

# Pharmaceutical public health guidance launched

New guidance on how pharmacists can improve the health of the public was published by the Department of Health last week.

“Choosing health through pharmacy” is a pharmaceutical public health strategy that follows on from last year’s White Paper, “Choosing Health.”

The guidance identifies public health targets that pharmacists have an impact on, such as smoking, obesity and sexual health, and de-

scribes how pharmacists can become health champions over the next 10 years.

“We want to see pharmacists and their staff in all parts of the country becoming involved in public health initiatives, instead of only some pharmacists in some parts of the country,” the guidance states.

Jim Smith, chief pharmaceutical officer for England, commented: “Publication of ‘Choosing health through pharmacy’ is a

watershed for pharmacy. It puts pharmacy on a strong footing, alongside other public health professionals, to improve the health of people in England.”

The strategy was jointly developed by a consortium comprising the Royal Pharmaceutical Society, the Faculty of Public Health, the UK Public Health Association and PharmacyHealthLink.

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## Guidance for consultant posts announced

Guidance for the development of consultant pharmacist posts in hospitals and primary care trusts in England was published by the Department of Health last week.

The guidance has been produced to ensure that patients receive a consistent standard of care and that consultant posts are transferable across organisations.

The title “consultant pharmacist” is only to be used by pharmacists appointed to posts approved by strategic health authorities following submission of a business plan. Consultant posts should be centred around four main functions: expert practice; research, evaluation and service development; education, mentoring and overview of practice; and professional leadership.

Tony West, president of the Guild of Healthcare Pharmacists and chief pharmacist at Guy’s and St Thomas’ NHS Foundation Trust, told *The Journal*: “Consultant pharmacists are not to be seen as something that exists currently with a new badge. They are

there to help drive change and ensure that the NHS and patients get the most from medicines.”

The competencies required for the posts are taken from the advanced and consultant level competency framework designed by the Competency Development and Evaluation Group (a collaboration of specialist, practising and academic pharmacists in the South East).

NHS organisations employing pharmacists who are already using the title consultant pharmacist should submit these posts for retrospective approval by local approval panels.

Eileen Neilson, head of policy development at the Royal Pharmaceutical Society, said: “It will mean that there are pharmacists both in hospital and primary care with a higher level of clinical expertise . . . and these pharmacists will be able to provide care to patients with the most complex needs.”

The full guidance is available via *PJ Online* ([www.pjonline.com/links/pj](http://www.pjonline.com/links/pj)).

## Scottish Executive will not amend zero discount list

The Scottish Executive will not be amending the list of drugs subject to zero discount following the revised discount terms announced by GlaxoSmithKline and IVAX, it emerged this week.

Frank Owens, chairman of the Scottish Pharmaceutical General Council, told *The Journal* that he had received a letter from the Scottish Executive Health Department which stated: “We are not satisfied that there is any logical reason for regularly adjusting the list of drugs categorised as zero discount items. We therefore do not intend to constantly amend the list of ZD items as this may only serve to further encourage market behaviour that would frustrate our objective of transparently delivering the target rate of discount claw-back in a way that is predictable to both the Department and contractors.”

Mr Owens commented: “Difficult as the situation may now be, the last thing we need is for the reimbursement process to be put under further strain with other manufacturers following the GSK route. Unless GSK reconsiders, there is a now a very real possibility that SEHD and SPGC will require to conduct a further proprietary discount inquiry — something, given the significant effort required, that neither SPGC, nor I suspect SEHD, would wish to consider at this point in time. I doubt further whether contractors would welcome the prospect of yet another survey so soon after the last.”

## New pharmacy contract launched by Reid



John Reid (left) talks to pharmacist Prakash Mahtani at the launch

Secretary of State for Health John Reid visited Warwick Pharmacy in London on 1 April to launch the new community pharmacy contract. At the launch, Kensington, Chelsea and Westminster Local Pharmaceutical Committee secretary Rekha Shah told the minister: “[Connection] of

pharmacists to the NHS care records service is the most important factor for the contract to work most effectively.”

□ **2005 Regulations** The National Health Service (Pharmaceutical Services) Regulations 2005, SI 2005 No 641 have now been published by HM Stationery Office.

### General election briefing

The Society has sent a pharmacy election briefing to candidates in the general election (p433).

### Practice guidance on obesity

The Society has issued new practice guidance to help pharmacists give advice on obesity (pp433 and 435).

### Society's new Council

The Society's new Council must not focus on regulation to the exclusion of wider issues, says the President (p434).

The Society

## More contract details announced

The Pharmaceutical Services Directions 2005 for advanced and enhanced services in England were published last week, giving an indication of what services pharmacies will be able to offer under the enhanced services tier of the new community pharmacy contract.

The directions state that each primary care trust is authorised to arrange with pharmacists for the provision of a number of additional pharmaceutical services, which it defines in broad terms.

The services listed in the directions include:

- Minor ailment schemes
- Supplementary prescribing and prescriber support services
- Medication review, medicines assessment and compliance services

- Stop-smoking services
- Care home, delivery and schools services
- Disease specific medicines management
- Screening and anticoagulant monitoring

Other services include: gluten-free food supply, language access services, needle and syringe exchange, and on-demand availability of specialist drugs services.

The Pharmaceutical Services Negotiating Committee told *The Journal* that the specifications for enhanced services, which it had hoped might be published as early as May, will now not be available until the summer.

□ **Control of entry** Guidance on the control of entry regulations have been published on the Department of Health website and now includes information on rural dispensing.

## PCTs take responsibility for prison pharmacy

Responsibility for commissioning health services in prisons in England is being transferred to primary care trusts a year ahead of schedule.

In 2002 the Home Office announced that all health services should be commissioned by PCTs by 1 April 2006, and last April 34 prisons completed their transfers.

Stephen Ladyman, health minister, announced last week that 86 more prisons have now had their health care services, including pharmacy services, commissioned by 63 local primary care trusts. This leaves four prisons to transfer responsibility by next year.

Alastair Monk, a pharmacist at Durham prison, told *The Journal*: "This transfer of responsibility could have opportunities for prison pharmacy, depending on the level of engagement between prison health care and the PCT." He explained that since Durham prison pharmacy services became commissioned by Durham and Chester-le-Street



**Prison pharmacy: services improving**

PCT, active involvement by its PCT prison development manager has resulted in improvements in the pharmacy workforce, formulary development and budgeting.

In Wales commissioning for public sector prisons is expected to transfer to local health boards in April next year.

## All over 65s to be offered pneumococcal immunisation

Immunisation against pneumococcal infection is to be offered to everybody in England and Wales aged 65 years and over, the Department of Health and the Welsh Assembly Government have announced.

The immunisation programme for older people started in August 2003 when people aged 80 years and over were offered the vaccine. This was extended to include people aged 75 years and over in 2004. The DoH says that patients can be vaccinated at any time during the year but adds that doctors will be inviting patients for vaccination from April.

### News in brief

#### Funding for osteoporosis

The Department of Health has announced £20m extra funding for osteoporosis service improvements and dual energy x-ray absorptiometry (DXA) scanners. Bone density scanning is usually performed in hospitals, but portable DXA scanners have previously been used in an osteoporosis screening pilot in a pharmacy in North-East London (*Medicines Management* 2002;[5]:5). The pilot was not rolled out on a larger scale due to lack of funding.

#### Let PCTs buy oxygen headsets

The Pharmaceutical Services Negotiating Committee recommends that contractors do not buy new headsets for oxygen patients and that they ask their primary care trust to provide them. Contractors are likely to receive compensation for current headsets based on a percentage of cost.

## MHRA lacks discipline and leadership, says Health Select Committee

Tighter controls on the promotion of new drugs and an urgent review of the Medicines and Healthcare products Regulatory Agency have been called for by the House of Commons Health Select Committee.

In a report on the influence of the pharmaceutical industry, the committee warns that the MHRA lacks the discipline and leadership needed to protect patients' health needs.

The review should focus on the need for greater independence from the Government and the pharmaceutical industry, as well as greater transparency and accountability. The committee also wants the regulatory standards underpinning new drug reviews to be examined, along with systems for reporting and evaluating adverse drug reactions.

The committee says that the system for regulating medicines "is at times frustrating, arguably with excessive attention to unimportant detail and insufficiently effective". It adds that the regulator has been "insufficiently rigorous about its public health responsibilities".

A consequence of this is that medicines are not used safely, the report states.

But the committee does not restrict blame to the MHRA and pharmaceutical manufacturers. "Inappropriate prescription of medicines by GPs is of particular concern," the report adds. "Some have prescribed selective serotonin reuptake inhibitors, for instance, on a grand scale."

The report concludes that there should be a public inquiry whenever a drug is with-

drawn on health grounds. It also recommends restrictions on prescribing by non-specialist doctors, that prescribing by pharmacists and nurses should be carefully monitored and that sponsorship of the pharmaceutical industry should be transferred to the Department of Trade and Industry so that the Department of Health can concentrate on promoting health.

Recording concern that health professionals might be unduly influenced by gifts and hospitality provided by drug companies, the committee says that professional bodies, including the Royal Pharmaceutical Society, should keep registers of declaration of interests by their members.

The Select Committee's report is available via *PJ Online* ([www.pjonline.com/links/pj](http://www.pjonline.com/links/pj)).

# Pilot sites will address racism in mental health care

Seventeen pilot sites across England will pioneer best practice in eliminating racial discrimination in mental health services, the Department of Health announced last week.

The sites will support the implementation of "Delivering race equality in mental health care", an action plan for reducing inequalities in black and minority ethnic patients' experience of mental health services, published by the DoH in January.

Peter Pratt, chief pharmacist of Sheffield Care Trust and Doncaster and South Humber NHS Trust, told *The Journal* that there is work to be done to address discrimination in mental health care. However, he believes that much can be achieved by implementing existing guidance. "By ensuring drug treatment is in accordance with current basic principals of good practice pharmacists can play their part in preventing discrimination in mental health," he said.

The National Institute for Clinical Excellence recently issued guidance on the short-term management of disturbed or violent behaviour (*PJ*, 26 February, p224). Mr Pratt said that this guidance reminds pharma-



BSIP LA/Flini-Herrera/SPL

## Black people are more likely to receive multiple medicines than white people

cists that people from some ethnic groups may be at a higher risk of receiving inappropriate drugs or doses. "By following these recommendations, which include having a specialist pharmacist as part of the team who use rapid tranquillisation, we can also help prevent discrimination from happening," he said.

David Taylor, chief pharmacist, South London and Maudsley NHS Trust, said that there are many drug-related aspects to race in mental health. He said that at least one UK study suggests that polypharmacy is more common in black people than white people. "Pharmacy staff should be making sure that different racial groups are prescribed [medicines] to the same standard, taking into account differences in metabolism and body weight," he added. He also pointed out that certain racial groups may be more prone to some adverse effects, particularly diabetes, and pharmacists should ensure that monitoring of adverse effects is equal between races.

Patient choice is another important area. The NICE guidance states that patients should make an informed contribution to the choice of their antipsychotic. Mr Pratt commented: "The lack of written information in an appropriate format and language means that some people will not have the opportunity to develop advance directives or have a meaningful involvement in their choice of treatment."

The pilot sites will be asked to develop project plans by the end of May.

## News in brief

### Long-term care consultation

Draft regulations on commissioning NHS long-term care were issued for consultation by the Department of Health this week. The regulations aim to overcome the problem of which primary care trust should commission care for a patient outside his or her area of residence. The consultation ends on 29 June. The document can be accessed via *PJ Online* ([www.pjonline.com/links/pj](http://www.pjonline.com/links/pj)).

### Instalment dispensing

Diazepam will be added to the products that GPs in England can order to be dispensed in instalments on NHS prescriptions from 14 April. Currently, only buprenorphine and Schedule 2 Controlled Drugs can be prescribed in this way.

## DTB claims that simvastatin reclassification was flawed

The way in which simvastatin became an over-the-counter medicine was "flawed" and represents a "poor model" for future POM to P switches, according to *Drug and Therapeutics Bulletin* (2005;43:25).

In the April issue of *DTB*, the rationale for reclassifying simvastatin 10mg is reviewed and several concerns about the process are raised. In particular, *DTB* claims that the Medicines and Healthcare products Regulatory Agency exaggerated the proportion of favourable responses made to the public consultation.

After analysing 80 of the 100 responses, *DTB* says that 31 per cent offered at least some support, 35 per cent clearly opposed it and the rest offered no clear opinion either way. "Even if all 20 of the withheld responses are assumed to have been in favour of the reclassification, only 45 per cent of all respondents at most could be described as supporting the proposal," says *DTB*. At the time, the MHRA reported that "about two

thirds of respondents were in favour of the proposal". A spokeswoman for the MHRA refuted the suggestion that the consultation was misrepresented. She said the decision to reclassify simvastatin 10mg was taken following advice from the Committee on Safety of Medicines, which had full access to all responses to the consultation.

*DTB* also suggests that the reclassification was not based on robust evidence. No published clinical studies have determined the effect simvastatin 10mg has on coronary heart disease morbidity or mortality and extrapolations made from meta-analyses may be over-optimistic in their predictions, it says. "As a result, the UK population has, in effect, now been enrolled in a large experiment without adequate monitoring of benefits or risks."

□ **Bipolar disorder** The April issue of *DTB* also considers the role of drug treatments for acute manic or depressive episodes in adults with bipolar disorder (*ibid*, p28).

## APPG seeks details of how health policies of the main political parties will affect pharmacy

Details of the three main political parties' policies in relation to pharmacy are being sought by the All-Party Pharmacy Group.

The group's chairman, Howard Stoaite, has written to the front bench health spokesmen for the Labour, Conservative and Liberal Democrat parties seeking details of their policies and plans relevant to pharmacy in both the community and secondary care sectors.

Dr Stoaite said: "We are keen to hear from each of the parties how their health policies

will affect pharmacy services and pharmacists. This is not about party political point-scoring. It is intended to provide a focus for the group's work after the election and to inform those interested in pharmacy issues about each of the main parties' relevant plans. We will post information on our website once we receive it."

□ **Society briefing** In an election briefing issued this week, the Royal Pharmaceutical Society has called on the next Government to put pharmacists at the heart of health policy.

□ **Pharmacist candidate** Sandra Gidley, a practising pharmacist who is the Liberal Democrat member of Parliament for Romsey until the dissolution of Parliament next week, is standing for re-election. Mrs Gidley successfully defended her seat in the 2001 election, with a majority of 2,370 over the Conservative candidate (47 per cent vs 42.1 per cent).

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# Gram-negative bacteria danger is being ignored

The threat of multidrug-resistant Gram-negative bacteria is being overshadowed by the focus on Gram-positive infections such as methicillin-resistant *Staphylococcus aureus*, latest UK figures suggest. And microbiologists are warning that although there are a number of useful antibiotics for Gram-positive bacteria, either recently licensed or in development, there is little on the horizon to cope with multidrug-resistant Gram-negative bacteria.

Data from the British Society for Antimicrobial Chemotherapy and the Health Protection Agency were presented at the European Congress of Clinical Microbiology and Infectious Diseases earlier this week. They show that multi-resistant isolates of *Klebsiella* spp, *Enterobacter* spp, *Citrobacter* spp and most notably *Escherichia coli* are now firmly established in the UK. For instance, multi-resistant *Klebsiella* spp rose from under 5 per cent of isolates in 2002 to over 8 per cent in 2003.

Mark Wilcox, professor of medical microbiology at the University of Leeds, said: "The real worry is that with Gram-negatives we are in the same position we were in with MRSA 10 years ago.

"We thought then that we'd run out of options for antibiotics but drug companies have come up with new treatments effective against Gram-positives but rather taken their eyes off the ball with Gram-negatives."

Professor Wilcox pointed out that tigecycline (*PJ*, 13 November 2004, p709) is the only broad spectrum antibiotic on the near horizon. It is likely to be launched in the US in the next few months and in the UK towards the end of the year, he added.

"When it is launched we will have to ensure that we use it responsibly. The worst thing that could happen would be for people to start throwing it around," Professor Wilcox said.



DR Gary Gaugler/SPL

***Escherichia coli*: multi-resistant isolates are now firmly established in the UK**

## News in brief

### MeReC updates HRT advice

Evidence points to an overall net harm for use of hormone replacement therapy in chronic disease prevention, *MeReC Bulletin* advises. The latest issue of the bulletin concludes that risks associated with HRT use should be communicated clearly. It also points out that the risk-benefit profile for individual women will change over time, making regular review necessary. The bulletin concludes that short-term use of HRT is effective for relief of menopausal symptoms.

### Diuretics first line

Diuretics should be used first line for both black and non-black patients with high blood pressure, data from the ALLHAT study show. The analysis was conducted to determine whether an angiotensin converting enzyme inhibitor or calcium channel blocker is superior to a thiazide diuretic in reducing cardiovascular disease incidence in racial subgroups (*JAMA* 2005;293:1595).

## Routine use of vitamins and minerals in elderly patients not supported by evidence

There is insufficient evidence to support the routine use of multivitamin and mineral supplements to reduce infections in elderly people but further research is warranted, a new study shows.

Researchers conducted a meta-analysis of eight randomised controlled trials, although an inconsistency in the outcome measures meant that only a proportion of the studies could be analysed for each variable.

The researchers note that although previous studies have shown that supplementation with different nutrients improves immune status in elderly people, many used vaccine responses and surrogate markers of immune response as outcome measures, and the clinical importance of these findings is still a sub-

ject of debate. The new analysis shows that the mean annual number of days spent with infection was reduced by 17.5 in patients taking multivitamins and minerals compared with placebo (three studies,  $P < 0.001$ ).

However, overall, the evidence was of poor to moderate quality, heterogeneous and conflicting, say the researchers. They also note that levels of reporting of adverse effects were poor.

The researchers say that the results are sufficiently encouraging to warrant further studies in this area and recommend a multi-arm trial comparing different doses of micronutrients with a minimum follow-up of 12 months (published on *BMJ Online First* www.bmj.com).

## Community pharmacy set to improve men's health in Fife

Community pharmacy will play a key role in a project to be launched next week that aims to improve men's health.

The Fife healthy men project will help men to access health services, particularly those who live in areas of social deprivation, explained Nicola Carlyle, communications officer at NHS Fife. "Research in Fife shows that men are 50 per cent less likely than women to go to a GP. So the point of the exercise is to identify different ways to engage men," she said. This is where community pharmacy fits in.

Seven community pharmacies will offer men "top to toe" health checks. "Originally, we had planned for the pharmacists to carry out the checks but, since each takes 30 to 40 minutes, we decided that it would be better

to train pharmacy technicians to gather the routine data. We have standard operating procedures in place, including for the blood pressure, cholesterol and blood glucose checks," said Ms Carlyle.

At the end of the assessment, the pharmacist examines the data and provides health information and advice to the man or, if appropriate, refers him to a GP or other service. This includes fast-track referral into alcohol, weight management, smoking cessation and genito-urinary medicine services. In addition to being available from pharmacies, health checks will also be offered by local health centres and in workplaces. The project has been awarded Scottish Executive funding and will run until the end of 2006. Pharmacies will be paid £20 per health check.

Access to *PJ Online* is free to all

### Website developments

*Prescribing & Medicines Management* has its own home page on *PJ Online*, in common with *The Pharmaceutical Journal*, *Hospital Pharmacist* and *Tomorrow's Pharmacist*.  
www.pjonline.com/pmm

# Six conditions responsible for 90pc of child deaths

Almost 90 per cent of all deaths among children under five years of age are attributable to just six conditions, according to the World Health Organization, which published its annual World Health Report this week.

The 2005 report "Make every mother and child count" lists the conditions as acute neonatal conditions, mainly preterm birth, birth asphyxia and infections, which account for 37 per cent of the total, lower respiratory infections, mostly pneumonia (19 per cent), diarrhoea (18 per cent), malaria (8 per cent), measles (4 per cent) and HIV/AIDS (3 per cent). The report says that most of the deaths are avoidable and calls for greater use of interventions such as oral rehydration therapy, antibiotics, antimalarial drugs and insecticide-treated bednets. It also promotes use of vitamin A and other micronutrients, breastfeeding and immunisation.

According to the WHO, about 530,000 women die in pregnancy or childbirth each year and more than four million newborns die within the first days or weeks of life. And each year 10.6 million children die before they reach the age of five years.

"For optimum safety, every woman, without exception, needs professional skilled care when giving birth," the report says, adding that continuity of care for the newborn in the following weeks is vital.

"This approach has the potential to transform the lives of millions of people," says Lee Jong-wook, director general of the WHO.

□ **Reproductive health library** The WHO has also released a new version of its online reproductive health library this week ([www.rhlibrary.com](http://www.rhlibrary.com)). The library includes reviews of advances in family planning and the prevention and treatment of illness and death



Andy Crump, TDR, WHO/SPL

**In children under five years of age 8 per cent of deaths are caused by malaria**

related to pregnancy and childbirth. It is also available on a CD-ROM and is free of charge to subscribers in developing countries.

## Guidance on access to drugs in developing countries issued

Guidance for pharmaceutical companies on how they can increase access to essential medicines in developing countries was issued by the Department for International Development last week.

The document encourages companies to:

- Engage in differential pricing of essential medicines
- Increase research into diseases affecting developing countries
- Report on programmes to increase access to essential medicines

The DFID recognises, however, that the burden of responsibility for increasing access to essential medicines does not just rest with the pharmaceutical industry. The whole international community needs to work in partnership, it says, to make medicines more affordable and increase the number of new medicines developed for diseases affecting developing countries. "Increasing people's access to essential medicines in developing countries" is available via a link on *PJ Online* ([www.pjonline.com/links/pj](http://www.pjonline.com/links/pj)).

## Medicines trade balance slips

Britain's trade surplus in pharmaceuticals fell by 5.5 per cent to £3.4bn last year.

The latest figures from the Association of the British Pharmaceutical Industry show that not only has the pharmaceutical balance of trade slipped, but companies are also reducing spending on research and capital development. R&D expenditure in 2003 — the latest year for which figures are available — fell from £3.3bn to £3.2bn and expenditure on buildings and equipment fell to £753m, compared with a five-year average of £925m.

Announcing the figures this week, ABPI president Vincent Lawton said: "It is not always easy to identify precisely why so many key areas should have dipped, but it is clear that the continuing threat posed by animal extremists is a contributory factor."

He added that the figures provided a warning that the industry, which is the most highly regulated industry in the UK, should not be overburdened with bureaucracy.

"We are operating on a global basis and no company can be expected to invest in the UK if the environment here is not sufficiently welcoming."

## DOTS can reduce transmission and incidence of drug-resistant TB

A strategy that includes a short course of directly-observed therapy (DOTS) can rapidly reduce the transmission and incidence of both drug-susceptible and drug-resistant tuberculosis in settings with moderate rates of multidrug-resistant TB, according to research published this week.

Kathryn DeRiemer, Stanford University Medical Centre, California, and colleagues, conducted a study involving 436 patients in southern Mexico between 1995 and 2000. In 1996 changes were initiated in this area to bring it in line with the World Health Organization recommended DOTS strategy for TB control in Mexico.

The researchers screened people who reported coughing for longer than 15 days and identified patients with pulmonary TB.

Retreatment cases were defined as patients who had previously received at least 30 days of anti-TB therapy.

Patients were followed up annually and three indicators of transmission were estimated for each 12-month period — the incidence rate of pulmonary TB, the percentage of pulmonary TB cases that were clustered and the rate of pulmonary TB with primary resistance to at least one first-line drug.

The results showed 323 cases of newly diagnosed TB, 109 retreatment cases and four patients whose previous treatment status was unknown.

The incidence rate of TB decreased by 54.4 per cent ( $P=0.00048$ ) over five years. The percentage of cases that were clustered decreased by 62.6 per cent ( $P=0.02$ ) and the

size of the clusters also decreased. The number of new cases resistant to at least one first-line drug decreased by 84 per cent ( $P=0.004$ ). By 2000, there were no new cases of multidrug-resistant TB and the rate of multidrug-resistant retreatment cases had decreased ( $P<0.0001$ ).

However, the researchers highlight that although the rates of transmission and incidence of TB decreased significantly, the rates of treatment failure and mortality among patients with multidrug-resistant TB remained unacceptably high.

"Additional measures, such as drug-susceptibility testing and standard or individualised therapy, are needed to improve clinical outcomes," the researchers say (*Lancet* 2005;365:1239).

# New commission to replace CSM

On 30 October, the Commission on Human Medicines will replace the Committee on Safety of Medicines and the Medicines Commission (*PJ*, 20 November 2004, p734). A maximum of 18 members plus a chairman will form the CHM, with advertisements for positions being placed this month. Consultation on the future of the Veterinary Products Committee and a proposed new Herbs Advisory Committee are ongoing.

The changes are part of a review of the committees established under Section 4 of the Medicines Act 1968 to advise ministers. Two Section 4 committees — the Advisory Board on

the Registration of Homoeopathic Products and the British Pharmacopoeia Commission — are not affected.

The CHM appointments will be managed by the NHS Appointments Commission, which will also be advertising for chairmen and members of the other Section 4 committees.

People who work in the pharmaceutical industry or hold shares in drug companies will not be allowed to sit on the new CHM. This prohibition will not apply to members of new expert advisory groups that will be created to advise the CHM on products or general safety issues.

# Pharmaceutical industry responds slowly to NHS

The pharmaceutical industry is responding too slowly to changes in the health service to meet the needs of today's NHS, the results of a study suggest.

Market information group Taylor Nelson Sofres questioned heads of medicines management and prescribing at primary care trusts, GPs and patient groups on behalf of Takeda UK. Most PCT leads thought that pharmaceutical companies were still operating as they had five to 10 years ago. Three-quarters of PCT leads believed that pharmaceutical companies should avoid a purely product-focused

approach and 80 per cent thought that they should work in partnership with primary care organisations to develop local strategies to meet local needs.

Respondents also questioned whether traditional sales representatives could meet the requirements of the modern NHS: 45 per cent of PCT leads and 40 per cent of GPs believed that their knowledge of new products would be unaffected if they never saw another pharmaceutical sales representative.

# Ranbaxy settles price fixing claim with the Department of Health

Ranbaxy, one of the generics companies being sued by the Department of Health over allegations of price fixing and overcharging, has reached an out-of-court settlement with the Government.

It has agreed to pay the DoH £4.5m with no admission of liability. The company is also to cooperate with ongoing investigations.

Turning up the pressure on other companies that the DoH is suing, Jim Gee, DoH director of counter fraud services, said that an institutional shareholder of one of the remaining defendant companies had approached the DoH because it is worried about the impact the case is having on share prices.

## Food supplement law in doubt

An advocate general of the European Court has said that a European Directive that restricts the availability of food supplements is invalid because it does not reflect legal principles of fairness and sound administration. The opinions of advocates general are rarely rejected by the court.

## Co-op sales up

United Co-op Healthcare has announced a 9 per cent rise in sales, to £131m, for the financial year ending on 22 January. More than 10 million prescriptions were dispensed over the year.

## NHS learning budget

The NHS Institute for Learning, Skills and Innovation will have a budget of £80m for 2005–06, as well as £20m for transition costs. It will be established by July 2005 as a special health authority at the University of Warwick.

# Roche falls foul of ABPI code

Roche recently breached the Association of the British Pharmaceutical Industry's code of practice by promoting Xenical (orlistat) direct to more than 14,000 patients.

Following a complaint from a primary care trust adviser in July last year, the Prescription Medicines Code of Practice Authority decided that contacting members of the public to advertise a prescription medicine was a sufficiently serious matter to refer the case upwards to the PMCPA appeal board.

The appeal board ruled that even though the letter had only been sent to people who had registered with Roche's XenicalMAP (motivation, advice, pro-active support) scheme the company had been extremely careless in sending the letter out without being sure that every recipient was still taking the medicine.

Although the letter did not explicitly suggest that people should ask to be prescribed Xenical, it did mention the product five times and stated: "So, if your weight's crept back on and you're feeling the need to lose a few pounds again you might want to discuss this with your GP."

# MAO-B inhibitor shows promise in parkinsonism

Rasagiline, a new monoamine oxidase B inhibitor, is an effective adjunctive treatment for Parkinson's disease and can improve symptoms associated with levodopa treatment, an 18-week trial has shown.

Rasagiline is a selective, irreversible, blocker of MAO-B but, in contrast to its predecessor selegiline, is not converted into amphetamine metabolites, suggesting a different pharmacological profile.

The study involved 687 Parkinson's disease patients who were being treated with levodopa, dopamine agonists and other antiparkinsonian therapies. Patients were randomly assigned to rasagiline (1mg taken as a single oral daily dose), entacapone (200mg

with every levodopa dose) or placebo. Compared with placebo, rasagiline reduced the duration of "off-time" experienced by patients (ie, periods of the day with poor or absent motor function) and improved motor symptom control. The reduction in off-time was of similar magnitude to that observed for entacapone.

The European researchers, led by Olivier Rascol of Toulouse university hospital, say that the beneficial effects were independent of age and of adjunct use of dopamine agonists, both of which are clinically relevant. "That the efficacy of rasagiline is unaffected by dopamine agonists is especially relevant in patients with Parkinson's disease; they are

often highly medicated and rasagiline can be given without the need for titration," they write. Rasagiline also appeared to be well tolerated, including among elderly patients (over 70 years) with no evidence of increased hallucinations (*Lancet* 2005;365:947).

In an accompanying editorial, Carl Clarke of the University of Birmingham suggests that the new drug is likely to find favour with neurologists and geriatricians. "The fact that efficacy and safety were similar in [patients over 70 years] will be of particular interest to geriatricians because older patients with Parkinson's disease are more likely to have adverse events with the addition of new medication," he says (*ibid*, p914).

## Diabetes gene identification could lead to new therapy

A gene that appears to play a critical role in the development of type 1 diabetes has been identified by researchers at the North Shore-Long Island Health System in Manhasset, New York. The gene is responsible for making an immune system messenger called macrophage migration inhibitory factor (MIF), a protein involved in the regulation of the immune system. Last year, the researchers showed that ISO-1, a synthetic compound developed by them, prevented the onset of diabetes by inhibiting MIF (*PJ*, 10 April 2004, p441).

In the latest experiments, the researchers gave a chemical known to induce diabetes to mice that they had specifically bred to lack the MIF gene. They found that the mice were resistant to the development of diabetes.

Yousef Al-Abed, one of the researchers, says: "[The gene] is not the only factor involved in this complex disease, but it is certainly a promising target for its prevention and treatment." He adds that identification of the gene could lead to gene therapy to prevent the disease, possibly by disrupting the network of genes involved in its development.

The study findings were presented at the 229th national meeting of the American Chemical Society in San Diego last month.

## Place for cannabinoid compounds in cardiovascular disease

Drugs that affect cannabinoid receptors might have a place in the management of cardiovascular disease, results from two recent studies reveal.

In the first, a phase III clinical trial involving 1,507 patients, researchers demonstrated that improvements in cardiovascular risk factors achieved with the selective CB1 inhibitor rimonabant (20mg daily) were maintained in the second year of treatment.

Compared with placebo, rimonabant led to greater reductions in waist circumference (5.7cm vs 1.8cm,  $P<0.001$ ) and to improved weight loss (22.0 per cent of patients lost more than 10 per cent of their initial body weight compared with 6.3 per cent of patients given placebo,  $P<0.001$ ). Metabolic parameters, such as high-density lipoprotein cholesterol and triglycerides, were also improved. The two-year data were presented at a meeting of the American College of Cardiology held in Orlando, Florida, last month.

The second study, conducted in laboratory mice, suggests that a component of cannabis, delta-9-tetrahydrocannabinol (THC), is able to halt atherosclerotic disease progression. European researchers administered oral THC to mice with established atherosclerosis. The doses (about 1mg/kg daily) were lower than the level required to activate the CB1 receptor, say the researchers, but were able to pre-



Patients lost weight while on rimonabant

vent the accumulation of immune cells in blood vessels by binding to CB2 receptors. "Our results suggest that cannabinoid derivatives with activity at the CB2 receptor may be valuable clinical targets for treating atherosclerosis," the researchers conclude (*Nature* 2005;434:782).

□ **Cannabis-induced psychosis** A report of psychotic effects experienced by two volunteers taking cannabis-based therapies as part of a clinical trial has been published (*BMC Psychiatry* 2005;5:17). The subjects reported severe anxiety and impaired psychomotor functions after being given low doses of THC (blood concentrations of less than 10ng/ml).

### Cranberries for vascular function

Using a model of hypercholesterolaemia researchers have shown that cranberry juice can improve vascular function and may protect against heart disease. Pigs with a genetic defect developed high cholesterol and atherosclerosis. However, those fed cranberry juice powder for six months had blood vessels that behaved more like the vessels of normal pigs ([www.iups.mcw.edu](http://www.iups.mcw.edu)).

## Overactive bladder treatments show differences in efficacy

Differences between antimuscarinic treatments for overactive bladder syndrome are beginning to emerge.

A meta-analysis conducted by UK researchers was presented at the European Association of Urology Congress last month. It compared withdrawal rates associated with antimuscarinic drugs (both licensed and unlicensed in the UK) based on 56 randomised placebo-controlled trials.

The meta-analysis showed a greater risk of withdrawal for oxybutynin (relative risk 1.4

compared with placebo) than for tolterodine (relative risk 0.7 compared with placebo) and no differences in rates when comparing placebo with the newer agents solifenacin and darifenacin.

Data from a study involving 1,355 patients comparing tolterodine (4mg) and solifenacin (5mg and 10mg) suggested a better outcome for patients taking solifenacin, which was more effective in treating urge incontinence ( $P=0.001$ ) and was associated with less use of pads and fewer episodes of incontinence.