

PSNC to face challenge over decision to cut period of treatment fee until April

A CHALLENGE to the Pharmaceutical Services Negotiating Committee decision to accept the suspension of the period of treatment fee for the remainder of the financial year as a way of avoiding a global sum overpayment is possible.

Imran Khan, a vice-chairman of North East London Local Pharmaceutical Committee, told *The Journal* that he had been receiving telephone calls from contractors throughout England who are upset by the PSNC's decision. He intended to form an action group to call for a special meeting of LPCs to discuss the PSNC attitude. The action group might even consider some form of legal challenge to the PSNC.

"They have alienated a sector of the contractors they represent," Mr Khan said.

The core of the complaint is that removing the period of treatment will have a disproportionate effect on a subset of contractors who dispense prescriptions from doctors who persist in prescribing for long periods, rather than issue repeat prescriptions at 28 day intervals. "They are talking



Imran Khan: What is the evidence base for the PSNC's decision?

about saving £4m," Mr Khan said. "That's the equivalent of 0.1p off the dispensing fee for a month for all contractors. It's only those who dispense high volume prescrip-

tions who will suffer. The PSNC has taken a decision to penalise those who already lose dispensing fees under the system. I'm sure we could all afford to give up 0.1p for a month."

Mr Khan is concerned that the PSNC's decision to accept the Department's proposal has no sound basis. He said: "What was the evidence they used to come to their decision? We don't think they used any evidence at all."

Godfrey Horridge, financial executive at the PSNC, declined to add to a statement issued by the PSNC chief executive, Sue Sharpe (see p885).

Mrs Sharpe said that options were discussed at length by the PSNC's contract planning committee in November. In the absence of a specific proposal from the Department at that time no conclusion was reached. When the Department made its proposal later, PSNC members were asked for their views by e-mail. Their decision was based on the discussions that took place in November.

OFT control of entry report delayed until new year

THE long-awaited report from the Office of Fair Trading on the control of entry into pharmacy contracts has been delayed until January 2003 at the earliest.

A spokeswoman for the OFT told *The Journal* that the report is now expected to be published "early in the new year". The OFT had previously said that it would publish the report before the end of 2002 and had been expected to hold a press conference to do so this week.

The Pharmaceutical Services Negotiating Committee has speculated that one reason why the publication of the OFT report was postponed from this week was to avoid its simultaneous appearance with a report from the New Economics Foundation (NEF) think tank. This has suggested that

neighbourhood shops in Britain's smaller towns and villages are approaching economic collapse.

The NEF report "Ghost town Britain" says that roughly one-fifth of all small local shops and services, around 30,000 businesses, closed between 1995 and 2000 and that over the next 10 years it could reach a third of businesses on current trends. It suggests that if the number of small shops in a locality falls below a critical mass there could be a "tipping point" beyond which local economies collapse as the amount of money circulating is insufficient to maintain all the businesses. Furthermore, it suggests that this point could be approaching rapidly.

The report says that such neighbourhoods would then "become food and enter-

prise deserts with poor nutrition and ill health (eg, diabetes, heart disease and mental health problems)" and that there would be knock on effects to the local economy and environment through the loss of part-time jobs, increased vandalism and other crime and increased car use.

The report calls on the Government to review the rules governing the opening of new supermarkets and the prices they charge, extend discretionary rate relief to small stores, public houses and community pharmacies where local economies are in decline and support the use of experimental local currencies.

Copies of the executive summary to the NEF report can be found through the *PJ Online* links page (www.pjonline.com/links).

ETP pilots set to continue into 2003

THE electronic transmission of prescriptions pilot schemes are expected to continue into the new year.

The three ETP pilots were designed to test whether the existing paper-based prescription system could be replicated using electronic transmission and the pilot consortia were required to provide a certain volume of prescription data for analysis by the end of 2002.

The Pharmacy2u consortium, which also includes Hadley Healthcare and EMIS, says that it intends to continue its pilot into a second phase in 2003, subject to approval by the Department of Health. The consortium

is to be renamed, to avoid confusion with Pharmacy2u's existing mail order pharmacy business. The new name was not available as *The Journal* went to press.

Both the TransScript and the Flexiscript pilots are also expected to continue, subject to approval.

Diane Drew, communications manager at PharMed, which is leading the TransScript consortium, said that there was benefit in continuing because prescription volumes were building up. "ETP fits in with the expanding information technology agenda for the National Health Service," she added.

BRIEFLY

Essential small pharmacy targets

The annual target payment for contractors in the Essential Small Pharmacy Scheme has been increased to £41,800, in line with the global sum increase. The ESPS threshold for 2002-03 is 24,360 prescriptions with a maximum monthly ESPS payment of £2,990. In order to make a back payment from April 2002, the maximum monthly payment will be increased to £3,760 for January 2003 only. There are 265 contractors in England and Wales who receive payments under the ESPS.

Pharmacists should make PCTs aware of what they can deliver, says minister

COMMUNITY pharmacists should be pushing on the doors of primary care trusts with their projects for delivering the Government's health care agenda, according to junior health minister David Lammy.

Speaking at an All-Party Pharmacy Group meeting on 11 December, Mr Lammy said that pharmacy is crucial to delivering much of the agenda, and if pharmacists meet resistance from their PCTs, they should report back to the Department of Health.

On the community pharmacy contract, Mr Lammy said that NHS payments to pharmacists need to be taken seriously and looked at closely. The national contract is a leftover from a past agenda, and with the need to localise pharmacy provision it has become a handicap. The right payment mechanism is fundamental to ensuring that pharmacists play a bigger part in the NHS, but the mechanism will have to be reformed carefully because other issues must also be considered.

On the pharmacy workforce, Mr Lammy said that the Department's skill mix project is fundamentally important. All



David Lammy: the national contract is a leftover from an old agenda

pharmacy staff should be fully engaged and their skills fully used in a more flexible way.

Mr Lammy warned that supplementary prescribing by pharmacists will not happen overnight. Pharmacists based in general

practice surgeries should be the first to embark on prescribing, he suggested, because the relationship with the GP is important at a time of change in the NHS.

On information technology, he said that IT offers tremendous challenges throughout the NHS — not just for pharmacy — but there is a long way to go, and other important issues need to be tackled before the NHS can move on with IT.

During a question session, Hemant Patel, a member of the Royal Pharmaceutical Society's Council, said that community pharmacists have been putting their case locally for years, but in his experience every proposal is blocked on the ground that it will increase the drugs budget. PCTs need to be given direction. Another Council member, Andrew Burr, said that his PCT has told him that no money is available for pharmacy because the GPs are out of pocket — even though pharmacy can provide services that help GPs save money.

Mr Lammy said that the PCTs are where the agenda is. He would find a way to encourage them to take pharmacy's proposals seriously.

Government accepts that vets must give written prescriptions

THE Department for the Environment, Food and Rural Affairs has accepted most of the main conclusions of the independent Marsh report into dispensing by veterinary surgeons, including that veterinary prescriptions should be written immediately after a diagnosis has been made.

After formal consultation on the report, which was written by a review group led by Professor Sir John Marsh, the Government has accepted eight of the 14 recommendations made, rejected one and deferred decisions on five others awaiting ongoing reviews by the European Commission and the Competition Commission. Some of the

other recommendations accepted are that veterinary pharmacy services should be improved in order to reduce costs; farmers, veterinarians and pharmacists should draw up health plans for farm animals; all those involved in prescribing or dispensing medicines for animals should undertake continuing professional development; and cat and dog wormers should be available through pet shops.

The Government rejected a proposal that generic medicines for humans should be prescribed for companion animals, saying that this would hinder the development of species-specific medicines in the future.

LPS contractors are better protected

LOCAL pharmaceutical services contractors can object to new pharmacy contracts. They can do this in a way that is denied to conventional contractors faced with competition from LPS applicants.

The National Health Service (Local Pharmaceutical Services Etc) Regulations 2002, which came into effect on 12 December, give LPS contractors the right to object to applicants on the grounds that they are neither necessary nor desirable for the proper provision of pharmaceutical services. LPS applicants are exempt from this test.

No free broadband

THERE is to be no free broadband internet access for pharmacies in the foreseeable future. David Lammy, the Parliamentary Under-Secretary of State with responsibility for pharmacy, has told Parliament that there are "no specific plans to provide broadband connectivity to pharmacies".

Answering a question posed by the secretary of the All-Party Pharmacy Group Mark Todd, Mr Lammy said that the need for pharmacy broadband access will be reviewed as the NHS IT strategy develops. Apart from that, it was restricted to pharmacies taking part in electronic prescription transfer pilots.

BRIEFLY

Generic prices

The Department of Health's maximum prices scheme for generic medicines is to continue. After consulting generics manufacturers (*Pf*, 26 October, p596), Parliamentary Under-Secretary of State for Health Lord Hunt decided to make no changes. Discussions are continuing on long-term arrangements for supplying generics to the National Health Service.

Compliance studies needed

Researchers have called for more studies of innovative approaches to help patients use their medicines (*JAMA* 2002;288:2868). They reviewed published randomised controlled trials of interventions designed to improve compliance and found that most interventions were complex and not predictably effective.

MRSA deaths increasing

Deaths due to methicillin resistant *Staphylococcus aureus* (MRSA) are increasing, according to the Public Health Laboratory Service. The percentage of death certificates mentioning MRSA has increased threefold in a five-year period, from 7.5 per cent in 1993 to 25 per cent in 1998. The rise is unlikely to be due to improved reporting and further improvements in surveillance and control of health care associated infection should be a priority, the PHLS says.

Leukaemia treatment will be tailored to each individual's disease status

SUCCESSFUL treatment of leukaemia in the future will involve a combination of interventions tailored to individuals' disease status and prognostic markers, specialists heard at an American Society of Hematology meeting held in Philadelphia last week.

Two trials presented at the meeting showed that combining two active treatments, fludarabine (Fludara) and the monoclonal antibody alemtuzumab (Mab-Campath), was effective and safe in patients with chronic lymphocytic leukaemia (CLL). The first trial involved 56 patients with active disease who were previously untreated. They were given intravenous fludarabine 25mg/m² body area daily for five days every month for four months. Those who responded went on after two months to receive a six-week course of intravenous alemtuzumab 30mg three times a week.

Of the 56 patients, 27 per cent had a complete response and 43 per cent achieved a partial response. Ten months later, 87 per cent of patients were still alive. The authors say the results are extremely encouraging in

a patient population that is often difficult to treat successfully.

Meanwhile, a smaller European study suggests that giving these two treatments at the same time may induce a synergistic response with acceptable toxicity profiles, at least in a group of patients who have failed to respond to other treatments.

The trial involved 14 patients with relapsed or refractory CLL. All were pre-treated with alemtuzumab up to 30mg a day then given both drugs together. Preliminary results show that, of the 11 patients analysed so far, eight are in complete remission and a further one has had a partial response.

The authors suggest the combination is extremely effective with generally mild transitory side effects. However, they stress that a larger trial in this heavily pre-treated group of patients is needed.

Professor Clare Dearden, lead clinician in haemato-oncology at St George's Medical School in London, said: "With combinations we are now starting to see complete remission rates that make us believe we are

making real progress in CLL. Hopefully, with the development of useful prognostic markers, we can decide which patients are going to have the poorest outcome and be able to treat them effectively."

Imatinib proves effective in chronic phase of CML

MORE patients with newly diagnosed chronic-phase chronic myeloid leukaemia (CML) respond to treatment with imatinib (Gleevec) than to standard treatment, a new study shows.

The trial, which was presented at an American Society of Hematology meeting earlier this month in Philadelphia, is the first head-to-head trial comparing the two treatment regimens in this group of patients.

The trial involved 1,106 patients with CML aged 18–70 years who were randomly assigned to receive imatinib 400mg daily or to interferon alfa plus cytarabine. The target dose for interferon alfa was 5 mega units/m² body area daily and for cytarabine was

20mg/m² body area, given subcutaneously for 10 days every month. The data for 18-months' follow-up revealed that more patients randomised to imatinib than interferon alfa plus cytarabine achieved a normal blood count (97 per cent versus 69 per cent).

In addition, more than twice as many patients treated with imatinib than interferon alfa plus cytarabine showed major cytogenetic response — elimination of cells containing the Philadelphia chromosome, the genetic abnormality that characterises most cases of CML (87 per cent versus 35 per cent). Complete cytogenetic response occurred in 87 per cent of the imatinib group, compared with only 14 per cent of the interferon alfa plus cytarabine patients

($P < 0.001$). Progression-free survival at 18 months was greater with imatinib (92 per cent versus 73 per cent, $P < 0.001$).

Presenting the findings, Dr Richard Larson, University of Chicago, said: "The use of imatinib resulted in a significantly higher response rate and a longer period before the disease progressed. This should be viewed as a positive step forward in the treatment of CML."

Further data reported at the meeting showed that in patients who achieved complete cytogenetic remission, levels of BCR-ABL — the protein that activates signal transduction pathways, resulting in uncontrolled cell growth — continued to fall in patients treated with imatinib.

Vinorelbine not recommended as first-line treatment in advanced breast cancer

VINORELBINE (Navelbine) should not be used as first-line treatment for advanced breast cancer, according to the National Institute for Clinical Excellence.

In its guidance issued earlier this week, NICE says that there is insufficient evidence to suggest that first-line monotherapy with vinorelbine has advantages over other treatments, either in terms of clinical benefit or cost-effectiveness. However, it says that after failure of anthracycline-based first-line therapy, or if anthracycline therapy is unsuitable, vinorelbine monotherapy is a potentially useful choice because of its low toxicity. A choice of follow-up treatment should be

made by the patient and clinician after a discussion of the relative benefits of available drugs and their side effect profiles.

NICE adds that after looking at the available evidence it cannot recommend routine use of the drug in combination with other chemotherapy agents. However, the guidance outlines further research required to investigate the effectiveness of combination therapy.

Copies of the guidance are available on the NICE website (www.nice.org.uk) and can also be obtained from the NHS response line, 0870 1555 455, quoting reference number N0142.

BRIEFLY

Anastrozole benefit continues

Follow-up data from the Arimidex, tamoxifen alone or in combination (ATAC) study show that women treated with anastrozole (Arimidex) are more likely to be disease-free at four years than women treated with tamoxifen.

The data also show that the percentage of patients remaining disease-free for longer on anastrozole in comparison with tamoxifen has increased since the last analysis, from 2.0 per cent at three years to 2.4 per cent at four years. Data were presented at a San Antonio breast cancer symposium last week.

Emergency contraception options not always used

UPTAKE of emergency contraception among young women, especially those from deprived inner city areas, is influenced by perceptions of low risk of pregnancy and concerns about what others think, a qualitative study has shown.

Researchers interviewed 30 women aged 16–25 years from London who attended family planning clinics, youth groups and hostels for the homeless, to explore the role of social context in the use of emergency contraception. They found that attitudes and concerns of women, especially those from disadvantaged backgrounds, might make them less willing or able to take advantage of increased emergency contraception availability.

Some women did not seek emergency contraception because they thought that the risk of pregnancy was small when they missed or did not use contraception. In addition, experienced users of contraception said that over time they started to believe they were less at risk of pregnancy and relaxed their use of contraception.

Women also reported that they saw the need for emergency contraception as a personal failing and felt ashamed to ask for it. "Women . . . wanted to dissociate themselves from any negative connotations about themselves or their relationship if they sought emergency contraception," the researchers say. Limited knowledge, problems in accessing emergency contraception

and concerns about side effects also influenced non-use.

The researchers add that attitudes of pharmacists and general practitioners also affected decisions about whether to seek emergency contraception. "Consultations that focused largely on the risks that had been taken made the women feel told off and reluctant to reattend," they say.

The study is published in the *BMJ* (2002;325:1393).

Pharmacy owner challenges three-year rule in Irish Supreme Court

AN IRISH pharmacy owner is challenging in the Irish Supreme Court a European rule that prohibits newly qualified overseas pharmacists from running domestic pharmacies for three years.

"If it wasn't for the generosity of our neighbouring island, Britain, we'd have a major staff crisis in Irish pharmacy," said pharmacy chain owner Sam McCauley. "We have so few pharmacy college places here that huge numbers have to go to the United Kingdom to gain qualifications. But when they come back home after graduation they're not allowed to run a pharmacy. It's not just unfair, it's ridiculous."

Mr McCauley, who has a 10-outlet chain across the Irish Republic, has been campaigning to end the three-year rule.

Earlier this year, when the Irish Pharmaceutical Society threatened to prosecute him for promoting two UK graduates — one Irish, the other Scots — to run two of his shops in Cork, he challenged the three-year rule in the Irish High Court. He lost and was left with a legal bill of around 100,000. Now he is risking an even larger one by appealing to the Supreme Court.

"It's a matter of principle," he says. "The rule makes absolutely no sense when there is a chronic shortage of pharmacists in this country. At present, we have just one pharmacy school, at Dublin's Trinity College. That had been producing just 50 graduates a year, though the figure has now gone up to 70. New pharmacy colleges are planned in Dublin and Cork, but they won't be turning out graduates for at least five years."

Mr McCauley estimates that a third of the 3,000 pharmacists on the Irish register have been educated outside the country. "We couldn't offer them college places, but we now tell them they can't run a pharmacy. How can that be right?" he asks.

He believes the rule, which was intended to protect existing pharmacies from an influx of overseas competitors, is an anachronism, at a time when the Irish market is being deregulated.

He is confident about the Supreme Court appeal, which will be heard early in the new year, and takes comfort from the fact that the Irish Pharmaceutical Society was not awarded costs in the High Court action.

Boots seeks new senior executives

THE Boots Co Plc is to change both of its most senior executives next year with the retirement of its chairman and replacement of its chief executive.

In a statement issued on 15 December, Boots chairman John McGrath confirmed that he would retire in July 2003. Mr McGrath's replacement is likely to be Sir Nigel Rudd, currently deputy chairman of Boots. He added that a successor to chief executive Steve Russell is also being sought. Mr Russell will remain in post until a new chief executive is appointed.

The move comes with the share price of Boots, frequently referred to in the press as "the struggling chemists chain", lying at around 550p, half its level of three years ago.

BRIEFLY

EHC for Guernsey

Emergency hormonal contraception in the form of Levonelle-2 (levonorgestrel) is to become available through pharmacies in the Channel Island of Guernsey. It should be available early next year after a review of the island's medicines legislation by the States, Guernsey's parliament.

DTB celebrates 40th birthday

Last week the *Drug and Therapeutics Bulletin* celebrated its 40th anniversary. Health Minister Lord Hunt, speaking at a reception to mark the occasion, said that it was right for the Government and the public to acknowledge the organisations that have been at the forefront of upholding patient safety. "The *DTB* is one of the essential blocks" of the process and the 120,000 doctors and pharmacists who receive the publication value the quality and honesty of the information it provides.

Counterfeit Dettol

Reckitt Benckiser is alerting retailers about a batch of counterfeit Dettol. The fake product contains methanol and may cause skin irritation. Counterfeit bottles show the quantity as 500ml (16.92 FL oz), the manufacturer as Reckitt & Colman Inc, Wayne NJ 07474 0945 and include the American toll-free number 1800 228 4722. They have either no batch code or a poorly marked one with a "V" suffix. In other respects the packaging is practically identical to the genuine product. Further information from Reckitt Benckiser customer services on 0845 769 7079.

Asda joins CCA

Asda Stores is the latest supermarket pharmacy chain to join the Company Chemists' Association. Asda joins existing members, Boots The Chemists, Lloydspharmacy, Moss Pharmacy, Safeway, Superdrug, Sainsbury's and Tesco.

Use of echinacea to treat the common cold warrants further investigation

ALTHOUGH it is difficult to ignore the widespread use and persistent anecdotal reports of the benefits of echinacea, scientific evidence of its efficacy remains unconvincing. Nevertheless, the evaluation of echinacea as a treatment option for the common cold should continue to be investigated, according to Dr Ronald Turner, University of Virginia School of Medicine, Charlottesville.

In an editorial published in *Annals of Internal Medicine*, Dr Turner says that methodological flaws in studies have limited the acceptance of reported beneficial effects of various echinacea preparations on the common cold. The fact that different preparations of echinacea have different compositions has meant definitive studies have been difficult to perform.

Dr Turner also points out that neither the active component of echinacea nor its mechanism of action for treating the common cold have been defined.

“Unless an active constituent or combination of constituents can be identified or a desired biological activity defined, we cannot address such fundamental issues as dosing, bioavailability or pharmacokinetics,” he says

(2002;137:1001). In the same issue of *Annals of Internal Medicine*, researchers report that in a study of 148 subjects with recent onset common colds, unrefined echinacea provided no detectable benefit or harm, compared with placebo.

They assigned those in the echinacea group to receive an encapsulated mixture of unrefined *Echinacea purpurea* herb (25 per cent) and root (25 per cent) and *Echinacea angustifolia* root (50 per cent) taken in 1g doses six times on the first day of illness and then three times daily on each subsequent day of illness for a maximum of 10 days.

The preparation was found to have no effect on the duration or severity of symptoms, contradicting current published evidence, the researchers say. However, the preparation used had not been tested previously and may be ineffective because of bioavailability or phytochemical constituents. Also, the population studied, healthy undergraduate college students, may be among those who might not gain much benefit from echinacea (ibid, p939).

Dr Jo Barnes, lecturer in phytopharmacy, School of Pharmacy, University of London, told *The Journal*: “This is not the

end of the story for echinacea, more a twist in the tale.” The results of the study should not be extrapolated to other preparations of echinacea which have different phytochemical composition. She added: “Clearly, further research with well-defined preparations of echinacea are needed to determine whether they are efficacious in treating symptoms of the common cold”.

Pharmacists could advise patients about depression more extensively

PHARMACISTS could play a much greater role as first-line advisers on depression and its treatment, according to researchers from the department of medicines management at Keele University.

Mary Landers and colleagues interviewed 20 community pharmacists about their involvement in the management of depression and discovered that pharmacists generally saw their role as encouraging patients to take antidepressants. They also found that pharmacists provided technical information, mainly when the first prescription for antidepressants was dispensed. However, the range and nature of questions that patients asked suggest that pharmacists are viewed as experts on both the illness and on medicines.

The researchers comment that some pharmacists are attempting to respond to the needs of patients who do not want to consult their GP about depression. They add that in some cases patients' needs are surpassing pharmacists' skills.

They say: “The type and extent of support pharmacists provided to patients was constrained by their reluctance to risk conflict [with general practitioners]. In this respect community pharmacists are regularly faced with ethical dilemmas . . . where the needs of the patient and the intention of the physician may apparently be at odds.”

The researchers conclude that professional boundaries need to be redefined if the care of patients with depression is to be improved (*International Journal of Pharmacy Practice* 2002;10:253).

Other *IJPP* papers

- Practice-based pharmaceutical services: a systematic review (A. Fish)
- Patient receipt of, and preferences for receiving, antidepressant information (B. Sleath and K. Wurst)
- Perceptions of young women using SSRI antidepressants — a reclassification of stigma (P. Knudsen *et al*)
- Attitudes of community pharmacists in the Netherlands towards adverse drug reaction reporting (A.C. van Grootheest *et al*)
- Nurse prescribing from the community nurse's perspective (K.A. Luker and G.A. McHugh)
- Pro-Change adult smokers program: Northumberland pilot (C. Anderson and A. Mair)

Further evidence on HRT and cardiac risk

HORMONE replacement therapy (HRT) does not reduce the overall risk of further cardiac events in postmenopausal women who have survived a myocardial infarction, according to the results of a major trial.

Researchers found no difference in the frequency of recurrent heart attack or cardiac death at two-year follow-up among a group of some 1,000 women, aged 50–69 years, who were treated either with 2mg estradiol valerate or placebo daily. There was also no difference in all-cause mortality between the two groups.

The study adds to the growing body of research evidence that concludes HRT should not be used for the secondary prevention of heart disease (*Pf*, 30 November, p774).

However, in an accompanying commentary, Dr Jacques Rossouw, of the United States National Heart, Lung and Blood Institute, says the role of HRT in primary prevention is less clear, and suggests endogenous oestradiol may protect younger women against coronary heart disease.

“If so, then transdermal oestrogen, which more closely mimics human physiology, may eventually hold more promise for primary prevention than oral oestrogens,” he says.

The study is available online via the *Pf Online* links page (www.pfonline.com/links) and is published in this week's edition of *The Lancet*.