

# Concerns raised with Privy Council over new Charter

Eleven past-presidents and two former heads of the law department of the Royal Pharmaceutical Society have written to the Privy Council to express grave concerns about the Council's petition for a new Royal Charter.

Ann Lewis, Secretary and Registrar of the Society commented: "It is open to anyone to send their views on the draft Charter to the Privy Council Office during the gazetting period, which closes on 23 January. It is for the Privy Council to consider the submissions it receives. We will respond to any request for information or comment that we receive from the Privy Council Office."

In their letter, the 11 past-presidents ask the Privy Council to advise the Society to gain its members' approval before a new Charter is granted. They write that they are concerned that the objects in the proposed new Charter differ profoundly from those in the present Charter. "The duty of the Society to regulate the profession (which we do not oppose) has never been founded in the Charter. The Society, as established under its Charter, is a professional body, and the addition to the Charter of regulatory objects is a very substantial change, the nature and effect of which has not been properly explained to the members nor agreed by them. The object relating to representation of members has



**Gordon Appelbe says the Council has broken the rules on Charter changes**

similarly been altered without adequate explanation to or agreement of the members," they say.

Meanwhile, in a separate letter, Gordon Appelbe and Sue Sharpe, writing as former heads of the law department at the Society, say that the Council has not followed correct procedure. They write: "The present Royal Charter includes, in Article 20, procedures

that must be followed for any amendment of the Charter. These require that a majority of three-fourths of members of Council support the proposed change, and that it then be supported by three-fourths of members attending and voting at a special general meeting. The Council has not followed this procedure. We believe that the Council must, as a minimum, comply with the requirements prescribed for any amendment to the present Charter when seeking a new Charter." They also point out that at the special general meeting in June 2003, a resolution was passed unanimously that a referendum of members on any proposed new Charter be held. A referendum has not been held.

Speaking at a press briefing this week, Miss Lewis said that if the Charter petition were unsuccessful, "we will be back at square one". This could be a disadvantage, she explained, because of progression with the Section 60 order. "The Section 60 order would proceed and any new Charter would then be subject to that," she said. "In terms of the order, it is better for the Charter to be in the lead since matters in the Charter are more under our control than matters in legislation are."

Miss Lewis confirmed that the Society expects that a three-month consultation on the Section 60 order will take place later this year.

## Health department says wait before putting DIY NHS branding on community pharmacies

Community pharmacists in England are being told by the Department of Health not to rush into spending money on NHS branding for their pharmacies.

A spokesman said that the Department is currently exploring ways of helping pharmacies use NHS branding. An announcement should be expected in a few months.

A statement said: "Specific guidelines showing how the NHS identity can be used in pharmacy environments to highlight the services pharmacists provide are in development. We are currently working with pharmacists and stakeholders to ensure that the guidelines are appropriate and we expect them to be released shortly."

Following visits to a number of pharmacies, proposals from the NHS branding unit are to be put to the Pharmaceutical Services Negotiating Committee in February.

Alastair Buxton, head of NHS services at the PSNC, said: "Branding will be included in the new contract discussions. There needs to be a value attached to NHS branding, because the multiples, in particular, jealously guard their brands. I can't imagine that pharmacists will want to put up the NHS logo left, right and centre. It would be wise for people to wait until guidance is given."

For the National Pharmaceutical Association, Colette McCreedy said that NHS branding is a good idea, but pharmacists should not have to pay for it and it should not replace pharmacy's green cross. "The green cross is our brand as a profession and is recognised throughout Europe," she said.

A year ago, community pharmacies in Scotland were sent window stickers and posters bearing the NHS in Scotland logo (*PJ*, 11 January 2003, p40). The Scottish pharmaceutical care strategy included a commitment from the Scottish Executive Health Department to encourage community pharmacies to display NHS branding. No financial incentives were offered.

A survey by the Scottish Consumer Council in 2002 found that only half of those asked considered pharmacies to be part of the NHS (*PJ*, 30 November 2002, p769).

According to the Department of Health: "The NHS mark has over a 90 per cent spontaneous recognition rate among the public and has high levels of trust and credibility. Using the NHS corporate identity correctly makes it easy for the public and patients to be reassured that the services provided are part of the NHS family, providing NHS services in line with its values."

### The Society

#### Staff training requirements

The Society has published guidance for pharmacists on how to ensure that dispensing and pharmacy assistants involved in pharmacy services can continue working without needing a new qualification when the regulation of such assistants begins next year (centre pull-out and p67).

#### Practice research awards

Pharmacists are being invited to apply for 2004 practice research awards (p68).

#### New Society staff

The Society has appointed of a new head of practice at Lambeth and a development officer for Wales (p68)

#### Supplementary prescribing

A briefing paper for opinion formers promotes the benefits of supplementary prescribing by pharmacists (p69)

#### Aspirin labels and inserts

Clarification of the legal requirements for aspirin and aloxiprin labels and inserts is given in a Law and Ethics Bulletin (p71).

# Vitamin D supplements may protect against MS

Women who take vitamin D supplements may have a lower risk of developing multiple sclerosis than women who do not take supplements, according to recent research.

Investigators studied data collected from the US Nurses Health Study and Nurses Health Study II, which involved almost 190,000 women. They looked at the women's diets and use of multivitamin supplements at baseline and every four years, as well as the levels of 25-hydroxyvitamin D in the women's blood. Results were adjusted for known MS risk factors such as age, smoking and latitude of residence at birth. Of the 187,563 women included in the study, 173 women developed the disease.

The researchers found that women with the highest intake of vitamin D supplements (at least 400 IU per day) were 40 per cent less likely to develop MS than women who did not use supplements. Women who had a high intake of vitamin D from a combination of food and supplements also had a lower risk of developing MS, but those who had a high intake of vitamin D from diet alone were not

## Multivitamin use was associated with reduced incidence of MS

found to be any less at risk of developing the disease.

However, the researchers acknowledge that because supplemental vitamin D intake used by women in the study was mainly from multivitamins, the effects of vitamin D can

not easily be isolated from the effects of other vitamins in the formulations. Furthermore, they point out the difficulty of separating the contribution of diet and the effects of sunlight on circulating levels of vitamin D.

The researchers suggest that future studies should measure the levels of vitamin D in the blood before the onset of MS, and that it may be important to assess whether supplementation with the vitamin slows the progression of the disease (*Neurology* 2004;62:60).

☐ **Sunlight and MS** More data emerged this week to support the association between exposure to sunlight and development of MS. Researchers from the Institute of Health Sciences in Oxford say that a minimum level of exposure to the sun per year may provide protection from the disease. They studied records of people with MS and other neurological disease and found that prevalence of skin cancers associated with prolonged, continuous exposure to sunshine was lower than average in people with MS (*Journal of Epidemiology and Community Health* 2004; 58:142).

# Opinion divided at Boots over statin switch

A survey of Boots pharmacists has revealed mixed opinions about the potential reclassification of simvastatin as a pharmacy medicine.

The survey, carried out by the Boots Pharmacists Association, indicated an equal split between those in favour of and those against the reclassification.

An opinion that summed up the responses was: "I think it is difficult to simplify the argument as for and against reclassification. In my opinion, the proposed reclassification has too many holes in it, including absence of monitoring, lack of coherent follow-up and poor supporting evidence for the use of simvastatin at this dose.

"However, I am not opposed to the reclassification of simvastatin per se. I entirely agree

that pharmacists need to embrace the reclassification but we must ensure that it is on our terms."

Some of the points raised in support of the switch include the fact that it could be the start of chronic disease management in the community, that patients will have better access to a proven medicine and that it is a chance for pharmacists to extend their role.

Several pharmacists suggested simvastatin should be sold under a protocol or only by pharmacists. Those against the move highlighted safety, and a lack of testing and monitoring as particular concerns. "Will the price of the product also take into account the level of counselling required to be given by the pharmacist," asked one respondent.

# Antiviral drug reduces herpes transmission

A person infected with herpes simplex type 2 (HSV-2) can reduce the risk of genital herpes transmission to their partner by taking a single daily dose of valaciclovir (Valtrex), results from a new study show.

An international team of researchers followed 1,484 heterosexual couples for eight months. One partner in each couple had symptomatic genital HSV-2. The infected persons were randomly assigned to either 500mg valaciclovir daily or placebo and their partners were evaluated each month for signs and symptoms of HSV-2 infection.

The researchers found that the partners of those treated with the antiviral drug were

much less likely to become infected with HSV-2 than the partners of those given placebo.

"The results were in addition to any effects that may have been attributable to counselling or safer-sex practices used by the study population," say the researchers.

At the end of the eight-month period, clinically symptomatic HSV-2 infection had occurred in 16 of the partners of those given placebo compared with 4 of the partners of those who took valaciclovir. Couples who used condoms and valaciclovir had the lowest transmission rate (*New England Journal of Medicine* 2004;350:11).

## News in brief

### Epilepsy drug for MS

The antiepileptic drug levetiracetam (Keppra) may prove to be an effective treatment for controlling the symptoms of spasticity in patients with multiple sclerosis, say American researchers. They reviewed the medical records of 11 patients treated with levetiracetam and found that phasic spasticity, but not tonic spasticity, decreased. Three patients incidentally reported improvements in neuropathic pain (*Archives of Neurology* 2003;60:1772).

### Low tar not safer

The risk of dying from lung cancer is the same for smokers of very low tar cigarettes as it is for those smoking low and medium tar brands, a US study of almost one million people shows. The risk was higher for people who smoked non-filter cigarettes and substantially lower in those who quit smoking or never smoked (*BMJ* 2004;328:72).

### Tobacco control plan in Scotland

An extra £4m is to be invested into smoking cessation plans launched this week in Scotland by deputy health minister Tom McCabe. The strategy, which includes a consultation on smoking in public places, can be accessed at [www.scotland.gov.uk](http://www.scotland.gov.uk).

# Trastuzumab fails to impress in lung cancer trial

Trastuzumab (Herceptin) has failed to improve outcomes for patients with non-small-cell lung cancer, a study reveals.

The patients were taking part in a trial to test whether trastuzumab added any benefit to treatment with gemcitabine and cisplatin — standard chemotherapy for non-small-cell lung cancer (NSCLC). However, those treated with trastuzumab in combination with gemcitabine and cisplatin did no better than patients treated with gemcitabine and cisplatin alone.

Trastuzumab is a humanised monoclonal antibody developed by Roche to target cells that overexpress human epidermal growth factor receptor 2 (HER2). It provides clinical benefits in HER2-positive breast cancer and has previously been shown to have anti-tumour activity in preclinical models of lung cancer.

In the latest study, researchers led by Ulrich Gatzemeier, lung and chest surgery centre, Grosshansdorf Hospital, Germany, randomly assigned 101 patients with HER2-positive NSCLC to receive either conventional chemotherapy for up to six 21-day cycles or conventional chemotherapy plus trastuzumab. They found no significant

## Lung cancer: only a few patients gained from adding trastuzumab therapy

difference between response rates (41 per cent for patients treated with conventional chemotherapy versus 36 per cent for patients treated with trastuzumab). Progression-free survival was also similar for the two groups.

However, a small subgroup of patients with strong overexpression of HER2 (HER2 3+) did seem to benefit from addition of trastuzumab to their chemotherapy.

“Five out of the six patients with extremely high levels of HER2 responded better than other HER2 patients. It was nearly eight-and-a-half months before their disease progressed,” said Dr Gatzemeier.

However, he added that the group of patients with the highest expression of HER2 made up less than 2 per cent of the patients originally screened for trial eligibility. “Our data suggest that although nearly 60 per cent of NSCLC patients overall are HER2 positive, any possible benefit of trastuzumab is likely to be confined to under 5 per cent of all patients with advanced NSCLC.” (*Annals of Oncology* 2004;15:19.)

Carsten Reinhardt, Roche’s international medical manager for Herceptin, told *The Journal* that at the time the trial was designed, the HER2 expression pattern of NSCLC was not so well known. “We now know that Herceptin works best in HER2 3+ patients.” Dr Reinhardt added that the company was concentrating on more promising disease areas, such as breast cancer.

## DTB gives cautious welcome to second-line use of two newer antifungal agents . . .

Voriconazole (Vfend), a new triazole antifungal agent, is a reasonable choice for second-line treatment against systemic fungal infections, according to the *Drug and Therapeutics Bulletin* (2004;42:5). However, the *DTB* is not convinced by the claim that this drug is superior to amphotericin B at increasing survival rates in patients with invasive aspergillosis.

The January issue of the bulletin also considers the place of caspofungin (Cancidas), a

new echinocandin antifungal that has activity against *Candida* and *Aspergillus* spp. While the *DTB* acknowledges that this drug is better tolerated than conventional amphotericin B it suggests there is little evidence to justify its use, “except possibly as a second-line treatment in patients with life-threatening invasive candidiasis”. The *DTB* concludes: “Neither caspofungin nor voriconazole should be used for empirical treatment of fever in patients with neutropenia.”

## . . . but criticises transdermal contraceptive patch website

Evra, the new contraceptive patch, is twice as likely to be discontinued because of unwanted effects as the combined oral contraceptive, according to the *Drugs and Therapeutics Bulletin* (2003;41:89). It has also criticised the way Janssen-Cilag has promoted the product on a specially designed website.

Joe Collier, editor of *DTB* said: “Evra . . . does not seem to offer compelling clinical advantages over standard oral contraceptives and is much more expensive. What is more, there is no convincing evidence to back up the promotional claim improperly made to patients that Evra is just as effective as the contraceptive pill.”

In response, a spokeswoman for Janssen-Cilag, told *The Journal*: “There have been two

head-to-head studies comparing Evra with an oral contraceptive pill and neither study has shown a significant difference in efficacy. In a US survey of 8,000 women, nine out of 10 Evra users said they preferred Evra to their previous method of birth control, and three million women worldwide are using Evra.”

She explained that the website referred to by the *DTB* is only intended for use by women who have already been prescribed the patch, and requires the product licence number to be entered to log on.

□ **Other DTB topics** The December and January issues of *DTB* review the management of bronchiectasis and the use of performance-enhancing drugs, respectively (2003;41:91 and 2004;42:1).

## Scotland rejects new drugs for cancer and Alzheimer’s

Use of pegylated liposomal doxorubicin (Caelyx) for metastatic breast cancer is not recommended for use within NHS Scotland, says the Scottish Medicines Consortium in guidance issued this week.

The SMC says that although this formulation has a less harmful effect on the heart than conventional doxorubicin, it is associated with other serious events. “It is significantly more expensive than the standard preparation and its cost-effectiveness in managing breast cancer has not been addressed [by the manufacturer, Schering Plough],” the SMC states.

In separate guidance, the SMC also rejects the use of zoledronic acid (Zometa) for skeletal-related events in prostate cancer and the use of memantine (Ebixa) for Alzheimer’s disease. The guidance on memantine followed a resubmission by Lundbeck, the product’s manufacturer, after the SMC failed to endorse its drug in its December guidance.

Propofol emulsion (Propofol Lipuro), used for general anaesthesia, and the combination product Stalevo (levodopa, carbidopa and entacapone), used to treat patients with Parkinson’s disease, were accepted for use.

Guidance recommending restricted use was issued for two further drugs — topiramate (Topamax) for epilepsy and caspofungin (Cancidas) for invasive candidiasis.

From spring 2004, Scottish health boards will be obliged to follow SMC recommendations. Until now its role has been advisory.

# Guidance for brand name prescriptions updated

Guidance on dispensing and endorsing prescriptions which bear both a brand and generic name for a product has been updated.

Particular problems have arisen with computer generated prescriptions for co-proxamol that also carry the name of the blacklisted proprietary preparation Distalgesic. The Prescription Pricing Authority has been interpreting this as an order for the proprietary product and has been disallowing prescriptions.

According to the Pharmaceutical Services Negotiating Committee, this has been a problem with some GP computer systems. The PPA is alerting system suppliers of the problems being caused. Prescriptions for non-blacklisted products, eg, fluoxetine (Prozac), are also being interpreted as orders for proprietary products and are being reimbursed at list price, regardless of endorsements, under normal Drug Tariff rules.

The Royal Pharmaceutical Society's fitness to practise and legal affairs department has issued the following guidance for community pharmacists and their staff:

## Some computer-generated prescriptions are causing problems

**Brand for brand** When a branded product is prescribed and another brand with the same product licence number is supplied this is unlikely to be an offence under the

Medicines Act 1968 provided the item is not mislabelled. Although, under the Code of Ethics, pharmacists are not supposed to substitute specifically named products without prescriber and patient approval, except in emergencies, it might be difficult to argue that a product with the same marketing authorisation was not of the nature and quality required.

**Brand and generic** If the prescription bears both the brand and generic names of a product then, except in emergencies, the brand should be supplied unless the prescriber confirms otherwise. In cases of ambiguity, pharmacists should make further checks as to which product should be supplied.

**Branded generic** The brand ordered should be supplied other than in emergencies or on approval of the prescriber.

Further details are available from the PSNC National Prescription Research Centre (tel 020 8441 8427).

# London pharmacists demand co-ordinated action after knife attacks on pharmacy staff

Pharmacists in north-east London are demanding that action is taken to co-ordinate an appropriate response following knife attacks on pharmacy staff.

Hemant Patel, secretary to North-East London Local Pharmaceutical Committee, has written to Neil Gerrard, Labour MP for Walthamstow, seeking a meeting with him and representatives of local pharmacists, the police and primary care trusts.

Mr Patel says this meeting is urgently needed "so that the matter can be dealt with speedily and with the seriousness it deserves before someone gets seriously injured or killed".

The letter comes in the wake of a series of attacks on pharmacy staff in Redbridge, Barking, Dagenham, Havering and Newham. Two men are said to be involved, one of whom has brandished a long knife and demanded cash.

Mr Patel says that pharmacists are concerned about slow response times from police. Pharmacies are seen as soft targets by criminals because of long opening hours, easy access to desirable goods, money and drugs and increasing numbers of female staff, he adds.

All seven community pharmacy forums in north-east London are scheduled to discuss the matter at their next meetings.

## Boots to shed up to 1,000 jobs at Nottingham HQ

The Boots Company is expected to announce that it is shedding up to 1,000 of the 3,000 jobs at its head office in Nottingham.

Staff were to be told of the exact nature of the cuts on 15 January, after *The Journal* went to press.

The cuts come ahead of the company's Christmas trading statement, to be announced on 16 January.

The cuts will form part of a £100m savings package being put in place by new chief executive Richard Baker.

Around 500 jobs at Nottingham were cut last year.

## Errors on NPA malaria chart

The National Pharmaceutical Association's blue information chart on malaria prophylaxis is being reprinted owing to an error on the original version.

In the "key to regimens", the last regimen should read: "PROPHYLAXIS 6 — no chemoprophylaxis required. Use insect repellents, mosquito nets and wear long sleeved clothing after dusk." For the United Arab Emirates, the prophylaxis should be regimen 6 for all areas.

Members are asked to discard the blue copy on receipt of the reprinted copy, which will be pale yellow. The reprinted copy will be included with the February issue of the *Supplement*.

## News in brief

### NPA payroll service

The National Pharmaceutical Association is offering its members a fully managed payroll service for their staff, in conjunction with Ceridian Centrefile. The service will calculate pay, produce payslips and make payments on behalf of pharmacy businesses.

### PSNC funding guide

The Pharmaceutical Services Negotiating Committee has updated its guide to sources of funding for community pharmacy. It covers primary care trust budgets, planning cycles, local delivery plans and funding streams. Copies can be downloaded from the PSNC website.

### Care records contracts

Local contracts to run the NHS Care Records Service for the North West & West Midlands and Eastern regions of England have gone to CSC and Accenture, respectively.

### Pfizer joins CoMedis

Pfizer Pharmaceuticals has joined the CoMedis online transfer order and information service. Pfizer will provide information about its prescription medicines. Its non-prescription medicines are already available through the service.

# European reforms will speed up access to new drugs

Agreement on reformed European pharmaceutical legislation was reached in the European Parliament on 17 December 2003. The reform, first proposed in July 2001, updates and consolidates European Regulations and Directives that have been introduced over a number of years. The new rules are expected to improve and speed up access to new and innovative pharmaceutical products.

Changes to be introduced include a fast-track European Agency for the Evaluation of Medicinal Products (EMA) authorisation procedure, conditional authorisation for products and a harmonised data protection period in order to reward innovation. There will be clearer rules and procedures for generic manufacturers, which will be allowed to start testing their products in advance of patent expiry.

Compulsory central authorisation through the EMA will be extended from biotechnology products to medicines to be used to treat AIDS, cancer, diabetes, neurodegenerative disorders and orphan diseases. After four years this will be further extended to include treatments for autoimmune and viral diseases.

Conditional one-year authorisation will be possible for new products expected to be of significant therapeutic benefit. Companies will have to undertake to carry out further studies for review at the end of the conditional authorisation period. New medicines might also be made available in advance of full authorisation on a compassionate basis. This is intended to allow compassionate use anywhere in Europe when clinical trials are geographically restricted.

The new data exclusivity rules mean that generic competition will not be allowed until 10 years after authorisation of the original product, with the possibility of an additional year of market exclusivity if a new indication for the original product is authorised. The re-



European parliamentarians have agreed to revised pharmaceutical rules

search-based pharmaceutical industry has had to accept that generics manufacturers will be allowed to develop their products and gain authorisation before expiry of the 10 or 11 years of market exclusivity so that they can market their competing products as soon as exclusivity ends.

Data exclusivity will also be introduced for over-the-counter medicines, with manufacturers who generate data to justify prescription to OTC switches being given a

guaranteed one-year head start over their rivals, with the possibility of a second year for a new indication. The UK Medicines and Healthcare products Regulatory Agency currently allows manufacturers a three-month advantage.

Although the European Association for the Self-Medication Industry (AESGP) welcomes the change, it is disappointed that only one or two years' data exclusivity has been granted.

AESGP director-general Hubertus Craz said: "Unfortunately, the compromise allows only one year instead of three years as proposed by the European Parliament and will therefore not maximise the innovative capability of the self-care industry."

The Proprietary Association of Great Britain, however, is pleased overall. Gopa Mitra, head of public affairs, said: "It's a little disappointing that the exclusive period is only one year — we were hoping for two or even three years. But one year is better than nothing and is more than the three months currently given by the MHRA."

"Even though this package does not fully meet the needs of the research-based pharmaceutical industry, we recognise that compromises had to be made," said Brian Ager, director general of the European Federation of Pharmaceutical Industries and Associations. "It is now in everyone's interest to avoid any delay to the implementation of this important legislation, which will set in place a pharmaceutical regulatory framework to meet the needs of all 450 million citizens in the enlarged European Union."

An Association of the British Pharmaceutical Industry spokeswoman said that the compromise agreement is one with which the industry is happy.

Ratification of the agreement now lies with the EU's Council of Ministers.

## GSK's \$5bn tax bill

GlaxoSmithKline has been served with a claim for \$2.7bn (£1.5bn) in taxes by the US for the years 1989–96. Further claims could push the bill to over \$5bn.

The claim centres around the use of transfer pricing by the former Glaxo and GlaxoWellcome companies. Transfer pricing is used by pharmaceutical companies to allocate for tax purposes the costs of research, manufacturing and sales of products to different country subsidiaries. The American claim says that Glaxo's transfers were inconsistent with those of other companies, including SmithKline Beecham, now part of GSK. The claim follows the collapse of talks between UK and US tax authorities over the issue.

The company said that the taxes it paid in the US for 1989–2000 were more than sufficient to reflect its US operations.

## European Court quashes Bayer's €3m PI fine

The European Commission has lost its appeal against the quashing of its decision to fine Bayer €3m for restricting supplies of Adalat in Spain to try to prevent parallel importing to the UK. The European Court dismissed the appeal in a case that has been running since 1996 (*PJ*, 27 January 1996, p121).

Bayer began restricting supplies of Adalat (nifedipine) to Spain in 1989, prompting Spanish wholesalers to complain to the European Commission. The commission decided, incorrectly, that there was collusion between the wholesalers and Bayer in breach of European competition law and imposed a €3m fine. The fine was quashed by the court (*PJ*, 11 November 2000, p706) because there had been no anti-competitive agreement between Bayer and the wholesalers. The court rejected the commission's argument that the

ongoing relationship between the wholesalers and Bayer indicated that the wholesalers agreed with Bayer's supply restrictions.

Last year, the court's advocate general recommended that the commission's appeal should be quashed (*PJ*, 31 May 2003, p739).

The European Association of Pharmaceutical Companies, which champions the cause of pharmaceutical parallel trade in Europe, believes that there are more than 40 outstanding complaints from European wholesalers about supply restrictions awaiting examination by the European Commission. The association says that officials in Brussels must speed up their analyses and consider all options open to them to free up trade. The EAEPIC wants officials to concentrate on competition rules such as those designed to prevent abuse of dominant market positions.

# UniChem says it will maintain twice-daily pharmacy deliveries

UniChem sees no need to drop its commitment to twice-daily deliveries to its community pharmacy customers unless major changes in the market require it to do so.

David Coles, recently appointed managing director of UniChem, told *The Journal* last week that he had queried the high level of service offered to pharmacies. Mr Coles was formerly UK managing director of the logistics group DHL.

"The level of service is important in this market," Mr Coles said. "This is a customer-driven requirement. Pharmacists want this in order to offer the necessary level of service to their customers. Even if there was greater consolidation in the pharmacy market, good service and thus twice-daily deliveries would be just as, if not more, important."

Mr Coles said that he foresees pharmacy wholesalers continuing to adapt to the changing market, with some developments likely in centralised dispensing and mail order services. However, he does not expect major changes unless the pharmacy market itself changes, perhaps as a result of the new contract and alterations to control of entry.



**David Coles: twice-daily service is driven by customer requirements**

UniChem is increasing investment at its 10 wholesale depots and is updating IT and building extra capacity at them. "We are a good solid business, but there must be no complacency. We can always get better by listening to our customers," Mr Coles said.

## Debate over deodorant use and breast cancer reignited

Esters of *p*-hydroxybenzoic acid (parabens), which are used as preservatives in underarm deodorants and antiperspirants, can be detected in samples of tissue from human breast tumours, say researchers.

The finding has fuelled debate over whether these chemicals, which are thought to be oestrogenic, have contributed to the rising incidence of breast cancer. However, toxicologists have warned that no causal association has been found.

The latest research, published in the *Journal of Applied Toxicology* (2004;24:5), reveals that parabens accumulate in human breast tissue and that the levels measured could exert oestrogenic effects. However, the authors of an accompanying editorial (*ibid*, p1) write: "The detection of parabens in breast tumour tissue should not be taken to imply causality of the individual cancer, because the findings are essentially coincidental in nature." They add that normal breast tissue, and other tissue, was not analysed.

Richard Sullivan, head of clinical programmes at Cancer Research UK, said: "No causal relationship has been found between underarm cosmetics containing parabens and breast cancer. There is also no robust population-based evidence to suggest a link."

## More bad news for ephedra

People who use dietary supplements containing ephedra and caffeine could be putting themselves at risk of developing heart problems, research suggests.

The finding, published this week in *JAMA* (2004;291:216) follows a decision by the US Food and Drug Administration to ban the sale of ephedra-containing products.

Brian McBride, from the University of Connecticut Schools of Pharmacy, and colleagues studied the effects of a popular herbal preparation containing 19 ingredients including ephedra (12mg) and caffeine (40mg) in 15 healthy volunteers. Compared with those who received placebo, volunteers given ephedra and caffeine had a longer maximal QTc interval and higher systolic blood pressure. "Overall, 53 per cent of participants had QTc interval increases of at least 30 milliseconds while taking the dietary supplement," say the researchers.

Preliminary data from the study were presented at the American Heart Association congress held in Orlando last year (*PJ*, 22 November 2003, p702).

In the UK, ephedra can be supplied by herbal practitioners after a one-to-one consultation, providing that the maximum dose does not exceed 600mg and that the maximum daily dose does not exceed 1,800mg. Above these limits, supply must be made from a registered pharmacy under the supervision of a pharmacist.

## Medicine adverts appeals process clarified

Rules covering the way in which pharmaceutical companies can appeal against complaints about their promotional activities have been clarified by the Prescription Medicines Code of Practice Authority.

Companies are reminded that appeals need to be lodged within 10 working days of notification of an adverse ruling by the authority. Documents submitted to support an appeal need to highlight new information and not merely repeat points discussed in the original complaint. In addition, it restated that a complaint of "bringing the industry into disrepute" is reserved for the most serious cases, normally involving inappropriate financial payments, threats to patient safety or repeated breaches of the code of practice.

Disease awareness campaigns were among the complaints dealt with by the PMCPA and reported in its quarterly review. Pfizer complained about information about the Lilly Icos product Cialis (tadalafil) which appeared on the NetDoctor website, saying that it promoted a prescription medicine to the public. Lilly said that it did not have editorial control over the website and the complaint failed.

The Stepwise campaign, run by Novartis to raise awareness of fungal nail infections, was also cleared of promoting a prescription medicine, Lamisil (terbinafine), despite being criticised by the *BMJ*.

The *Sunday Herald* was also unsuccessful in complaining about an obesity awareness campaign run by Roche.

### PJ Online

#### Continuing professional development

A list of all CPD articles since January 2002. The articles are listed by subject, series and in publication order.  
[www.pjonline.com/CPD](http://www.pjonline.com/CPD)

#### Reports

Links to reports of various organisations' meetings and conferences, including the British Pharmaceutical Conference and *The Pharmaceutical Journal* and *Hospital Pharmacist* conferences. Also included are reports of Royal Pharmaceutical Society Council meetings and Statutory Committee reports.  
[www.pjonline.com/reports](http://www.pjonline.com/reports)

# Further evidence for efalizumab in plaque psoriasis

Efalizumab, a humanised monoclonal antibody recently approved in the US for treatment of patients with chronic moderate to severe plaque psoriasis (*PJ*, 13 December 2003, p807), has shown further evidence of efficacy.

In a phase III double-blind trial, 556 patients with moderate to severe plaque psoriasis were randomly assigned to receive 12 weekly doses of subcutaneous efalizumab 1mg/kg or placebo. The efalizumab-treated patients experienced reduced frequency and severity of psoriasis symptoms, particularly in the severity of itching and scaling. In the efalizumab group, 27 per cent of patients achieved at least 75 per cent improvement on the psoriasis area and severity index, compared with 4 per cent in the placebo group.

Katrina Simister, assistant director, new medicines scheme, at the National Prescribing Centre, Liverpool, told *The Journal*: "Trials

comparing the drug to existing standard treatments, for example, methotrexate, ciclosporin or systemic retinoids, would help define its place in therapy. Compelling evidence of long-term efficacy and safety data would seem prudent before these 'biologic' agents are used on a widespread basis.

"However, they may have a role in treating some individuals who have moderate to severe disease and who are either unresponsive, or have developed toxicity to other therapeutic options."

Efalizumab was shown to be generally well tolerated, with serious adverse effects occurring in 2 per cent of patients compared with 1 per cent of placebo-treated patients. The most commonly occurring adverse events during the initiation of efalizumab were mild to moderate flu-like symptoms following the first one or two injections (*JAMA* 2003;290:3073).

**Patients with plaque psoriasis who are unresponsive to other therapies could benefit from treatment with efalizumab**

## News in brief

### Garlic product halts tumour

Producing allicin (diallyl thiosulfinate), an active component of freshly crushed garlic, *in situ* can halt tumour growth, researchers from Israel have shown. They bound the enzyme alliinase from garlic to a monoclonal antibody against a specific tumour marker, ErbB2. In the presence of amino acid alliin, tumour-localised alliinase produced allicin, which effectively killed ErbB2-expressing cells *in vitro* (*Molecular Cancer Therapeutics* 2003;2:1295).

### Six-pronged malaria vaccine

A vaccine against malaria that contains six different parasite proteins has shown efficacy in a study conducted by researchers from the University of Oxford. They used the vaccine to induce a broad immune response in mice (*Proceedings of the National Academy of Sciences* 2004;101:290).

### Target for jaundice treatment

Researchers have shown that a component of a chinese herbal tea remedy for jaundice activates a hepatic receptor which increases clearance of bilirubin. The tea, Yin Zhi Huang, was found to activate the androstane receptor CAR and induce bilirubin metabolism in mice expressing the receptor. The receptor is a potential target for drug therapies for jaundice, they say (*Journal of Clinical Investigation* 2004:113:137).

## Snail venom leads to effective analgesic

Ziconotide, a synthetic version of a peptide found in the venom of *Conus magus*, a marine snail, is an effective analgesic in patients with severe chronic pain, data from two new studies indicate.

Research published last week in *JAMA* confirms the drug's efficacy in treating pain caused by cancer or AIDS (2004;291:63). At the same time, data issued by Elan, the company developing the drug, reveal that ziconotide reduces neuropathic pain at lower doses than have been used in previous trials.

The first study involved 111 patients with pain caused by cancer or AIDS that was not effectively eased by systemic or intrathecal analgesics. Patients were assigned to receive ziconotide or placebo for five to six days followed by a five-day maintenance phase for responders and crossover to the opposite treatment group for non-responders. Pain intensity was assessed using a visual analogue scale.

The researchers found that pain intensity scores improved by 53.1 per cent in patients treated with ziconotide compared with 18.1

per cent for patients given placebo ( $P<0.001$ ). The effects of ziconotide did not diminish during the maintenance phase of treatment. More than half the patients in the ziconotide group reported moderate to complete pain relief, whereas less than a fifth of the placebo group reported similar responses. Opioid use decreased in the ziconotide group by 9.9 per cent but increased in the placebo group by 5.1 per cent.

There were several adverse events associated with ziconotide use, including 14 involving the nervous system. However, the researchers say that starting at a lower dosage, using smaller increments, and increasing the interval between dose titrations tended to reduce their frequency.

These points were dealt with in the second, as yet unpublished, trial. Elan reports that in this study, there were few serious side effects, with an incidence similar to placebo.

The company expects ziconotide, an N-type calcium channel blocker, to reach the US market by early 2005.

## Vaccine on way for all strains of meningitis

Researchers have developed an inactive form of the meningococcus bacterium that triggers an immune response against all strains of meningitis in mice.

They demonstrated that the bacterial gene component phoP is involved in regulation of virulence, and engineered a phoP mutant which they showed to be avirulent in mice. The mice infected with the inactive strain of meningitis C developed an immune response that destroyed the infecting strain and also showed cross-reactive bactericidal activity

against strains of groups A and B, by binding to the surface of the meningococcus.

This type of cross-reactive protection is seen following meningococcal disease, say the researchers, and identification of the proteins that regulate this response could lead to development of a full meningococcal vaccine for humans. In addition to being used to identify cross-reactive protective antigens in the meningococcus, the phoP mutant is itself a potential live attenuated vaccine, they add (*Infection and Immunity* 2004;72: 338).