head of practice told *The Journal*: "The guidance must be applied and implemented in conjunction with each accountable officer to ensure that CDs are supplied appropriately and when needed."

"Safer management of Controlled Drugs: a guide to good practice in secondary care (England)" is intended to build on the advice on CDs provided in the revised Duthie report (*PJ*, 5 March 2005, p264). It is available on the DoH website (www.dh.gov.uk).

Article p555

Oncology consultant pharmacist appointed

Nicola Stoner, lead cancer pharmacist at Oxford Radcliffe Hospitals NHS Trust, has been appointed a consultant pharmacist. She believes it is the first such post in the area of oncology. Dr Stoner received confirmation of her new title last week following a rigorous application process for retrospective approval of the post according to Department of Health guidance issued in 2005 (*PJ*, 9 April 2005, p409).

The title "consultant pharmacist" can only be used by pharmacists appointed to posts approved by strategic health authorities following submission of a business plan. Consultant posts are centred around four main functions: expert practice; research, evaluation and service development; education, mentoring and overview of practice; and professional leadership. In 2006, there were 12 consultant pharmacists working within the NHS.

Dr Stoner is an independent prescriber (*PJ*, 13 January, p44) who has worked in the area of oncology for nearly 17 years. She completed a PhD in antiemetics in cancer chemotherapy at the beginning of her career.

Dr Stoner is principal visiting fellow at the school of pharmacy, University of Reading, where she works to develop links between Oxford Radcliffe Hospitals NHS Trust and the university. Her NHS post is partly funded by Cancer Research UK and she spends some of her time working in the Cancer Research UK clinical research unit, where she is involved in phase I, II, III and IV clinical trials.

Dr Stoner is also an expert in gene therapy and is working with the European Association of Hospital Pharmacists on setting standards for pharmacists for handling gene therapy in a clinical setting in preparation for when licensed products become available.

A new cancer centre is due to open in Oxford in April 2008 and will bring together cancer services, including chemotherapy, radiotherapy and surgery, across Oxfordshire. "The centre aims to be a centre of excellence and having allied health care professionals working within it at consultant level will help with recruitment and retention," Dr Stoner told *The Journal*.

Test purchases show flaws in pharmacy medicine controls

Evidence that sales of decongestants, including pseudoephedrine-containing products, are not properly controlled in all pharmacies has been published by the Medicines and Healthcare products Regulatory Agency.

A series of test purchases organised by police and trading standards officers in Cleveland and using 15-year-olds as buyers found that the children were able to buy multiple packs of decongestants from a range of pharmacies and general wholesalers. The children also asked for iodine and matches because it was thought that this would raise suspicion over the purchases — iodine and match heads are used in the chemical reaction to convert ephedrine and pseudoephedrine to methylamphetamine.

The young people attempted to buy six packets of various decongestants from each pharmacy or general wholesaler visited. The purchases were made three weeks after the Royal Pharmaceutical Society warned pharmacists to treat requests for inappropriately large quantities of products containing ephedrine or pseudoephedrine with caution (*PJ*, 27 January, p114).

The MHRA's published evidence states that in each case the purchases were not challenged. However, it goes on to say that sales were limited to two packs in each pharmacy, except in one case, where six packs were passed through the till in three batches of two.

Overall, the test purchases amounted to 45 packs of decongestant products, 12 of which contained pseudoephedrine. The other 33 packs had phenylephrine as the active ingredient.

David Pruce, director of practice and quality improvement at the Royal Pharmaceutical Society, commented: "The Society is not familiar with the precise details of what happened in Cleveland, however, we do have some concerns that the study may not have been conducted in a robust manner. In response to the MHRA consultation on proposals to restrict the availability of medicines containing pseudoephedrine and ephedrine we are calling for tighter control within pharmacy (limiting maximum pack size and restricting to one pack per purchase). Should these changes come into force then pharmacists would carry them out as rigidly as they do for any other sales of medicines."

The MHRA has also published a number of other documents setting out the background to the proposal to make all ephedrine- and pseudoephedrine-containing products prescription only, including an edited version of an Association of Chief Police Officers report on illicit methylamphetamine laboratories.

SMC announces latest approvals and rejections

Protein kinase inhibitor dasatinib (Sprycel; Bristol-Myers Squibb) has been approved by the Scottish Medicines Consortium for use in NHS Scotland for the treatment of adults with chronic myeloid leukaemia (CML) with resistance or intolerance to previous therapy including imatinib mesylate.

However, the SMC rejected the drug's use for patients with the accelerated or blast phases of CML.

It also rejected the use of dasatinib for adults with acute lymphoblastic leukaemia with resistance or intolerance to previous therapy, saying that the economic case was not sufficiently robust.

Infliximab (Remicade; Schering-Plough) was accepted for patients with severe plaque psoriasis who have failed to respond to or are unsuitable for other systemic therapies. But it recommended that infliximab should not be used for maintenance treatment of fistulating active Crohn's disease or severe active Crohn's disease, or to treat adults with moderate to severe active ulcerative colitis.

The SMC also accepted the following products:

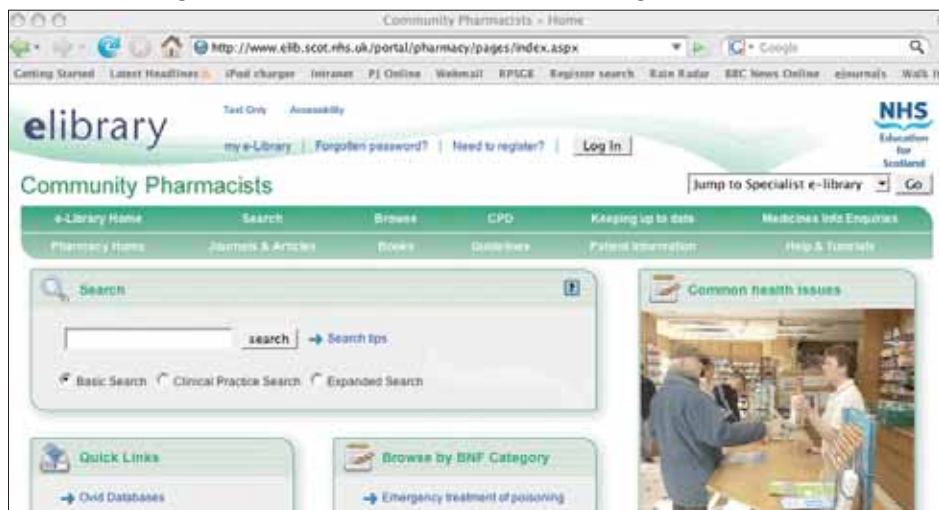
- Azelaic acid gel (Finacea; Valeant) for the topical treatment of papulopustular rosacea
- Desmopressin oral lyophilisate (DDAVP Melt; Ferring) for the treatment of vasopressin-sensitive cranial diabetes insipidus, and post-hypophysectomy polyuria and polydipsia
- Desmopressin oral lyophilisate (DesmoMelt; Ferring) for the treatment of primary nocturnal enuresis
- Dibotermim alfa implant kit (InductOs; Wyeth) for the treatment of acute tibia fractures, as an adjunct to standard care using open fracture reduction and intramedullary nail fixation, in adults for whom there is risk of non-union
- Docetaxel (Taxotere; sanofi-aventis) for the induction treatment of patients with unresectable locally advanced squamous cell carcinoma of the head and neck in

combination with cisplatin and 5-fluorouracil, restricted to patients for whom induction chemotherapy is appropriate

- Lanthanum carbonate chewable tablets (Fosrenol; Shire) for use as a phosphate-binding agent in the control of hyperphosphataemia in chronic renal failure patients on haemodialysis or continuous ambulatory peritoneal dialysis
- Sitaxentan sodium (Thelin; Encysive) for the treatment of patients with pulmonary arterial hypertension classified as WHO functional class III, to improve exercise capacity (restricted to specialists in the Scottish Pulmonary Vascular Unit)

Products rejected by the SMC on economic grounds were buprenorphine transdermal patches (BuTrans; Napp), dexrazoxane (Savene; TopoTarget), standardised allergen extract of grass pollen (Grazax; ALK-Abelló) and topotecan (Hycamtin; Merck).

e-Library opened to community pharmacists



Community pharmacists in Scotland can now use a new information resource, launched last week by NHS Education for Scotland (NES).

The Community Pharmacy e-Library has been designed to give pharmacists simple, direct access to information required in everyday practice. It is part of the NHS Scotland e-Library.

Arlene Brailey, assistant director, NES Pharmacy, explained that community pharmacists had been identified as infrequent users of the NHS Scotland e-Library. "Community pharmacists from all over Scotland were interviewed to find out why this was the case, and to identify the sorts of questions they need help answering. From this research, the new Community Pharmacy e-Library portal was built."

The research indicated that community pharmacists want quick access to evidence-based information. So categories of common health issues and diseases (set out according to the chapters of the British National Formulary) are on the pharmacy e-library home page. Clicking on a category provides links to evidence-based information for individual conditions.

The pharmacy e-library also provides links to patient information leaflets, guidelines, books and journals. Some require an Athens password (which pharmacists can apply for by clicking the "need to register" button). In addition, it has a continuing professional development section containing details of events and training opportunities.

The Community Pharmacy e-Library can be found at www.elib.scot.nhs.uk/pharmacy.

DTB supports switching to generic simvastatin

There is a strong argument for switching patients from branded statins to generic simvastatin, according to the current issue of *Drug and Therapeutics Bulletin* (2007;45:33).

However, switching to simvastatin is not appropriate for all patients, *DTB* warns. The potential benefits, unwanted effects and costs need to be considered, along with special circumstances such as renal impairment and drugs being co-prescribed.

Nonetheless, simvastatin should be the first-line option for most patients with established cardiovascular disease, it says. Atorvastatin (Lipitor) should be reserved for second-line treatment or for patients intolerant of simvastatin. Patients who experience drug interactions with simvastatin may fare better with pravastatin, but the weaker lipid-lowering effects of pravastatin make it a less attractive first choice, *DTB* argues.

"Switching the million people in the UK currently on atorvastatin 10mg or 20mg daily to simvastatin 40mg daily, plus using simvastatin 40mg daily for the 1.6 million prescriptions of statins to meet the NICE guidelines for primary prevention, could save as much as £2bn over the next five years," it suggests.

This month's *DTB* also provides an update on drugs for hyperactivity in childhood (ibid, p37). It recommends that drug treatment should only be used as an adjunct to other interventions and that, since current evidence does not allow clear distinction between methylphenidate, dexamfetamine and atomoxetine in terms of efficacy, the longer history of use with methylphenidate is a compelling reason for preferring it as a first choice.

Doctors highlight cases of OTC medicines misuse

Large-scale research is needed to monitor and assess the extent of dependence on legal non-prescription drugs, a letter in the *BMJ* last week suggests. However, some research in this area has already been published in pharmacy journals.

Two doctors write that, in the past three months, they have come across three patients with addiction to Nurofen Plus (ibuprofen and codeine phosphate). All three, they write, had started using the product appropriately but had subsequently escalated their use as they became tolerant to codeine. They also highlight postings on the website of the charity Over-Count, which suggest that over 4,000 registered users are addicted to Solpadeine (paracetamol and codeine).

The doctors state that there is no official statistics on the extent of OTC drug dependence and suggest that research in this area is needed.

However, Catriona Matheson, senior research fellow, department of general practice and primary care, University of Aberdeen, told *The Journal* that her research team and several others have published papers on over-the-counter medicines misuse in pharmacy

journals, which would not have been picked up via the doctors' Medline search.

She added: "It was useful of the authors of the letter to highlight this problem to the medical profession but they should not assume pharmacists are not well aware of this."

"Managing OTC misuse is an integral part of a pharmacists' everyday tasks and research has shown that they manage this in a stepwise manner. First, when product misuse becomes apparent they might ensure it is behind a counter, then kept out of sight and finally, as with codeine linctus, many stop stocking it altogether." She added that some pharmacists also keep registers of people requesting products.

Dr Matheson highlighted the need for greater co-operation between pharmacy and general practice. "In some areas referral notes to GPs have been used to raise awareness of this issue for individual patients. However, if no feedback or response is given pharmacists are unsure if this is worthwhile."

In response to the *BMJ* letter, Reckitt Benckiser, manufacturer of Nurofen Plus, pointed out that Nurofen Plus is only avail-



Christopher Hall/Dreamstime.com

OTC analgesics misuse is recognised by pharmacists

able in a restricted pack size and is labelled to state that patients should see their doctor or pharmacist if they need to take it for longer than three days.

□ **Patient information ignored** Research conducted among 1,012 adults on behalf of Tesco Pharmacy last month indicates that almost one third of its customers (32 per cent) never reads instructions on painkiller packs.

Patients should use one pharmacy for all their medicines, says WHO

Patients should be encouraged to use a single pharmacy for all their medicines and for information about them, the World Health Organization has recommended.

As part of a set of nine safety solutions launched last week, the WHO recommends that systems should be developed to collect and document information about all medicines a patient is taking and generate a list of these at all stages of treatment. The list should include prescription and non-prescription medicines, vitamin and nutritional supple-

ments, potentially interactive food items, herbal preparations and recreational drugs. The source of patients' medicines should also be included and, where appropriate, community pharmacists should be involved in collecting and validating this information.

To this end, the WHO recommends encouraging patients and families to use a single pharmacy, not only as a provider of medicines but as a source of information about medicines.

Patients and their caregivers should also be encouraged to maintain an accurate list of all

medicines patients are taking, the WHO says. It suggests that consideration should be given to developing community systems to support this.

The WHO's nine safety solutions involve tackling problems with medicine names, patient identification, patient hand-overs, body site identification, electrolyte solutions, medicine accuracy at care transitions, catheter and tubing connections, injection devices and hand hygiene. They are available from the WHO website (www.who.int) and via *PJ Online* (www.pjonline.com/links/pj).

Follow epoetin indication and dosing restrictions, EMEA says

Epoetin products should be used strictly in accordance with the indications and dosing recommendations set out in their summaries of product characteristics, the European Medicines Agency (EMA) has warned this week in a public statement.

The EMA is reviewing the safety of all epoetin products centrally authorised by the agency in light of new data that suggest a possible effect on tumour progression in patients with cancer and an increased risk of serious cardiovascular complications in patients with chronic renal failure.

A review by the EMA's Committee for Medicinal Products for Human Use (CHMP) and its Pharmacovigilance Working Party undertaken in 2004 resulted in revised dosing recommendations for the use of epoetins in patients with cancer. The EMA is now reminding prescribers that epoetins are only

authorised for the treatment of anaemia in patients with solid tumours who are receiving chemotherapy. "There is some evidence that epoetins may be associated with increased morbidity and mortality when used in patients with solid tumours not receiving chemotherapy," it stresses.

The agency says there is evidence that aiming for a target haemoglobin concentration above 12g/dl when treating chronic renal failure patients with epoetins is associated with an increase in mortality and serious cardiovascular morbidity. The EMA writes: "The CHMP is currently holding further discussions with expert groups to consider whether tighter dosing instructions should be issued in this regard. In the meantime, physicians should exercise caution when considering raising haemoglobin concentrations above 12g/dl."

Tutor training days

The Society is planning a series of free training days for preregistration tutors and is conducting a survey to determine the level of interest among current and prospective tutors (p565).

AGM financial questions

The Society has extended its deadline for the submission of financial questions for answer at the annual general meeting (p565).

Long service certificates

Eight pharmacists have been awarded certificates recognising service of 15 years or more on branch committees (p566).

The Society

Primary care trusts' performers lists up for review

Lists kept by primary care trusts of health professionals and organisations approved to work in the NHS in England are being reviewed by the Department of Health.

The DoH wants to hear about the benefits and disadvantages of the current system, which requires doctors, dentists and pharmacy contractors (but not individual pharmacists) to be listed by PCTs so that they can be stopped from working in the NHS in cases of serious transgression.

The review is considering: whether some or all of the system is needed; replacing individual PCT lists with a central list; the consequences of leaving NHS disciplinary action with PCTs or transferring responsibility to professional bodies; how to remove opera-

tional difficulties if the system stays with PCTs; and what guidance is needed to make sure any new system works.

The review is intended to lead to a system that meets the Government's aim following the reviews of medical and non-medical regulation. That aim is, the Government has said, that "professional regulation must create a framework that maintains the justified confidence of patients in those who care for them as the bedrock of safe and effective clinical practice and the foundation for effective relationships between patients and health professionals."

So far as pharmacists are concerned, the review document says: "Plans to introduce supplementary list provisions for individual employee pharmacists were deferred in 2006.

We were awaiting the outcome of the consultation on the regulation of pharmacists and the Royal Pharmaceutical Society's duties and powers. That process is now complete and we are considering [the] next steps."

Joy Wingfield, professor of pharmacy law and ethics at the University of Nottingham, said of the performers list system: "It's a jeopardy too far. I'm glad to see that the review questions the need for the NHS list at all." She added that PCTs need to apply consistent criteria for investigation and referral and expressed concern about the investigatory skills and competence of PCT staff.

Anyone wishing to contribute to the review can e-mail rab.harkins@dh.gsi.gov.uk before 15 June.

Society commended

Royal Pharmaceutical Society processes for appointing and training members of its new disciplinary committees have been commended for their independence by the Council for Healthcare Regulatory Excellence.

The CHRE performance review for 2006–07 also commends the Society for its commitment to evidence-based policy.

Commenting on the time taken to produce the Pharmacists and Pharmacy Technicians Order 2007, the review says: "Delays in the passing of this legislation have caused a risk to public protection: there were a number of potential circumstances arising in health cases which indicated the potential for risk to the public while awaiting these new powers." It adds that also put the Society's reputation at risk.

Pharmacists detect more adverse drug events from drug charts than other health care workers, US study suggests

Pharmacists detect more adverse drug events (ADEs) when reviewing drug charts than other health care workers, a US study suggests (*American Journal of Health-System Pharmacy* 2007;64:842).

The researchers identified 13 studies that examined different health professionals' ability to detect ADEs, including adverse drug reactions and medication errors, and which could be reasonably compared.

Their analysis showed a mean weighted ADE detection rate of 0.33 ADEs per admission for pharmacists compared with 0.16 per admission detected by non-pharmacists (doctors in all but one study, where nurses and

medical record administrators were used as reviewers).

"Despite the heterogeneity, there is strong evidence that pharmacist-led interventions based on chart review report a higher ADE rate among inpatients. Our data suggest that pharmacists are the most thorough chart reviewers," they say.

However, the researchers warn that dedicating full-time clinical pharmacist positions to ADE chart review is expensive and difficult to justify. They suggest that automation of chart review would provide a potential solution but would need to incorporate the cognitive reasoning used by pharmacists.

Pharmacist allowed to appeal Controlled Drug conviction

Pharmacist Gary Fisher is to be allowed to appeal against his conviction in March 2006 for conspiracy to supply cocaine.

In a preliminary hearing in London's Appeal Court last week, Mr Justice Burton said that the trial judge's claimed misdirection of the jury — he told them they could convict on the cocaine charges even if they were not sure that particular drug was involved — was cause for concern. "The prosecution named the drug, namely by alleging a conspiracy to supply cocaine, but the learned judge left it open to the jury to convict in the way in which we have described," he said. "It

remains for the full court to decide whether that is the correct interpretation."

It was the prosecution's case at his trial that Mr Fisher, formerly of Upton St Leonards, Gloucestershire, had, over a period of years, supplied 20kg of mannitol, which is commonly used to double the apparent quantity of cocaine. When his pharmacy at Matson, Gloucestershire, was searched, £50,000 in bundled cash was found in a safe in the toilet floor.

Mr Fisher, who is listed in the Royal Pharmaceutical Society's practising register, is currently in prison and is due to be released in November.

Co-op buys nine branches

The Co-operative Pharmacy has acquired seven pharmacies in South Yorkshire from GH Rock (Chemists) Ltd and two in South Wales from Mayberry and Morris. This brings the number of pharmacies owned by the group to 482, not changing its position as the third largest pharmacy chain in the UK.

Consumers trust pharmacists

Pharmacists are the second most trusted professionals after firefighters, according to a *Reader's Digest* survey of 1,900 of its customers. The two groups topped the poll with 96 and 97 per cent of respondents trusting them, respectively. Airline pilots, nurses and doctors were the next most trusted groups (95 per cent, 94 per cent and 91 per cent, respectively).

BMA proposes alternative approach to health reform

An alternative approach to health reform is proposed in a discussion paper published by the British Medical Association this week.

"A rational way forward for the NHS in England" proposes that Parliament should establish and appoint an NHS board of governors, responsible for ensuring compliance

with the NHS constitution and accountable to Parliament. An executive management board would guide the performance and national operation of the NHS.

The BMA also calls for a list of national core services and for health professionals to be involved early when shaping health policies.

Once-yearly zoledronic acid reduces fracture risk

A once-yearly infusion of zoledronic acid reduces the risk of vertebral, hip and other fractures in postmenopausal women, according to new research. The finding supports earlier work showing zoledronic acid decreases bone turnover and improves bone density for at least 12 months after infusion, and suggests that the drug could be a useful treatment option where adherence to oral medication for osteoporosis is a problem.

Researchers assigned 7,765 women to receive a single 15-minute infusion of zoledronic acid or placebo at baseline, at 12 months and at 24 months. After three years, 310 women (10.9 per cent) in the placebo group had experienced a vertebral fracture compared with 92 women (3.3 per cent) in the zoledronic acid group (relative risk 0.30, 95 per cent confidence interval 0.24 to 0.38). Similar reductions in risk were seen after one and two years.

The incidence of hip fracture was also reduced (2.5 per cent for women given placebo



Eye of Science/Science Photo Library

Osteoporosis: bone density can be improved with zoledronic acid

compared with 1.4 per cent for women treated with zoledronic acid), as were all other prospectively defined categories of fracture, including non-vertebral fractures and

clinical vertebral fractures ($P < 0.001$ for all comparisons).

“Given the relatively poor adherence to oral bisphosphonate therapy in clinical practice, annual infusion of zoledronic acid may provide a promising approach to reducing fracture risk,” the researchers conclude.

The study, supported by Novartis, is published in *The New England Journal of Medicine* (2007;356:1809).

The author of an accompanying editorial (ibid, p1878) describes the data as impressive and says that the absence of long-term adverse effects on renal function is reassuring, as is the lack of evidence linking zoledronic acid with osteonecrosis of the jaw. However, she highlights the increase in atrial fibrillation seen in women treated with zoledronic acid as an unexpected adverse effect. “A causal relationship must be given serious consideration,” she writes.

Zoledronic acid is not currently licensed in the UK for the treatment of osteoporosis.

UniChem launches scheme for preregistration training

UniChem has launched a preregistration training programme to support independent pharmacists who want to take on a trainee.

Sanjay Pathak, UniChem's commercial services manager, said: “The purpose of the programme is to provide a one-stop shop, comprehensive and cohesive training and support package for both the trainee and their tutor. The course incorporates regular monthly communications with UniChem's professional services team and is strongly underpinned with an emphasis on developing competent and confident pharmacists.”

The company says that the course comes as a result of shared knowledge from within Alliance Boots. All training materials, as well as tutor and trainee support, will be centrally provided by UniChem.

Pharmacists should screen for diabetes risk

Pharmacists are being encouraged to identify people at high risk of developing type 2 diabetes in a consensus statement published by the International Diabetes Federation.

The statement recommends using a simple check list for risk factors, including central obesity, family history of diabetes, cardiovascular history, diabetes during pregnancy and treatment with drugs known to increase diabetes, including glucocorticoids, beta-adrenergic antagonists and thiazides.

People considered at high risk should then be advised to have their plasma glucose level measured. Those confirmed to be at risk should be prioritised for lifestyle interventions to prevent disease progression.

Shailen Rao, chairman of the Primary Care Pharmacists' Association and previously head of medicines management and diabetes

lead at Hillingdon Primary Care Trust, said: “Pharmacists are better placed than most health care professionals for this type of screening because they are based in the community and see many people who are not ill.” He added that pharmacists should aim to provide a “full circle” approach to diabetes care, supporting the medication needs of people already diagnosed with diabetes as well as helping to find those at risk.

Sir George Alberti, national director for emergency access and the UK representative on the consensus group, said: “This is one of the greatest public health challenges of the 21st century.”

He added: “Pharmacists can play a major role in screening those at risk.”

The IDF consensus on type 2 diabetes prevention is available online (www.idf.org).

Anti-EGFRs will cause magnesium loss in almost all patients

Almost all cancer patients treated with monoclonal antibodies that target epidermal growth factor receptors (EGFR) will have some degree of hypomagnesaemia, research suggests.

Previous retrospective studies had shown severe magnesium loss (grades 3 and 4 hypomagnesaemia) in a small proportion of patients given anti-EGFR drugs. Magnesium loss can cause dizziness, weakness, cardiac abnormalities and generalised convulsions.

Sabine Tejpar, of the University Hospital Gasthuisberg, Leuven, and colleagues measured the degree of hypomagnesaemia in 98 patients with metastatic colorectal cancer treated with EGFR-targeting antibodies with

or without combined chemotherapy. All but three (97 per cent) of the patients had decreased serum magnesium concentrations during treatment compared with baseline measures (mean serum magnesium slope -0.00157 mmol/L/day, 95 per cent confidence interval -0.00191 to -0.00123) and this change was lower than that seen in the control group not receiving antibody treatment (0.00014 mmol/L/day, -0.00026 to 0.00055).

The authors conclude: “Careful monitoring of serum magnesium is warranted during the duration of treatment because symptoms of hypomagnesaemia can easily remain unrecognised.” (*Lancet Oncology* 2007;8:387.)

PJ Online

Access to *PJ Online* is free to all

Industrial Pharmacist

The latest Industrial Pharmacists Group newsletter is now online.
www.pjonline.com/backissues

Independent prescribing

A series that follows four pharmacists as they develop as independent prescribers.
www.pjonline.com/series

Readership survey

Hospital Pharmacist is conducting a readership survey, with a prize draw.
www.pjonline.com/survey

WHO criticised for being too reliant on expert opinion

The World Health Organization has been criticised for being too reliant on expert opinion when it formulates policy. The criticism coincides with an initiative it has launched to improve data sharing among researchers, health care professionals and the public.

Writing in the online version of *The Lancet* (9 May, www.thelancet.com), Andrew Oxman, of the Norwegian Knowledge Centre for the Health Services, Oslo, and John Lavis, of the Centre for Health Economics and Policy Analysis, McMaster University, Hamilton, Canada, call on the WHO to make more use of systematic reviews of relevant research when developing its policies and recommendations.

The two researchers interviewed WHO department directors (or their delegates) to find out how WHO recommendations are developed. They also reviewed a sample of WHO reports containing recommendations.

“Expert committees or meetings of experts were almost always convened when developing recommendations whereas only a few directors mentioned having commissioned systematic reviews to inform the work of these expert groups,” the researchers say. This approach to developing recommendations goes against WHO’s own guidelines for developing recommendations, they add.

In response, Tikki Pang, of the WHO’s department of research policy and co-operation, and Suzanne Hill, of its medicines policy and standards unit, concede that WHO practices might be less than optimal. They note that a guidelines review committee, to provide support to WHO departments developing recommendations, has been proposed and that continuing education in guidelines development should be offered to WHO staff. “Basing guidelines on explicit and transparent consideration of the best evidence is cru-

cial to WHO’s international credibility, standing and reputation,” they say.

The concerns over the WHO’s approach to policy development were raised at the same time as the WHO launched an initiative to improve data sharing. Its Clinical Trial Search Portal will act, the WHO says, as an entry point into high quality clinical trial registers with global search functions.

“The Clinical Trial Search Portal is a collaborative international initiative led by WHO that facilitates the identification of all clinical trials, regardless of whether or not they have been published,” explained Tim Evans, assistant director general, information evidence and research, WHO. “The portal represents an enormous step towards greater access, transparency and accountability of health research globally,” he added.

The WHO Clinical Trial Search Portal can be accessed at www.who.int/trialsearch.

£25m boost to Nottingham health research

Drug discovery will be among five key areas tackled by a new £25m research centre at the University of Nottingham.

The Centre for Biomolecular Sciences, due to be officially opened after *The Journal* went to press this week, will also focus on cancer research, stem cell science, bacteriology and regenerative medicine. Researchers from the university’s schools of pharmacy, medicine, chemistry, molecular biology, human development, mathematics and engineering will collaborate with the 300 scientists who will work at the centre.

Kevin Shakesheff, director of the centre and a pharmacist, said that the scientists who will be based at the centre have already made breakthroughs that have resulted in the launch of new medicines and the formation of biotechnology companies.

At a ceremony in The Netherlands last month, Professor Shakesheff received the Pharmaceutical Sciences World Congress’s



The new research centre in Nottingham

Research Achievement Award. The award was presented in recognition of his work on the application of injectable polymers to regenerative medicine.

Deaths from air pollution may rise as climate changes

Changes in air pollution over the next half century could cause hundreds of extra deaths and hospital admissions each year, the Department of Health and the Health Protection Agency have warned.

In an update to the 2002 report “Health effects of climate change in the UK”, the DoH and HPA look at areas in which there have been developments since the original research was conducted.

They say that although the levels of some important pollutants may decline over the next 50 years, the concentration of ozone is likely to rise. “The increases are likely to be significant,” the report warns. “With the least constraining assumptions (no threshold of effect assumed) up to 1,500 extra deaths and hospital admissions per annum might be expected.”

The report also suggests that changes in agriculture and wildlife management may increase the incidence of tick-borne diseases and that, although malaria outbreaks in the UK are likely to be rare and on a small scale, prompt reaction to any outbreaks will reduce the chances of endemic malaria transmission in the UK. Consequently, the DoH and HPA argue, a surveillance system should be established to monitor the distribution and abundance of arthropod vectors in the UK.

The report is available from the DoH website (www.dh.gov.uk) and via *PJ Online* (www.pjonline.com/links/pj).

Health professionals Health professional organisations are well placed to highlight the public health dangers of climate change, the British Medical Association argues in a report this week. They can also catalyse change in the rest of the NHS and draw attention to the health benefits associated with greener economic activity and lifestyles, the BMA says.

Centralised control planned for advanced therapies in EU

Centralised European Union authorisation for advanced therapies came a step closer last month when the European Parliament adopted a proposed Regulation.

The decision means that the three EU institutions — parliament, commission and the Council of Ministers — agree that a single regulatory process for gene therapy, cell therapy and tissue-engineered products should replace the current 27 separate national systems. The main elements of the planned Regulation include:

- A centralised marketing authorisation procedure

- A multidisciplinary expert committee for advanced therapies within the European Medicines Agency
- Tailored technical requirements to suit the characteristics of advanced therapies
- Strengthened requirements for risk management and traceability
- Special incentives for small- and medium-sized businesses

A spokeswoman from the European Organisation for Rare Diseases said the Regulation will benefit patients with uncommon disease through robust centralised assessment of safety, efficacy and quality of advanced therapies.