

New contract depends on OFT report

THE Department of Health is waiting for the Office of Fair Trading to report on community pharmacy competition before it takes forward proposals for a new community pharmacy contract.

That was revealed by the Department's chief pharmaceutical officer, Dr Jim Smith, at the northern regional pharmacy conference on 20 June.

Dr Smith also explicitly acknowledged that skill mix issues, intended to free pharmacists from routine pharmaceutical duties so that the National Health Service can make better use of their skills, will increase community pharmacy contractors' costs. He cited community pharmacy as a perfect example of a public-private partnership.

Sue Sharpe, chief executive of the Pharmaceutical Services Negotiating Committee, has welcomed Dr Smith's public



Sue Sharpe



Jim Smith

acknowledgement that skill-mix changes would cost money, not save it.

She is also pleased that the Department has recognised that community pharmacy is a public-private partnership.

"At last we have acknowledgement of the arguments we have been putting forward," Mrs Sharpe said.

Commenting on Dr Smith's statement about the new contract, Mrs Sharpe said: "We have had discussions with the Department and have arrived at a good degree of common understanding as to what should go in a new contract. But the Department has said that it will wait for the OFT report before agreeing it."

The PSNC has argued that health service planning objectives should predominate over any competition concerns. The Department has made it clear to the PSNC, and

has stated in its pharmacy plan, that it wants to maintain controls over new pharmacy contracts in general, but that it also wants to make changes in respect of out-of-town centres.

"They will want to give careful consideration to the views of a watchdog body," Mrs Sharpe said.

Regulatory reform date for pharmacy

A DATE has been set by the Government for the modernisation of pharmacy regulation.

In a Parliamentary written reply on 25 June, Mr David Lammy, Parliamentary Under-Secretary of State for Health, said: "We are working with the Royal Pharmaceutical Society of Great Britain to bring forward an order under section 60 of the Health Act 1999 in 2003 to modernise the professional regulation of pharmacy, which is expected to include the necessary powers to implement a compulsory obligation for pharmacists to participate in continuing professional development."

Patients can order repeats in ETP pilot

PATIENTS involved with the Pharmacy2U electronic prescription transmission pilot can now order repeat prescriptions online and check their entire electronic prescription history.

After logging on to a secure web server using a username and password, patients from the nine GP surgeries involved in the pilot can ask for repeat prescriptions, check the status of any prescription requests they have made before, see their complete electronic prescription history and alter their personal and contact details.

Pharmacy2U receives electronic prescriptions from 27 GPs at the nine surgeries and delivers dispensed medicines to patients within a couple of days.

Pharmacy2U says that prescription management is an added-value service for its users and is not part of the formal ETP pilot.

Welsh pharmacy strategy to be published in draft this month

A DRAFT pharmacy strategy for Wales is to be published by the National Assembly for Wales before the end of July.

During a short debate on community pharmacy on 27 June, Jane Hutt, the assembly's Health and Social Services Minister, said that the paper will focus on meeting the pharmaceutical needs of individuals. Comments on the draft will be taken into account before a final document is produced which, Ms Hutt, said will help shape the future of pharmacy in Wales over the next 10 years.

"The future of pharmacy in primary care will depend on its ability to make the best use of pharmacists' skills across the NHS, including community pharmacy," Ms Hutt told the assembly. She agreed with assembly members who said that a more strategic approach to medicines management was needed in Wales and that community pharmacists could play a key role.

Eleanor Burnham, assembly member for North Wales (Lib Dem), called for

lifestyle clinics to be run by pharmacists. She reported that one such clinic at Neyland, Pembrokeshire, had helped a 31-stone smoker with diabetes give up smoking and halve his weight in 14 months. His diabetes was now controlled.

"That success story shows the important role of community pharmacists in reducing health problems before they reach the stage of NHS treatment," she said. "Lifestyle clinics run by community pharmacists should be rolled out across Wales." She urged Ms Hutt to support a bid from Community Pharmacy Wales for 40 clinics.

Ms Burnham also called for pharmacists' formal training to encompass alternative medicine, including aromatherapy.

Geraint Davies, assembly member for Rhondda (Plaid Cymru), who is a pharmacist, said that proposals to delay legislation to provide for repeat dispensing in Wales had caused great concern in the profession (*PJ*, 22 June, p865).

UKMI technician course launched

A COURSE in medicines information for pharmacy technicians has been launched by the United Kingdom Medicines Information Pharmacists Group.

The course has been designed for technicians who are already working in medicines information roles and involves pre-course tasks, a residential course, and a training period followed by competency based assessments. It mirrors other role development schemes run throughout the National Health Service.

The pre-course tasks aim to bring all the

participants, each with different experience in medicines information, to a similar point in terms of understanding the functions of medicines information services. The first cohort of 26 technicians from around the United Kingdom recently attended a residential course held at Aston Business School.

A second cohort for the course will be identified following evaluation of the first course.

Course details can be found on the web at www.smmit.nhs.uk/ukminedinfoctr.htm.

Call for change to guidelines following publication of Heart Protection Study

GUIDELINES on the management of coronary heart disease should be changed so that a statin is considered for anybody at increased risk of heart attack or stroke regardless of their blood cholesterol level. This recommendation follows publication of the Heart Protection Study in *The Lancet* this week (2002;360:7).

"The clear message from this study is: 'Treat risk — not cholesterol level'," said Professor Sir Charles George, medical director of the British Heart Foundation.

Researchers from the Heart Protection Study collaborative group estimate that implementing the study findings, which were presented last November at the American Heart Association conference in Los Angeles (*PJ*, 17 November 2001, p701 and 24 November 2001, p740), would more than triple the number of people benefiting from statins and could save an extra 10,000 lives each year. In the United Kingdom, the number of people treated with statins would increase from a current figure of less than one in 20 of the population aged over 40 (or about one million people) to about one in eight (about three million people), they say.

In the study, 20,536 adults with coronary heart disease, arterial disease or diabetes were randomly assigned to receive either 40mg simvastatin or placebo daily for

five years. Death from all causes occurred in 14.7 per cent of patients given placebo compared with 12.9 per cent of those given simvastatin ($P=0.0003$). This was mainly due to an 18 per cent relative reduction in the coronary death rate in patients assigned simvastatin (5.7 per cent versus 6.9 per cent, $P=0.0005$).

The National Service Framework for Coronary Heart Disease recommends that high risk patients — those with diagnosed coronary heart disease and those who are at a greater than 30 per cent risk of coronary heart disease over 10 years — should receive treatment with lipid-lowering drugs to reduce cholesterol levels to below 5mmol/L. However, the Heart Protection Study results suggest that there are substantial benefits among high-risk patients considered to have normal or low cholesterol levels.

Professor Rory Collins of the clinical trial service unit at Oxford University and lead investigator said: "HPS shows unequivocally that statins can produce substantial benefit in a very much wider range of high-risk people than had been thought." He added that it was not known how cost-effective implementing these findings would be. "We do recognise that the drug costs will be significant. But, we believe that the level of

benefit in these high-risk patients is so great that treating them will be extremely cost-effective."

The researchers comment that most patients who would benefit from statins would already be known to their doctors because of their past medical history. Dr Jane Armitage, clinical co-ordinator for the study, said: "Implementing these findings does not require massive public health education campaigns by governments. It simply needs the guidelines to be changed so that doctors check their medical records and identify those patients with vascular disease or diabetes who we now know would benefit substantially from statin therapy."

The Heart Protection Study also assessed the effects of using antioxidant vitamin supplements (600mg vitamin E, 250mg vitamin C and 20mg beta-carotene daily) in people at high risk of vascular disease. Use of these supplements appeared to be safe and increased blood vitamin concentrations. However, they did not produce any significant reductions in the five-year risk of heart attacks, strokes, cancers or other major outcomes (ibid p23).

NPA says Society reform plans were on target two years ago

THE Royal Pharmaceutical Society should go back to reform proposals produced by its Health Act Working Party two years ago and submit these, or an amended form of them, as its plan for regulatory reform for the profession.

That is the view of the National Pharmaceutical Association's management board, formulated at its June meeting.

Considering the Society's consultation paper "What will the Council look like in the future: (1) responsibilities and composition" the NPA board was unable to see how the proposed model of a small professional majority would achieve the aim of retaining both professional and regulatory functions with an appropriate balance between the two roles.

A modern regulatory function will require a significant lay presence on the Council and a narrow professional majority, while a professional body will need a larger professional majority, the NPA says.

The NPA board's view is that the model proposed by the Society is exclusively based on a regulatory function and that this is evidenced by the fact that throughout the document the Society relies upon existing regulatory bodies including the General Medical Council, General Dental Council

and General Optical Council, as comparators.

Two years ago, the Society's Health Act Working Group put forward proposals to leave the Council unchanged and create a number of committees with delegated authority to focus upon aspects of professional regulation (*PJ*, 22 April 2000, p616). The board says that these have been rejected because a Council whose structure does not fulfil the requirements of a modern regulator will not retain its regulatory powers, but that this conclusion has been reached without exploring alternative models.

"In deciding to retain a regulatory and professional body function 'under one roof', the Society wants to make the most of the unique position it holds as both a professional body and a regulator," the NPA says. "In doing this, it is by definition setting itself apart from other regulatory bodies and it must surely follow that a different constitutional model will be needed if it is to adequately perform both functions."

If the model proposed in the paper is adopted, the NPA believes that the Society should make it clear that in re-configuring the Council composition to fall into line with other regulatory bodies, the Society is making itself just that, a regulatory body.

IN THIS ISSUE

SOPs for dispensing
Standard operating procedures for the dispensing process should be up and running in all pharmacies by 2005, says the Royal Pharmaceutical Society. Guidance on developing and implementing SOPs is published this month in the latest edition of 'Medicines, ethics and practice: a guide for pharmacists' (p36), and the implications are examined in a News Feature this week (p12).

Anglia pharmacy school opens in 2003

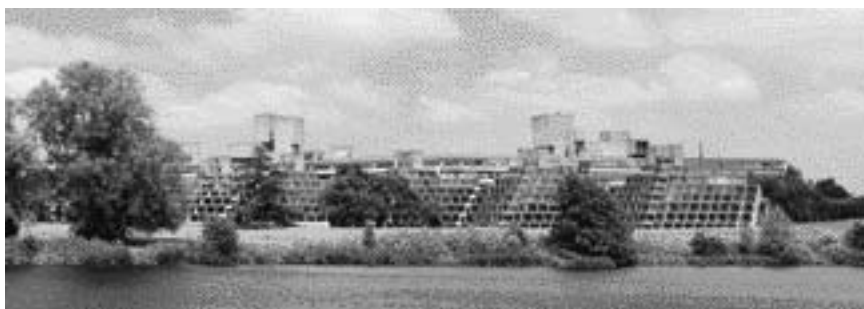
A NEW pharmacy degree starts at the University of East Anglia (*PJ*, 5 May, 2001, p208) next year. The course is expected to help address the shortage of pharmacists in the east of England, which is the part of the United Kingdom with the highest vacancy rate for pharmacists.

There has been a National Health Service academic pharmacy practice unit (APPU) based at the UEA since 1994. Now the university expects to welcome its first 72 undergraduates to a four-year master of pharmacy degree in September 2003.

The APPU's director and regional specialist in pharmaceutical quality assurance, Bob Shaw, said he was delighted at the university's expansion into the field.

"There is a national shortage of graduate pharmacists, which is especially acute in the eastern region, but there is currently no school of pharmacy here. This is a very welcome move," he said.

The UEA's dean of chemistry and phar-



Seventy-two pharmacy students will start their MPharm degrees in Norfolk next year

macy, Professor Andrew Thomson said: "Pharmacy is a science-based subject which sits well alongside chemistry. The development of this new degree course is a natural progression for UEA, which enjoys a strong reputation in both science and health disciplines. This is particularly timely with the opening of our new joint venture school of medicine."

"We have met representatives of the pharmacy community from all over the eastern region, and they have expressed great enthusiasm for the plans," said Professor Thomson.

"We will be working closely with hospital and retail pharmacists who will come in as teacher-practitioners to share professional skills with the students."

Pharmacist jailed for NHS fraud

A YORKSHIRE pharmacist has been sent to jail for six months after being convicted of defrauding the National Health Service of nearly £9,000.

Sitting at Leeds Crown Court on 14 June, Judge Peter Hunt told Bhupinder Bharj, of Grange Park Mews, Morley, that dishonestly depriving the NHS of funds was a breach of trust and that he had a public duty to send him to prison.

Nicholas Dry, prosecuting, told the court that between October 1998 and September 2001, Mr Bharj had made fraudulent claims from his pharmacy at 227 Dewsbury Road, Leeds. He had endorsed prescriptions to say that he had, for example, dispensed five 100ml bottles of medicine, rather than one 500ml bottle. By doing this with one particular brand he was paid £6.40 instead of £2.70. An investigation by an NHS fraud team had discovered false claims

for 4,389 items amounting to £8,894.47 and Mr Bharj was arrested in January this year. He admitted making false claims and said that he believed he had sometimes been paid for larger quantities when he had dispensed smaller ones.

Mr Dry told the court that 18 years ago Mr Bharj had been convicted of an offence involving a stolen cheque and had been fined.

In mitigation, Mark McKone told the court that Mr Bharj would no longer be able to practise as a pharmacist and would sell his business to make full compensation. He had qualified in 1980 and had learned of overcharging almost as part of his training. It became almost acceptable and pharmacists justified it because there were some financial losses with out-of-date stock and giving patients more tablets than were prescribed. It was often viewed as a balancing exercise.

NPA supports supplementary prescribing plan

GOVERNMENT proposals to allow pharmacists to be supplementary prescribers (*PJ*, 20 April, p521) have been generally supported by the National Pharmaceutical Association.

Although they endorsed most of the proposals, NPA board members decided at their June meeting that they strongly opposed the principle set out in the consultation paper that prescribing and dispensing responsibilities should be kept separate. Separation is not needed because two health professionals will be involved in the care of patients, the NPA believes.

In general, the NPA supports all the proposed legislative requirements and agrees with the recommendation that supplementary prescribing should not be restricted to a specific list of clinical conditions because flexibility was needed where patients had multiple conditions, all of which might be managed by a supplementary prescriber.

There is also NPA support for the proposal that the range of medicines suitable for supplementary prescribing should not be restricted.

However, there is concern at the NPA over possible training and accreditation requirements for pharmacists and nurses to become supplementary prescribers. Board members believe that community pharmacists will be at a distinct disadvantage if required to undertake a minimum number of days of teaching contact time. They believe that distance learning will be a more appropriate route and that the key issue is for pharmacists to be able to demonstrate core competencies if they want to become supplementary prescribers.

NPA considers individual members

INDIVIDUAL pharmacist membership of the National Pharmaceutical Association is being seriously considered by its management board.

At their June meeting, members of the NPA board considered a discussion paper as part of the implementation of the association's five year strategic plan. One of the plan's objectives is to maximise NPA membership. Board members decided that, while remaining faithful to its core membership — community pharmacy owners — a pharmacist membership category would benefit members as a whole by ensuring that pharmacists receive appropriate support services to enable them to practise to a high standard, by strengthening the NPA's represen-

tational voice and by increasing revenue.

The proposal means that pharmacist members might get a range of services including: access to the information department and its resources; training/continuing professional development materials; NHS service development resources; professional indemnity (a range of options tailored to suit particular needs); financial services (pensions, banking, mortgages and other loans, tax and accounting, private health insurance); and lifestyle services (holidays, travel insurance, car purchase). There might also be a pharmacists' forum where pharmacists could discuss issues that affect them in practice. The forum's views could help inform NPA decision making and policy.

Hormone replacement therapy offers no protection against heart attacks . . .

LONG-TERM use of hormone replacement therapy (HRT) in postmenopausal women does not reduce the risk of heart attack or death, say researchers. Furthermore, such therapy increases the risk of venous thromboembolism and biliary tract surgery and does not seem to offer any benefit for other major disease outcomes.

These conclusions come from HERS II, a follow-up to HERS (heart and estrogen/

progestin replacement study), a randomised, placebo-controlled trial to determine the effects of estrogen plus progestin in older postmenopausal women with heart disease (see Panel).

The researchers previously reported that risk of heart attack increased among women during the first year of HRT (*Pf* 29 August 1998, p300) and that coronary events among hormone-treated women then seemed to decrease over the next several years. The researchers speculated that the results were a consequence of early thrombotic effects masking HRT's cardioprotective effects. This led to the recommendation that women with coronary heart disease should not start taking HRT because of the immediate increased risk but that women who had used HRT for several years could continue therapy.

However, data from the current study suggest that the trend toward a reduced risk of heart attacks does not persist. Over the seven years of the combined studies, there was no overall reduction in risk for coronary events among women taking hormones. "These results raise the possibility that the early increase in risk of coronary heart disease events observed in HERS, as well as the

decrease in risk during years three to five, may have occurred by chance," the researchers say. They also suggest that chance may explain their finding that risk of hip fracture was higher among women treated with HRT than among women treated with placebo (*JAMA* 2002;288:49 and 58).

Trial details

HERS II was a 2.7-year follow-up of the 4.1-year HERS study. Participants in HERS were randomly assigned to receive either 0.625mg conjugated estrogen plus 2.5mg medroxyprogesterone acetate, or placebo daily.

During the HERS II follow-up the women chose whether or not to take hormones based on advice from their doctor (many in the hormone group continued taking hormones and few in the placebo group began). A total of 2,763 postmenopausal women with coronary heart disease were enrolled in HERS.

. . . but appears safe in heart disease

LOW-DOSE hormone replacement therapy (HRT) can be given to postmenopausal women with coronary heart disease, new trial data indicate.

The WHISP (women's hormone intervention secondary prevention) study tested whether it was safe to give a low-dose HRT regimen (estradiol 1mg daily plus norethisterone 0.5mg daily) to women who had experienced acute coronary syndrome with-

in the past 28 days. No difference was seen in the incidence of death, myocardial infarction, stroke or cardiovascular admissions in women treated with HRT (n=47) compared with that for women given placebo (n=48). Women were treated for between three and 12 months. The results of the Novo Nordisk-funded study, were presented at the 10th World Congress on the Menopause, held in Berlin last month.

Oral contraceptives not associated with increased risk of breast cancer

CURRENT or former use of oral contraceptives is not associated with an increased risk of breast cancer among women aged 35 to 64 years, say researchers in the United States.

The researchers conducted a case control study in which 4,575 women with breast cancer and 4,682 controls were interviewed. Seventy-seven per cent of the women with breast cancer and 79 per cent of the controls had used some type of oral contraceptive pill.

The investigators found that the relative risk of breast cancer was 1.0 (95 per cent confidence interval, 0.8 to 1.3) for women currently using oral contraceptives and 0.9 (0.8 to 1.0) for those who had previously used them compared with the risk among controls. There was no significant increase

in risk for women who had used oral contraceptives for long periods, for women who had begun taking oral contraceptives before 20 years of age, for those with a first degree relative with breast cancer or for those taking a higher dose of estrogen. The risk was similar for women aged between 35 and 44 years and those aged between 45 and 64 years, and among white and black women (*New England Journal of Medicine* 2002;346:2025).

In an accompanying editorial (*ibid* 2078), Dr Nancy Davidson and Dr Kathy Helzlsouer, Johns Hopkins University, Baltimore, say: "The study provides further reassurance that oral contraceptive use, even for a long period, is not associated with an increased risk of breast cancer."

BRIEFLY

Pharmacist at centre of MMR debate
Research led by pharmacist Paul Shattock, director of Sunderland University's Autism Research Unit, is at the centre of the latest MMR debate to be reported in the national press. Mr Shattock reports that abnormalities have been found in the urine of children whose parents believe that their child's condition was caused by MMR vaccination. The data have not been published.

SIGN postnatal depression guidance
The Scottish Intercollegiate Guidelines Network has issued guidance on the management of postnatal depression. The guidance includes recommendations for drug treatment and considers issues that need to be addressed when drugs are prescribed during pregnancy and when a mother is breast feeding. The guidance is available on the SIGN website (www.sign.ac.uk).

Sibutramine risk/benefit favourable
A safety review of sibutramine conducted by the European Agency for the Evaluation of Medicinal Products has concluded that the risk-benefit profile of the anti-obesity drug remains favourable. The EMEA was asked to reassess the safety and efficacy of sibutramine by the Italian health ministry.

Gehe agrees to buy Irish Unicare chain

GEHE has agreed to buy the Irish Unicare chain some five months after pulling out of a /152m purchase deal.

Legal action by Unicare, seeking to have the original contract enforced, was due to start in the Irish High Court in Dublin this month. The new deal now agreed is understood to include an additional /2m to meet the Irish chain's legal costs in preparing for the court action.

The German group agreed a purchase price for the 29-strong Unicare chain last October, and the takeover was sanctioned by the Irish Competition Authority. But in January, the Irish Health Minister announced that pharmacy regulations were being revoked and the sector deregulated. Within weeks, Gehe declared it was pulling out of the Unicare deal, claiming it would be impossible for the chain to deliver on performance targets.

Behind-the-scenes negotiations have now led to a compromise. The new purchase price has not been revealed, but is reported to be some /30m below that originally agreed, and both sides have declared themselves happy with the outcome.

Gehe now has 46 pharmacies in Ireland, making it the largest chain ahead of Boots, which has 30 pharmacies.

SPF condemns minister for ignoring pharmacy violence

THE Scottish Pharmaceutical Federation (SPF) has condemned the Scottish Health Minister, Malcolm Chisholm, for failing to take a Parliamentary opportunity to condemn violence and threats directed at community pharmacists and their staff.

"Threats and actual acts of violence are on the increase in Scotland's pharmacies," said Mr Ian Johnstone, chairman of the SPF. "The Minister's failure to address this in Parliament is not acceptable."

His comments came after questions in the Scottish Parliament on 27 June from the convener of the Health and Community Care Committee, Margaret Smith. Ms Smith highlighted the case of community pharmacists confronted by violent patients and asked whether the Scottish Executive planned to do anything about it or to change the law to make assault against public sector workers the more serious offence of aggravated assault.

Mr Chisholm said that this was a matter for the Lord Advocate, not the Minister of Health and Community Care.

Ian Johnstone said: "The Minister chose not to reply to this specific question. We understand and have the greatest sympathy with other health care professionals who

face threats and actual violence but the Minister and the Scottish Executive have completely missed the point. On a daily basis community pharmacies, which have as a necessity an open door policy, are visited by 600,000 people. A minority of these, who are mainly drug abusers, regularly pose a threat, be it potential or actual."

Mr Johnstone added: "We are deeply frustrated that the Minister did not take the opportunity to address our growing concerns nor appeared to understand that violence to NHS staff and contractors is not confined to hospitals and surgeries. It is an everyday reality for community pharmacists and one which urgently requires to be addressed by the Scottish Executive."

BRIEFLY

Online internet training
Online internet training for pharmacists, students, lecturers and researchers has been launched by King's College London at www.sosig.ac.uk/vt/s/pharmacist/.

Tablet crushing by nurses widespread

THE practice of crushing tablets is widespread in nursing homes in the United Kingdom, with 84 per cent of nurses having crushed tablets or opened capsules for patients over the past 12 months, according to Dr David Wright, lecturer in pharmacy practice at the University of Bradford.

Dr Wright warns: "The crushing or opening of medication results in unlicensed administration with the liability lying solely with the nurse if unauthorised or shared with the prescriber if authorised." He advises that nurses should, as an absolute minimum, seek advice from a pharmacist before crushing medicines.

Dr Wright has shown that crushing tablets or opening capsules in response to swallowing difficulties or for administration via enteral feeding tube takes place in over 80 per cent of nursing homes on at least a weekly basis. "With the availability of most oral medicines as a liquid formulation, the majority of reported crushing or opening that is taking place is unnecessary," he says.

A sample of 540 nurses working in nursing homes completed a questionnaire about how they administer medicines and the problems they face.

They reported that, on average, 15 per cent of nursing home residents had difficulty swallowing tablets and capsules and that 5 per cent regularly spat out their medicines.

Nurses responded to these difficulties by mixing medicines with food (56 per cent of nurses), omitting the dose (27 per cent) and tablet crushing (61 per cent).

Most nurses said they would be willing to ask the prescriber for a liquid alternative but over half stated that the prescriber might recommend that medicines be crushed or opened.

In the study, 82 per cent of nurses said they would consult a pharmacist if advice was needed but 10 per cent said that they never sought advice before crushing tablets or opening capsules (*Nursing Standard* 2002;16:33).

Sodium cromoglicate fails in URTIs

A STUDY designed to test whether sodium cromoglicate would be a useful treatment for upper respiratory tract infections (URTIs) has shown that the drug does not shorten the duration of infection.

Sodium cromoglicate inhibits ICAM-1, an intracellular adhesion molecule that is the receptor for 90 per cent of human rhinoviruses. This, and the results of several efficacy studies, has raised the possibility that sodium cromoglicate could be a treatment for viral infections of this type.

However, when Dr Chris Butler and colleagues from the University of Wales College of Medicine, Cardiff, assigned 290 children with suspected acute viral URTI to receive either intranasal 4 per cent sodium

cromoglicate spray or intranasal normal saline spray they found no difference in response between the groups.

A subgroup analysis showed that sodium cromoglicate was equally ineffective for children who were seen early on in their illness, for children who did not have a runny nose, and for children aged five years and older.

These findings, say the researchers, suggest that any lack of efficacy was not caused by the children presenting too late for treatment to be effective, nasal secretions preventing contact with target molecules, or caregivers struggling to give the nasal spray to young children (*Lancet* 2002; 359:2153).

United Kingdom to grow its own opium

SUFFICIENT opium poppies for the production of morphine and codeine for medicinal use in the United Kingdom are to be grown domestically. The Home Office said that following small-scale trials last year, 400 hectares (1.54 square miles) of opium poppies are now growing in the UK.

Historically, British opium supplies have been obtained overseas and processed by Macfarlan Smith, based in Edinburgh. Now, the domestically grown crop means that supplies will be less vulnerable to the seasonal and market fluctuations associated with imported supplies.

The locations at which the poppies are being grown are to be kept secret.

Lansoprazole reduces ulcer recurrence for patients on aspirin

LANSOPRAZOLE (Zoton) reduces the risk of recurrences of ulcer complications in patients taking low-dose aspirin, according to researchers from the department of medicine and surgery, University of Hong Kong.

The researchers conducted a randomised controlled trial involving 123 patients. Those entered into the study had presented with ulcer complications and had proven *Helicobacter pylori* infection. All patients had been receiving low-dose aspirin (less than 325mg daily) for at least one month and had a disease that required long-term low-dose aspirin therapy.

H pylori infection was eradicated with a one-week course of triple therapy (lansopra-

zole, amoxicillin and clarithromycin). This was followed by five weeks of ulcer treatment with 20mg famotidine twice daily. If ulcer healing was achieved and *H pylori* infection eradicated, patients then went on to receive trial medication — 100mg aspirin, plus either 30mg lansoprazole or placebo, once daily. After an average follow-up of 12 months the researchers found that 14.8 per cent of patients in the placebo group experienced recurrence of ulcer complications, ie, bleeding, perforation or obstruction, compared with only 1.6 per cent of patients in the lansoprazole group ($P=0.008$).

The study is published in *The New England Journal of Medicine* (2002;346:2033).

BRIEFLY

Herbal medicines consultation extended

A Medicines Control Agency consultation on the regulation of herbal medicines has been extended until 31 July. The extension is to give manufacturers more time to produce evidence in support of claims that regulation will reduce the availability of products (*PJ*, 6 April, p454).

AAH sponsors concert tour

AAH pharmaceuticals is to provide a lorry and driver for a one week tour of Great Britain and The Netherlands by the National Youth Orchestra of Scotland.

Candesartan reduces risk of stroke in elderly

THE angiotensin-II receptor antagonist candesartan (Amias) reduces the risk of non-fatal stroke in elderly patients with mild hypertension, researchers reported at a meeting of the International and European Societies of Hypertension held in Prague last week.

The results come from the SCOPE (study on cognition and prognosis in the elderly) trial, which was carried out in 15 countries, including the United Kingdom.

In the trial, 4,937 patients with treated or untreated hypertension, aged between 70 and 89 years, were assigned to receive either candesartan 8mg or placebo once daily.

Those patients whose blood pressure remained high were given additional anti-hypertensive treatment. The recommended add-on treatment was hydrochlorothiazide 12.5mg once daily and, of the patients in the placebo group, 84 per cent were assigned add-on treatment.

The researchers found that candesartan reduced the risk of non-fatal stroke by 28 per cent — non-fatal stroke occurred in 68 patients taking candesartan (n=2477) and 93 patients in the placebo group (n=2460).

They also found that patients taking candesartan had an 11 per cent risk reduction in major cardiovascular events (cardiovascular death, non-fatal myocardial infarction and non-fatal stroke) and showed a beneficial trend towards a delay in the onset of type II diabetes, although neither of these trends achieved statistical significance when compared with the control group.

Professor Gary Ford, University of Newcastle, and lead researcher for SCOPE in the UK, told *The Journal* that he thought that significance was not achieved in these cases because the add-on antihypertensive treatment received by patients in the placebo group had resulted in better blood pressure control than expected.

He commented that the results of the study confirm that blood pressure lowering in the elderly is beneficial in reducing stroke.

The researchers also found that cognitive function was maintained in patients taking candesartan despite that fact that lowering blood pressure in the elderly is thought to increase the rate of cognitive decline.

Asian patients miss out on cholesterol lowering drugs

PATIENTS in general practices with a greater south Asian population are less likely to be prescribed lipid-lowering drugs than patients in practices with a higher proportion of white patients, a study in this week's issue of the *BMJ* shows (2002;325:25). This is despite south Asian patients being at a higher risk of coronary heart disease than white patients.

Mahendra Patel, School of Pharmacy, University of Bradford, and colleagues identified the proportion of south Asian patients at 62 general practices in one health authority in England. They then determined the number of daily doses of all lipid-lowering drugs prescribed to these patients.

Commenting on their finding, the researchers say: "This may be surprising given the higher cardiovascular morbidity and mortality among south Asian people in the United Kingdom and a possible need for lipid-lowering treatment that is equal to, if not greater than, that for the white population."

A standard assessment to determine the extent of unmet need and risk profiles at the level of the individual patient is required, the researchers conclude.

Advertisement

COX-2 inhibitor close to launch shows similar efficacy to traditional NSAIDs

VALDECOXIB, a new cyclo-oxygenase (COX) 2 inhibitor, provides similar pain relief to older non-steroidal anti-inflammatory drugs (NSAIDs) but with better gastrointestinal tolerability, according to trials in osteoarthritis and rheumatoid arthritis presented last month at the European League Against Rheumatism (EULAR) meeting in Stockholm.

In the osteoarthritis trial, 1,019 patients with osteoarthritis of the knee were randomly assigned to receive valdecoxib 5mg, 10mg or 20mg once daily, naproxen 50mg twice daily, or placebo, for 12 weeks. Arthritis assessments made at baseline and at two, six and 12 weeks showed that valdecoxib at doses of 10mg and 20mg was as effective as naproxen ($P < 0.05$ versus placebo) in relieving symptoms of osteoarthritis. However, endoscopic examination showed fewer patients had ulcers with valdecoxib than with naproxen.

In the rheumatoid arthritis trial, 722 adults were randomised to receive valdecoxib

20mg or 40mg once daily or diclofenac SR 75mg twice daily. Results showed similar efficacy for both valdecoxib and diclofenac based on

standard measures of patient-reported pain relief and functional ability. The incidence of endoscopically detected ulcers was 6 per cent in patients treated with 20mg valdecoxib, 4 per cent in those given 40mg valdecoxib and 16 per cent in the diclofenac group ($P < 0.001$).

Presenting the findings, Dr Frank McKenna, consultant rheumatologist, Trafford General Hospital, Manchester, said: "The study results suggest that valdecoxib is significantly less likely to cause ulcers than diclofenac and may be an option for the long-term treatment of the pain and inflammation of rheumatoid arthritis."

Valdecoxib has faster onset of action than other agents in models of acute pain. It is currently being evaluated for marketing authorisation in the European Union, and is already approved for treating osteoarthritis,

adult rheumatoid arthritis and primary dysmenorrhoea in the United States. It is being developed by Merck Sharp & Dohme and is expected to be launched in the United Kingdom later this year.

Osteoarthritis treatment may be safe with aspirin

A NEW treatment for osteoarthritis, licofelone, the first of a group of agents known as LOX-COX inhibitors, could make it possible for patients with co-existing cardiovascular risk factors to achieve effective and safe pain relief while taking aspirin, new data in rats suggest. Data were presented at the European League Against Rheumatism (EULAR) meeting in Stockholm last month.

Licofelone blocks not only cyclo-oxygenase (COX)-1 and COX-2 but also 5-lipoxygenase (LOX), so addressing the role of leukotrienes in the arthritic inflammatory process. It may also spare the gastric mucosa in patients taking aspirin, for cardiovascular risk factors, by simultaneously inhibiting LOX as well as COX pathways, researchers say.

Professor Stefano Fiorucci, associate professor of gastroenterology at the University of Perugia, Italy, said that patients taking aspirin for cardiovascular risk factors needed effective pain management with no increased risk of myocardial infarction or gastrointestinal damage and that licofelone was an appropriate treatment option. "We will have to wait for clinical data, but animal data look extremely promising," he said.

In a phase III study presented at the meeting, licofelone was shown to have equal efficacy to non-steroidal anti-inflammatory drugs such as naproxen with reductions in the risk of developing gastrointestinal damage. Researchers randomly assigned 710 patients with osteoarthritis of the knee to receive licofelone 100mg or 200mg or

naproxen 500mg, twice daily. They found that all three treatments were equally effective in relieving pain.

The incidence of gastrointestinal ulcers was, however, lower in patients treated with licofelone than in those treated with naproxen.

A phase II study compared licofelone 200mg and 400mg with naproxen 500mg, twice daily, and placebo in 118 patients with knee osteoarthritis. Each patient was given an endoscopy after just four weeks of treatment.

There was no evidence of damage to the gastric mucosa in any of the patients assigned to receive licofelone or placebo. But 20 per cent of those taking naproxen had signs of ulceration.

Novel strategy for anti-obesity drugs

A DUODENAL hormone has been found to be a potential target for anti-obesity drugs, researchers report. Secretion of this hormone, gastric inhibitory polypeptide (GIP), is induced by the absorption of ingested fat or glucose and links overnutrition to obesity.

The researchers found that mice lacking the receptor for GIP that were fed a high-fat diet were protected from both obesity and insulin resistance. They comment that in the absence of the receptor, fat is used as the preferred energy source rather than accumulating in adipocytes and causing obesity.

The study is to be published in *Nature Medicine*.

Enzyme inhibitor improves symptoms of peripheral neuropathy in diabetic patients

AN ENZYME inhibitor in development, LY333531, improves the symptoms of diabetic peripheral neuropathy, according to the results of a phase II trial. Eli Lilly, developing the inhibitor, says that LY333531 selectively inhibits protein kinase C beta in vascular, retinal and renal tissues. Activation of this enzyme under conditions of hyperglycaemia is one of the main mechanisms of microvascular complications in patients with diabetes.

Researchers randomly assigned 205 patients with type 1 or type 2 diabetes and diabetic peripheral neuropathy to receive LY333531 or placebo. They found that, compared with placebo, LY333531 led to

improvements in neurological symptoms — notably in the lower limbs and reflexes, which are most affected by diabetic peripheral neuropathy. Improvements in symptoms such as numbness, prickling, aching pain, burning pain and lancinating pain were seen in 83 patients given LY333531.

LY333531 is also being investigated for the treatment of diabetic retinopathy and diabetic nephropathy. Eli Lilly expects to apply for a licence for LY333531 in the United Kingdom for use in the treatment of diabetic retinopathy within the next two years. Data were presented at the 62nd scientific sessions of the American Diabetes Association held in San Francisco last month.

Novel antibiotic for targeting resistant pathogens in early stage development

A NOVEL broad-spectrum antibiotic that targets resistant pathogens has been entered into early stage development by Aventis Pharma. Phase I trials of the antibiotic, AVE-6971, are expected to begin next year.

Dr Frank Douglas, executive vice-president for drug innovation and approval, Aventis, speaking at the company's research and development day in London last month, said that AVE-6971 has a different mechanism of action to fluoroquinolones and linezolid and works by inhibiting topoisomerase IV, an enzyme involved in bacterial DNA replication. It is bactericidal against methicillin-resistant *Staphylococcus aureus* and has good oral efficacy in mouse models.

Several other drugs in early-stage devel-

opment were also highlighted at the meeting. An orally active immunomodulator for the treatment of multiple sclerosis that blocks pyrimidine synthesis, 1726, has entered phase II trials, and a new, non-hypnotic, serotonin (5-HT_{2a}) antagonist, 100,907, has been shown in a recently completed phase I trial to be promising for improving sleep quality.

AVE-7688, in development for the treatment of hypertension and congestive heart failure, has also been found, in preclinical trials, to be more potent than ACE inhibitors in preventing renal disease. Dr Douglas commented that this agent may be used for the prevention of diabetic neuropathy as well as treatment.

A colorectal cancer vaccine in the pipeline, ALVAC-CEA, which works by eliciting a tumour-specific response without toxicity, has been shown to stabilise disease in one-third of patients studied over a two-year period. Aventis is currently working on a second vaccine to target multiple antigens.

A new formulation of docetaxel (Taxotere), LIT-976, has an improved safety profile over the current formulation and has the potential to be used in combination with other antineoplastic agents.

At the meeting, Aventis announced that Lantus (insulin glargine), a recombinant basal insulin analogue for once daily delivery, is expected to be launched in the United Kingdom later this year.

Two potential agents for acute myeloblastic leukaemia identified

TWO new agents that might be useful for the treatment of patients with acute myeloblastic leukaemia (AML) have been identified, researchers report in *Cancer Cell*. Both agents, CT53518 and PKC412, inhibit tyrosine kinase FLT3 receptors, mutations of which have been found in over a third of patients with AML.

Dr Louise Kelly, Brigham and Women's Hospital, Boston, Massachusetts, and colleagues report that CT53518 has high oral bioavailability in animal studies and a good safety profile in chronic administration. Therapeutic efficacy of CT53518 was demonstrated in a nude mouse model and in a bone marrow transplant model of AML cell lines expressing the most common mutation of FLT3. The researchers say that apoptosis was induced by CT53518 in these AML cells, a result similar to that observed when BCR/ABL-positive leukaemia cells are treated with imatinib (Gleevec).

The researchers conclude that based on similar reports of efficacy of imatinib in the treatment of chronic myeloid leukaemia blast crisis, CT53518 shows great promise for treating AML patients and clinical trials are under way (2002;1:421).

Dr Ellen Weisberg, Dana-Farber Cancer Institute, Boston, Massachusetts, and colleagues have also identified a potent inhibitor of the tyrosine kinase FLT3 receptor. The inhibitor, PKC412, is cytotoxic to mutant and wild-type FLT3 tyrosine kinases, as well as primary cells expressing mutant FLT3 receptors, and has potential as an antileukaemia agent, they say (ibid, p433).

Cytotoxic agent shows promise in MS treatment

AN INTERCALATING agent currently in phase III trials for the treatment of non-Hodgkin's lymphoma is also showing promise for the treatment of multiple sclerosis (MS).

Italian researchers compared the effects of the agent, BBR 2778, with mitoxantrone, a cytotoxic antibiotic (approved in the United States for the treatment of MS), in an experimental model of MS.

They found that both drugs, when repeatedly administered intravenously, were effective in preventing disease relapses, but better efficacy was seen with BBR 2778 than with mitoxantrone at the dose tested. Both drugs had a similar effect on reducing total white blood cell counts, but a greater reduction in lymphocytes was seen with BBR 2778. The researchers say that unlike mitoxantrone, with which dose-related cardiotoxicity can occur, BBR 2778 showed no evidence of having cardiotoxic properties.

Data were presented at the 12th meeting of the European Neurological Society held in Berlin last week. BBR 2778 is being developed by Novuspharma, Bresso, Milan.

Long-acting bronchodilator improves exercise tolerance in COPD

A NEW long-acting inhaled bronchodilator, tiotropium, has been found to improve exercise tolerance by over 20 per cent in patients with chronic obstructive pulmonary disease (COPD), according to results presented at the COPD3, International Meeting on Chronic Obstructive Pulmonary Disease, held in Birmingham last month.

Exercise intolerance is characteristic of advancing COPD, with resulting lower levels of exercise leading to deconditioning. In a double-blind, controlled trial 187 patients were assigned to receive either tiotropium 18µg daily or placebo. They were allowed to continue taking regular pulmonary medication, including inhaled beta-agonist bronchodilators, oxygen, steroids and theophylline, but not inhaled anticholinergic bronchodilators.

Mean baseline endurance time was 491.7 seconds. The difference in endurance time between tiotropium and placebo was 66.8 seconds at week three and 105.2 seconds by week six ($P=0.0098$). Tiotropium reduced breathlessness experienced by these patients taking exercise. Professor O'Donnell, Queen's University Ontario, Canada, involved in the research, said that these results were akin to those found with exercise training and that tiotropium appeared to be effective in relieving symptoms and increasing activity levels in COPD.

Tiotropium is expected to be launched in the United Kingdom this autumn. It is being developed by Boehringer Ingelheim and co-promoted by Pfizer and Boehringer.

Correction

Valdecoxib is being co-developed by Pharmacia and Pfizer and not be Merck Sharp & Dohme (p10).