

PSNC chairman: pharmacy's confidence is shaken

Community pharmacy's confidence has been shaken by the Government's failure to develop new advanced services, and investment made by pharmacy contractors has gone unrewarded. Chris Hodges, Pharmaceutical Services Negotiating Committee chairman, was to make these points at the committee's annual dinner this week, after *The Journal* went to press. Health minister Dawn Primarolo was due to attend the dinner in London.

"When we agreed the pharmacy contract with the Department of Health three years ago, it was on the basis of the concept of fair funding," Dr Hodges was due to say. "The money paid to pharmacies by the NHS was calculated and agreed as being fair to the 9,750 pharmacies in England and fair to the NHS. Today, as a direct result of the changes to control of entry made by the Department of Health, there are 10,300 pharmacies and that number is growing. What was fair funding for 9,750 is not — and cannot be — fair funding for 10,300."

He was also due to say: "In recent months there have been huge dips in NHS income

for pharmacies and that has put many under real pressure. Pharmacies large and small have been struggling to break even because of the huge swings in NHS payments. That is unacceptable. Pharmacists need funding stability and certainty so they can invest in and deliver new services. The financial attrition that pharmacies are experiencing is causing many to cut back on resources at precisely the time that the NHS should be developing them."

He told *The Journal* that although the pharmacy contract provided a good basis for fair funding and new services it was under great pressure. Dr Hodges was due to call on

Ms Primarolo to work with the PSNC to tackle the financial issues highlighted.

Dr Hodges was also expected to call for more nationally agreed advanced pharmacy services, specifically a minor ailments service, a weight management service and a range of screening and diagnostic services, in addition to services designed to manage long-term conditions such as diabetes and asthma.

Concerns about loss of the protected professional allowance for low-volume pharmacies were raised at the local pharmaceutical committee conference that preceded the dinner (p296).

Less fluctuation in reimbursement expected for coming year

Pharmacy contractors in England should see smaller fluctuations in their NHS reimbursement in the coming financial year than happened this year. The Pharmaceutical Services Negotiating Committee is working with the Department of Health to try to obtain the results of the necessary invoice inquiries sooner so that adjustments to Drug Tariff prices intended to achieve target income, including the annual uplift, can be made in July 2008 for the 2008–09 financial year and then in April 2009 for the 2009–10 financial year.

"The issue is to achieve smoother delivery of income," said Mike Dent, PSNC head of finance, adding that the analysis of invoices was also being refined so that the PSNC needed to discuss fewer queries with the DoH.

Lansley tells of category M "boom and bust"

Greater transparency is needed in pharmacy reimbursement, shadow health secretary Andrew Lansley argues in a letter to *The Journal* this week. Large overpayments and subsequent cuts in Category M prices have led to a "boom and bust" pattern that is in no one's interests, he writes.

The details of the funding of the pharmacy contract must be disclosed and discussed, he insists. "The implications are too important. This involves several billion pounds of public spending."

Additional pharmacy services could have been commissioned from the resources spent on excess payments for dispensing Category M medicines, Mr Lansley believes, and the Government must be challenged over its management of the pharmacy contract.

Letters p305

Oral contraception PGD starts in Manchester

Pharmacy sexual health services in Manchester have been relaunched with the addition of a patient group direction (PGD) for supplying oral contraception.

Karen O'Brien, associate director for primary care commissioning at Manchester Primary Care Trust, told *The Journal* that 10 pharmacies had started offering the PGD this week, linked in with the sexual health services already in place. She explained that women who ask for emergency hormonal contraception at one of the pharmacies are to be offered the PCT's chlamydia service (which includes testing, treating and tracing) as well as oral contraception under the PGD, if appropriate.

The pharmacists involved have been trained and accredited to take on the new enhanced service, and will provide initial and repeat courses of either a combined oral contraceptive or a progesterone-only pill.

Banksy artwork appears on London pharmacy wall



Artwork by graffiti artist Banksy on the wall of an Islington pharmacy, London

In brief

Revised Society election details

Amended information about pharmacists seeking election to the Royal Pharmaceutical Society's Council has been issued by the Society. Michael Holden is standing for election to an unreserved seat on the Council and for the English national constituency reserved seat; Nicholas Barber is standing only for an unreserved seat, and not as announced last week (*PJ*, 8 March, p265).

Budget

In his Budget statement made on 12 March, the Chancellor of the Exchequer said that since 1997 spending on the NHS has almost doubled in real terms and the focus for the NHS over the next decade will be creating "world-class services".

Prescription charge rises by 25p to £7.10 in England

Prescription charges in England are to rise by 25p to £7.10 per item on 1 April.

Announcing the increase last week, health minister Dawn Primarolo said: "In England, 88 per cent of prescription items are free of charge thanks to our extensive exemption arrangements."

In 2006, fewer than 7 per cent of prescription items dispensed by community pharmacies in England were chargeable at the point of dispensing. A further 5 per cent of items were dispensed to patients who had prepayment certificates.

Reacting to the announcement, Paul Bennett, chairman of the Royal Pharmaceutical Society's English Pharmacy Board, said: "We urgently need a review of the current system of prescription charges and exemptions in England — they are presently both illogical and unfair. There are clear disadvantages under existing arrangements, particularly for non-exempt patients



Nesilcock/Dreamstime.com

Prescription charges go up England, but fall in Scotland

who require long-term medication for multiple chronic conditions."

Mr Bennett said that there was a case for abolishing charges in England, but that the implications of doing so were considerable and should be considered carefully.

"The Society firmly believes in better access to prescribed medicines for all patients without the constraints of a financial barrier," he went on. "However, we must approach these issues with our eyes wide open and with a clear understanding of the implications of such reforms for pharmacists, GPs, patients, healthcare services and the pharmaceutical industry."

A review has already been carried out internally by the Department of Health following an investigation by the House of Commons Health Committee (*PJ*, 28 October 2006, p507).

A DoH spokesman said that consultation on proposed changes was expected soon.

NHS prescriptions are free in Wales and charges will be phased out in Scotland by 2011. The prescription charge in Scotland will fall to £5 on 1 April with further cuts to £4 in 2009 and £3 in 2010 before abolition the following year.

Former pharmacist fights confiscation order

Former pharmacist Mohammed Shabir, of Wigton Lane, Leeds, who was jailed after defrauding the NHS of £464 (*PJ*, 20 August 2005, p216) is fighting a £200,000 confiscation order imposed by the High Court.

In the Appeal Court last week, Lord Justice Thomas accepted that the case was of importance to the way in which the proceeds of crime are confiscated.

Operating from the Cardigan Road Pharmacy, in Leeds, between May 2003 and November 2004, Mr Shabir altered prescription forms so that it looked as though patients who had paid the prescription charge had claimed exemption. He also claimed for the cost of drugs he had not dispensed. He was convicted of false accounting and obtaining money transfers by deception in July 2005 and was jailed for nine months on the basis that his benefit from the crime was £464.

But in January 2006, the High Court ordered that he forfeit £212,464 because all the claims for payment made on the falsified forms, even legitimate claims, were part of his benefit from crime.

Lord Justice Thomas said that if prosecutors are obliged to sort through complex transactions, and painstakingly separate the dishonest from the legitimate, then the deliberately draconian Proceeds of Crime Act 2002 might become unworkable. But he added that it would be harsh if expenses fidlers and others were obliged to pay confiscation orders which bore no relation to their true dishonest gains.

Lord Justice Thomas adjourned the case for further information to be gathered on how Mr Shabir's criminal benefit was calculated. The case is expected to return to court in late April.

Low volume concerns raised

Concerns about losing the protected professional allowance for low-volume pharmacies, particularly in view of the possible impact of Lord Darzi's proposed polyclinics, were raised at the Pharmaceutical Services Negotiating Committee's local pharmaceutical committee conference in London this week.

Protected payments for low-volume pharmacies will stop at the end of this month after the agreed three-year period comes to an end. Sue Sharpe, chief executive of the PSNC, explained that this was the longest period for which the PSNC could secure payments for established pharmacies. Beyond this period, all pharmacies would have to be entitled to the same payments.

A resolution was tabled by Kensington, Chelsea and Westminster LPC, that called for extension of protected payments, but it was withdrawn in view of the likely impact on all contractors if payments were extended to new low-volume pharmacies.

John Hewitt, secretary of Bexley, Bromley and Greenwich LPC, argued that the resolution was incredibly important for all contractors. "It is frightening to think of the number of contractors who will finish up as low-volume contractors," he said. "We need more protection for low-volume pharmacies in the slim hope that more contractors will survive in the interim period before the DoH realises that the Darzi proposals are a disaster."

In response, Mrs Sharpe said: "There seems to be a general consensus that we must campaign against moves that are going to undermine the fabric of the present pharmacy network." She added that the PSNC also recognises that, with a review of the contract expected to be triggered by the White Paper, it needs to be attentive to volume thresholds in the light of what could happen.

MP says nursing regulator is fundamentally dysfunctional

Criticism of the Nursing and Midwifery Council this week is to result in intervention by the Council for Healthcare Regulatory Excellence and the Charity Commission.

In an adjournment debate, Jim Devine (Livingston, Lab) said that the NMC had a culture of bullying and racism affecting both staff and council members.

Quoting a former council member, Mr Devine said: "The NMC is a fundamentally dysfunctional organisation where the priority is on maintaining the status quo at the expense of proper transparency and integrity, where funds are being misspent and the trustees are being systematically prevented from doing what they are supposed to do."

Mr Devine said that it was not unusual for council decisions to be ignored or circumvented and that standing orders were routinely put aside to . . . prevent the council's consideration of legitimate business."

An attempt had even been made to exclude some members from a debate because of the way they had voted in the past, he said.

Ben Bradshaw, health minister responsible for professional regulation, is to write to the CHRE and the Charity Commission to encourage them to "play a role in resolving the NMC's long-standing problems".

The NMC has rejected Mr Devine's allegations and welcomes the opportunity for independent scrutiny.

Law change to force companies to report all ADRs

Legislative changes that will force pharmaceutical companies to report adverse drug events promptly, regardless of the source, will be introduced in the UK by the end of the year after a decision not to prosecute GlaxoSmithKline for allegedly withholding important safety data from its clinical trials on Seroxat (paroxetine) in children.

GSK rejects any suggestion that it withheld drug trial information since results from its paediatric studies were documented and submitted to regulators in accordance with regulatory requirements.

Alastair Benbow, medical director for GSK Europe, said: "We firmly believe we acted properly and responsibly in first carrying out this important clinical trials programme and then informing the regulatory agencies when we identified a potential increased risk of suicidal thinking and behaviour in patients under 18."

However, the Medicines and Healthcare products Regulatory Agency has made it clear that it believes GSK could and should have reported the information earlier than it did and says the new rules will leave companies in no doubt about their obligations to disclose information promptly.

The outcome of the MHRA's four-year criminal investigation, the largest of its kind



Stockphoto.com/Dreamstime.com

Depressed young people should not be treated with Seroxat

in the UK, was published last week. After considering the investigation, Government lawyers have decided that, because of a gap in legislation, there is no realistic prospect of a conviction in the case and it should not proceed to criminal prosecution.

Legislation in force at the time did not require companies to inform the regulator of safety information when the drug was being used or tested outside its licensed indications.

Writing to GSK, Kent Woods, chief executive of the MHRA, said that tightening the law should be unnecessary in an industry that relies so heavily on public trust and aspires to high ethical standards. "I would have thought it self-evident that such information should be made available promptly to the regulator in order that action can be taken to protect public health. However, that moral responsibility now needs to be insisted upon by the unambiguous force of the law."

The MHRA advised prescribers that Seroxat should not be prescribed for children under 18 years old (*PJ*, 14 June 2003, p813) after GSK submitted information in 2003 showing that this population had a higher risk of suicidal behaviour if taking Seroxat than if taking placebo and that the drug was ineffective for treating depression in children.

The MHRA had two main concerns about GSK's conduct, detailed in the report of its investigation: first, "... the length of time between completion of some of the trials included in the analysis which had raised the safety issue and the communication of this to the agency" and, secondly, that this important safety concern was conveyed in a briefing document about a proposal to extend Seroxat's licence to include children.

News feature p302

Boots refers two-thirds of PGD clients to their GPs

GP referral rates are high for customers attending patient group direction (PGD) programmes for erectile dysfunction and weight management run by Boots The Chemists.

An audit has shown that more than four in five customers, presenting for the erectile dysfunction service, and two in three, attending the weight loss programme, were referred to their GPs for further investigation.

Customers who were found to have raised blood pressure or blood glucose were excluded from PGD supply of orlistat for weight loss and sildenafil for erectile dysfunction (raised cholesterol was another exclusion criteria here). Some 257 customers attended the erectile dysfunction clinic in Manchester and 391 attended the weight loss programme. Although the erectile dysfunction service is still being piloted, Boots has rolled out the weight loss service nationally (262 stores with 485 pharmacists). The company's other national PGD programmes are for hair retention using finasteride (142 stores with 215 pharmacists) and chlamydia screening and treatment using azithromycin (344 stores with 803 pharmacists).

Services are run on an appointment basis. All consultations are confidential, but patients are recommended to see their GP if they do not fall within the inclusion criteria for that particular PGD.

Reckitt accused of hindering competition

Reckitt Benckiser has been accused of delaying the introduction of generic alginate compound products as alternatives to Gaviscon by impeding the publication of a generic name and by slowing down the introduction of a monograph by the British Pharmacopoeia Commission.

Relying on information provided by a company whistleblower, the BBC *Newsnight* programme said last week that delays to the introduction of a generic equivalent to Gaviscon cost the NHS an extra £40m after the expiry of the product's patent in 1999.

The company's delaying tactics started in 2000 when Gaviscon's then proprietor Reckitt & Colman challenged the BNF's authority to coin titles for compound products. This was two years after the Department of Health asked the BNF to come up with a generic name for Gaviscon-type products. (The BNF is recognised by the Medicines Act 1968 as a compendium that is allowed to name and describe pharmaceutical products.)

Three years passed before the BNF was able to obtain final Counsel's opinion that it could do this and which gave approval for the proposed process.

Consultation on the proposed generic name — compound alginate oral suspension — was announced in April 2003 (*PJ*, 19 April 2003, p542). But the process was soon halted

after the British Pharmacopoeia Commission decided that it should produce a monograph instead (*PJ*, 5 July 2003, p542).

Newsnight revealed that it was Reckitt Benckiser that persuaded the BP commission to do this. An internal company e-mail (obtained by *Newsnight*) said that the company was "devising a plan to extend the development of a generic name for as long as possible".

Commenting on the e-mails obtained by *Newsnight*, Reckitt Benckiser said: "We are deeply concerned by the inappropriate sentiment expressed in some of the historic internal correspondence reported. . . . We also refute much of what has been reported which implies a power and influence we simply do not possess."

The Department of Health has now asked *Newsnight* to send details of its investigation to the NHS Counter Fraud Service.

In a statement, Reckitt Benckiser said that it had not objected to the publication of a monograph-driven generic name, which the relevant regulatory authorities could have published at any time without reference to any third party.

And it also said: "The company made appropriate challenges where it was felt it was justified to ensure patients are prescribed the right treatment. These were within the law and relevant regulations."

Health tests need to be evaluated Hearts ageing faster

Diagnostic health tests should be evaluated and regulated in a similar way to medicines, according to a report published this week.

The Royal College of Pathologists and the PHG Foundation (a public health and genetics charity) are calling for information about the performance and usefulness of tests — ranging from cholesterol testing kits to genetic tests — to be stored in a publicly accessible database, equivalent to the British National Formulary. Healthcare professionals should then be encouraged to use only the tests with sufficient evidence of clinical performance.

Commenting on the report's launch, Evan Harris MP said: "At a time when the NHS cannot afford even all those carefully evaluated tests and treatments that are known to save or improve lives, it cannot be right for there to be a free-for-all on tests which are of dubious value and require the NHS to spend scarce resources investigating or reassuring the worried well."

The report says that, despite NHS laboratories having sophisticated systems to ensure the analytical accuracy of tests, no system is in



Sebastian Czaplinski/Dreamstime.com

Diagnostic testing: concerns raised over use of NHS monies to reassure the worried well

place to ensure the clinical effectiveness of individual tests. It says that this system is analogous to "having a pharmaceutical industry with tight control of the chemical purity of drugs, but with no formal requirement for evidence that a drug benefits patients".

As well as helping healthcare professionals to order tests that are proven to be useful and cost-effective, a new regulatory system will help protect the public who purchase these tests over the counter or via the internet.

There are concerns that these tests are sold with heavy marketing, but that patients are not aware of the risks. To help address this, a new patient guide, "Making sense of testing", has been published by the charity Sense About Science.

The guide highlights that the market for home tests used by the "worried well" is now worth £99m a year.

The guide also explains that tests are only one part of diagnosis, and in some cases can cause harm. It says that many of the tests available are not researched or adequately regulated, and describes concepts such as false negative and false positive results.

Hearts are ageing faster than they should, with the average middle-aged adult's heart having the characteristics of a heart five years' older than the chronological age of its owner, an analysis of heart health checks by Lloydspharmacy suggests.

The analysis, based on a sample of more than 3,000 tests conducted on adults less than 60 years old, revealed that smokers' hearts appear to be 14 years older than their owners' actual ages. Non-smoking men have hearts that are four years' older, whereas non-smoking women have a heart age that matches their chronological age.

"People move into a higher coronary risk category when they reach their 40s," said Andy Murdock, Lloydspharmacy's pharmacy director. "The good news is that there is a lot that can be done to reduce risk. The important thing is to identify people who have an elevated risk early and then help them alter their lifestyle accordingly."

In the analysis, heart age was calculated using an interactive online tool based on a protocol developed by researchers at Unilever and Boston University, Massachusetts, using factors such as blood pressure, cholesterol levels, diet and lifestyle.

□ **Lung age** Telling smokers their "lung age" improves the likelihood of them quitting, UK researchers have found. They examined the effect of expressing results from spirometric assessment of lung function in terms of lung age (the age of an average healthy individual with the same result) as opposed to a figure for forced expiratory volume at one second (FEV1).

A total of 561 smokers took part in the study. Of the 280 smokers who were told their lung age, 13.6 per cent had stopped smoking at 12 months compared with 6.4 per cent of those given their FEV1 result (*BMJ Online First*, 6 March, www.bmj.com).

Pharmacies not protected by anti-violence provisions for NHS

Community pharmacists will not be given the same level of protection from abusive patients as hospital-based health staff.

That seems to be the Government view, expressed by Lord Bassam of Brighton, a Home Office spokesman in the House of Lords.

During a debate on the Criminal Justice and Immigration Bill this week, Lord Bassam opposed a proposed amendment that would have extended a new criminal offence of causing nuisance or disturbance on NHS premises to cover community pharmacies and hospices.

As drafted, the offence will be committed if the behaviour takes place in an NHS hos-

pital building, its grounds or in other buildings within the grounds.

He said: "Simply extending these provisions, which are specifically designed for hospitals, to the wider NHS is both unjustifiable and would make them unfit for purpose as it would assume the problem exists in the same way in other healthcare settings as it does in hospitals, and that the correct method to deal with nuisance or disturbance behaviour in these settings is to remove the person from the premises." Lord Bassam added: "I do not consider that the problem is identical in other healthcare settings or that the solution to deal with the problem in other healthcare settings should be the same."

UniChem returns to BAWP

UniChem has rejoined the British Association of Pharmaceutical Wholesalers as a full member, it was announced this week. The BAWP has expressed regret at the circumstances surrounding UniChem's departure from the association last year (*PJ*, 14 April 2007, p417) and believes it will be strengthened by the wholesaler's return.

New chief executive for AIMp

Colin Baldwin has been appointed chief executive of the Association of Independent Multiple Pharmacies (AIMp). Mr Baldwin, former chief executive of the Company Chemists' Association, is to take over from Roy Carrington, who retires in April.

In brief

Access to *PJ Online* is free to all

PJ Online

Headache

A new article for community pharmacists on managing headaches, plus a continuing professional development series on headache, migraine and facial pain, and a link to the Migraine Action Association. www.pjonline.com/headache

Hospital Pharmacist

The March issue of *Hospital Pharmacist* is now online. There are reports and presentations from the *Hospital Pharmacist* conference, a careers article about a psychiatric liaison pharmacist, and the *Guild Matters* newsletter. www.pjonline.com/hp

SMC approves infliximab for child Crohn's disease

Infliximab (Remicade) can be used in Scotland for treatment of paediatric patients with severe active Crohn's disease, the Scottish Medicines Consortium has decided in its latest round of appraisals. Patients aged six to 17 years who have not responded to conventional treatment, including a corticosteroid, an immunomodulator and nutrition therapy, or who cannot tolerate such treatments, are now eligible to receive infliximab.

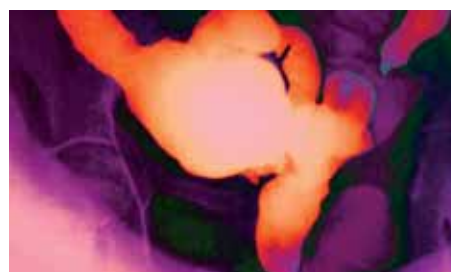
The SMC has also accepted zoledronic acid (Aclasta) 5mg solution for infusion for restricted use for post-menopausal women with osteoporosis who cannot tolerate, or are unsuitable for, oral osteoporosis treatments.

In addition, daptomycin (Cubicin) has been approved for treatment of *Staphylococcus aureus* bacteraemia associated with complicated skin and soft tissue infections or with right-sided

infective endocarditis, but only for adults with known or suspected methicillin-resistant *S aureus* infection and on the advice of local microbiologists or infectious diseases specialists. Daptomycin, the SMC says, costs more than some alternative treatments but does not require therapeutic drug monitoring.

The SMC has approved diclofenac injection (Dyloject) for treatment or prevention of pain, used only in the post-operative setting and administered intravenously.

Both follitropin alfa (Pergoveris) and mesalazine 1,200mg gastroresistant prolonged-release tablets (Mezavant XL) have been accepted for their licensed indications. Salmeterol/fluticasone 50/500µg (Seretide 500 Accuhaler) was rejected by the consortium for symptomatic treatment of patients with chronic obstructive pulmonary disease.



Sovereign, ISM / Science-Photo Library

Crohn's disease can be treated with infliximab

The SMC has recommended that bevacizumab (Avastin) should not be used for the first-line treatment of patients with advanced or metastatic renal cell cancer, in combination with interferon alfa-2a, in the absence of a submission from the licence holder.

PPRS renegotiation used as reason to limit comment on Health Select Committee report

Renegotiation of the Pharmaceutical Price Regulation Scheme is being used by the Government as a reason for not commenting on a Parliamentary recommendation that the National Institute for Health and Clinical Excellence should assess all new medicines for cost-effectiveness when they are launched. The recommendation was made in a House of Commons Health Select Committee report earlier this year (*PJ*, 5/12 January, p4).

The Government's response to the report, published last week, says that the PPRS is currently being renegotiated and that it cannot comment on the recommendation because the renegotiation might be relevant to NICE's appraisal process.

The PPRS is being renegotiated as a result of an Office of Fair Trading investigation. One of the OFT's recommendations was that all new drugs should be appraised for clinical and cost-effectiveness (*PJ*, 24 February 2007, p208).

The Association of the British Pharmaceutical Industry has welcomed the

Government's response. "The price paid for a medicine or any other treatment has to be seen in the context of the overall value it brings — including benefits, such as savings in hospital care and social services as well as quality of life improvements for patients," said ABPI commercial director David Fisher.

"NICE's decisions have been made on far too narrow a basis, with the result that many innovative medicines have not been made available to all patients who could benefit from them. We shall eagerly participate in these discussions with the aim of putting that right."

Commenting on the select committee's recommendation that an independent body should determine a cost-effectiveness threshold to be used by NICE when assessing treatment, the Government says that the potential benefits, such as greater independence and wider debate, do not outweigh the disadvantages. Besides which, the Government says, the evidence on quality adjusted life years available to any separate body would be no better than that available to NICE.

Tell parents fever is natural response to infection, says DTB

Parents and carers should be reassured that fever is a natural response to infection and may help combat infections, this month's *Drug and Therapeutics Bulletin* recommends.

There is little evidence on the effects of antipyretic drug therapy on discomfort associated with fever and insufficient evidence on whether antipyretic drugs help to prevent febrile seizures, the *DTB* says.

"However, a child who is distressed or uncomfortable because of the fever or associated symptoms, such as myalgia or headache, is likely to benefit from treatment with paracetamol or ibuprofen," it suggests.

In line with National Institute for Health and Clinical Excellence guidance the *DTB* says there is no clear advantage from using paracetamol and ibuprofen either together or alternately. The *DTB* also recommends paracetamol as the preferred option for children with renal impairment or dehydration, or who are at risk of gastric bleeding or ulceration.

Scottish contractors to receive one-off public health service payment

Community pharmacy contractors in Scotland are to receive a one-off supplementary payment of almost £950 next month for work already carried out as part of tier two of the public health service, which involves displaying public health campaign material in the window of their pharmacies.

An NHS circular, published this week, explains that originally it had been planned for one campaign to take place each quarter but that four campaigns have been fitted into the

nine months since July. Therefore, the circular states: "It has been agreed that public health service payments for 2007-08 will be reset as if public health service had been in place for a full year." Eligible contractors will receive a one-off payment of £942.89 with their payment for February dispensing (to be paid in April).

☐ **ePharmacy funding** Details of how and when ePharmacy infrastructure funding will be paid were also published by the Scottish

Government this week. The payments (£100 per month plus an initial £250) are for installing and maintaining software to support the electronic acute medication service (eAMS).

The additional payment for processing prescriptions electronically (eClaim) will be calculated automatically from ePharmacy Message Store data and be reported on the monthly remuneration report from the Practitioner Services Division.

Novel vaccine reduces BP by targeting angiotensin II

Targeting angiotensin II with a virus-derived vaccine — CYT006-AngQb — has been shown to reduce hypertension in a study published last week in *The Lancet* (2008;371:821). However, the authors of an accompanying editorial (ibid, p788) raise concerns about the safety of circulating angiotensin II antibodies.

In the phase IIa study, 72 patients were randomised to receive either 100µg or 300µg of the experimental vaccine or placebo at weeks 0, 4 and 12. Ambulatory blood pressure was measured for a 24-hour period both before treatment and at 14 weeks.

Patients given 300µg of CYT006-AngQb experienced reductions in ambulatory daytime blood pressure (significant for systolic [$P=0.015$] but not for diastolic measurements), compared with those on placebo. The 300µg dose reduced the early morning surge in blood pressure for both systolic and diastolic measurements, compared with placebo ($P<0.0001$ and $P=0.0035$, respectively).

“The drop in blood pressure was especially pronounced in the early morning when the

renin-angiotensin-aldosterone system [RAAS] is most active and when most cardiovascular events occur,” the study authors write. “This effect was not anticipated at the beginning of the study. By contrast, small molecule inhibitors of the [RAAS], while lowering blood pressure over 24 hours, do not affect the surge in early-morning blood pressure.”

Influenza-like symptoms occurred in three patients receiving the 100µg dose, in seven receiving 300µg and in none in the placebo group, and these effects were mild and transient. Such effects are thought to originate from the activation of the innate immune system that occurs after immunisation, the authors say.

They also suggest that optimising the immunisation regimen with shorter dosing intervals and a higher dose could lead to higher antibody titres and a more robust antihypertensive effect. “Later stage clinical trials will be needed to show efficacy and safety in a broader hypertensive population,” they add.

The authors of the editorial, Ola Samuelsson and Hans Herlitz from

Sahlgrenska University Hospital, Sweden, believe that vaccination against high blood pressure might solve many of the problems around non-compliance but they spell out a number of concerns over the safety of the strategy.

They say that the long half-life of the antibodies against angiotensin II — some 17 weeks — “raises the question of whether it will be safe to inhibit the actions of circulating angiotensin II for several months without the ability to quickly reverse inhibition, which is easily done for drugs by withdrawal of treatment”.

They acknowledge the study authors’ finding that the blood-pressure lowering effect was greatest during the early morning when the RAAS is most stimulated but point out that situations can occur when a patient would need a fully activated RAAS.

“Another important safety issue is whether repeated stimulation of the immune system by booster doses of an endogenous peptide linked to a virus-like particle can cause autoimmune disease,” they add.

Patient safety campaign will kick off in July

A patient safety campaign to reduce harm and save lives in the NHS in England is to be launched in July. The campaign is being developed and led by a team of NHS staff, and is supported by the National Patient Safety Agency, The Health Foundation and the NHS Institute for Innovation and Improvement.

Steve Brown, director of pharmacy at United Bristol Healthcare NHS Trust, is part of the core campaign team, which includes clinicians, managers and patient safety representatives. He told *The Journal* that the campaign’s aims will be published soon but would seek to change the culture of patient safety and encourage everyone to participate.

The campaign will promote the use of a number of evidence-based interventions, which will be considered at awareness events being held around England next month. Mr Brown encouraged pharmacists to attend these events.

The campaign is being directed by Stephen Ramsden, chief executive of Luton and Dunstable NHS Foundation Trust, which was the first site in England to take part in the

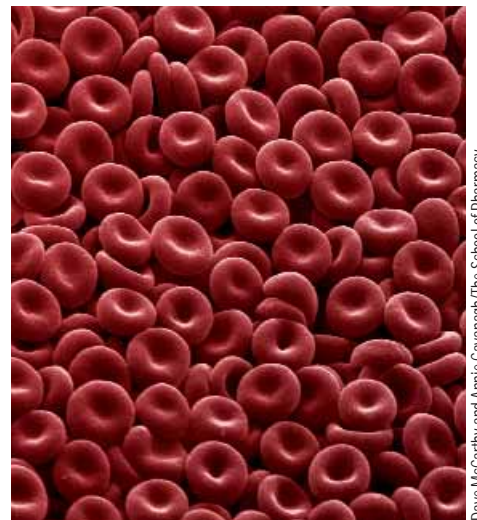
Safer Patients Initiative (*PJ*, 28 July 2007, p95).

Sir Liam Donaldson, England’s chief medical officer, said: “The NHS campaign will be a key component of a national patient safety strategy to prioritise patient safety and embed it into the fabric of everyday practice. It is a unique and timely opportunity to intensify efforts to implement interventions that continuously reduce risks to patients.”

The campaign will be voluntary and will initially focus on NHS acute trusts since this is where there is the most evidence for achieving significant improvements in patient safety. A series of workshops will be held around England from 1–9 April where NHS staff can find out more about the campaign and be involved in shaping it. Staff can register for the April events through the NPSA website (www.npsa.nhs.uk) or directly at <https://secure2.symphonyem.co.uk/patient-safety-campaign>.

Scotland has already set up a similar campaign — the Scottish Patient Safety Alliance — which was launched last year (*PJ*, 17 March 2007, p300). Initiatives are also being developed in Wales and Northern Ireland.

School of Pharmacy images among Wellcome winners



Colour-enhanced scanning electron micrograph of red blood cells

Scientists working at the School of Pharmacy, University of London, have produced five award-winning colour-enhanced scanning electron micrographs in the Wellcome Image Awards 2008 (previously the Biomedical Image Awards).

The micrographs, produced by experimental officer Dave McCarthy and multimedia unit manager Annie Cavanagh, show a carpet of red blood cells, clusters of breast and prostate cancer cells, a house fly on sugar crystals and *Clostridium difficile*. The images are among 22 award winners on display in the Wellcome Collection Atrium in London.

Goldshield reaches settlement with Scottish Government

Goldshield — one of the generic medicine suppliers accused of illegal price fixing — has reached a settlement with the Scottish Government. A similar agreement was reached with the English Department of Health last year (*PJ*, 30 June 2007, p758).

Goldshield has agreed to pay £750,000 in compensation on a full and final basis and with no admission of liability. Part of the deal includes a promise to co-operate with the Scottish Government in continuing claims against a number of other companies.

Study supports use of aromatase inhibitors after tamoxifen use ends

Women who finished tamoxifen treatment for breast cancer several years ago may still benefit from taking letrozole to reduce their risk of recurrence further, according to the lead researcher of an international study.

Paul Goss, Massachusetts General Hospital cancer centre, Boston, and colleagues conducted a multicentre phase III trial to examine the efficacy of letrozole started after adjuvant tamoxifen in postmenopausal women with hormone receptor-positive early-stage breast cancer.

They found that, compared with placebo, letrozole reduced the risk of breast cancer recurrence by 63 per cent (hazard ratio 0.37, 95 per cent confidence interval 0.23–0.61; $P < 0.0001$) and the risk of cancer spread by 61 per cent (0.39, CI 0.20–0.74; $P < 0.004$) in women who had completed five years of tamoxifen therapy one to seven years earlier. The researchers note that there were more

self-reported cases of osteoporosis and more clinical fractures in the women who were treated with letrozole. The study is published online ahead of appearing in the April issue of the *Journal of Clinical Oncology* (<http://jco.ascopubs.org>).

In a separate analysis of the same trial (ibid), researchers led by Hyman Muss, professor of medicine at the University of Vermont, Burlington, conclude that the reduced risk of breast cancer recurrence persisted among all age groups, including women over 70 years, although was only statistically significant for disease-free survival in women under 60 years.

□ **Exemestane benefit** A third study (ibid) confirms that women who receive extended treatment with exemestane, another aromatase inhibitor, soon after completing five years of tamoxifen treatment also have a reduced risk of breast cancer recurrence.

Gwent pharmacies called on to help raise awareness of illegal dealing of medicines

Pharmacy customers in Gwent are being asked to pass on any information they have about individuals involved in dealing prescription medicines and illicit drugs.

Gwent Police has issued pharmacies with 20,000 leaflets asking for people to pass on information about those involved in such illegal activity. From this week, the pharmacies will be handing out the leaflets when they dispense prescriptions. Information can be given anonymously to Crimestoppers on 0800 555 111.

Roger Booth, pharmacy officer for Gwent Police, told *The Journal* that the campaign is a continuation of other work the force has been doing to raise awareness of safety issues around illicit drugs and misuse of prescription drugs. Gwent Police already alerts pharmacists to these issues through its community safety messaging scheme.

Concerns around the dealing of illicit drugs have been recognised by pharmacists and the public for some time, Mr Booth said. In addition, a number of prescription medicines have considerable value on the street, including some used to treat children, such as methylphenidate, as well as diazepam and temazepam. Gwent Police is now trying to raise awareness of issues relating to misuse of prescription drugs and has welcomed the fact that all pharmacists have embraced the scheme, he said.

Mr Booth also explained that other pharmacy products may be used in the preparation of illicit drugs, such as pseudoephedrine



Leaflets, available in Welsh and English, will be handed out with medicines

and ephedrine, used to manufacture the Class A Controlled Drug methylamphetamine, and ammonia, used to wash crack cocaine. Pharmacists should alert police to any concerns they have that substances may be being used by those dealing prescription and illicit drugs, Mr Booth stressed.

Paul Gimson, chief executive of Community Pharmacy Wales, commented: "[Community pharmacists'] expertise, coupled with community pharmacy being located in the heart of Gwent communities, means their involvement in an initiative like this could have a real impact on illegal drug use."

Drug development

Novartis reports everolimus success

Investigation of everolimus — also known as RAD001 — has been stopped early by Novartis after the primary endpoint of its study was successfully met. Interim results from the phase III research showed significantly better progression-free survival for patients with advanced kidney cancer who received the drug, compared with those on placebo. Patients in the placebo arm of the study are to be offered everolimus. Novartis expects to apply for European regulatory approval later this year.

Broccoli sprouts and bladder cancer



Extract of broccoli sprouts (pictured) could help to protect against bladder cancer, a rodent study suggests (*Cancer Research* 2008;68:1593). Researchers

demonstrated significant, dose-dependent inhibition of bladder cancer development for rats fed broccoli sprout extract along with a bladder carcinogen, compared with those given the carcinogen only.

Lilly axes inhaled insulin

Eli Lilly and Company has terminated its inhaled insulin programme — AIR Insulin — a joint venture with Alkermes Inc. The programme, currently in phase III, has been axed not because of safety concerns during trials, Lilly says, rather as "a result of increasing uncertainties in the regulatory environment, and a thorough evaluation of the evolving commercial and clinical potential of the product compared to existing medical therapies". Responding to the news, rival biopharmaceutical firm MannKind said it remained "absolutely committed" to its Technosphere Insulin product, which is in phase III trials.

New anticancer treatment proposed

Scientists have designed a compound to protect a protein that normally helps suppress tumours but that is inactivated in almost all human cancers. One reason for this inactivation is an interaction between this protein (called p53) and a particular oncoprotein. The experimental compound, MI-219, selectively blocks this interaction. Mice given MI-219 daily for 14 days had a 75 per cent reduction in tumour xenograft growth compared with controls ($P = 0.0011$). The authors suggest clinical investigation of MI-219 as a cancer treatment (*PNAS Early Edition*, 3 March, www.pnas.org).