

Generics companies are sued for £28m

THE Government is suing three generics companies for damages of more than £28m plus interest, alleging that the companies conspired to fix the supply and price of warfarin products and, as a result, overcharged the National Health Service.

The civil proceedings, which are separate from the Serious Fraud Office investigation of six generics companies, were instigated at the High Court on 20 December 2002. The Secretary of State for Health, the Prescription Pricing Authority and 28 strategic health authorities in England are suing Norton Healthcare Ltd, and its subsidiary Norton Pharmaceuticals, Regent-GM Laboratories and Goldshield Group Plc, and its subsidiaries Goldshield Pharmaceuticals and Forley Generics. The claim covers the period 1996 to 2000.

Jim Gee, director of the NHS Counter Fraud Service (CFS), said that further civil proceedings are likely as a result of ongoing CFS investigations into the supply of other generic products.

Norton Healthcare (now trading as IVAX Pharmaceuticals) said it believes that



Investigations are continuing into the pricing and supply to the NHS of other generics

its sales of warfarin have always been in compliance with all applicable laws and regulations. "The company strongly refutes the

allegation and is co-operating fully to provide all the relevant information to repudiate this claim," it said in a statement.

MCA asks for views on freedom of information and ending section 118

THE Medicines Control Agency has launched a public consultation on commercial and other aspects of confidentiality enshrined in the Medicines Act 1968, section 118 and its associated Regulations, and whether they should be modified.

MLX 292, issued by the MCA in late December 2002, sets out three different options, without favouring any of them: to retain the statutory prohibition on officials releasing information gathered by the MCA for licensing purposes, to amend the provisions or replace them with similar laws, or to repeal them in their entirety.

However, the consultation letter adds that some information would have to

remain confidential, even if the prohibition on disclosure is removed. Legitimate trade secrets would continue to be protected, as would other, undefined, "legitimate commercial, regulatory and confidential information".

The consultation has been started because the Lord Chancellor has asked all Government departments to review their statutory bars to disclosure because of the expected full implementation of the Freedom of Information Act 2000 in January 2005 (*Pfj*, 7 December 2002, p801).

The consultation letter can be found via the links section of *Pfj Online* (www.pfjonline.com/links).

PCTs in England get three-year budgets for the first time

PRIMARY care trusts in England have been told how much money they will have to spend on health care over the next three years.

This is the first time that financial allocations have been made for more than one year at a time. It is also the first time that local National Health Service organisations have been funded directly by the Department of Health, rather than through a tiered management structure.

The Department says that the new three-year funding will allow PCTs to make medium-term plans, rather than plan only for the short-term.

Every PCT will see its budget rise by at least 28.08 per cent over three years, with most getting increases below 32 per cent. Seven PCTs, however, will see budget increases of more than 40 per cent over three years. These mainly cover urban and inner-city areas with high levels of poverty and social deprivation.

Secretary of State for Health Alan Milburn said: "The resources are being distributed according to a new, fairer funding formula. Poverty and deprivation cause excess morbidity and mortality. They bring extra costs to local health services. The new formula reflects those costs by using better measures of deprivation and by taking greater account of unmet health needs."

PCTs will be expected to meet all costs from the allocations they have been given, including the additional costs of pay reform, new drugs and treatments, and service expansion.

Kava products banned from 13 January

PRODUCTS containing the herbal ingredient kava are to be banned.

Following concern over liver toxicity of kava, which led to manufacturers being asked to withdraw products voluntarily from the market in December 2001, the ingredient is to be banned from all medicines from 13 January 2003. Parallel legislation being drawn up by the Food Standards Agency will prohibit the inclusion of kava in food products and dietary supplements.

Dr Liz Williamson, from the University of London School of Pharmacy, said: "The liver toxicity associated with kava, although rare, is idiosyncratic. Because of the limited data available a risk to benefit assessment, which is routinely completed for all licensed medicines, is not possible. No specific risk

factors have been identified and it is not possible to predict who is at risk before they use kava. In addition, no measures to reduce the risk, or the severity of liver reactions, are available."

IN THIS ISSUE

Diets and the internet

Eaten too much turkey and Christmas pudding? Thinking of going on a diet? An article on p28 looks at what information about dieting can be obtained from the internet and suggests some websites that offer useful advice.

Thiazide diuretics preferred in ALLHAT as first step in treating hypertension...

THIAZIDE-TYPE diuretics should be the preferred choice for first-line treatment in patients with hypertension, researchers recommend, following the publication of a major trial comparing different classes of antihypertensive therapy. The researchers say that thiazides are unsurpassed in lowering blood pressure and reducing clinical events and are better tolerated and less expensive than other classes.

This recommendation echoes the British National Formulary, which states that a thiazide is first-line treatment for hypertension unless there is a contraindication or a specific indication for another drug (September 2002).

Jon Silcock, research practitioner at the University of Leeds, told *The Journal* that the study confirmed the role of thiazide diuretics as first-line treatments for hypertension. "However, the diuretic chosen for this trial (chlortalidone) is not widely used in clinical practice in the United Kingdom, the steps used to achieve goal blood pressure involve some additional agents that are obsolete, patients with known heart failure were excluded and there was no beta-blocker arm.

"Integration of these findings into clinical practice and guidelines will require careful consideration of class effects and therapy combinations." He added that the good news for drug budget holders was that the cheapest agent had been shown to be the most effective one.

In the Antihypertensive and Lipid-lowering Treatment to prevent Heart Attack Trial (ALLHAT), researchers compared chlortalidone (Hygroton) with lisinopril (Zestril) and amlodipine (Istin). Neither lisinopril nor amlodipine was found to be superior to chlortalidone in preventing coronary deaths or increasing survival

(*JAMA* 2002;288:2981). Another study arm using the alpha-blocker doxazosin (Cardura) was stopped in 2000 after doxazosin was found to be less effective than chlortalidone (*Pf*, 25 March 2000, p460).

In an accompanying editorial (ibid, p3039) Dr Lawrence Appel, Johns Hopkins University, Baltimore, comments: "The results of ALLHAT are robust, unambiguous and generalisable, especially to the

broad population of patients with stage 1 or 2 hypertension." He says that the results provide definitive data on selecting the best initial therapy and compelling evidence that thiazide diuretics should be the initial drug of choice for patients with hypertension, especially compared with the two drugs used in the study. The results will have greatest impact on those with newly diagnosed hypertension.

Results from the ALLHAT study

In the Antihypertensive and Lipid-lowering Treatment to prevent Heart Attack Trial (ALLHAT), researchers determined whether treatment with a calcium channel blocker or an angiotensin-converting enzyme inhibitor lowered the incidence of coronary heart disease (CHD) events compared with treatment with a diuretic. They randomly assigned 33,357 subjects aged 55 years or older with hypertension and at least one other CHD risk factor to receive chlortalidone 12.5mg to 25mg (n=15,255), amlodipine 2.5mg to 10mg (n=9,048) or lisinopril 10mg to 40mg (n=9,054) daily for planned follow-up of four to eight years.

The researchers found that neither of the comparator drugs was superior to the diuretics in preventing major coronary events or in increasing survival. Chlortalidone was better than amlodipine (by about 25 per cent) in preventing heart failure, although it did not differ from amlodipine in overall cardiovascular disease prevention. Chlortalidone was superior to lisinopril in lowering blood pressure and in preventing cardiovascular events — stroke, heart failure, angina and coronary revascu-

larisation. However, no significant differences in CHD and stroke rates were found between chlortalidone and amlodipine.

The researchers say that chlortalidone was better tolerated than the other agents in the trial. However, angioedema occurred four times more often in those assigned chlortalidone. Cholesterol levels, the prevalence of hypokalaemia and new diabetes were all higher in the chlortalidone group than the other groups at two and four years of follow up. They say: "Overall, these metabolic differences did not translate into more cardiovascular events or into higher all-cause mortality in the chlortalidone group compared with the other two groups."

The researchers comment that the although the results apply directly to chlortalidone, amlodipine and lisinopril, they may also broadly apply to the drug classes used in the study. They conclude: "Although diuretics already play a key role in most antihypertensive treatment recommendations, the findings of ALLHAT should be carefully evaluated . . . and be widely applied in patient care."

... while moderate lipid lowering adds little benefit

MODERATE reductions in lipid levels using pravastatin (Lipostat), carried out as part of the ALLHAT trial comparing different antihypertensives, failed to show reductions in mortality compared with usual care.

In the lipid-lowering trial arm of the Antihypertensive and Lipid-lowering Treatment to Prevent Heart Attack Trial (ALLHAT-LLT), 10,335 patients, drawn from the 42,418 participants initially entered in the main ALLHAT trial (see above), were randomised to receive either 40mg pravastatin daily or usual care on an open-label basis. In order to be randomised for this arm they had to have at least one additional cardiovascular risk factor and a low-density lipoprotein cholesterol (LDL-C) level of between 3.1 and 4.9mmol/L (2.6 to 3.3mmol/L for patients with known heart disease). The trial started in 1994 and after

an average of 4.8 years of follow-up, there was no significant difference in all-cause mortality between the two groups (relative risk 0.99, 95 per cent confidence interval 0.89–1.11) with six-year mortality rates of 14.9 per cent for pravastatin versus 15.3 per cent with usual care. Coronary heart disease event rates were slightly lower in the pravastatin group but not significantly so (relative risk 0.91, 0.75–1.09).

Reductions in LDL-C of 28 per cent in the pravastatin group and 11 per cent in the usual care group were seen in a random sample of patients after four years' treatment. The ALLHAT trial co-ordinators say that these "modest reductions", and the subsequent results of the trial, show the need for adequate reductions of LDL-C levels in clinical practice (*JAMA* 2002;288:2998).

In an accompanying editorial (ibid,

p3042), Dr Richard Pasternak, division of cardiology, Massachusetts General Hospital, Boston, says that, to some extent, the ALLHAT-LLT trial was overtaken by events. Shortly after it started the Scandinavian Simvastatin Survival Study (4S) showed benefits of statins in high-risk CHD patients. By the end of the ALLHAT-LLT over a quarter of the usual care group were taking statins and only 70 per cent of the pravastatin group were still taking 40mg daily, reducing the difference between them. Rather than showing that statins do not work, Dr Pasternak suggests that statins may be less effective in the primary care setting in which they were used in ALLHAT-LLT. One of the main lessons of the trial is the need to increase patients' compliance with treatment in routine practice, he concludes. "This is not a small challenge."

CBE for ABPI's Trevor Jones in New Year honours list



Trevor Jones

PROFESSOR Trevor Jones, FRPharmS, has been made Commander of the Order of the British Empire in the Queen's new year honours list. Professor Jones is director general of the Association of the British Pharmaceutical Industry.

Archy Kirkwood, Liberal Democrat Member of Parliament for Roxburgh and Berwickshire, receives a knighthood in the honours list. Mr Kirkwood studied pharmacy at Heriot-Watt University but never registered as a pharmacist.

BRIEFLY

Lloyds looks overseas

Lloydspharmacy recruited 101 pharmacists from Spain and Portugal in the first 10 months of 2002 and offered places for a further 83 to start before the end of January 2003. In addition, 150 South African pharmacists were recruited with another 50 to follow.

NICE should not ask if illness is "self-induced" — citizens council

THE National Institute for Clinical Excellence should not consider whether a disease or condition is "self-induced" when drawing up guidance for the National Health Service, the institute's citizens council has decided.

The citizens council, which was established in November 2002, published its first report on 20 December 2002. The council considered the question: "What should NICE take into account when making decisions about clinical need?" It focused on the most important features of diseases or conditions, additional factors relating to individual patients and the weight that should be given to the views of groups representing patients, carers and health care professionals. During its meeting, the council took advice from a range of expert witnesses from academia, health care organisations and NICE itself.

Among the most important features of diseases the citizens council believes should be considered are: the severity of pain or symptoms, fatal or contagious disease, lack of alternative treatments, long-term effects, number of patients affected, effects on qual-

ity of life, fluctuations in the condition, side-effects encountered and the resources available. Whether or not is self-induced should not be an issue.

Patient aspects that are of significance include: values of the patient, ability to make informed decisions, age, fitness to undergo treatment, ability to self-manage conditions, family history and consideration of a holistic approach.

The citizens council says that factors which should not be considered include social and economic attributes and how loud the "voice" of the patient is.

Citizens council member Bob Osborne, a retired airline pilot, said: "We realise that the NHS has professionals who are more than qualified to make decisions on clinical need. What is sometimes missing is a common sense viewpoint that the public can relate to."

The report will be considered by the NICE board at its next public meeting in Lancaster on 15 January. A formal response will then be issued on the NICE website alongside the council's report (www.nice.org.uk).

Put forward topics to NICE for guidance

THE National Institute for Clinical Excellence is asking health care professionals and members of the public to suggest conditions and treatments for which it should develop guidance.

NICE is piloting a topic suggestion scheme through its website until 31 January. Details of how proposals will be assessed can be found on the Department of Health website. Suggestions for appraisal topics can also be made in writing to the Department of Health or through the National Co-ordinating Centre for Health Technology Appraisal website.

The websites can be found via the *PJ Online* links page (www.pjonline.com/links).

ROYAL PHARMACEUTICAL SOCIETY NEWS

Modernisation programme

In a new year message, the President of the Royal Pharmaceutical Society, Marshall Davies, reviews the progress of the Society's modernisation programme during 2002 and examines areas in which major decisions need to be made during 2003 (p31).

Funding for practice research

An article produced in the Royal Pharmaceutical Society's pharmacy practice research division draws attention to sources of funding in 2003 for research training for pharmacists and for pharmacy practice research projects (p34).

Drug price competition has little effect on NHS buying, PPRS study finds

PRICE competition is not a major driver of the market for branded pharmaceuticals within the National Health Service, according to a new study of how the Pharmaceutical Price Regulation Scheme works.

The study was conducted following the renegotiation of the PPRS in 1999 and covers the part played by prices in the scheme up to the end of 2000. It was conducted in seven parts, run jointly by the Department of Health and the Association of the British Pharmaceutical Industry.

The study found that the market for selling branded pharmaceuticals to the NHS is fragmented into many sub-markets. Of these, 61 per cent had a dominant firm supplying more than 40 per cent of that sub-market in 2000, a slightly lower figure than

in 1995. The average time for a second product to appear in a new sub-market is three years (range 0–9 years), with a third product likely to appear within another year.

The study found that, for branded pharmaceuticals, price competition is muted. Later entries to a sub-market are normally lower in price than the first product, but the incumbent normally maintains the largest market share and price cuts in response to a new competitor are rare. No well-defined relationship between price and volume of prescribing was found in the study. Prescribers choose drugs on the basis of clinical efficacy, safety, tolerability and convenience to the patient, the report says.

The only area where price competition appears to have a significant effect is in hos-

pitals, which account for just under a fifth of the market. Here competitive tendering is more common and the use of generics is greater.

A summary of the results of the study were published as part of the sixth annual review of the PPRS, issued by the Department of Health on 19 December 2002. Overall, the report says that the PPRS is working as intended. Most companies which are party to the scheme have submitted their required annual financial return within the agreed timetable. No price rises have taken place without the Department's approval. Neither the Department nor the Association of the British Pharmaceutical Industry has yet taken up its option to call for an interim review of the 1999 PPRS.

Use Tamiflu for prevention not treatment of 'flu, says DTB

OSELTAMIVIR (Tamiflu), a new oral influenza drug, should be used for the prevention of influenza, in addition to vaccination, but not treatment, according to *Drug and Therapeutics Bulletin*.

Reviewing oseltamivir in its December issue, the DTB says that while vaccination against influenza offers 70–80 per cent protection, outbreaks can still occur in vaccinated people due to changes in surface antigens on circulating strains of the virus.

The use of oseltamivir for preventing influenza has been studied in three large trials, but these tended to exclude patients who might be most at risk of complications from an infection. One trial, in 548 elderly nursing home residents, most of whom had been vaccinated, found that 75mg of oseltamivir once daily for six weeks after an influenza outbreak at or near the home, reduced the incidence of infection by 91 per cent.

Studies of the drug for treating acute influenza-like illness found that 75mg twice daily reduced the duration of the illness by around one day. "Annual vaccination is the cornerstone of prophylaxis for all those at risk from influenza and its complications," the DTB concludes. However, should an outbreak of influenza occur in nursing homes or similar institutions, prophylactic treatment of both residents and staff with oseltamivir would be reasonable, it adds (2002;40:89).

n Influenza levels low The number of GP consultations for influenza-like illness remains low this season and is within the range expected for this time of year, according to the Public Health Laboratory Service. Latest figures show that the consultation rate for the week ending 22 December was 20.5 per 100,000 population.

Deregulation wrong — Irish minister

A MINISTER in the Irish government has spoken out against deregulation of the sector even though a policy decision to open up the market has already been taken and is soon to be implemented.

Mr Tim O'Malley, deputy minister in the health department and a former president of the Irish Pharmaceutical Union, has said that deregulation is wrong and will be detrimental for the consumer.

Mr O'Malley was not in government when the original decision was taken, having won a parliamentary seat for the first time in the general election in May 2002.

Although his party supports deregulation, Mr O'Malley insists that pharmacy should be an exception. He attaches great importance to what he calls "the ethos of

community service in pharmacy" and feels this is best served by restricting the number of outlets an individual can open. In some areas, he claims, this ethos has deteriorated. He blames this on "the greed of a small number of chemists, who opened chains of shops with the sole aim of profit". A pharmacist, he believes, can only give a proper service in one location and to the people with whom he or she has direct contact.

Minister O'Malley's criticism is timely, with a report due later this month on how the open market is to be regulated, including the level of competition, the role of multiples like GEHE and Boots and the allocation of state health service contracts.

The IPU will be consulted before legislation gives effect to the new system.

PJ Online

PJ Online contains the editorial contents of *The Pharmaceutical Journal*, *Hospital Pharmacist*, *Medicines Management*, *International Journal of Pharmacy Practice* (abstracts), *Pharmacy Assistant* and *Tomorrow's Pharmacist*.

There is a contents page for each publication which is similar to the printed versions. Although the editorial content is the same, the presentation on *PJ Online* is markedly different, with extensive use of PDF files as well as normal web (html) pages.

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All bulletins issued since 1992 are available on *PJ Online*. Bulletins for 2001 and 2002 are listed in date, alphabetical and subject order.

www.pjonline.com/lawandethics

Reunions

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