

# MHRA negligent over Seroxat, says MIND chief

MIND, the mental health charity, has accused the Medicines and Healthcare products Regulatory Agency of negligence. It argues that the agency failed to warn doctors until last week not to prescribe, in the first instance, above the recommended dose of paroxetine (Seroxat) (see below).

The accusation was made by Richard Brook, MIND's chief executive, as he resigned from an expert group reviewing selective serotonin reuptake inhibitors. Mr Brook was advised that he faced prosecution by the MHRA if he published data that led to the warning being issued last week. Mr Brook said that the data have been in the hands of the MHRA for more than 10 years.

In his resignation letter, Mr Brook said: "Despite four major regulatory reviews during this period and considerable consumer reporting and disquiet, the Committee on Safety of Medicines failed either to identify or communicate these key facts. As far as I am aware, the MHRA has not seen fit to acknowledge or address what in my view appears to be extreme negligence."

Separately, Mr Brook said: "On [11 March] the MHRA at last published information advising that many thousands of men and women in this country may have been taking Seroxat at a dose that was unsafe. What they failed to mention — and what I am now making public — is the fact that the regulator had the data on which the basis of this decision was made for well over a decade as part of the original licence application. Either they didn't understand the full implications of the available medical data at the time or, worse, those data were fully understood and they failed to act."

In Mr Brook's view this amounts to extreme negligence and a clear dereliction of



**Richard Brook: Four reviews by the MHRA failed to establish key facts**

the MHRA's duty to safeguard the well-being of the British public.

Mr Brook told *The Journal* that MIND had asked the MHRA to publish the relevant licensing data so that there could be a sensible public discussion. The MHRA had refused and MIND considered seeking a judicial review of that decision.

Instead, because a judicial review would have meant a considerable delay, MIND told the MHRA that it would publish the data itself unless prevented by an injunction. The injunction application would have been resisted on public interest grounds.

At this stage, on 8 March, Lord Warner intervened and obtained agreement from MIND to delay publication. Later that day, Mr Brook received a letter from the MHRA

chief executive, Kent Woods, in which he was advised that he would be prosecuted if data were published.

The prosecution would have been under Section 118 of the Medicines Act 1968, which prohibits the disclosure of licensing information.

Mr Brook said: "We have an amazingly secretive set of laws that prevent sensible discussion. Why can't we put this information in the public domain? It should be freely available to researchers."

A Department of Health spokeswoman said that the data held by the MHRA had accumulated as and when licence applications were made for different indications. The current review was the first time that the data had been looked at as a whole across the range of indications. New evidence had also come to light on how widespread prescribing of doses higher than 20mg was.

She added that Mr Brook's concerns were being taken on board. Lord Warner, the Parliamentary Under-Secretary of State responsible for the MHRA, is expected to meet Mr Brook to hear his concerns next week.

Commenting on Mr Brook's resignation, Liberal Democrat health spokeswoman Sarah Teather said: "Richard Brook was offered a place on the board that reviews these medicines because of his knowledge of the needs of patients. Serious questions must be asked by ministers as to why someone who represents patient rights and interests feels that he cannot continue on the working group. The public must be assured that medicine review bodies are impartial and responding to the needs of the patient, as well as the pharmaceutical industry. Ministers must ensure the system for assessing prescription drugs is beyond reproach."

## Start paroxetine at 20mg for depression

Prescribers have been reminded that the starting dose for paroxetine in adults should be 20mg daily for most indications.

Gordon Duff, chairman of the Committee on Safety of Medicines, has written to health professionals after a CSM review found that as many as 17,000 patients were started on doses of paroxetine above 20mg last year.

Patients with depression currently treated successfully at higher doses should continue at this dose but new patients should receive the recommended daily dose of 20mg. Patients not doing well at higher doses should have their treatment reviewed and a change of treatment should be considered. The recommended daily dose of paroxetine for adults with obsessive compulsive disorder or panic disorder is 40mg.

Professor Duff says there is no evidence from clinical trials to suggest that the efficacy of paroxetine in the treatment of depression is

increased at doses above 20mg. He adds: "The adverse events that occur soon after starting therapy may be difficult to distinguish from the underlying condition. There is evidence that increasing the dose in this situation may be detrimental."

A spokesman for GlaxoSmithKline, manufacturer of Seroxat, expressed surprise at the MHRA statement. "We do not agree with the MHRA's assertion that there is no evidence of increased effectiveness above these recommended doses." He said that data from clinical trials show that some patients benefit from taking paroxetine above the recommended levels for these indications.

□ **Paediatric prescriptions** The use of antidepressants in children is increasing, say researchers in a letter to the *BMJ* (20 March, p711). They report a 4.5-fold increase in the rate of prescriptions for selective serotonin reuptake inhibitors between 200 and 2002.

## Budget boosts NHS research

Research in the NHS has been given a boost by the Chancellor of the Exchequer, Gordon Brown, in his budget statement delivered to the House of Commons on 17 March.

Mr Brown announced a 10-year framework for medical science. He said that, modelled on the successful National Cancer Research Institute, the plan would fund specialist research institutes for other diseases. A new National Clinical Research Network would bring private and public sectors and medical charities together. By 2008 the combined budget for medical research and NHS research and development would approach £1.2bn a year.

On general funding for the NHS, Mr Brown confirmed a previously announced decision that the NHS would receive a 10 per cent cash rise — 7.2 per cent in real terms — each year to 2008. This would support plans for greater flexibility, diversity and local accountability in the NHS.

# Another pharmacist awarded Harkness Fellowship

Rachel Elliott, clinical senior lecturer at the University of Manchester school of pharmacy and pharmaceutical sciences, has been awarded a Harkness Fellowship by the US Commonwealth Fund.

The Harkness Fellowships in Health Care Policy provide a unique opportunity for mid-career health services researchers and practitioners from the UK, Australia and New Zealand to spend up to 12 months in the US, working with health policy experts and conducting original research. Dr Elliott is the third UK pharmacist to be given this award.

Dr Elliott hopes to spend a year looking at the economic impact of policies to improve adherence to medicines based in a US academic institution. She believes that adherence is of crucial importance to health care in terms of public health, patient safety and health care financing. "My position is that lack of understanding of adherence undermines efficiency of public health policies. Furthermore, policies to improve adherence may be at odds with health policies promoting greater patient choice," she says.

She hopes to examine the relative importance to patients of factors such as cost, risk/benefit of medicines, perception of disease severity and the patient-professional relationship in one particular disease group,

such as hypertension. She believes that the potential findings will contribute to the formulation of policies for both government and professional bodies.

Dr Elliott has been based in the drug use and pharmacy practice group at the University of Manchester since 1996. She is currently clinical senior lecturer and programme director for the MSc/diploma in clinical and health services pharmacy.

"I am very excited to have the opportunity to work in the US with leading experts in health care policy, health economics and medication use research," Dr Elliott says.

The award runs from September 2004 to September 2005.

Rachel Elliott

Jason Lock

## The Harkness Fellowship

Harkness Fellowships in Health Care Policy are offered by the US Commonwealth Fund — a private foundation established in 1918 by Anna M. Harkness with the "broad charge to enhance the common good" and which now supports independent research on health and social issues. The fund provides support for fellows to study how the US approaches health policy issues, to share lessons learnt from their home countries, and to develop a multinational perspective and network of contacts to facilitate policy exchange and collaboration that continues beyond the fellowship.

The fund's programme areas include improving health insurance coverage, access to care and improving the quality of health care services. Its programmes also focus on specific groups, including underserved populations, young children, and the frail elderly. The fund has this year added two UK fellowships, also for travel to the US, supported by the PPP Foundation ([www.cwmf.org/fellowships](http://www.cwmf.org/fellowships)).

## Target of 1,000 prescribers unlikely to be met

There is "still some way to go" before the profession meets the government target of 1,000 pharmacists who are supplementary prescribers by the end of the year, according to Peter Wilson, consultant to the Royal Pharmaceutical Society and its lead on supplementary prescribing.

His comments came as he revealed that the number of postgraduate supplementary prescriber courses in England, Wales and Scotland has increased to 18 with more in the pipeline.

Dr Wilson added that the courses' popularity varied because pharmacists were influenced by the location and design of the individual

programmes. He said: "These are the two major factors influencing their decision. Some programmes require students to be there in person every day for a week at a time while others require them to be there a day a week.

"Some of the courses are heavily oversubscribed while others have generated less interest. There is still some way to go to meet the government target."

□ *P&MM Prescribing & Medicines Management* will now be produced as a pull-out section in *The Journal*, as in this issue. This will give all pharmacists a chance to understand the impact that colleagues can have in medicines management and related issues.

## News in brief

### ESRC recognition for Nottingham

The centre for pharmacy, health and society, at the University of Nottingham, has gained accreditation by the Economic and Social Research Council for its postgraduate training programme. This means it is now eligible to receive ESRC support for PhD studentships. Nottingham is the first pharmacy school to receive ESRC recognition.

### Oestrogen-alone trial stopped

Investigators for the US Women's Health Initiative have revealed that taking HRT based on oestrogen alone over the long term does not appear to affect heart disease or increase risk of breast cancer but does increase risk of stroke.

### HPV linked with psoriasis therapy

Psoriasis patients treated with psoralens and ultraviolet light therapy have an increased prevalence of human papilloma virus in their skin, say researchers. The virus may be partly responsible for the increased prevalence of skin cancer seen among these patients (*Archives of Dermatology* 2004;140:317).

## Benefits from acupuncture when treating chronic headache

Acupuncture can provide persisting, clinically relevant benefits for primary care patients with chronic headache, particularly migraine.

This is the finding from an open trial of 401 patients recruited by their GPs. The patients reported several days of headache every week, mostly migraine-type headaches.

They were randomly allocated to receive either usual care, or up to 12 additional acupuncture treatments over a three-month period. Patients completed a diary of headache and medicines use for four weeks at the start of the study and then again at three

months and one year. Compared with controls, acupuncture patients used 15 per cent less medicines, made 25 per cent fewer visits to their GP and took 15 per cent fewer days off work. Headache score at 12 months was lower for acupuncture patients, who also reported the equivalent of 22 fewer days of headache per year.

The authors suggest that, in the light of their results, expansion of NHS acupuncture services for headache should be considered (published online at *BMJ Online First* 16 March 2004).

# Europe to offer child medicine research incentives

Pharmaceutical manufacturers are to be given incentives to carry out child-safety studies on medicines for use in Europe. Special paediatric licences will also be available for generic medicines to give generics manufacturers an incentive to do the work.

Following consultation which started two years ago (*PJ*, 16 March 2002, p349), the European Commission has published proposed new medicines legislation that will extend the market exclusivity of patented products or grant new exclusive paediatric licences when such studies are conducted.

A draft commission regulation says that applications for new marketing authorisations or applications for new indications, dosage forms or routes of administration for existing products still under patent must include the results of studies in children conducted according to previously agreed paediatric investigation plans.

There will be a waiver and deferral system to make sure that child research is only carried out to meet the therapeutic needs of children and when it is safe and ethical to do so. Products for which data are submitted will get an extra six months patent protection, re-



**Children have been left behind by developments in drug technology**

gardless of whether the data show positive or negative results.

Different rules are proposed for generic medicines because there are no patents to extend. In these cases, paediatric safety studies will be rewarded with paediatric use marketing authorisations (PUMAs) exclusive to the manufacturer that generates the data. Generics manufacturers do not generally have substantial resources for research and development beyond equivalence studies and have little ex-

perience of clinical trials, so the EU will provide money to fund or part-fund such studies through a MICE (Medical Investigation for the Children of Europe) fund.

Sharon Conroy, chairman of the Neonatal and Paediatric Pharmacists Group, said: "This is likely to be the most important legislation on children's medicines that we will see in the foreseeable future. It is likely to change the situation we have been in for many years where we have not got suitable licensed medicines for children. It will be good to get it up and running as soon as possible."

She said that the current situation means that there is a lack of science-based dosing information for children which leads to dangers of toxicity or ineffectiveness of medicines. New dosage forms would also be helpful.

"Children have been left behind by developments in pharmaceutical technology," she added. "For example, the new melt technology would be wonderful for kids. It would overcome such a lot of the problems we have in formulating medicines for children. They can't spit it out."

The draft regulation is open for comment until 9 April.

## Medicines among worst aspects of hospital experiences for children

"Needles", "awful-tasting medicine" and "being in pain" are among the worst aspects of being a child in hospital, according to some responses in a report published last week.

The report, "Children's voices project", published by the Commission for Health Improvement, comprises feedback from children and young people about their experience and expectations of health care.

It was compiled from 59 separate reports from voluntary bodies and statutory organisations and includes over 750 pieces of feedback. To qualify for entry, responses had to come directly from children, not from parents

or other carers. A database of all the information included is to be available as a web-based record, with appropriate additions and analyses possible.

As well as pharmaceutical matters such as poor-tasting medicine, children often complained that they did not understand explanations of conditions and treatments. One child said there was not enough time to have things explained and another complained that staff only explained things "to Dad".

The report highlighted the vulnerability to infection of children in hospital and the unnecessary time they spent there. It also em-

phasised that children should not have to wait for medicines when in pain.

Sharon Conroy, chairman of the Neonatal and Paediatric Pharmacists Group, said that there were often no alternatives to injections or poor-tasting medicines for children. She lamented the continued lack of medicines licensed for paediatric use, saying that her centre — Derbyshire Children's Hospital — had to use dispersed or crushed adult tablets for many children, although they tried to give choices wherever possible. Children were usually not involved even in taste-testing of paediatric formulations, she added.

## Industry sponsorship of trials has increased dramatically

Industry sponsorship of clinical trials has increased dramatically over the past 20 years, according to Canadian pharmacists.

The pharmacists, from the University of British Columbia, reviewed 500 randomly selected clinical trials published over the 20 years from 1981 to 2000 in five prominent medical journals — *Annals of Internal Medicine*, *BMJ*, *JAMA*, *The New England Journal of Medicine* and *The Lancet*.

They found that pharmaceutical industry sponsored trials were common and had increased over time. Affiliation between authors and industry sponsors also appeared to be increasing, they add.

In their review, the percentage of trials funded by the industry increased from 26 per

cent in the early 1980s to 62 per cent by 2000. The percentage of articles written or co-written by pharmaceutical industry employees increased from 8 per cent in the early 1980s to 66 per cent by 2000 (*Annals of Pharmacotherapy* 2004;38:579).

However, they acknowledge that observed increases may be due largely to increased disclosure of drug trial funding, improving transparency.

A commentator advises that the review does not mean industry studies cannot be trusted. He suggests that the continued increase in studies with industry support throughout the 1990s reflects an increase in research budgets by major companies throughout this period (*ibid*, p714).

### The Society

#### ■ Omeprazole practice guidance

The Society has published practice guidance on OTC omeprazole (p363).

#### ■ VPG weekend conference

The Veterinary Pharmacists' Group is heading for Stratford-upon-Avon for its 2004 weekend conference (p363).

#### ■ APG committee election

Nominations are sought for the Academic Pharmacy Group Committee (p364).

#### ■ Children's medicine meeting

The Society is to co-host a conference on children's medicine (p364).

# UK hypertension guidelines updated

Blood pressure guidelines, updated by the British Hypertension Society (BHS), now include a treatment algorithm to aid more logical use of antihypertensive drugs, alone and in combination (summarised in the *BMJ* 2004;328:634).

The 1999 version of the guidelines advised starting patients on the least expensive drug, usually a thiazide diuretic. But the 2004 guidelines recommend that treatment for white and younger hypertensive patients (under 55 years) should start with an angiotensin converting enzyme (ACE) inhibitor, angiotensin receptor blocker or beta blocker, while treatment for black and older hypertensive patients (over 55 years) should start with a calcium channel blocker or a diuretic.

Indications and contraindications for treatment remain similar to the 1999 guidance, although more hypertensive patients with early signs of renal disease or heart failure are likely to be prescribed ACE inhibitors or angiotensin receptor blockers than before.

The BHS continues to stress that most hypertensive patients will require more than one drug to control their blood pressure. It recommends combining drugs which inhibit the renin-angiotensin system with those that do not.

The target blood pressure for most patients remains 140/85mmHg or lower (minimum target <150/90mmHg), with a target of 130/80mmHg or lower for those with diabetes, renal impairment or established cardiovascular disease.



**Blood pressure target for most patients remains at 140/85mmHg or lower**

The BHS predicts an extended role for pharmacists, nurse practitioners and other health care professionals in detecting, monitoring and treating high blood pressure and cardiovascular risk, if blood pressure control is to be improved in the UK.

Recent research has estimated that 42 per cent of people aged 35–64 years in the UK have blood pressure over 140/90mmHg (*JAMA* 2003;289:2363) and good control is achieved in only 10 per cent of the hypertensive population (*Hypertension* 2004;43:10).

## New protease inhibitor for HIV infection launched

Adults infected with HIV-1 who have already received antiretroviral treatment may benefit from a new protease inhibitor launched on 10 March. Atazanavir (Reyataz), manufactured by Bristol-Myers Squibb, is the first protease inhibitor licensed in the UK with once daily dosing.

The recommended dose is 300mg daily, taken with ritonavir 100mg once daily and with food. Ritonavir is used to boost the pharmacokinetics of atazanavir, to increase efficacy and reduce dose frequency. The new drug has been associated with a more favourable lipid profile and less diarrhoea than a combination of ritonavir and lopinavir.

Margaret Johnson, clinical director of HIV/AIDS services at the Royal Free Hospital, London, said: “[Atazanavir] is as effective as standard care but it has a low pill burden. It also has a favourable lipid profile which may be important for cardiovascular and cerebrovascular disease, and possibly for lipodystrophy.” The most commonly observed side effect in a study of atazanavir with ritonavir was hyperbilirubinaemia, but it was not associated with an increased risk of liver injury or treatment discontinuations. Other side effects include jaundice, nausea, vomiting and diarrhoea.

**Notice-board p346**

## Gene variation explains abacavir hypersensitivity

Researchers have identified a genetic variation associated with hypersensitivity to abacavir (Ziagen).

They say that 5 to 9 per cent of HIV-infected patients taking abacavir become hypersensitive within a month. Symptoms include fever, rashes, gastrointestinal upset and profound lethargy. The syndrome has proved fatal in rare cases.

The researchers studied the genotypes of 248 HIV patients treated with abacavir, of whom 18 developed a severe reaction to the drug. Seventeen of these hypersensitive patients had similar variations in the genes HLA-B\*5701 and Hsp70-Hom, which are near each other on chromosome 6. This

genetic combination was present in only one of the 230 patients who tolerated the drug well.

In the trial cohort, the authors predict that only 14 patients would have needed genetic screening to prevent one case of hypersensitivity. However, they warn that their findings might not apply to non-Caucasian patients. They say that prospective genetic testing for abacavir hypersensitivity is likely to be highly predictive. In populations of European descent, in which one of the variations is relatively common, testing is also likely to be cost-effective (*Proceedings of the National Academy of Sciences* 2004; 101:4180).

# Health Secretary announces case management sites

Health Secretary John Reid announced a new programme for chronic disease management at a Birmingham conference last week.

He said that the Government was launching a funded programme to establish “case

tients with the greatest burden of illness healthy for longer”.

In Britain around 17.5 million people suffer from chronic disease and the figure is expected to grow. The World Health Organization has estimated a doubling of chronic disease in the over 65s by 2030.

Dr Reid explained that in “case management”, patients with complex needs were identified and supported by skilled practitioners working holistically in an integrated care system. The aim was to provide alternatives to inpatient hospital care by building capacity and developing services in primary and community settings.

The demonstrator sites, currently being selected, aimed to achieve the following:

- Maintain health and promote well being
- Detect early changes in the patient's condition and prevent unnecessary hospital admission
- Facilitate safe early discharge, when admissions did occur
- Access ways to identify their target populations

PA Photos

## Dr Reid described the impact chronic disease has on people's quality of life

management demonstrator sites” within each strategic health authority. These would “provide co-ordinated patient-centred care within a whole systems approach to keep pa-

Dr Reid commented that several primary care trusts had already been encouraged to

adopt co-ordinated and integrated services. The American organisation Kaiser Permanente was partnering a number of PCTs to share lessons in this type of care, with the focus on managing chronic conditions to avoid unnecessary hospital admission. Nine PCTs were implementing the US Evercare model to keep elderly people healthy and offering a range of services in the community to treat patients in the least intensive setting.

A pilot of active management at Castlefields Health Centre, Cheshire, had shown a 15 per cent reduction in admissions for older people and an average 31 per cent shorter hospital stay (from 6.2 days to 4.3 days).

Although Dr Reid did not mention the place for pharmacy in his plans, David Pruce, director of practice and quality improvement, Royal Pharmaceutical Society, told *The Journal*: “This cannot be done without pharmacy input. It is all about keeping people out of hospital and helping people make the most of their medicines. It ties in with concordance and medicines management.” He emphasised that pharmacy had to be part of the chronic care solution, adding that the profession had to position itself as such.

## Pharmacists should do more in care homes

Greater involvement of pharmacists in the management of medicines in registered care homes has been called for by the National Care Standards Commission.

In a report, the commission says that more than half of all care homes fail to meet national minimum standards for handling medicines. One in 10 does not even begin to meet the standard. The report says that community pharmacists have an important part to play in helping care homes with medication. “Their more frequent and regular involvement would be welcomed by the sector as a whole. . . . We recommend that care providers and other agencies should consider the future role and involvement of pharmacists in medicines management issues.”

The report is available via *PJ Online* ([www.pjonline.com/links/pj](http://www.pjonline.com/links/pj)) and will be covered in greater detail in *The Journal* next week.

## New public protection measures for Scotland

New rules governing the inclusion of all health professionals on health board lists of primary care practitioners have been proposed for Scotland. The effect will be to widen the checks currently carried out on community pharmacists, GPs, dentists, optometrists and ophthalmic medical practitioners.

Practitioners will be required to make enhanced Criminal Records Bureau disclosures when asked to do so by health boards and to declare any gifts from patients or relevant financial interests.

Changes to the workings of the NHS disciplinary tribunal will mean that anyone disqualified from practising in primary care in one local health board area cannot practise anywhere else in Scotland. The NHS Tribunal will also be able to disqualify practitioners on grounds of unsuitability by reason of professional or personal conduct and health boards will be able to suspend practitioners locally to protect patients or when it is in the public interest.

People convicted of murder, whether in the UK or overseas, will be automatically disqualified from practising in the NHS.

Advertisement

# GSK reprimanded over medicines-review nurse

GlaxoSmithKline has been reprimanded over the actions of an asthma-audit nurse, sponsored by the company, who made unauthorised changes to a GP repeat prescription database.

The Prescription Medicines Code of Practice Authority ruled that GSK had failed to uphold the high standards expected under its code of practice and ruled that the company had brought discredit upon and reduced confidence in the pharmaceutical industry. The case is reported in the PMCPA's quarterly report.

The case involved a complaint from the partners of a general practice who alleged that a nurse, sponsored by GSK to conduct asthma patient reviews, had made changes to patients' therapy on the practice database

(adding Seretide to all but two patients' treatment regimens) without authorisation. This was highly inappropriate and unethical, according to the complainants.

A similar complaint was made against Novartis after a company employee made changes to patients' statin prescriptions without authorisation (*PJ*, 29 September 2001, p418).

The PMCPA noted that GSK's instructions for carrying out the audit had not been followed. The agreed procedure was that nurses were allowed to enter data onto the computer database only after all the GPs had signed a therapy change register.

GSK submitted that the audit nurses believed they had been given permission to make treatment recommendations on the

computer and that the practice nurse would obtain approval. However, GSK did not provide documentation to show they had been given permission.

The panel also considered that the asthma patient review was in effect linked to the prescription of Seretide, which was also a breach of the code.

**DTB complaints** Complaints made to PMCPA by the *Drug and Therapeutics Bulletin* over the promotion of Cerazette (desogestrel) and Ebixa (memantine) have resulted in reprimands for the products' manufacturers. The PMCPA ruled that a claim made by Organon about Cerazette's efficacy was misleading and that a claim made by Lundbeck about Ebixa's effects on patients' independence was misleading and could not be substantiated.

## Parallel imports can be repackaged

Parallel importers can repackage branded medicines if they need to do so to gain market acceptability for these products.

After putting questions to the European Court, the Court of Appeal upheld an earlier High Court judgment against Boehringer Ingelheim, Glaxo Group, SmithKline Beecham and Eli Lilly.

"Parallel importers are entitled to do more than just render the packaging lawful for UK marketing," Lord Justice Jacob ruled. "They are entitled to replace the packaging if that is what is necessary to overcome a strong resistance in the market to relabelled boxes."

The judge rejected the argument that pharmacists could overcome patient hostility to original packs that are covered with stickers by more explanation. "Poorly people want their pills, not explanations," he said, adding: "Pharmacists have better things to do than explain things to concerned patients."

Lord Justice Jacob ruled that replacing the brand name on the box with the non-proprietary name while the brand name still appears on the actual product or its immediate packaging does not amount to passing off. He said that there was no evidence that a pharmacist or patient had ever been deceived. He added that replacement packaging that bears the originator's brand name plus the parallel importer's mark caused no damage to the claimants' reputation and exclusivity.

**Parallel importing on the wane** Parallel importing into the UK grew by only 1 per cent from 2002 to 2003. In the previous three years, growth had been three times greater than that of the pharmaceutical market overall. The decline is not explained by patent expiries, according to IMS. Leading brands have shown significant decreases in trade lost to parallel imports. Even so, parallel imports account for 19 per cent of UK brand sales.

## News in brief

### Name change leaflets

Leaflets to help patients understand changes to the names of many medicines have been produced by the National Pharmaceutical Association. They explain that British Approved Names are being brought in line with recommended International Non-proprietary names (*PJ*, 13 March 2003, p311) and list changes so that pharmacists can highlight those that apply to individual patients' treatments. See also **Society** p364.

### Numark PI service

Numark has launched a one-stop parallel import service for its pharmacy customers together with Phoenix Healthcare Distribution Ltd. Purchases will qualify for rebates of up to 6 per cent.

## PJ Online

### IJPP

Abstracts from the March issue of the *International Journal of Pharmacy Practice* are now available. [www.pjonline.com/IJPP](http://www.pjonline.com/IJPP)

### Hospital Pharmacist links

News pages and articles in both *The Pharmaceutical Journal* and *Hospital Pharmacist* contain references to internet links [www.pjonline.com/links/pj](http://www.pjonline.com/links/pj) [www.pjonline.com/links/hp](http://www.pjonline.com/links/hp)

### Diabetes

A three-part continuing professional development series on diabetes, including dietary management and drug treatment. [www.pjonline.com/links/diabetes](http://www.pjonline.com/links/diabetes)

## Genzyme OFT fine halved

Genzyme has won a partial victory over the Office of Fair Trading after appealing to the Competition Appeal Tribunal (CAT) against a £6.8m fine imposed for breaking UK competition law (*PJ*, 5 April 2003, p467).

The OFT had ruled that Genzyme's had breached the Competition Act 1998 because the price it charged the NHS for Cerezyme (imiglucerase) included home delivery and home care services, so ensuring that only the company or its own contractors could provide such services. The CAT upheld OFT rulings that Genzyme must offer Cerezyme to distributors at a negotiated price that allows them an appropriate margin, but it cut the fine imposed to £3m plus interest.

Cerezyme is used to treat Gaucher's disease, which affects only about 300 people in Britain and 40,000 worldwide.

## Lipitor is top seller worldwide

Lipitor (atorvastatin) was the biggest selling medicine worldwide in 2003, with global sales of US\$10.3bn (up 14 per cent from 2002). The next was Zocor (simvastatin), with sales down 4 per cent at \$6.1bn followed by Zyprexa (olanzapine), up 13 per cent at \$4.8bn. Overall, the top 10 sellers generated worldwide sales up 14 per cent, with only Zocor recording any reduction.

Across all medicines, global sales were up 9 per cent in 2003 at \$466.3bn. Total sales in Europe were up 8 per cent at \$115.4bn. In the UK, sales through community pharmacies alone were up 9 per cent at \$12.9bn.

The fastest growing product was Nexium (esomeprazole), with global sales up 62 per cent at \$3.8bn. The figures come from IMS, which monitors global sales of 1 million prescription brands.