

## Announcements expected soon

Important announcements on the future of the Royal Pharmaceutical Society's Charter and the new community pharmacy contract were expected to be made at the end of this week, after *The Journal* went to press.

On the matter of the Society's new Charter, the Privy Council was expected to announce its decision on whether or not it would recommend the Charter to the Queen for Royal Assent.

This follows the Council's decision to submit the draft Charter to the Privy

Council last month (*PJ*, 25 September, p445). The Privy Council met on 13 October to discuss the draft Charter but no announcement was made before *The Journal's* deadline.

Meanwhile, the Pharmaceutical Services Negotiating Committee was meeting to finalise the details of the funding of the new community pharmacy contract. An announcement is expected to be made within the next week.

Details will follow in next week's *Journal*.

## PSNC announces dates for new contract roadshows

The dates for the roadshows about the new community pharmacy contract have been announced this week by the Pharmaceutical Services Negotiating Committee.

The roadshows will be open only to pharmacy contractors (or their authorised managers) and local pharmaceutical committee members. Each will consist of a presentation by the PSNC followed by an opportunity to ask questions about the new contract.

A number of roadshows will be run simultaneously on dates over the next few weeks. The dates and places for the roadshows are:

- 31 October: Birmingham, Maidstone and Runcorn
- 4 November: Preston and Mold
- 7 November: Basingstoke, Brighouse, Cambridge and South Mimms
- 8 November: Carmarthen and London
- 11 November: Plymouth and Newport
- 14 November: Bristol, Darlington, Nottingham and Llandrindod Wells

Further information including details of the venues is available on the PSNC website ([www.psn.org.uk](http://www.psn.org.uk)).

## Trigger questions useful to identify medicines support need

The inclusion of four simple questions during the single assessment process (SAP) to trigger referral for an in-depth medication review can have a significant impact on the quality of patient care. This is the conclusion of a project that published its final report this week (at [www.london.nhs.uk](http://www.london.nhs.uk)).

The project, carried out by the London older people services development programme, identified 55 older people out of a sample of 68 who had an unmet pharmaceutical care need. Of these, 32 were referred for a detailed medication review.

The medication reviews showed that 88 per cent of older people needed an alteration to one of more of their medicines. As a result of the pharmacist's assessment, 40 per cent of prescribed medicines were changed. Furthermore, 25 out of the 32 older people required support from a community pharmacist to manage their medicines better.

Ian Philp, national clinical director for older people's services, Department of Health, commented: "Many older people are taking multiple medications and would benefit from a review by a pharmacist. This report highlights how improved assessment by front-line health and social care staff can identify older people who would benefit from this."

The review process involved a SAP assessor asking four previously identified "medicines trigger" questions as part of the SAP. The four questions are: Do you need help getting a regular supply of your medicines? Do you always take all of your medicines the

### Older people need help with medicines

way the doctor wants you to? Can you swallow and use all of your medicines and get all of your medicines out of their containers? Do you think that some of your medicines could work better?

If the response to any of these questions was "yes", the patient was referred to an assessing pharmacist for an in-depth medication review. The pharmacist drew up a pharmaceutical care plan that was sent to key people involved in the care of the patient. A community pharmacist then implemented the pharmaceutical care package and was responsible for monitoring progress. A follow-up review was undertaken after six months.

The project won a Pharmaceutical Care Award earlier this year (*PJ*, 3 July, p16).

Gary Watson/SPL

### Concern over CHRE powers

The Society's Council is to convey to the Council for Healthcare Regulatory Excellence its unease over a CHRE decision that, when investigating reasons for the apparent under-prosecution of cases, it has power to requisition evidence given in confidence to a regulator but not seen by its disciplinary committee (p579).

### Registration category

Pharmacists in "grey areas" of practice are to be offered advice by the Society on whether they should join the new practising register or the non-practising register (p581).

The Society

## SOS appeals for money to fund legal bills with the support of seven Council members

Seven members of the Royal Pharmaceutical Society's Council are supporting an appeal for funds to pay the costs of the four Society members whose court action ultimately led to the redrafting of the Charter currently with the Privy Council.

The appeal — by the Save Our Society campaign — aims to raise over £300,000 to pay the legal bills incurred by Hassan Argomandkhah, Mark Koziol, Graham Phillips and Mike Williams in their failed action for a High Court ruling. They unsuccessfully

argued that 16 members and former members of the Council and the Society acted outside the Charter when they petitioned the Privy Council for a new Charter.

The legal action caused the Privy Council to halt consideration of the proposed new Charter until legal proceedings ended. This was not until after the 2004 Council election, at which all seven available seats were taken by SOS supporters, including Mr Argomandkhah and Mr Phillips.

The proposed Charter was then amended by the new Council taking into account some of the SOS aims and resubmitted to the Privy Council last month.

"By having the courage to stand up for the rights of all of us in the profession, they have helped us," the appeal says. "Now the time has come for all of us to help them."

The seven Council members supporting the appeal are Gerald Alexander, Martin Astbury, Shiv Bagga, Sultan Dajani, Davan Eustace, Maurice Hickey and Noel Wicks.

# Pregnant women take medicines despite risks

Only 17 per cent of women avoid taking medicines during pregnancy despite the possible risk to the fetus, research has shown (*European Journal of Clinical Pharmacology* 2004;60:355).

Of 14,199 women surveyed, only 7.6 per cent did not report use of any medicinal product throughout their entire pregnancy. After exclusion of iron, folate, vitamins, supplements, herbal and homoeopathic products and skin emollients, 83 per cent of those completing all questionnaires had used conventional therapeutic drugs.

Analgesics, mostly paracetamol but also aspirin, were taken by 39 per cent of women during the early stages of pregnancy. Iron preparations were used by 33 per cent, 22 per cent took folic acid supplements and 23 per cent used antacids in mid to late pregnancy.

A requirement for medication is not surprising, considering that pregnant women suffer from a variety of symptoms, says the study's author, Judith Headley of the University of Bristol's department of community-based medicine. However, she observed that minor ailments were often self-treated with over-the-counter products.

She also suggests that some women turn to alternative therapies in order to avoid taking conventional medicines and may end up taking non-standardised herbal preparations.

"It is a long time now since the world was shocked by the effects of thalidomide, so perhaps it is time to remind women who may become pregnant that some drugs can be harmful and that they should seek advice from a health professional before self-medicating," Dr Headley warns. "All the research appears to suggest that the reported incidence of drug use in pregnancy is higher in recent years."

In response to the findings of the study, the British National Formulary issued a statement repeating its advice that medicines should be avoided during pregnancy as far as possible. However, it added: "Given that occasionally the potential for harm might be overstated, it is important to bear in mind that pregnant women can become worried and anxious if they are told that they should not have taken a medicine (even though the evidence for that medicine doing harm is weak).

"It is important to understand how many women have taken medicines during pregnancy, but it is even more important to determine the clinical outcome of their pregnancy."

**Pregnant women should seek advice before self-medicating**

## Pharmacists can reassure women who have epilepsy

Most women with epilepsy who continue to take antiepilepsy drugs are likely to have normal pregnancies with good outcomes, according to Hannah Cock, consultant neurologist at St George's Hospital medical school, London. "Pharmacists can reassure them about this," Dr Cock was speaking after publication of data highlighting the potential for developmental problems in the offspring of women exposed to antiepilepsy drugs.

The study showed that IQ scores for children exposed to valproate were lower than for other therapies (*Journal of Neurology Neurosurgery and Psychiatry* 2004;75:1575).

## Healthcare Commission needs effective teeth

The Healthcare Commission should have effective teeth and ensure that guidance from the National Institute for Clinical Excellence is implemented everywhere in England and Wales.

So stated Andrew Curl, deputy director general of the Association of the British Pharmaceutical Industry when he spoke at a media lunch earlier this week.

Mr Curl was responding to comments made by Sir Michael Rawlins, chairman of NICE, who two weeks ago urged patients' groups to take the NHS to court if it fails to provide the drugs and treatments NICE recommends. Professor Rawlins told an audi-

ence at a fringe meeting of the Labour Party Conference: "What I would love to see is a group of patients' organisations taking one trust to judicial review. It doesn't even have to get to court — but it would send the message out."

Mr Curl pointed out that although NICE was set up to end postcode prescribing it was widely acknowledged that it still occurred.

Kevin James, managing director of Wyeth UK, also speaking at the ABPI lunch, said that in some cases the uptake of new drugs was slow because the infrastructure was not always in place, for example the employment of skilled nurses to monitor patients.

## Additional funding for Agenda for Change

An extra £30m will be given to NHS organisations to help fund the implementation of Agenda for Change, it was announced last week.

The funding is to be used by NHS organisations to release staff to spend time negotiating or implementing Agenda for Change. For example, it could be used to employ locums to cover staff who sit on job evaluation boards or who are involved in negotiating local implementation deals.

Making the announcement, health minister John Hutton said: "The costs incurred by NHS organisations in releasing key trade

union representatives to participate in the implementation of the new pay system will be the first priority for the extra resource."

The money will be given to Strategic Health Authorities to distribute.

This week, a number of documents about Agenda for Change were published by the Department of Health. These include a booklet explaining the new pay system to staff, an NHS Knowledge and Skills Framework, and a new edition of the NHS Job Evaluation Handbook. All are available on the DoH website and can be accessed via links on *PJ Online* ([www.pjonline.com/links/pj](http://www.pjonline.com/links/pj)).

## NHS criminal record checks

New NHS staff who may come into contact with patients will be required to have a criminal record check from early next year, Health Minister John Hutton announced this week.

The Criminal Records Bureau checks will involve searching information held on the Police National Computer and by the Department for Education and Skills.

All staff with direct patient contact will be required to have these checks, as will any staff whose daily work may provide access to patients, such as maintenance workers. Although some NHS trusts already carry out criminal record checks, these checks are currently only mandatory for staff working with children.

## New workplace rules in force ETP will be up and running soon

New grievance, disciplinary and dismissal rules for all employers came into force on 1 October. The Pharmacy Mutual Insurance company has warned pharmacists who are employers that if they do not follow them they will face additional financial penalties at employment tribunals.

In essence, employers who are considering disciplinary action against any employee must put any complaint against the employee in writing, hold a meeting with the employee to discuss the matter and offer an appeal meeting where a decision is disputed.

Employees who have a grievance against their employers must follow the same rules. Failure by either party to follow this procedure will automatically count against them in any subsequent employment tribunal proceedings.

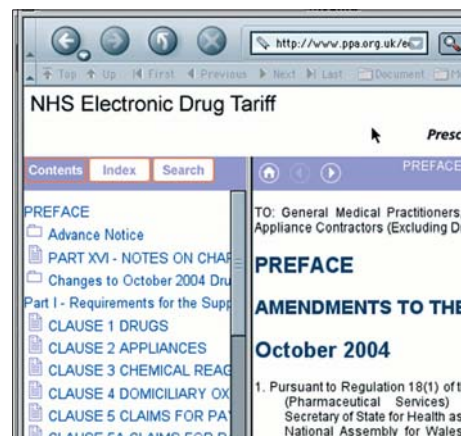
Employees also now have a statutory right to be accompanied by a companion or trade union official at any meetings of a disciplinary nature.

Electronic prescribing is likely to get off the ground within the next 12 months, the Prescription Pricing Authority predicts.

ETP (electronic transmission of prescriptions) is just one of three developments that are expected to pose a challenge to the PPA, according to its annual report for 2003–04. The others are new prescribers and modernised pharmacy services.

A further change presaged in the annual report is the gradual demise of the Drug Tariff in its printed form. The electronic Drug Tariff was launched on 1 May this year with the expectation that the printed form would be phased out as users transfer to the online version.

The report also makes clear that prescription pricing rules are likely to be simplified so that more prescriptions are priced according to automated rules, rather than needing personal attention from PPA staff. Likely changes include simpler dispensing fees and a single



**Electronic drug tariff will supersede printed version**

zero discount list. Simplification of the essential small pharmacies scheme is also suggested.

## NPA plans to promote pharmacy ownership NPfIT costs balloon

The benefits of pharmacy ownership should be promoted more strongly by the National Pharmaceutical Association, the NPA board decided at its meeting in September.

“With the new contract and the move from a supply to a clinical role, we believe that there will be renewed interest in owning a pharmacy,” said John D’Arcy, chief executive of the NPA. A range of options to promote ownership will be developed and discussed at the next NPA board meeting.

Meanwhile, issues around control of entry and the “balanced package of measures” were highlighted during an earlier meeting between the NPA and health minister Rosie Winterton. Mr D’Arcy explained: “We told her that we were pleased to see movement from the first proposals but that we still have concerns about the ‘choice and competition’ test. By definition, every new application will increase choice and competition. If the key test is ‘necessary and desirable’ then ‘choice and competition’ must be subservient to that.” Mr D’Arcy added that this could lead to

unforeseen consequences that would frustrate primary care trusts’ ability to plan services. He predicted that the new measures would result in 250 pharmacies opening initially. “At a time when we have a new contract, we need solidity in the marketplace,” he said.

Among the other items on the agenda, the board expressed concerns over the proposed POM to P switch of Calpol suspension (*PJ*, 7 August, p178). “It is a paradox that only two years ago the Government re-regulated paracetamol by imposing a maximum pack size and now plans to de-regulate Calpol,” commented Mr D’Arcy.

However, it was supportive of proposed European legislation that includes the introduction of a year’s data protection for new results as part of POM-to-P switches, an obligation on companies to test patient information leaflets on user groups and an obligation on manufacturers to tell the Medicines and Healthcare products Regulatory Agency about new information on a medicine’s risks and benefits (*PJ*, 7 August, p175).

Procurement costs for the NHS National Programme for Information Technology are likely to be dwarfed by the overall implementation cost.

Known procurement costs to date amount to £6.2bn, but an NPfIT spokesman has revealed that it was always expected that the total cost could be as much as £31bn.

“It is generally accepted in the IT industry that implementation costs are some three to five times the cost of procurements,” *Computer Weekly* quotes the spokesman as saying. “That is reflected in the business case that was made for the national programme.”

Two months ago, it was announced that NPfIT and its implementation is to be the subject of an inquiry by the National Audit Office (*PJ*, 4 September, p303).

## Hospital pharmacies should adopt online ordering systems

Hospital pharmacy departments are not making the most of technology when it comes to managing medicines, according to Jeff Bulmer, director of AAH Hospital Service.

AAH Pharmaceuticals has more than 94 per cent of community pharmacies ordering electronically but only 40 per cent of hospital pharmacies. Mr Bulmer said that hospitals that switch to electronic ordering and invoicing can potentially save millions of pounds. He added that, although many hospitals use technology effectively, some hold back from

introducing it to all areas — including pharmacy for procurement, invoicing and medicines management.

“Where ordering and invoicing are involved technology is a nettle they are fearful to grasp. Unless you know accurately what drugs are coming into the hospital system and are able to keep track of them, how do you know accurately what they are, where they are going and how they are being used, and what the need might be to make repeat purchases,” he asked.

### NPfIT chief to leave

Aidan Halligan, deputy chief medical officer and the civil servant with joint responsibility to see through the Government’s National Programme for IT (NPfIT), is to leave the Department of Health to take up a leading role in Ireland. Professor Halligan is to become chief executive officer of the Irish health service executive next April.

### ETP bulletin board

Pharmweb has launched a discussion group for pharmacists interested in electronic transmission of prescriptions (see [www.pjonline.com/links/pj](http://www.pjonline.com/links/pj)).

News in brief

# Docetaxel improves survival when hormones fail

Docetaxel (Taxotere) improves survival rates in men with advanced prostate cancer when hormone treatment fails, data from two studies show.

In the first study, more than 1,000 men were assigned to docetaxel (given weekly or every three weeks) plus prednisone or standard chemotherapy — mitoxantrone plus prednisone.

Men treated with docetaxel every three weeks survived longer and had improved response rates compared with men given mitoxantrone (median survival 18.9 months compared with 16.5 months,  $P=0.009$ ).

Overall, compared with the mitoxantrone group, patients in the docetaxel groups had better pain control and quality of life and more frequent prostate-specific antigen responses, but also experienced more adverse effects (*New England Journal of Medicine* 2004;351:1502).

The second study involved just under 800 men, also with advanced androgen-refractory prostate cancer, who were assigned to stan-

dard chemotherapy or docetaxel plus estramustine. Again, survival was prolonged in men treated with the docetaxel-based regi-

men (17.5 months compared with 15.6 months,  $P=0.02$ ).

Disease progression was also delayed among these men — median time to progression was 6.3 months in the group given docetaxel and 3.2 months for the group given mitoxantrone ( $P<0.001$ ). The researchers warn that these benefits must be balanced with an increased rate of adverse effects seen with the docetaxel plus estramustine regimen (*ibid*, p1513).

Nick James, professor of clinical oncology at the University of Birmingham and UK principal investigator of the first study, said: "Prior to docetaxel, no drug has ever shown a survival benefit for men with hormone-resistant prostate cancer. These results completely alter the standard treatment paradigms for the disease."

Sanofi-Aventis, manufacturer of Taxotere, hopes to receive regulatory approval for the drug's use in patients with hormone-refractory prostate cancer in the next three months.

## Prostate cancer: chemotherapy can improve survival

## Corticosteroids raise two-week death rate

Compared with placebo, the use of corticosteroids to treat head injury is associated with an 18 per cent higher risk of death within two weeks, a new study has shown (*Lancet* 2004;364:1321).

Corticosteroids have been used in the treatment of head injury for 30 years, because it is thought that post-traumatic inflammatory changes contribute to neuronal degeneration. Although previous studies had suggested that corticosteroids may slightly reduce the risk of death, the trials had been too small to provide conclusive results.

The CRASH (corticosteroid randomisation after significant head injury) trial aimed to provide a definitive answer. In May 2004, the data monitoring committee disclosed the unmasked results to the steering committee, which stopped recruitment to the trial.

A total of 10,008 patients with head injury from 239 hospitals in 49 countries were randomly allocated corticosteroids (methylpred-

nisolone) or placebo for 48 hours after admission to a hospital emergency department. Mortality data during the first two weeks were obtained for 9,964 patients: 21 per cent of patients allocated corticosteroids died, compared with 18 per cent of patients allocated placebo.

Although the mechanism behind this increased mortality is not clear, the authors highlight the importance of their finding: "Our early results show that corticosteroids should not be used routinely to treat head injury, whatever the severity.

"By clearly refuting a mortality benefit from corticosteroids in head injury, the CRASH trial results should protect many thousands of patients from any increased risk of death associated with these drugs."

Given the importance of the two-week findings, the authors decided to publish early; the results of their six-month data will be reported in a later paper.

## DTB questions first-line use of insulin analogues

The latest issue of *Drug and Therapeutics Bulletin* questions the first-line use of insulin analogues (2004;42:77).

DTB reviewed 42 studies comparing short-acting analogues with conventional insulin. The review found that the use of short-acting analogues led to a small decrease in HbA<sub>1c</sub> levels in patients with type 1 diabetes, but not type 2, and although the overall frequency of hypoglycaemia was not reduced, severe hypoglycaemia occurred less often.

DTB also reviewed studies looking at the longer-acting analogues detemir and glargine. Patients treated with insulin detemir show similar HbA<sub>1c</sub> levels to those on isophane insulin, although detemir appears to reduce nocturnal hypoglycaemia in patients with type 1 diabetes.

Insulin glargine, which is used once daily, seems to reduce nocturnal hypoglycaemia in patients with type 1 or 2 diabetes. It also appears to reduce fasting blood or plasma glucose concentrations in patients with type 1 diabetes. However, there is inconclusive evidence that it reduces HbA<sub>1c</sub> levels in patients with type 1 diabetes or HbA<sub>1c</sub> levels and frequency of mild symptomatic hypoglycaemic events in patients with type 2 diabetes.

Ike Iheanacho, editor, DTB, said: "On current evidence, insulin analogues represent a useful option for patients who experience problematic hypoglycaemia. Further research is needed to justify their first-line use in preference to longer-established conventional types of insulin."

The latest issue of DTB also features a review of laser treatment for skin problems.

## Servier offers medicines management resource pack

A medicines management resource pack has been produced by Servier Laboratories for use by pharmacists and other health care professionals.

The pack pulls together medicines management resources from the National Prescribing Centre, the National Primary and Care Trust Development Programme, the Medicines Partnership and some primary care organisations. It describes medication review and repeat dispensing processes and provides related templates that can be adapted for

local use. The company also plans to sponsor 36 medicines management meetings throughout the UK to help provide an overview of medicines management to primary care organisations as well as further develop and implement local medicines management strategy.

A limited number of the resource packs are available. Pharmacists interested in receiving a copy or setting up a medicines management meeting should e-mail their contact details to [info@mmresources.co.uk](mailto:info@mmresources.co.uk).

# Exclude health from European cross-border rules

All health services should be excluded from the scope of a proposed European directive on cross-border services, the Pharmaceutical Group of the European Union has said.

The planned directive would ban a range of licensing and authorisation requirements in all service sectors so that businesses in any part of the European Union could offer services in any other member country based on requirements set by the country in which they are primarily based.

A PGEU position paper warns that service providers should always be subject to the rules of the country in which services are provided. To do otherwise would mean providers of services in the same country could be subject to different rules.

The PGEU paper says: "Many countries link the establishment of new pharmacies to the number of inhabitants in a given area or to the characteristics of the territory (eg, low population density, mountainous areas). The application of such population and geograph-



## Europe: is the integrity of UK health services under threat?

ical criteria has proven to be a key element in the organisation of national health care systems, designed to guarantee high quality, accessible pharmacy services throughout the national territory."

PGEU president Pedro Capilla said: "The proposal as it stands does not take due account of the special nature of health services and could therefore have undesirable effects

on the organisation, financing and long-term sustainability of the health care sector."

A detailed joint response by UK pharmacy organisations to a Department of Trade and Industry consultation sets out the extent to which the planned directive cuts across provisions intended to guarantee the integrity of UK health services.

Among other concerns, they warn that primary care trusts would be unable to ensure that pharmacists and the premises from which they operate were suitable and posed no risk to the public unless publicly funded health services were excluded from the directive's scope.

The proposed directive also includes a provision that could mean that NHS dispensing contracts would have to be time-limited. The response warns that this could mean that the business risk of opening a new pharmacy was not justified because of the length of time that it takes to recover launch costs from trading profits.

## MSD to reimburse Vioxx prescription charge

Merck Sharp & Dohme says it will reimburse patients who paid the NHS prescription charge for their supply of Vioxx (rofecoxib) before its withdrawal earlier this month (*PJ*, 9 October, p505).

The company says that patients can call a helpline — 0800 106024 — to request a form, which they should then fill in and return to MSD, along with the empty box in

which their Vioxx was dispensed. The company estimates that just under 400,000 patients were taking the drug when it was withdrawn. An MSD spokeswoman told *The Journal* that over 70 per cent of these patients were likely to be exempt from paying a prescription charge. She added that the company did not expect to be inundated with requests for reimbursement.

## EMA to review COX-2 heart data again

Following the worldwide withdrawal of rofecoxib (Vioxx and Vioxx Acute) earlier this month (*PJ*, 9 October, p505), the European Medicines Evaluation Agency has decided to review the cardiovascular safety of all licensed cyclo-oxygenase-2 selective inhibitors.

It says it will examine available long-term data on cardiovascular safety for celecoxib (Celebrex), etoricoxib (Arcoxia), parecoxib (Dynastat), rofecoxib and valdecoxib (Bextra)

by the end of October. The EMA has previously reviewed this class of drug and concluded, in November 2003, that the overall benefits of COX-2 inhibitors outweighed the risk of side effects for the target patient population.

However, at that time, the EMA did recommend that the drugs should be used with caution in patients with a known history of heart disease.

## UK treasurer for international pharmacy group

Wally Dove, a member of the National Pharmaceutical Association management board, was elected treasurer of EuroPharm Forum at its annual meeting last week.

This year's meeting was attended by 27 of the 34 EuroPharm Forum member countries and concentrated on linking research with practice.

Emphasis was placed on the importance of having closer links between the two and in-

volving practitioners when designing studies and on having clear marketing and communications strategies in order to roll projects out into practice.

The aim of EuroPharm Forum is to improve health in Europe according to priorities set by the World Health Organization through dialogue and co-operation between national pharmaceutical associations and the WHO.

### News in brief

#### Lloyds wins marketing award

Lloydspharmacy has won a corporate social responsibility award for its work in raising awareness of the chain's free diabetes testing service. Over 500,000 people have been tested of whom 25,000 have been referred to their GP. The award, which is organised by *Marketing Week*, celebrates market success through socially responsible and sustainable behaviour.

#### Moss expands in Waitrose

Moss Pharmacy has opened five more branches in Waitrose stores. This brings the total number of Moss in-store pharmacies in Waitrose stores to eight.

#### Phoenix to open 14th depot

Phoenix is to open a new depot in St Albans, Hertfordshire. The 12,000sq ft warehouse, the company's 14th depot, will service the area within the M25 orbital motorway.

#### New funds for Medway

A grant of £100,000 from the Office of the Deputy Prime Minister is to be invested in laboratories for the new Medway school of pharmacy, at the universities of Kent and Greenwich. The laboratories will include a dispensary, a clinical skills laboratory, an aseptic laboratory and a pharmaceutical technology laboratory.

## Monthly ibandronate effective

Monthly treatment with the oral bisphosphonate, ibandronate, achieves similar increases in bone mineral density in women with postmenopausal osteoporosis as once-daily dosing, according to data reported at meeting of the American Society for Bone Mineral Research in Seattle earlier this month.

The MOBILE (monthly oral ibandronate in ladies) study randomised 1,609 women with postmenopausal osteoporosis to monthly ibandronate or the currently approved daily regimen (2.5mg daily), in addition to calcium and vitamin D supplements.

After one year, lumbar spine mineral density increased by 3.9 per cent in women on daily therapy, compared with 4.1 per cent in those on monthly ibandronate (100mg) and 4.3 per cent in women given the drug as

50mg doses on two consecutive days each month.

Cyrus Cooper, professor of rheumatology at the University of Southampton and one of the study investigators, commented on the practice implications: "Compliance with osteoporosis treatments tends to be poor because it is an asymptomatic condition which progresses silently until fractures occur. To maintain bone density and protect against fractures it is important that patients with osteoporosis remain on therapy, which might prove easier with once monthly treatment."

Further studies reported at the conference showed that up to 80 per cent of patients taking a daily bisphosphonate and up to 60 per cent of those on a weekly bisphosphonate discontinued treatment within one year.

## Fuzeon wins international innovation award but Roche concerned about uptake

Fuzeon (enfuvirtide) has been recognised by the award of the 2004 International Prix Galien to Roche, its manufacturer, for the most innovative new medicine.

The company, which shared the UK Prix Galien with Wyeth earlier this year (*PJ*, 2 October, p454), said that innovation was only one milestone of Fuzeon's success. "The next crucial step is getting the drug to those who need it."

Walter Osswald, president of the International Prix Galien jury, commented: "Fuzeon was considered as the clear winner . . . because it represents . . . the only new class of anti-retroviral HIV drugs to emerge in the past eight years. Fuzeon markedly contributes to a significant increase in patients' quality of life."

Janet Sanburg, international business leader for Roche, told *The Journal* that the company recognised that many patients eligible for treatment with enfuvirtide, which is given as an injection, were not taking it up.

To address this, Roche has set up a nurse training programme to teach patients self-injecting techniques. The company has also provided telephones to some patients so that new patients can discuss with them any treatment concerns they might have. Roche also recommends that doctors suggest to patients that they try the treatment for three months. "This is not such a big step for patients," said Dr Sanburg.

## Green light for six new therapies in Scotland

Six therapies assessed by the Scottish Medicines Consortium this month have been accepted for use within NHS Scotland.

Bondronat (ibandronate) receives a double endorsement — it can be used for treatment of hypercalcaemia associated with cancer and also to prevent skeletal events in patients with breast cancer and metastatic bone disease.

Other treatments that were accepted for use were Velcade (bortezomib) for multiple myeloma, Imigran Radis (sumatriptan succinate) for migraine and Nexium (intravenous

esomeprazole) for gastro-oesophageal reflux disease when oral therapy is not appropriate.

OxyNorm (oxycodone) and Yentreve (duloxetine) received more cautious welcomes and were accepted for restricted use. Oxycodone can be used for the treatment of moderate to severe pain in patients with cancer who have difficulty tolerating morphine or diamorphine therapy. Duloxetine can be used as part of an overall management strategy for stress urinary incontinence in addition to pelvic floor muscle training.

### SSRIs provide modest benefit in selected IBS patients

**Clinical question** Are selective serotonin reuptake inhibitors effective for the treatment of irritable bowel syndrome?

**Bottom line** Paroxetine in a dose of 10mg to 40mg per day provides at least a small benefit in terms of overall well-being for patients with irritable bowel syndrome who have already tried a high-fibre diet. We do not know the true magnitude of this benefit because of the way the results are reported. We also do not know whether selective serotonin reuptake inhibitors are more effective than tricyclic antidepressants.

**Synopsis** Although tricyclic antidepressants are somewhat effective for irritable bowel syndrome (IBS), it is less clear whether selective serotonin reuptake inhibitors (SSRIs) are similarly helpful. Patients for this study came from two groups: (1) patients presenting to the gastroenterologist on a low-fibre diet who did not improve on a high-fibre diet; and (2) patients presenting for care who were already eating a high-fibre diet. They were randomised to either placebo (n=43) or paroxetine 10mg per day, increasing the dose to 20mg or 40mg per day if there was no improvement at the lower dose (n=38). The mean age of patients was 46 years, 74 per cent were women, and most had diarrhoea-predominant IBS. Eight patients withdrew from the paroxetine group and seven withdrew from the placebo group; approximately half in each group because of perceived adverse drug effects. The primary outcome was overall well-being

measured using a five-point scale, where an increase of 0.5 points equals a clinically significant improvement. A clinically significant improvement was reported by 63.3 per cent of patients receiving paroxetine compared with 26.3 per cent receiving placebo ( $P=0.01$ , number needed to treat [NNT] 2.7). The benefit was similar for the subset of patients with a Beck Depression Inventory score of less than 10. Although there was a small improvement in food avoidance for the patients taking paroxetine, there was no difference in work or social function. When patients were asked at the end of the 12-week study whether they wanted to continue the study medicine, 84 per cent in the paroxetine group said yes compared with only 37 per cent in the placebo group ( $P<0.001$ , NNT 2). The mean improvement in scores for well-being are not reported for the two groups, though.

**Level of evidence** 1b (individual randomised controlled trial with narrow confidence interval)

**Reference** Tabas G, Beaves M, Wang J, et al. Paroxetine to treat irritable bowel syndrome not responding to high-fiber diet: a double-blind, placebo-controlled trial. *American Journal of Gastroenterology* 2004;99:914–20.

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