

# White Paper aims to expand pharmacists' frontline role

Pharmacists across England are set to play a bigger role in delivering frontline healthcare following publication last week of the Government's "landmark" White Paper, which indicates that primary care trusts will in future be directed to commission certain services from community pharmacies.

Chief pharmaceutical officer for England, Keith Ridge, said: "This is a landmark document for both patients and pharmacy. When implemented, it will underpin better care of patients with medicines, will be a major contribution to improving the health of the population and should complete the transformation of pharmacy to a clinical profession."

The long-awaited White Paper "Pharmacy in England — building on strengths, delivering the future" sets out the Government's vision of pharmacies as healthy living centres — promoting health, preventing illness and providing a range of new services to complement the work of GPs.

Proposals include a nationally available minor ailment scheme, support for people with long-term conditions, screening for vascular disease and some sexually transmitted infections and a bigger role in vaccination.

The Government plans to direct all PCTs to commission certain services from pharmacy contractors according to local needs. This additional category of service — directed enhanced services — will provide a useful mechanism in addition to advanced

and local enhanced services, it says. The approach could be used for the proposed national minor ailment scheme and for support of people with long-term conditions.

The White Paper sets out a direction of travel but key to making it happen will be renegotiating the community pharmacy contract, said health minister Ben Bradshaw as he launched the document. NHS Employers, on behalf of PCTs, has been tasked with working with the Pharmaceutical Services Negotiating Committee to see how the White Paper proposals can best be incorporated within the contract. In addition, two new pharmacist clinical directors will be appointed by the Department of Health later this year to help implement the White Paper plans — one will focus on delivery in the community and primary care and the other on delivery in hospitals.

The Government will be holding a series of public engagement events around England, starting on 1 May in London, to hear what patients, consumers, the NHS and healthcare professionals have to say about the planned changes.

It will then consult on key proposals this summer when the forthcoming primary and community care strategy (part of the Darzi review) is complete. These will include reform of the way in which the NHS contracts for services and changes to exemptions for 100-hour pharmacies (see below).



The PSNC has confirmed that work to implement proposals will begin immediately, with NHS Employers and the PSNC discussing a number of key issues. The community pharmacy contractual framework will be refreshed over the next two years as new services are developed, it said.

A series of impact assessments on specific proposals in the White Paper is also published. All documents are available on the DoH ([www.dh.gov.uk](http://www.dh.gov.uk)) and via *PJ Online* ([www.pjonline.com/pjlinks](http://www.pjonline.com/pjlinks)).

Details of the proposals in the White Paper and reaction from the profession can be found in two **News features** (p429 and p430).

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## Drawbacks of 100-hour pharmacy rules recognised by Government

Significant drawbacks to market-entry exemptions for 100-hour pharmacies are recognised in the new pharmacy White Paper, which incorporates the Government's response to Anne Galbraith's review of contractual arrangements. Both the White Paper and the Galbraith report were published last week.

The White Paper acknowledges that 100-hour pharmacies have improved access in some areas but it also recognises the concerns of independent pharmacies that are subject to increased competition and those of primary care trusts, which are unable to plan strategically or to commission further clinical services because of the costs arising from each new pharmacy. Four options are identified, which the Government will consult on this summer:

- Introducing a distance restriction on new 100-hour pharmacies of 1.6km or 2km from existing 100-hour pharmacies
- Imposing a requirement on new applicants to justify a need for the 100-hour pharmacy
- Contracting successful applicants using local pharmaceutical services contracts so PCTs can avoid the fixed costs they currently incur from surplus provision
- Strengthening the requirements for the specific services a 100-hour pharmacy pro-

vides, for example, linking applications to developments outlined in the White Paper

The Government favours combining the first and last options since policy on exemptions to market entry would then be aligned with national priorities identified in Lord Darzi's interim review.

The White Paper says that PCTs' commissioning skills need to be strengthened before they can take on full responsibility for commissioning — one of the options suggested in the Galbraith report (see Panel). This suggests that, as PCT commissioning evolves, control of entry regulations could eventually be replaced with contracting mechanisms that are based on safety, quality and outcomes.

The Government believes that commissioning in the future must foster a shift away from the dispensing service to more clinically focused pharmaceutical services. To achieve this long-term strategic direction, commissioning must meet local needs and link to practice-based commissioning; arrangements for contracting and payment mechanisms for such services must be revised; and high quality and safety in the delivery of services must be ensured. Immediate improvements that can be made to ensure high quality and safety

of services include setting more robust standards for essential and advanced services and harmonising accreditation standards for similar enhanced services.

The White Paper also proposes introducing financial incentives and penalties as well as more effective sanctions to address poor performance.

### The Galbraith report

The Galbraith report identifies a need to strengthen primary care trusts' commissioning roles to stimulate competition and to ensure that future contractual arrangements are founded on the quality of services to be provided rather than on market entry. The report recommends that PCTs should undertake more rigorous pharmaceutical needs assessments and that they should be able to terminate contracts when pharmacies perform poorly. The report concludes that neither further moves to more advanced or essential services nor simple deregulation would meet these objectives. It identifies two possible options: complete devolution of contracting responsibilities to PCTs; or the introduction of the concept of "any willing provider" for the provision of essential services, with more contestability for enhanced services.

# Survey reveals extent of workplace bullying in NHS

Some 14 per cent of pharmacy staff working in the NHS have been harassed, bullied or abused by a colleague at work and 7 per cent by a manager, according to the results of the annual NHS staff survey published last week.

But nearly two thirds of the incidents (63 per cent) went unreported, the statistics reveal. At the same time, 80 per cent of pharmacy staff who took part in the survey said they had been the victim of physical violence on one or two occasions from either patients or service users, their relatives or members of the public. Some 16 per cent said it had happened between three and five times.

The figures for pharmacy reflect a trend across other NHS workforce groups highlighted in the report and are based on answers to a questionnaire sent to 391 trusts between October and December last year. There was a 54 per cent response rate. Around 2,400 pharmacy staff took part.

The report by the Healthcare Commission on behalf of the Department of Health says: "Over the last three years there has been little change in the proportion of staff who have been physically attacked or abused at work in the preceding 12 months, despite campaigns to tackle these issues."

Across the NHS workforce, 13 per cent of staff reported being physically attacked by patients or their relatives in the past year; 27 per cent said they had been harassed, bullied or

abused — 8 per cent by their manager or team leader and 13 per cent by colleagues.

The report adds: "Levels of violence, harassment and bullying against staff in the NHS nationally appear remarkably high. Individual employers in the NHS need to examine their results and take action to address these high levels."

The survey also showed that 45 per cent of pharmacy staff were working up to an extra five hours a week unpaid with 11 per cent clocking up between six and 10 hours of unpaid work weekly.

Some 19 per cent did more than five hours paid overtime a week while 3 per cent reckoned their overtime tally was between six to 10 hours weekly. But the majority, 80 per cent, said they did not usually work between 7pm and 7am.

Staff in the annual survey, now in its fifth year, were also asked about their experience of errors, near misses and incidents during the previous 12 months. Of the pharmacy staff who responded, 15 per cent said they had



Nearly two thirds of bullying incidents were unreported

witnessed an error that could have affected a member of staff in the past month while 45 per cent said they had been aware of an error during that time, which could have impacted on a patient.

Clinical assessment or treatment issues were behind 89 per cent of the errors; 15 per cent could be traced back to staffing levels and 14 per cent were the result of poor communication, the report reveals. A third of pharmacy staff said they were given information about changes that were being made following an error.

## Increased pay package proposed for hospital pharmacists . . .

Pharmacy staff look set to receive a cumulative pay rise of nearly 8 per cent over the next three years.

Health Secretary Alan Johnson announced a proposed pay deal for all staff working under NHS Agenda for Change earlier this week. The offer has been agreed by the Department of Health, NHS Employers, Unison and the Royal College of Nursing.

Under the new proposals NHS staff across the UK would receive a 2.75 per cent pay rise from April 2008, a 2.4 per cent increase

in 2008–09 and a 2.25 per cent increase in 2010–11, with the opportunity to reopen negotiations if inflation is higher than expected.

David Thornton, chairman of the terms and conditions committee of the Guild of Healthcare Pharmacists, commented: "There are a number of good points within the proposal. In particular, this year's pay award implements the Pay Review Body's recommendation of [an increase of] 2.75 per cent in full from April across all four [home] countries. The opportunity to reopen talks if

inflation is higher than expected is a welcomed safeguard for years 2 and 3."

Mr Thornton pointed out that the proposals also suggest reducing the number of incremental points (salary rates within each pay band) in bands 6 and 7.

"This could have a positive impact on a large number of pharmacists allowing faster pay progression thereby narrowing the salary gap between the managed and private sectors," he said. He added: "We will need to look closely at the proposals before making a formal recommendation to our members."

## . . . along with "golden handcuff" payments for five years' service

Newly qualified pharmacists who go on to work in the NHS for five years should receive a retention bonus, the NHS Pay Review Body has suggested.

In its latest report it acknowledges that there is a problem retaining pharmacists as they reach their third year of service in the NHS, and suggests that bonuses similar to the "golden handcuff" payments in some private sector organisations should be made.

"The aim of offering such a bonus after five years' service would be to increase the

supply of pharmacists to the NHS beyond the point at which they often leave, and to enable experienced pharmacists to pass on their expertise to the newly qualified pharmacists who join after them," the report states.

The NHS Pay Review Body has rejected calls from Unite (the Guild of Healthcare Pharmacists' parent union) for a national recruitment and retention premium for band 6 and 7 pharmacists, equivalent to £4,000 per year, reasoning that this might encourage

newly qualified pharmacists to join the NHS, receive the extra money and then leave to join the private sector.

David Thornton, chairman of the guild's terms and conditions committee, said that the proposed five-year-service bonus would need to be "a significant sum" to compensate for the £10,000 annual salary differential between pharmacists working in the NHS and the private sector over their initial five years. "It will also need to recognise existing as well as future postholders," he added.

# Response to Clarke report is generally favourable

Initial responses from pharmacy groups to the Clarke Inquiry's report into a future professional body for pharmacy, although positive, have highlighted concerns over how the proposed changes will be put into effect.

Catherine Duggan, United Kingdom Clinical Pharmacy Association chairman and Royal Pharmaceutical Society Council election candidate, said that the purpose, focus and function for a new professional body set out by Nigel Clarke in his report were ambitious and laudable. "The UKCPA would be interested in taking a lead on the committee of specialist interest groups with others to ensure these aims are achieved," she said.

However, she believes that the structural changes and practical implications recommended in the report do not fully support the inquiry's vision for a new organisation.

"These tend to focus on retaining much of the status quo and retaining the existing sectors and groupings: a risk when taking soundings from the profession rather than considering the functions of a radical new body," she stated. She added that opportunities for pharmacy arising from last week's White Paper (see p423) would require barriers between sectors and groups within the profession to be broken down.

"We need a new organisation that takes the best of all our groups and specialisms," Dr Duggan said. "If we are not brave enough now, we could end up with something very similar to what we currently have, rather than a body that is fit for purpose and that provides true and effective leadership."



Catherine Duggan

Dr Duggan also believes the Society's name needs to change: "Calling the leadership body a royal college would allow us to retain what is good about the current Society and also fully incorporate the good work of other organisations. This would provide the change we need to move forward and reassure some within the profession that this is real change rather than a rebadging exercise for the sake of change."

Speaking for the Institute for Pharmacy Management International, general secretary Howard McNulty said: "Implementation of the Clarke report in an 18-month timescale will be a major challenge for the many different groups to put flesh on the skeleton outlined in the proposals. The IPMI looks forward to working with the Society and others to help meet this challenge."

Nevertheless, he said the report's recommendation that offering management advice be considered by the professional body "does not fully cover the role we envisaged or submitted in our evidence". The IPMI, he explained, sees the need for the professional body to develop pharmacy managerial standards and qualifications, as well as providing access to education, training and continuing professional development support to meet management competencies.

The College of Pharmacy Practice has confirmed that the recommendations are broadly in line with its views: "We are particularly pleased with the recommendation that a transitional committee should be established to oversee preparation for the new professional body and we look forward to working with colleagues from the Society and other organisations on this."

The Association of Pharmacy Technicians UK welcomed the report's recommendation that the new professional body should embrace the whole "pharmacy family", including registered pharmacy technicians, and the British Oncology Pharmacy Association was pleased to see a committee of special interest groups among the inquiry's suggestions.

The UKCPA, IPMI, CPP, BOPA and APTUK were among the organisations that supported the "Waterloo agreement" — a consensus statement on joint working towards a new professional body — in March last year (*PJ*, 31 March 2007, p357). The organisations plan to meet again on 14 April.

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## Few people use pharmacies for health screening or monitoring

Less than 1 per cent of the public visit their local pharmacy for health screening or monitoring, according to the results of market research commissioned by the Department of Health to support proposals outlined in the new pharmacy White Paper.

A greater proportion of adults (12 per cent) will seek health advice from pharmacists, but the main reason for a visit is to have a prescription dispensed, according to 86 per cent of the 1,645 adults in England who took part in the research. Most of the adults questioned (84 per cent) between 28 November and 2 December last year said they had visited a pharmacy at least once in the past 12 months — 78 per cent of them for a health-related reason.

On average, an adult in England will visit a pharmacy 14 times a year, the market research revealed, with 27 per cent of them buying over-the-counter medicines.

Women aged 35–74 years are the most frequent pharmacy users, as well as men aged over 55 years. The people pharmacists are least likely to encounter are 16- to 24-year-old men.

People are generally loyal to their pharmacy with 60 per cent tending to visit the same one, although a third of adults will use a variety of pharmacies.

Adults with long-term health conditions or disabilities who live in rural areas are most likely to use the same pharmacy all the time, the researchers discovered.

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## NPA opposes plan to register untrained people in emergencies

The National Pharmacy Association is opposing Government proposals to allow people without professional training to work as pharmacists during a national emergency such as an influenza pandemic.

The NPA wants only recently retired pharmacists, non-practising qualified pharmacists or preregistration trainees nearing the end of their training to be allowed to take on the responsibilities of practising pharmacists, including prescribing, during an emergency. The association is objecting to proposals in the Healthcare and Associated Professions (Miscellaneous Amendments) No 2 Order, which would allow non-pharmacists to have temporary professional registration.

In a statement the NPA said: "Allowing non-pharmacists to register and use the restricted title of pharmacist could damage long-term patient confidence in the profession." The organisation is worried that patient safety could be jeopardised if the power, which would be given to the registrar of the Royal Pharmaceutical Society or the General Pharmaceutical Council, is approved.

The comments by the NPA follow worries from the Society about the proposed changes to temporary registration during a national emergency (*PJ*, 1 March, p237). The Society is concerned that the professional fitness-to-practise rules may not apply to people given temporary registration. The Society is also asking the Government to extend temporary registration to cover the posts vacated by pharmacy technicians who may have to take on pharmacist duties during an emergency.

# Forth Valley pharmacists extend services for COPD

Community pharmacists in the Forth Valley have become the first in Scotland to provide patients with chronic obstructive pulmonary disease (COPD) a tailored pharmacy-based service.

Working according to a patient group direction the pharmacists will be able to offer patients antibiotics and corticosteroids as well as give advice about their condition and stop-smoking support.

Each pharmacy will be paid £200 for signing up to the scheme and a monthly retainer of £40. Another £20 is paid if more than 20 patients are seen under the scheme.

The money is, for the first time, being paid to pharmacists out of the budget traditionally set aside for GP enhanced services.

Pharmacist and chairman of the Forth Valley NHS board Ian Mullen said: "This is

the only board in Scotland chaired by a pharmacist and therefore I suppose we are committed to these kinds of issues and looking for ways to expand the clinical role of community pharmacists."

Campbell Shimmins, chairman of the Forth Valley pharmacy contractor committee and a board member, said: "We are an examining community so we see a lot of COPD. The initiative, which has been developed by our specialist respiratory pharmacist, is quite innovative — it allows us to prescribe in cases of acute exacerbation. It's an enhanced service which has been negotiated between the pharmacists, GPs and nurses and is being paid for out of primary care funds."

He added that the scheme would provide a showcase for the clinical skills that pharmacists have: "It reminds people that . . . we can

do other things which they would not traditionally expect from their pharmacy."

Forth Valley Health Board is also developing the role pharmacists can play in helping patients with osteoporosis as part of a wider falls prevention programme involving GPs and nurses.

Before dispensing, pharmacists will carry out a falls audit. They will ask the patient up to five questions to assess whether their medication puts them at risk of a fall or increases their chances of osteoporosis.

They will be able to refer patients back to their GP for a bone density scan if appropriate and also offer advice around falls prevention.

Some 54 of the 69 pharmacies in the district have so far signed up to both the falls prevention and the COPD scheme.

## Scottish Government highlights eAMS advice

The Scottish Government this week highlighted three areas within new online guidance for the electronic Acute Medication Service (eAMS) that pharmacists need to pay particular attention to.

The eAMS resource includes sections on how electronic transfer of prescriptions (ETP) works, the software that supports ETP and payment processing (ePay). A quick reference guide to eAMS is also being developed.

Alison Strath, principal pharmaceutical officer, Scottish Government, said that pharmacists should pay attention to advice on dealing with exceptions (ie, situations where the usual ETP process does not occur), for example, when a prescription has been amended by the GP, or when a prescription cannot be completely dispensed and an owing has to be created.

"Second, pharmacists . . . need to understand the principles of electronic endorsing and then consider how their patient medication record system supports them in carrying [it] out," explained Ms Strath.

"Third is housekeeping. It is critical for the successful running of ETP that regular housekeeping is carried out. This means managing electronic messages in the same way that paper prescriptions have to be managed now."



New guidance has been issued to help pharmacists implement eAMS

She added that as pharmacists complete each section of the pack they should consider how they might need to adapt some of their working practices.

The resource pack is published on the NHS Education for Scotland website and can be accessed via *PJ Online* ([www.pjonline.com/links/pjlinks](http://www.pjonline.com/links/pjlinks)). Paper copies of the pack will be sent to community pharmacies next month. Latest figures from the Scottish Government show that 269 GP practices and 173 community pharmacies in Scotland now have live eAMS software in place.

## Staged retention fees could be in place for 2009

Draft rules to allow staged payment of retention fees have been approved by the Council of the Royal Pharmaceutical Society.

The provisional rules under the Pharmacists and Pharmacy Technicians Order 2007 will need to be finalised so that they can go through the necessary Parliamentary process. Andrew Gush, the Society's Treasurer, said he hoped that everything would be in place to allow fees to be paid in quarterly instalments as part of the 2009 retention fee.

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## Phoenix acquires Munro

Munro Wholesale has been sold to Phoenix Healthcare. The sale follows the acquisition of Munro's retail pharmacy division by the holding company of LloydsPharmacy (*PJ*, 29 March, p353). The Munro Group will now trade as Strathclyde Pharmaceuticals and focus on parallel import and generic products.

Phoenix Healthcare says that Munro customers will see no interruption in service and that the same people will take calls, pick orders and deliver to pharmacies. The depots in Glasgow, Aberdeen and Belfast will continue to operate as normal.

## Placebo-controlled trial suggests omega-3 fatty acid does not prevent relapse in Crohn's

Omega-3 fatty acids are ineffective for managing Crohn's disease, an international study has shown (*JAMA* 2008;299:1690).

The results come from two trials involving 738 Crohn's patients recruited from centres in Europe, Israel, Canada and the US. The omega-3 fatty acid formulation used in the trials offered no benefit over placebo in preventing relapse in Crohn's disease. However, a

decrease in serum triglyceride concentration was observed in patients assigned to receive the omega-3 fatty acid preparation.

Lead author of the study Brian Feagan, director of Robarts Clinical Trials, University of Western Ontario, said: "A significant amount of time and money is spent annually on alternative therapies such as omega-3 fatty acids, without strong evidence that they are

beneficial to patients with inflammatory bowel disease." He went on: "I encourage Crohn's patients to focus on prescription medications that we know are effective for preventing relapse of disease, such as azathioprine, methotrexate, and tumour necrosis factor blockers." He pointed out that small, single centre clinical trials often overestimate the true effects of treatment.

# New oral anticoagulant launched

Dabigatran etexilate, the first new oral anticoagulant introduced in the UK since vitamin K antagonists were developed almost 60 years ago, is set to become available.

Marketed by Boehringer Ingelheim as Pradaxa, dabigatran etexilate is a direct thrombin inhibitor given as a fixed once-daily dose in capsule form. It is indicated for primary prevention of venous thromboembolism (VTE) in adult patients who have undergone elective total hip replacement surgery or total knee replacement surgery. There is no requirement for coagulation or thrombocytopenia monitoring and the drug is not affected by food intake so it can be given as a fixed dose, independent of meals and without dietary restrictions.

After oral administration, dabigatran etexilate is rapidly absorbed and converted by esterase-catalysed hydrolysis in plasma and the liver into dabigatran, a potent, competitive, reversible direct thrombin inhibitor. Boehringer Ingelheim says that, because dabigatran etexilate is not metabolised by cytochrome P450 enzymes, it has a low potential for drug-drug interactions.

Dabigatran etexilate is contraindicated in a number of patient groups and should be used with caution for people taking certain medicines that may increase risk of haemorrhage.



Boehringer Ingelheim GmbH

## Pradaxa stock will be available late April

Beyond its current licensed indications, dabigatran etexilate is also being evaluated for the treatment of acute VTE, secondary prevention of VTE, prevention of stroke for patients with atrial fibrillation and prevention of cardiac events for patients with acute coronary syndrome.

Dabigatran etexilate is the first oral direct thrombin inhibitor to be available in the UK. Safety concerns led AstraZeneca to terminate the development of its oral direct thrombin inhibitor ximelagatran in 2006 before the drug's UK launch (*PJ*, 25 February 2006, p222).

Boehringer Ingelheim says that Pradaxa will be available before the end of April.

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## Intensive reduction of blood pressure is protective post intracerebral haemorrhage

Lowering the blood pressure of individuals who have just had an intracerebral haemorrhage to below that specified by existing guidelines appears to reduce haematoma growth (*Lancet Neurology* <http://neurology.thelancet.com>, 5 April).

Australian and Chinese researchers compared an intensive BP-lowering strategy (target systolic BP 140mmHg) in 203 individuals with a standard strategy (target systolic BP 180mmHg) in 201 people with spontaneous intracerebral haemorrhage.

Computerised tomography revealed that haematoma growth was 13.7 per cent in the intensive treatment group compared with 36.3 per cent in the non-intensive group after 24 hours (difference 22.6 per cent, 95 per cent confidence interval 0.6 to 44.5 per cent;  $P=0.04$ ). Adverse events due to treatment or adverse secondary clinical outcomes were similar for both groups at 90 days.

The authors conclude: "Because intravenous treatment to lower blood pressure is relatively straightforward, is not hazardous, and is of low cost, if applied widely these effects could translate into major absolute benefits."

Advertisement

# Poor communication causes hospital admissions

Communication problems and lack of knowledge about a patient's medication or medical history are the main causes of preventable drug-related admissions to hospital, research suggests.

The research also indicates that community pharmacists sometimes think that giving advice about prescribed medicines is not their job. Others wrongly assume that GPs discuss medication with patients so fail to raise the issue when they dispense a prescription.

The research, published in *Quality and Safety in Health Care* (2008;17:109), involved 18 patients, eight informal carers, 17 GPs, 12 community pharmacists, three practice nurses

and four other healthcare staff. All the patients were admitted to a Nottingham teaching hospital between 1 January and 31 December 2004.

The community pharmacists reported that they were reluctant to challenge a patient's prescription — even if they thought it might be harmful — because they had insufficient information about a patient's medical and medication history, according to the study led by Rachel Howard from the University of Reading school of pharmacy.

GPs also had problems accessing complex electronic patient records and failure to update patient records after a home visit made

the problem worse. Computer systems sometimes let down GPs and pharmacists because the drug interaction alert system was inefficient, which meant clinical screening of prescriptions was difficult.

The researchers recommend that community pharmacists receive extra training to make sure they can use the computerised NHS patient care record to help reduce preventable drug-related admissions to hospital in the future.

Training to improve communication between prescribers and pharmacists is also necessary so that pharmacists find it easier to challenge potential problems in prescriptions.

## MHRA deems Actos advertorial misleading

An advertorial for Actos (pioglitazone) was "misleading" and failed to encourage the rational use of the product because the appropriate patient checks were not specifically mentioned, the Medicines and Healthcare products Regulatory Agency has announced.

The advertisement for the drug, which is manufactured by Takeda, appeared in the GP press — *Pulse* and *GP* — in January this year.

A corrective statement published this week by Takeda said that claims in the advertisement around cardiovascular risk were inconsistent with the summary of product characteristics, which warns that the product could cause fluid retention that may exacerbate or precipitate heart failure. The company has withdrawn the advertisement and promised not to use it again.

## Screen before prescribing carbamazepine

Individuals of Han Chinese, Hong Kong Chinese or Thai origin should undergo genetic screening before treatment with carbamazepine, the Medicines and Healthcare products Regulatory Agency has advised.

In April's *Drug Safety Update*, the MHRA recommends screening these groups for the human leukocyte antigen allele HLA-B\*1502, because the risk of carbamazepine-induced Stevens-Johnson syndrome is greater in patients who have this allele. The frequency of HLA-B\*1502 varies worldwide, but is highest in some Asian populations.

Patients who test positive for HLA-B\*1502 should not be treated with carbamazepine unless the expected benefit clearly outweighs the risk of serious skin reactions, the MHRA says.

## Antipsychotics prescribed for children despite lack of data

Concerns about the use of antipsychotic medicines for children have been raised by researchers from the School of Pharmacy, University of London. They suggest that some 9,500 children and adolescents aged 18 years and under had been prescribed antipsychotics by GPs in 2005, adding that prescribing of atypical antipsychotic drugs has increased despite the lack of conclusive evidence showing their superiority over older conventional antipsychotics.

Macey Murray, teaching and research fellow at the school's Centre for Paediatric Pharmacy Research, and one of the authors of the study — due to be published in the journal *Pediatrics* in May — told *The Journal* that the overall prevalence of prescribing of antipsychotics had nearly doubled during the years 1992–2005 from 0.39 to 0.77 per 1,000 patient-years. "We also found that the prevalence increased three-fold in children aged 7–12 years over the same time period," she added.

"Our study used data collected from GPs, but it is very likely the prescribing of these drugs was initiated by clinicians in secondary or tertiary care. The majority of GPs will tend to continue prescribing these drugs following advice from such specialists," Mrs Murray explained.

"We are concerned about the safety of antipsychotic drugs, particularly as there are lit-



Children with behavioural problems: antipsychotic use lacks safety data

tle data available. The clinical trials that have been conducted in children and teenagers are small studies so will have little safety data, particularly on rare side effects," she pointed out. "There needs to be more careful monitoring of the long-term safety of antipsychotics."

Accordingly, the research centre has already piloted a system for collecting such data in the UK and is in the process of developing it further.

## Study shows pioglitazone reduces atheroma volume

Two studies designed to show the effects of pioglitazone and rimonabant on the progression of atherosclerosis were published last week in *JAMA*, with the findings simultaneously reported at the annual congress of the American College of Cardiology in Chicago.

The first study revealed that pioglitazone reduces the progression of coronary atherosclerosis in patients with type 2 diabetes and coronary artery disease compared with glimepiride (*JAMA* 2008;299:1561). In 360 patients, ultrasonography showed that the primary outcome measure — change in percent atheroma volume (PAV) — increased by 0.73 per cent (95 per cent confidence interval 0.33 to 1.12) with glimepiride over 18 months, but decreased by 0.16 per cent (CI -0.57 to 0.25) with pioglitazone ( $P=0.002$ ).

By contrast, the second study failed to show an effect for rimonabant on change in PAV compared with placebo (*ibid*, p1547). The drug did have a favourable effect on a secondary endpoint, however, reducing normalised total atheroma volume over the 18-month study period by 2.2mm<sup>3</sup> (CI -4.09 to -0.24) compared with an increase of 0.88mm<sup>3</sup> (CI -1.03 to 2.79) for placebo.

Neither study revealed an effect on cardiovascular outcomes or mortality.