

Concern over revalidation ideas in regulation reports

Concerns over a potential conflict of interest if employers play a significant role in the revalidation of pharmacists are raised by several bodies responding to the reports "The regulation of the non-medical healthcare professions" and "Good doctors, safer patients", consultation on which ended last week.

The so-called Foster and Donaldson reports argue that although regulators will set standards for staying on the register, information already collected by employers (such as that from appraisals) should be used for revalidation purposes.

The Royal Pharmaceutical Society points out that revalidation might be used by health service providers as a way of getting rid of unwanted employees. It also highlights that employers could experience conflicting demands between meeting government-set performance targets and the need to protect the public.

The Pharmacists' Defence Association echoes these concerns. "It would be inconceivable to contemplate a situation where employers would be allowed to revalidate a pharmacist. This process would have the potential effect, in the highly commercial environment of community pharmacy, to prevent any pharmacists from resisting employer policies that they consider to be unsafe for patients," it says.

The Guild of Healthcare Pharmacists is also worried. "There needs to be a robust system of accreditation of employers and a



Information gained in appraisals could be used for revalidation purposes

means of redress for individuals treated unfairly." The Company Chemists' Association believes that it is premature to define in detail the arrangements that may be appropriate for revalidation of pharmacists. "At least two cycles of continuing professional development assessment will be required to determine their effectiveness before revalidation should be introduced," it says.

The need for a consistent approach between the regulation of medical and non-medical professions is also emphasised by a number of bodies. The Society says that in-

consistencies between the reports perpetuate "medical exceptionalism". "This was evident in the creation of separate reviews for medical and non-medical regulation, and persists in the conclusions of the two reports," it says. The Pharmaceutical Services Negotiating Committee agrees. "There is no reason why the regulation of all health care professions should not follow core principles," it says.

On separating the Society's professional and regulatory roles, the PDA says that this should be undertaken as a matter of urgency and that plans to implement the Section 60 Order should be suspended to allow for a timely separation of roles. The PSNC, too, is of the opinion that the Society should split; the National Pharmacy Association believes there should be "a split in the professional and regulatory roles". In reality, says the NPA, the Society has in recent times been moving in the direction of a regulatory role at the expense of being a professional body.

The Society expresses concerns about the lack of evidence for many conclusions in the Foster report and the lack of costings for the proposals. In its response, it says that there is no evidence that the non-medical regulators have been slow to identify or deal with serious failings, or evidence that they have slowed down the pace of change in respect of professional or service development.

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Community pharmacists could be in line for access to NHS mail

Community pharmacists in England could be given access to NHS mail, the secure national e-mail and directory service.

At a meeting between NHS Connecting for Health and several pharmacy bodies to discuss delivery of the electronic prescription service (EPS), NHS CfH said that it is actively investigating the potential for community pharmacies to be given access to NHS mail. More information will be made available in 2007.

The quarterly meetings involve NHS CfH, the Pharmaceutical Services Negotiating Committee, the Association of Independent Multiple Pharmacies, the National Pharmacy Association, the Company Chemists Association, the Co-operative Pharmacy Association and the Royal Pharmaceutical Society.

At the most recent meeting earlier this month, the pharmacy bodies learnt that, although 70 per cent of pharmacists who require access to the EPS have now obtained smartcards, the number of cards being issued each week has decreased substantially. The bodies are urging all pharmacists who do not yet have a smartcard to obtain one as soon as possible. Information on how to do this is available in the IT section of the PSNC's website (www.psn.org.uk) and via *PJ Online* (www.pjonline.com/links/pj).

ePharmacy certificate Community pharmacists in Scotland have been told to renew urgently their ePharmacy electronic certificate. These certificates ensure security on the system. Current certificates, which were installed by pharmacy software suppliers when they set up the e-minor ailments service, are about to expire. Further information about the process can be found on the community pharmacy contract website (www.communitypharmacy.scot.nhs.uk).

Lloydspharmacy ordered to pay compensation after steroid error

Lloydspharmacy is waiting to find out how much compensation it will have to pay a US lawyer after being found liable for the ill-health she suffered from an excessive dose of dexamethasone (*PJ*, 14 October, p440).

In the High Court last week, Mr Justice Keith ruled that pharmacist N'Guessan Gabla, then manager of the company's Selsdon branch in south London, "fell below the standards which could reasonably have been expected of a reasonably careful and competent pharmacist".

The judge said that the accepted wisdom was that pharmacists should consider whether prescribed medication was suitable for the patient. He added that the most significant criticism was that it should have occurred to Mr Gabla that the prescription for dexamethasone tablets that were eight times the strength of those that had been dispensed for Cathy Horton on seven previous occasions was a mistake.

"I have no doubt that what Mr Gabla should have done was to follow the instruction in the branch procedures manual and question the correctness of the prescription with [the prescriber] Dr Evans," the judge said.

The judge accepted that the deterioration in Ms Horton's health did not result from the tablets dispensed by Mr Gabla. It had only begun after a doctor in the US prescribed 4mg tablets after reading the Lloydspharmacy dispensing label. However, he ruled that there was a direct causal link between Mr Gabla's failure to question the prescription and the American doctor providing a 4mg daily dose.

Ms Horton is claiming £5m in damages, having already reached an undisclosed settlement of her claim against Earlsfield GP Timothy Evans, who wrote the prescription in question.

Contract test words altered

Changed wording for the control-of-entry test for new pharmacy contracts in England and Wales does not mean there will be any change to the criteria that primary care trusts and health boards will apply, the Department of Health has said.

From 1 March 2007, the criteria that new contract applications will have to meet — unless they are exempt from entry controls — will be of necessity and expediency, not necessity and desirability. The Pharmaceutical Services Negotiating Committee stated that the DoH has confirmed that this change is to ensure legislative consistency and will not change the application criteria.

The DoH reassurance reads: “Unless the contrary intention is shown, a consolidation Act is presumed to be a straight consolidation and does not change the law. The term ‘expe-

dient’ was adopted rather than ‘desirable’ to ensure legislative consistency within the Bill. The Consolidation Bill, once it receives Royal Assent and comes into force, will not change the basis on which primary care trusts and health boards are to continue to decide applications. They will continue to apply the ‘necessary or desirable’ criteria as set out in the NHS (Pharmaceutical Services) Regulations 2005 as amended.”

The new words appear in the NHS Act 2006 and the NHS (Wales) Act 2006, which received Royal Assent last week.

The two Acts consolidate the NHS Act 1977 with its subsequent amendments and divide it into separate Acts for England and Wales so that future amendments that apply separately to one or other of the two countries can be more easily understood.

Medicines in gift bags illegal

Goodie-bags handed to guests at a pharmacy awards dinner last month were illegal because they contained free samples of medicines, including prescription-only packs of Goldshield-brand ranitidine 150mg tablets. Other samples contained in the gift bags in-



Renschild/Dreamstime.com

Free samples of medicines may not be given away

Call for education to counter drug promotion

US campaigners against drug advertising have published four objectives (see Panel) that they say should be built into the education of all health professionals.

The objectives — developed by representatives of the American Medical Student Association, Healthy Skepticism, No Free Lunch and the UK-based PharmAware project — are set out in a paper published online

by the US Public Library of Science. The authors say that they should be pursued throughout all health professionals’ careers, starting in the first year of training and continuing in every subsequent year, including annual continuing professional development.

The authors accept that their recommendations challenge deeply held beliefs and that this will make them difficult to implement. However, they assert that the promotion of medicines and medical devices causes more harm than is generally realised, adding that their recommendations are necessary, but not sufficient, for removing the adverse influence of promotion on health professionals.

They say: “Improved regulation and redesigned incentive systems are also needed. . . . Our hypothesis — that implementing our recommendations will lead to improved health-care outcomes and earn increased public trust in the ability of health professionals to provide optimal treatment — deserves to be tested.”

cluded Bristol Laboratories paracetamol tablets and ibuprofen tablets.

Following a complaint to the Medicines and Healthcare products Regulatory Agency, Goldshield wrote to everyone who attended the event to ask for the ranitidine tablets back. *Pharmacy Business*, sponsor of the awards, agreed not to include medicines in gift bags again.

□ **Annual report** The first annual report of the MHRA Advertising Standards Unit was published last week. In the 12 months to August 2006, the MHRA received 172 complaints, of which 150 concerned medicines advertising: 84 of the complaints were upheld. The greatest number of complaints — 48 per cent — came from competitor companies. The report is the first to be produced by the standards unit as a result of a commitment given to Parliament following a House of Commons Health Select Committee inquiry into the influence of the pharmaceutical industry (*PJ*, 30 April 2005, p514).

Four drug promotion-related educational objectives

All health professionals should learn:

- How to evaluate evidence and make decisions
- That there is no proven way of getting more benefit than harm from drug promotion
- To avoid pharmaceutical and device promotion
- About the most reliable information sources

Pfizer answers customers

Pfizer has this week sent a letter to pharmacists and dispensing doctors addressing various questions raised by customers about the company’s distribution arrangements with UniChem.

In the letter, David Watson, head of trade, says that Pfizer is completing discussions with the profession via the Pharmaceutical Services Negotiating Committee, the Department of Health and other trade bodies, and will be announcing the new discount arrangements in the next two weeks.

The letter also reveals: “We do not rule out the possibility of working with more than one distribution partner in the future if we feel there are additional benefits for Pfizer, customers and ultimately patients.”

Contract favours multiples

The NHS pharmacy contract favours large pharmacy chains rather than small independent businesses, according to Verdict Research.

“Apart from the savings that can be made in administration and operating costs, large businesses also have the advantage of scale in IT implementation, best practice sharing, services marketing and contract negotiations for enhanced services,” said Verdict analyst Maureen Hinton.

Verdict’s report, commissioned by Lloydsparmacy, predicts strong growth in the market stimulated by the ageing population, which will drive growth in NHS prescriptions, which already amount to 77 per cent by value of the UK pharmacy market.

Enhanced services packages

Comprehensive packages for four “ready made” enhanced services have been developed by the Co-operative Pharmacy Group. The packages — for substance misuse, smoking cessation, minor ailments and emergency hormonal contraception services — also include prices.

The packages are aimed at primary care organisations (PCOs) and include a service specification, a draft service level agreement, guidance for setting up a patient group direction, training requirements and all supporting paperwork and marketing materials. The packages can be tailored to the individual requirements of PCOs, with a corresponding modification in price.

Community matrons “will not reduce admissions”

Community matrons are unlikely to reduce hospital admissions, but will be popular with patients, a review of similar case management systems published on *BMJ Online First* concludes (www.bmj.com, 15 November).

The review examined Evercare pilots in nine primary care trusts in England that, between 2003 and 2005, introduced case management of elderly people believed to be at high risk of emergency admission.

The authors say that the introduction of case management for frail elderly people provided an additional range of services in primary care and that the pilots have suggested ways to improve methods for identifying high-risk groups. However, their qualitative analysis found that case management had no significant impact on rates of emergency admission — one of the key aims of the programme — or on emergency bed days or mortality.

“We predict the same outcome from the newly introduced community matron policy, as the community matron model is based on the same principles as Evercare advanced primary nurses,” the researchers say.

The authors recognise, however, that their study had relatively low power to detect changes in outcomes and did not collect data on any direct measures of the health of the target population.

Alaster Rutherford, head of medicines management at Bristol Primary Care Trust, was involved with the Evercare pilot in Bristol. He told *The Journal* that one early lesson from Evercare was that data, in practices, PCTs and acute trusts, were not reliable. “It may well be that this research, which does have some serious methodological weaknesses, reflects that and there is now more effective targeting of patients needing enhanced care,” he said.

“For example, the assumption at the time was that recurrent admission patients were the priority, whereas far more sophisticated risk stratification tools are now available,” he added. “Also, experience has shown that whole-systems reforms need to accompany this case management approach and pharmacy has a big role to play in these reforms — changes which were not fully developed at the early stage this research was conducted.”



John Cole/Science Photo Library

Community matrons are likely to be popular with patients

Pharmacy has a significant role to play in preventing admissions and, more specifically, improving patients' outcomes outside hospital, he argued. “In Bristol, pharmacy was heavily involved in supporting Evercare from the outset, from identifying ‘high-risk’ patients, to extending the range of drugs which could be accessed quickly for patients in their own homes.”

Pharmacy care programme cuts blood pressure in over-65s

A pharmacy care programme can lead to better adherence to medication and improvements in blood pressure and cholesterol measures for patients over the age of 65 years, a study published online this week suggests (*JAMA*, 13 November, www.jama.com).

The US study involved 200 patients who participated in a two-month run-in observational phase followed by a six-month intervention, consisting of standardised medicines education, regular follow-up by pharmacists and dispensing in monitored dosage systems. Following the intervention phase, patients were randomised to continue with the pharmacy care programme or revert back to “usual care” for an additional six months. Participants were taking an average of nine long-term medicines.

Compared with the observational period, patients experienced improved adherence to medication (61.2 per cent to 96.9 per cent; $P<0.001$), reductions in systolic blood pressure (133.2mmHg to 129.9mmHg; $P=0.02$) and reductions in low-density lipoprotein cholesterol (91.7mg/dl to 86.8mg/dl; $P=0.001$) by the end of the intervention period.

At the end of the randomisation period, patients receiving usual care had lower adherence than those remaining on the pharmacy programme (69.1 per cent versus 95.5 per

cent; $P<0.001$). Systolic blood pressure was improved in the pharmacy group compared with the usual care group at the end of the six-month comparison. However, no significant difference was seen for cholesterol levels.

In an editorial (*ibid*), Ross Simpson, Jr, from the University of North Carolina, Chapel Hill, discusses the study's limitations. He says: “Because the usual care group was the reference group, the two groups in the randomised trial phase of the study had different levels of observation and different frequency of visits to the health facility after randomisation, and patients in the usual care group had an intervention that they had been receiving for six months removed. . . . [This introduced] a potential observation bias that favoured the intervention group, especially because adherence is a behaviour and observing a behaviour influences the behaviour.”

Alaster Rutherford, head of medicines management at Bristol Primary Care Trust, commented on the study: “I think it is hugely important for the development of community pharmacy service in the UK. The next step from medicines use reviews should be for concordance packages linked to specific medication regimens — this is generalisable research and the profession needs to emphasise this potentially significant contribution to public health.”

Far wider population would benefit from statin treatment

Lifetime statin treatment would be cost effective in a far wider population than that covered by current guidelines, a study published on *BMJ Online First* on 15 November suggests (www.bmj.com).

The researchers developed a model to estimate lifetime risk of vascular events, and costs of treatment and hospital admissions, for 20,536 men and women across the UK. Treatment with statins was cost saving, or cost less than £2,500 per life year gained, in people aged 35–85 years who had a five-year risk of a major vascular event of only 5 per cent at the start of treatment. “Statin therapy should be considered routinely for people across a wider age range and at lower risk of vascular disease than is currently the case,” they argue.

Alastair Gray, professor of health economics at Oxford University and one of the authors of the paper, told *The Journal* that a similar logic could be applied to extending eligibility for over-the-counter statins. “People who are at a lower level of risk than those currently eligible should be able to buy simvastatin OTC,” he said. However, he added: “Since simvastatin is available generically and we have shown that it is cost-effective or cost-saving for people with a 5 per cent five-year risk of a major vascular event, it might be better if it was made available for those people on the NHS.”

New analysis suggests all SSRIs pose risks to young

Young people taking antidepressants are at increased risk from self-harm or suicidal behaviour, according to a new analysis that supports previous studies.

It also indicates that fluoxetine, the only antidepressant to be given a favourable risk benefit profile by the Committee on Safety of Medicines for use in children and adolescents, may be no less risky than some other newer antidepressants.

Researchers from the University of Manchester's biostatistics group examined data collected from randomised placebo-

controlled trials of children and adolescents aged six to 18 years treated with fluoxetine, sertraline, citalopram, paroxetine, venlafaxine or mirtazapine.

Self-harm, suicidal thoughts or attempted suicide occurred in 71 of the 1,487 (4.8 per cent) young people treated with antidepressants compared with 38 of the 1,254 (3.0 per cent) given placebo. Expressed differently, this means that 57 young people need to be treated for one additional event to occur.

The researchers observed that fluoxetine was associated with an overall small risk of

any event (relative risk 1.6, 95 per cent confidence interval 0.9–3.1). The risk of suicide attempts was similar to but higher than that for paroxetine. However, they warn that the results for individual drugs and events need to be interpreted cautiously because they are based on small numbers with relatively few incidences of adverse events.

The researchers warn that to get an accurate picture of suicidal behaviour prospective studies are needed that do not exclude the most depressed suicidal children (*British Journal of Psychiatry* 2006;189:393).

Depression link to mortality in heart failure

Depression, but not antidepressant use, is associated with increased mortality in patients with heart failure, a prospective study has indicated.

Researchers from Duke University Medical Centre, North Carolina, collected data from over 1,000 patients admitted to hospital with heart failure between March 1997 and June 2003. The patients were followed up for an average of two years and seven months.

During follow up, 42.7 per cent of the patients died. Overall, antidepressant use was associated with increased mortality (hazard

ratio, 1.32; 95 per cent confidence interval, 1.03–1.69, $P=0.029$). However, the association disappeared after controlling for the presence of depression (1.20, 0.84–1.71).

Study author Wei Jiang said: "It can be impractical to make sure every patient with heart failure sees a psychiatrist. That is why it is so important to improve the knowledge and confidence of non-psychiatric professionals for care of depression."

The data were presented earlier this week at the annual scientific sessions of the American Heart Association held in Chicago.

SSRIs' effect on depression apparent within first week

Treatment with a selective serotonin reuptake inhibitor (SSRI) is associated with symptomatic improvement in depression by the end of the first week, according to a meta-analysis published in the *Archives of General Psychiatry* (2006;63:1217).

The researchers analysed data from 28 trials involving 5,872 subjects who received an SSRI or placebo. The pattern of response seen was tested against alternative models of onset of response.

The researchers found that the model that fit best was that where the incremental treatment effect was greatest in the first week, with a gradual decline in the magnitude of incremental benefits week by week.

A secondary outcome indicated an increased chance of achieving a 50 per cent reduction in Hamilton Depression Rating Scale scores by one week with SSRI treatment compared with placebo (relative risk 1.64; 95 per cent confidence interval 1.2–2.25). The absolute benefits increase further with time, say the researchers, so prescribers will continue to need to wait several weeks for key treatment goals, such as remission, to be met.

Boundary-breaking pharmacy wins UniChem award

Regent Pharmacy, in Shanklin, Isle of Wight, is this year's overall winner in the annual UniChem Pharmacy Awards (previously the UniChem Great Business Awards).

Presenting the award to proprietor Gary Warner last week, National Pharmacy Association chief executive John D'Arcy said that Regent Pharmacy epitomised modern pharmacy practice.

Seven other award winners were:



Gary Warner receives his award from John D'Arcy (left) and UniChem chairman Mike Smith (right)

- Promoting health care services in the community: David Badham, Stewart Pharmacy, Evesham, Worcestershire
- Working in partnership as part of a community health care team: Viv Farrell, United Co-op Healthcare, Stockport
- Enhancing the shopping experience: Duncan Murray, CG Murray and Sons, Stourbridge, West Midlands
- Most supportive technician in community pharmacy: Samantha Butler, Regent Pharmacy

- UniChem customer forum pharmacy student award: Laila Sameja, fourth year pharmacy student, Aston University
- Most innovative product launch to support community pharmacy: Imigran Recovery, GlaxoSmithKline
- Most supportive supplier to community pharmacy: Colgate-Palmolive

Regent Pharmacy was the overall winner of UniChem's Great Business Awards in 2000 (*PJ*, 25 November 2000, p781).

NHS modernisation continues

The Queen's speech this week promised to "carry through the modernisation of health care based on the founding principles of the NHS".

Measures in Tony Blair's last legislative programme included increasing the degree of choice for all patients and providing minor operations in enhanced GP surgeries close to patients' homes.

A background briefing paper said: "So far we have delivered faster and more convenient services, more personal care and a better patient experience."

"However, we still face the challenge of improving the quality of health care, increasing choice for patients and diversity in the system and improving the health and well-being of communities across the country."

Similar CV risk for etoricoxib and diclofenac shown

Risk of heart attack, death or stroke in arthritis patients treated with the cyclo-oxygenase-2 (COX-2) inhibitor etoricoxib is not statistically different from that in patients treated with the traditional non-steroidal anti-inflammatory drug (NSAID) diclofenac.

Data from the first large randomised controlled trial set up specifically to study the cardiovascular safety of a COX-2 inhibitor were presented earlier this week at an American College of Rheumatology meeting in Washington, at an American Heart Association meeting in Chicago and published online in *The Lancet* (13 November, www.thelancet.com).

The multinational etoricoxib and diclofenac arthritis long-term (MEDAL) trial involved randomising 34,701 patients with osteoarthritis or rheumatoid arthritis to receive etoricoxib 60mg or 90mg daily, or diclofenac 150mg daily. Average treatment duration was 18 months.

A total of 320 patients taking etoricoxib and 323 taking diclofenac had thrombotic cardiovascular events — with a hazard ratio of 0.95 for etoricoxib (95 per cent confidence interval 0.81–1.11) for patients who followed the trial protocol. Overall rates of upper gastrointestinal events — perforation, bleeding,

obstruction or ulcer — were lower with etoricoxib with a hazard ratio of 0.69 (0.57–0.83). But complicated, life-threatening upper gastrointestinal events were similar between the two groups.

Both doses of etoricoxib were associated with higher discontinuation rates due to hypertension and more patients discontinued etoricoxib 90mg due to oedema compared with those taking the non-selective NSAID.

Lead author Christopher Cannon, cardiologist at the Brigham and Women's Hospital in Boston, stressed the trial's limitations — the lack of a placebo group meant absolute cardiovascular risks with the drugs could not be calculated.

He said: "This doesn't answer all the questions about the cardiovascular safety of NSAIDs by any means but it does mean we have another big piece of the puzzle.

"When choosing a chronic pain treatment we have to take into account thrombotic and gastrointestinal risks as well as renovascular effects and, of course, efficacy." He added that he hoped guideline committees would use the results to produce advice for clinicians on how best to individualise treatment choices.

Diclofenac was chosen as the comparator because it is the most widely prescribed

NSAID and also because it does not interfere with the antiplatelet effects of low-dose aspirin, unlike naproxen or ibuprofen. About a third of patients in MEDAL were taking prophyllactic low-dose aspirin.

Ernest Choy, consultant rheumatologist at King's College Hospital, London, commented: "These data conclusively show that etoricoxib has the same cardiovascular risk profile as the most widely used NSAID in the world. But it is important to put into perspective the fact that the absolute increased risk of a CV event with an NSAID is small."

□ **Alzheimer's study data** Naproxen, but not celecoxib, is associated with an increased risk for cardiovascular harm compared with placebo, suggest safety data from a trial designed to test the two drugs as Alzheimer's disease treatments (*PLoS Clinical Trials* 2006;1[7]:e33).

The trial involved over 2,500 participants aged 70 years or older who had a family history of Alzheimer's disease. They were treated with either celecoxib (200mg twice daily), naproxen (220mg twice daily) or placebo. Follow up was planned for seven years but the trial was halted early, with median follow-up times of just under two years for each treatment arm.

Pioglitazone treatment shows promise for atherosclerosis in diabetes

People with type 2 diabetes treated with pioglitazone have slower progression of a particular marker for coronary atherosclerosis than those taking glimepiride, according to a study released online this week (*JAMA*, 13 November, www.jama.com).

Of 462 patients randomly assigned to treatment, 175 patients in the pioglitazone group and 186 in the glimepiride group were included in an analysis of carotid artery intima-media thickness (CIMT) — a marker for coronary atherosclerosis and independent predictor of cardiovascular events. Investigators found that, at 72 weeks, mean CIMT had

progressed less in pioglitazone subjects than in glimepiride subjects (–0.001mm versus 0.012mm, difference –0.013mm, 95 per cent confidence interval –0.024 to –0.002; $P=0.02$). Progression of maximum CIMT was also slowed in the pioglitazone group compared with the glimepiride group ($P=0.008$).

However, the authors concede that the study "was not powered to detect a difference in cardiovascular endpoints and, therefore, does not establish that treatment with pioglitazone compared with glimepiride will reduce these end points in patients with type 2 diabetes mellitus".



Atherosclerosis in carotid artery

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www.pjonline.com/support

National workforce census

An analysis of demographic data from the 2006 Register of Pharmaceutical Chemists.
www.pjonline.com/series

Traditional, Chinese and complementary medicine

Different approaches to medicine.
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Erdosteine launched in the UK for chronic bronchitis relief

A new drug for the symptomatic treatment of acute exacerbations of chronic bronchitis — a form of chronic obstructive pulmonary disease (COPD) — is now available in the UK. Erdosteine (Erdotin; Galen/Edmond Pharma) was launched this week to coincide with World COPD Day (15 November).

"Erdosteine has been available for over 10 years in 31 countries. Its launch in the UK is supported by a wealth of clinical data evaluating its tolerability," Anna Murphy, consultant respiratory pharmacist at Glenfield Hospital, Leicester, told *The Journal*.

Ms Murphy said that individuals with COPD, especially those with a significant

chronic bronchitis component, may suffer from recurrent exacerbations of their disease with an increase in volume and purulence of sputum. The clinical effectiveness of mucolytics is believed to result from their ability to reduce the viscosity of sputum, thereby increasing ease of expectoration, she explained.

She said that exacerbations have an impact on the costs of caring for people with COPD. "Compared with the cost of a hospital admission or an extended course of an antibiotic an appropriately prescribed 10-day course of erdosteine, at £5 per course, seems an attractive treatment," Ms Murphy suggested.

Notice-board p605

Anticoagulant drug-antidote combination safe for human use

A novel approach to anticoagulation, using an RNA aptamer-antidote combination, is safe for use in humans, say US researchers.

They argue that the occurrence of bleeding as a trade-off for effective anticoagulation is unacceptable and that there is a need for anticoagulants with more favourable safety profiles. They point out that unfractionated-heparin, currently the only antidote-reversible anticoagulant, has limitations because of its complex pharmacokinetics and the fact that its antidote, protamine sulphate, shares similar complexity and has serious cardiovascular side effects.

The researchers tested a drug-antidote pair composed of a specific aptamer-based inhibitor of coagulation factor IXa and its complementary oligonucleotide antidote in 85 healthy volunteers. As expected, activated clotting time and activated plasma thromboplastin time values were increased in subjects treated with the agent. And antidote administration reversed the pharmacological activity of the drug in less than five minutes.

"This novel construct represents, in essence, an anticoagulation system that provides a rapid and effective means to either attenuate or fully inhibit specific coagulation



Coagulation could be turned on and off

proteases, while maintaining haemostatic control through tailored administration of an inherently safe neutralising antidote. In effect this anticoagulation system has the potential to offer a molecular 'on-off' switch to pharmacologic anticoagulation."

The data were presented at the annual scientific sessions of the American Heart Association in Chicago this week and are published online in *Circulation* (<http://circ.ahajournals.org>).

The researchers are now testing the agent in patients with stable heart disease.

Oral vasopressin receptor antagonist improves serum sodium in hyponatraemia

Tolvaptan, an orally active vasopressin V_2 -receptor antagonist, is an effective treatment of hyponatraemia, new research shows. The drug promotes aquaresis — excretion of electrolyte-free water.

Researchers examined the effects of tolvaptan in two trials involving 448 patients with hyponatraemia (serum sodium <135mmol/L) from various causes (eg, chronic heart failure and cirrhosis).

They found that within eight hours of administering treatment, patients' serum sodium concentrations were significantly higher in those given tolvaptan than in those given placebo. More patients assigned to tolvaptan had normal serum sodium concentration on day four and day 30 than did patients assigned to placebo ($P<0.001$ for both). And when treatment was discontinued serum sodium concentrations reverted to levels similar to those seen in patients given placebo (*New England Journal of Medicine* 2006;355:2099).

The author of an accompanying editorial (ibid, p2146) suggests that future studies examine the potential of V_{1A}/V_2 -receptor antagonists.

Diabetes treatment promise from human stem cells

Stem cells derived from human bone marrow enhance the repair of insulin-producing beta-islet cells in the pancreases of diabetic mice, a study shows. The finding suggests that human mesenchymal stem cells (hMSCs) might be useful for treating human diabetes.

Researchers observed mice with high blood sugar that were treated with either hMSCs or a placebo infusion. Three weeks later, hMSC-treated mice showed higher levels of mouse insulin. The human stem cells differentiated into glomerular endothelial cells and were able to halt pathogenic changes in the glomeruli of the kidney.

The researchers hypothesise that stem cells might be able to boost insulin production in human diabetes and that the cells may also prevent kidney lesions caused by the disease.

The study is published in *Proceedings of the National Academy of Sciences* (2006;103:17438).

Viable male contraceptive delivered to testes

Viable male contraceptive pills may be closer to human trials following the successful development of a system to deliver a promising candidate drug direct to the testes.

The drug adjuvin has been shown to induce reversible infertility in rats, but it has low bioavailability and, when taken orally at doses high enough to be effective, results in liver inflammation in some animals. To circumvent these problems, researchers from the Centre for Biomedical Research in New York and the University of Rome developed a novel approach for delivering adjuvin direct to the testes (*Nature Medicine* 2006;12:1323).

They administered the drug parenterally and used a modified follicle-stimulating hor-

none as a carrier. This enabled them to induce reversible infertility in rats with a dose 100,000 times smaller than the oral dose needed to produce similar results and without the accompanying liver inflammation.

Meanwhile, another compound which had shown promise as a male contraceptive in animal studies has been found to have no effect on spermatogenesis in men (published online, <http://humrep.oxfordjournals.org>, 25 October).

Miglustat, which induces reversible infertility in mice, had no effect on sperm concentration, motility or morphology in normal men after six weeks of therapy, the researchers found.

Platelet growth factor helps hepatitis C patients start therapy

A drug that improves platelet counts may allow patients with hepatitis C and thrombocytopenia to benefit from antiviral therapy.

GlaxoSmithKline announced results from a phase II study of eltrombopag, a non-peptide oral platelet growth factor, at the annual meeting of the American Association for the Study of Liver Diseases in Boston, Massachusetts, last month. Eltrombopag, at a daily dose of 30mg, 50mg or 75mg, increased

platelet counts at day 28 and enabled between 71 per cent and 91 per cent of patients to initiate treatment with pegylated interferon. Fewer patients (between 36 per cent and 65 per cent) completed the 12-week course of antiviral therapy.

Of the 23 patients who were treated with the highest dose of eltrombopag, six experienced a drug-related adverse event (26 per cent) and one withdrew from the study.

Vaccine against *S aureus*

Scientists have created a vaccine against *Staphylococcus aureus*. They tested surface proteins from the bacterium and selected four with strong antigenic properties to use in the vaccine (*Proceedings of the National Academy of Sciences* 2006;103:16942).

In brief