

## Branded medicines' prices to be cut by 7 per cent

Branded medicines will go down 7 per cent in price from 1 January 2005, saving the NHS an expected £1.8bn over the next five years.

The reduction, which is the main feature of the new Pharmaceutical Price Regulation Scheme, is considerably more than the 4.5 per cent price reduction agreed when the scheme was last renegotiated in 1999.

The Association of the British Pharmaceutical Industry is taking a gloomy view of the new agreement, which it has been negotiating with the Department of Health for the past nine months.

"The price cut is unnecessary given the fact that medicines prices have fallen in real terms by some 15 per cent over the past 10 years, and that the NHS's medicines budget is remaining steady at about 12 per cent of expenditure," said Vincent Lawton, president of the ABPI.

However, the ABPI is recommending the voluntary agreement to its member companies as the best available. Other important aspects of the new scheme, some of which may make the package more acceptable to the industry, are:

- Companies will remain free to set the price of new medicines in the UK, unlike in France, where prices have to be negotiated with the government
- Firms will still be able to choose which products to reduce in price to meet the overall 7 per cent price cut. In some cases, companies will have been planning large price reductions as drugs come off patent, and these can be used to offset smaller or no reductions in the price of newer drugs
- A marketing allowance to replace the previous sales promotion allowance, which companies can set against income. There is no limit to the amount that companies can spend on marketing, but they will be able to offset £1m of their marketing budget, plus 4 per cent of turnover, plus a small additional allowance for each molecule
- An increase in information expenses which can be set against income, from 1.6 per cent to 4 per cent of turnover. This is a useful improvement, particularly since companies can now include the cost of providing information to the National Institute for Clinical Excellence and other government bodies in their information expenses.

### Technician regulation

The Society has announced a timetable for technician regulation (p697).

### Devolution

The Society's devolution review group has met stakeholders in Edinburgh and a further meeting is planned for Cardiff (p698).

## New contract could result in problems for Saturday services

Primary care trusts in England could face a crisis next year over the provision of a community pharmacy service on Saturdays.

One of the implications of the new community pharmacy contract is that contractors, although required to open for 40 hours a week, will be able to choose which 40 hours they wish to open.

Speaking at a Pharmaceutical Services Negotiating Committee new contract roadshow in Maidstone on 31 October, Sue Sharpe, PSNC chief executive, explained: "When the new contract begins, contractors will have to notify their opening hours to the PCT and these will become their contracted hours."

She suggested that if a contractor currently wants to adjust his or her opening hours, the prudent thing to do is to change them in April when implementation of the contract is planned. Longer-term, it will be possible for contractors to change their contracted hours by giving the PCT three months' notice.

Contractors at the roadshow pointed out that the closure of GP surgeries on Saturday

mornings, following the introduction of the new GP contract, is having an impact on community pharmacy's viability on Saturdays. "The cost of getting a pharmacist in for three, four or five prescriptions does not make it worthwhile," said Mrs Sharpe. The allowance in the new pharmacy contract could lead to many pharmacies choosing to open on Monday to Friday only.

"This is an issue of some difficulty for PCTs and the Government," commented Mrs Sharpe. "We have been clear that as a consequence of what they have done for GPs hours, they have created a problem that will lead to the closure of community pharmacies on Saturdays. We said 'do not leave it to us to pick up the mess you have made'."

The result could be PCTs having to fund a community pharmacy on Saturdays. "If a PCT wants a Saturday service and none of the pharmacies is providing it, then the PCT will have to negotiate funding to cover the cost of opening," said Mrs Sharpe. This should, at least, cover the cost of a pharmacist, a member of staff, and an allowance for lighting and heating.

## MHRA consults patients about ADR reporting



Left to right: Lord Warner with the three directors of Ask About Medicines Week Joanne Shaw, Melinda Letts and David Dickinson

The Medicines and Healthcare products Regulatory Agency has written to hundreds of patients inviting them to take part in a survey about the reporting of adverse drug reactions.

Speaking at the launch of Ask About Medicines Week in London, health minister Lord Warner, said: "The MHRA will begin a pre-pilot survey of patients who have experienced suspected adverse drug reactions during the year. The results of the survey will help to shape the future design of direct patient reporting systems. We want this to

be a scheme that listens to patients and takes their experiences of adverse drug reactions seriously."

Lord Warner welcomed the various initiatives that are part of AAMW and said he supported the key message of informed choice. He added that the Government wants to empower patients to manage their own care. "We are looking actively to improve availability of medicines OTC not just for acute, short term, self-limiting conditions, but also for long-term conditions," he said.

# Wanless calls for evidence to back self-care agenda

Primary care providers should be encouraged to test whether, given access to more information, people want to have a greater input in managing their own health, according to Derek Wanless, a former chief executive of NatWest bank and health service adviser.

Writing in a new report on self-care published by the Proprietary Association of Great Britain, Mr Wanless says: "It seems highly likely that many people with more information about their health, and their specific disease risks, due to both genetic and lifestyle factors, will want to manage their risks — but we should seek evidence to back this assumption."

He comments that electronic patient records would be important for mapping out

local prevalence of disease and should allow better targeting of disease management. "Providing access for pharmacists to aspects of patient records might help," he adds.

In the same report, David Colin-Thomé, national clinical director for primary care, Department of Health, suggests that pharmacists are key to the shift in thinking towards self-care. "I'm pleased to note that [pharmacists] have taken up the challenges offered by self-care with gusto, as the general thrust of the community pharmacy contract has been met with good support."

Ashok Soni, chairman of the National Pharmaceutical Association, writes: "Community pharmacy's contribution to the

successful integration of self-care can only be achieved when the wide range of UK self-care initiatives become truly 'joined up'. For example, one of the major obstacles in the way of maximising the potential of community pharmacy to free up capacity in the NHS comes from the fact that we are currently denied routine access to medical records." He comments that this can lead pharmacists to err on the side of caution when recommending treatments for conditions that might benefit from more radical solutions.

Self-care was the subject of a recent conference hosted by the Proprietary Association of Great Britain.

Meetings, p695

## Government officials mark launch of Ask About Medicines Week

Health ministers and chief pharmaceutical officers for England and Wales marked the launch of Ask About Medicines Week earlier this week.

Health minister Rosie Winterton visited Lloydspharmacy in Fallowfield, Manchester, where she launched a leaflet produced by the Royal Pharmaceutical Society to educate the public about antibiotic use.

Jim Smith, chief pharmaceutical officer for England, accessed information from new medicine guides for cholesterol lowering treatments via an internet terminal at Fairview Pharmacy in Middlesex.

At the launch in Wales, attended by Jane Hutt, health and social services minister for Wales, Don Wilkes, assistant pharmaceutical and prescribing manager, Pembrokeshire Local Health Board, said: "This week should not be seen as an isolated opportunity for action but as a springboard for the continuing development of the partnership between patients and health professionals."

As part of AAMW, MORI has released results from a new poll involving 1,864 adults. It revealed that 44 per cent of people who have been prescribed a new medicine during the past year think that they do not know enough about alternative treatment options and medicine choices available to them. One in three (34 per cent) think that there is not enough information available about the risks and benefits of medicines. Around half of the people asked, cited pharmacists as useful sources of information about prescribed medicines. Newer sources



Rosie Winterton with John Gibson, pharmacist manager at Lloydspharmacy, Fallowfield

of information, such as NHS Direct and the internet, were

less likely to be considered useful (both mentioned by 14 per cent).

## Half of GPs want bigger role for pharmacists in diabetes

Pharmacists should play an expanded role in the management of type 2 diabetes to relieve GP workload. This is the opinion of 48 per cent of GPs surveyed in research sponsored by GlaxoSmithKline.

Of the 215 GPs questioned, 56 per cent agreed that monitoring could be done by pharmacists to identify patients with type 2 diabetes whose condition was not controlled, 20 per cent thought that it could not and 24 per cent were not sure. Furthermore, 41 per cent of GPs said they would be willing to act on treatment recommendations made by the pharmacist for these patients. However, almost a third of GPs (31 per cent) said they would not be willing to do this and 28 per cent were not sure.

## Justify retention fee increases, says NPA

Increases in the Royal Pharmaceutical Society personal and premises retention fees need to be justified, says the National Pharmaceutical Association.

At their October meeting, NPA board members decided that it was impossible to tell whether or not the membership fee increase is justified because the Society has not explained sufficiently what it intends to do with the extra money raised. Fee increases should be reasonable and should be supported by a properly costed budget, they say.

There is also concern among NPA board members that the Society has not taken account of the number of members who will switch to the lower-fee non-practising register or who will leave the register completely. This could be a significant drain from the

register, they say, particularly when it is considered that around 30 per cent of the current register is "inactive" and of the remaining 70 per cent, around one third are engaged part-time. "It would be a paradox indeed if the effect of the proposed increase in retention fee resulted in a reduction in income for the Society," the NPA said.

So far as the premises fee is concerned, the NPA board describes the increase as unacceptable and not justified by the reasons given.

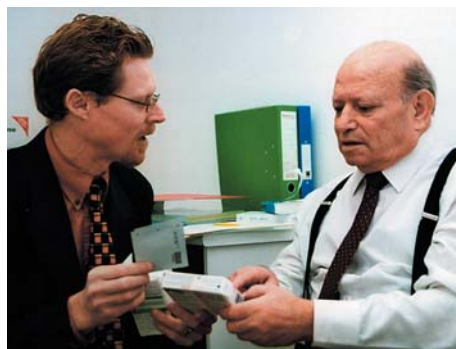
□ **Regulatory impact** The NPA is to ask its members for examples of burdensome red-tape. The organisation has been approached by the cabinet Office's Regulatory Impact Unit, which is to examine the regulatory burden facing pharmacists.

# Two weeks of debate before contract ballot

Contractors have two weeks to decide which way to vote in the ballot about the new community pharmacy contract in England and Wales. The deadline for returning ballot papers is 22 November. Initial reaction to the contract has been positive, although a number of concerns have been raised.

The first of the contract roadshows organised by the Pharmaceutical Services Negotiating Committee were held on 31 October. They were each attended by up to 150 contractors.

At one, in Maidstone in Kent, the consensus was that the requirement to have a consultation room in order to provide advanced services would be an obstacle. Barry Andrews, PSNC chairman, said that contractors had to rethink space allocation and consider losing retail space for a consultation area. One contractor said that many pharmacies do not have a large space to do this, plus the cost of a refit is prohibitive. Sue Sharpe, PSNC chief executive, pointed out that consultation areas could



Consultation areas demand a rethink

be the size of a table. She added that if premises are too small for a consultation area then there is a provision for contractors, with the consent of primary care trusts, to be able to carry out reviews in the patient's home, a GP surgery or a suitable room at a nursing home.

Contractors were also concerned about the different speeds at which primary care

trusts will implement repeat dispensing and how this will affect funding. Mrs Sharpe explained that £100m has been allocated for repeat dispensing of which, in the first year of the contract, £70m will be for transitional payments and £30m for repeat dispensing item fees. "Every pharmacist will get the £1,500 set-up fee irrespective of whether they get a repeat dispensing prescription in the pharmacy," she said. "As repeat dispensing grows, transitional payments will go down."

Patients' freedom to decide which pharmacy to use once electronic transmission of prescriptions has been introduced was also highlighted. Lindsay McClure, head of information services at the PSNC, explained: "There should be clear information for patients about the choice of pharmacies." But she added: "A large question remains over whether doctors will be able to nominate a patient's pharmacy." Discussions are ongoing but the PSNC is "very concerned" about this.

News feature, p675.

## NPA wants contract exit payments to be held over for three years

Exit payments under the new pharmacy contract should be available after three years, and not in the first year, according to the National Pharmaceutical Association.

As proposed, payments equivalent to the current annual professional allowance will be available to the proprietors of pharmacies with low dispensing volumes if they give up their NHS contracts before the end of March 2006.

But the NPA view, formed at its October board meeting, is that contractors might want to try to build up their businesses under the

new contract or transfer to a local pharmaceutical services (LPS) contract before giving up. So it has suggested that exit payments should only apply after three years of the new contract.

Board members are also concerned that some pharmacies will be seriously disadvantaged when electronic transfer of prescriptions is introduced. Their concern centres on proposals for the introduction of electronic signatures and paper tokens that patients will present to pharmacies so that they can download the relevant electronic prescription.

"It is essential that those pharmacies that do not have the necessary equipment to receive electronic prescriptions are not disenfranchised from dispensing them," board members say. They want prescribers to be encouraged to sign all prescriptions and paper tokens so that they are legally valid in their own right.

"Patients are likely to assume that tokens are prescriptions and will suffer a delay in receiving medicines if unsigned tokens are presented at a pharmacy that is incapable of handling ETP," they say.

## CCA companies will vote independently on contract

Company Chemists' Association members have denied that they will exercise a block vote on the new contract.

At a CCA directors' meeting held to discuss the new contract last week, the member companies confirmed that they will consider their own positions over the coming weeks and then submit individual ballot papers to the Pharmaceutical Services Negotiating Committee. The nine companies that make up the CCA are Asda, Boots The Chemists, Lloydspharmacy, Moss Pharmacy, Rowlands Pharmacy, Safeway, Tesco, Sainsbury's and Superdrug.

The CCA board also confirmed its commitment to supporting the Scottish Pharmaceutical General Council in its negotiations with the Scottish Executive Health Department on the new Scottish pharmacy contractual framework.

## DoH publishes a guide on the new contract for PCTs

A guide that sets out support available to primary care trusts about the new pharmacy contract was published this week.

Speaking at the Pharmaceutical Services Negotiating Committee conference on 3 November health minister Rosie Winterton said: "I am delighted to announce a programme of contract support for PCTs." It includes the guide (available at [www.natpact.nhs.uk/pharmacy](http://www.natpact.nhs.uk/pharmacy)), five roadshows for PCTs to be held in December, service implementation guides, a toolkit for pharmaceutical needs assessments and new training developments.

"I believe the new contractual framework will come to be recognised as a watershed for community pharmacy," Ms Winterton said.

Coverage of the conference, attended by 800 delegates including 350 PCT representatives, will appear in next week's *PJ*.

### PJ Online

#### Travel medicine

Information and links to help pharmacists advise the travelling public and define areas where pharmacists can work with other health professionals.  
[www.pjonline.com/series](http://www.pjonline.com/series)

#### Links

The links page is regularly updated. Currently it lists over 70 health organisations, 150 online journals, organisations, pharmaceutical companies and societies, various Department of Health websites and other online health resources.  
[www.pjonline.com/links](http://www.pjonline.com/links)

#### Letters to the PJ

Each week's *Pharmaceutical Journal* appears on *PJ Online* on Friday morning. However the letters pages are available as a PDF file by 5pm on Thursday.  
[www.pjonline.com/whatsnew](http://www.pjonline.com/whatsnew)

# CSM issues safety update on grapefruit and statins

Updated advice on the risks of drinking grapefruit juice while taking statins, issued by the Committee on Safety of Medicines and the Medicines and Healthcare products Regulatory Agency, and guidance on the risk of venous thromboembolism when taking oral contraceptives, are published in the latest issue of *Current Problems in Pharmacovigilance* (2004:30).

The bulletin says that recent pharmacokinetic evidence suggests that grapefruit juice should be avoided altogether when taking simvastatin, because even modest quantities of the drink can increase exposure to the drug. The bulletin includes a summary of advice for prescribing simvastatin together with other CYP3A4 inhibitors.

For atorvastatin (Lipitor), it says that caution should be exercised when combining it with any CYP3A4 inhibitor, and that patients taking it should avoid drinking large quantities of grapefruit juice. However, fluvastatin (Lescol) is metabolised by a different enzyme and pravastatin (Lipostat) and rosuvastatin (Crestor) are not substantially metabolised by cytochrome P450.

Regarding rosuvastatin, the bulletin em-

phasises that all patients must start on 10mg once daily and should only be titrated to 20mg if this is considered necessary after a four-week trial of 10mg. The 40mg dose is contraindicated in patients with predisposing risk factors for muscle toxicity and specialist supervision is recommended when this dose is initiated.

Turning to combined oral contraceptives, the bulletin says that although previous data have suggested that there might be a high rate of venous thromboembolism (VTE) in Yasmin (drospirenone/ethinylestradiol) users, interim data from a large cohort study suggest that the VTE rate is comparable to that for users of other combined oral contraceptives. It reminds readers that all combined oral contraceptives increase the risk of VTE, and that they should be prescribed with caution for obese women and those with a higher baseline risk.

Other advice in the bulletin is that patients taking warfarin should avoid consuming cranberry juice or other cranberry products unless the health benefits are considered to outweigh any risks, and that monitoring anti-factor-Xa activity may be helpful for patients being treated with low molecular weight he-



**Grapefruit juice should be avoided in patients taking simvastatin**

parins who are at risk of bleeding. The bulletin also contains reminders about the prescribing advice for paroxetine, the contraindications of thiazolidinediones (glitazones), flucloxacillin and serious hepatic disorders and the safety of traditional Chinese medicines and herbal remedies.

The bulletin can be accessed via a link on *PJ Online* ([www.pjonline.com/links/pj](http://www.pjonline.com/links/pj)).

## Patients need more information about complementary medicines

Patients are still not getting enough information about the use of complementary medicines and may not feel able to discuss the matter with health care professionals, new research has shown.

A survey carried out on behalf of Developing Patient Partnerships last month found that 71 per cent of people would like to discuss complementary medicine use with their GP or pharmacist. However, 38 per cent thought that most GPs disapprove of these medicines and 24 per cent said that they would be reluctant to tell their GPs that they were taking them. In addition, 29 per cent of people surveyed said that they would stop

taking their prescription medicine or over-the-counter medicine if they were going to use complementary medicine. Two thirds of the people surveyed said they were unclear about which complementary medicines are safe and 40 per cent of people were unaware of the dangers of mixing natural remedies with other medicines.

Edzard Ernst, director, complementary medicine, Peninsula Medical School, Exeter, commented: "These data confirm previous surveys suggesting that patients' need for information on complementary and alternative medicine is huge. Pharmacists should put themselves in a position where they can sat-

isfy this need." He added: "Talking about complementary medicine is all very well but, if this talk is not based on evidence, it is not useful, perhaps even the opposite. As the evidence in CAM is still very limited, this also means we need more CAM research and more dedicated funds to carry it out."

□ **DPP guides** Developing Patient Partnerships has produced a guide for health professionals called "Talking about complementary medicine" and a patient booklet called "Making complementary medicine work for you". They can be obtained through primary care organisations that are members of DPP.

## National patient group direction website launched

A website that will form a national resource on patient group directions (PGDs) is to be launched within the next few months. "It will be a central place where all of us can look for help and support to put PGDs in place," said Beth Taylor, specialist principal pharmacist, Southwark Primary Care Trust, London.

The website is being funded by the Department of Health and is being developed by a team at Guy's Hospital in London. One of the team's members, Chi Wong, said that the website will contain model templates along with news about PGDs, a discussion forum, frequently asked questions about PGDs and links to resources.

Speaking at a prescribing conference in

London in October, Ms Taylor explained that PGDs are one of an increasing number of tools pharmacists have to improve patients' access to medicines. "They are useful in areas where health care happens in a predictable fashion," she said.

"The PGD has to be crystal clear about what is included. There is no flexibility; the parameters for providing the drug have to be defined," she said. "They are not really a suitable tool when clinical flexibility is required."

Ruth Minton, nurse consultant for cardiac care at Dartford & Gravesham NHS Trust, added that PGDs are a useful adjunct to supplementary prescribing.

**Meeting report, p694**

## DTB cautious on probiotics

Optimum regimens for probiotics need to be clarified before these products can be advocated for treatment of gastrointestinal disorders, says the latest issue of *Drug and Therapeutics Bulletin*.

DTB reviewers suggest that the use of probiotics for children with acute diarrhoea and for treating antibacterial-associated diarrhoea shows promise.

However, they warn that probiotics seem ineffective in managing patients with Crohn's disease. There is also conflicting evidence as to whether probiotics prevent traveller's diarrhoea, relieve symptoms of irritable bowel syndrome or help to eradicate *Helicobacter pylori* infection (2004;42:85).

# European Court threat to parallel importing

Parallel importing is likely to be dealt a heavy blow in the European Court following the release of an advocate general's legal opinion that companies can limit supplies to countries where governments keep prices artificially low.

The opinion was put forward to the European Court last week after a group of Greek wholesalers challenged the refusal in November 2000 of GlaxoSmithKline's Greek subsidiary to meet orders for Imigran, Lamictal and Serevent. GSK said that exports by the wholesalers were causing shortages and started to supply the products direct to pharmacies and hospitals. It subsequently reinstated supplies to wholesalers, but refused to meet orders in full. The wholesalers claimed that this was an abuse of a dominant position and breached competition law.

Advocate general Jacobs concluded that a breach of competition law did not necessarily occur if the only reason for refusing to supply a product was to limit parallel trade. He fur-

ther concluded that such a refusal could be objectively justified if the price differential that gives rise to parallel trade is the result of state intervention.

The opinions of advocate generals are not binding on the court, but they are rarely rejected. Their role is to present reasoned opinions on the cases being heard by the court. Wholesale drug prices in Greece are the lowest in the European Union.

Pat Treacy, a competition expert at UK law firm Bristows, said: "State intervention in pricing across the European Union, which leads to widely varying prices, together with the rules on the distribution of pharmaceutical products mean that pharmaceutical companies may legitimately try to protect themselves against cheap imports. All the more so, since the price reductions are often not passed on to consumers."

The president of the European Association of Euro-Pharmaceutical Companies, Hans Bøgh-Sørensen, disagreed, saying: "Parallel

trade is the only form of price competition to monopolistic patent-protected brands, and Europe's already financially stretched public health care systems and patients will be the main losers if big multinationals can continue unabated to artificially limit supplies to wholesalers and partition the EU single market."

The EAEPC also believes that counterfeiting will increase if the advocate general's opinion is accepted by the court and companies are allowed to restrict supplies.

"The situation with product shortages, an inevitable and demonstrable side effect resulting from the imposition of supply quotas, would be expected to worsen, threatening patient health and increasing the workload of doctors and pharmacists," it said. "Market shortages may also attract the attention of counterfeiters, whereas up to now the frequency of counterfeit medicines found in the supply chain in Europe has been remarkably rare."

## News in brief

### Pharmacists CANDO!

Examples of best practice in primary care have been published by the NHS Alliance and the National Primary and Care Trust Development Programme (NatPaCT). CANDO! is a database of steps being taken by NHS trusts in England to improve care, many of which involve community pharmacists. Online and print versions are accessible via *PJ Online* ([www.pjonline.com/links/pj](http://www.pjonline.com/links/pj)).

### Society evidence session

The Royal Pharmaceutical Society and the National Pharmaceutical Association will be giving oral evidence to the House of Commons Health Select Committee's inquiry into the influence of the pharmaceutical industry on 11 November.

### Vantage training

Vantage Pharmacy's dispensing assistant course has been accredited by the College of Pharmacy Practice. The course demands completion of training modules and preparation of a portfolio of evidence of competence. Assistants who complete it will meet a Royal Pharmaceutical Society requirement that all dispensing assistants must have competence equivalent to a level 2 national vocational qualification in pharmacy services by 1 January 2005.

## Patented medicines will be allowed to be copied for use in developing countries

Generics manufacturers are to be allowed to make copies of medicines still protected under patent for export to under-developed countries. A proposed European Commission Regulation will implement a World Trade Organization agreement reached last year which is intended to help satisfy the need for affordable medicines in countries with no pharmaceutical industry of their own (*PJ*, 6 September 2003, p289).

Under the planned new rules, generics companies will have to try to negotiate licensing agreements with patent holders. If they cannot reach agreements on reasonable commercial terms they will be able to apply for compulsory licences. The new system will only apply to products for export to countries that have notified their needs to the World Trade Organization.

Products made under compulsory licences will have to be specially labelled and their reimportation into Europe will be prohib-



People in under-developed countries should benefit from cheaper medicines

ited. Medicines made in this way will also have to be a different shape or colour from the patented product, unless this is impossible or has a significant impact on price. Patent holders will be able to take legal action against the suppliers of any product that illegally reaches the European market.

## Mawdsleys offers help in bidding for service contracts

A scheme to help independent pharmacies bid for NHS service contracts from primary care trusts has been launched by the wholesaler Mawdsleys. John Davies, retail services director for Mawdsleys, said: "We want to ensure that independents are not overlooked and are on an equal footing when negotiating contracts for new NHS developments."

The scheme will involve: initial case assessment; appointment of an independent consultant to negotiate a contract on behalf

of the client; a project review, scenario planning for finance and marketing, benchmarking, business modelling, design, merchandising and refit services; and financial services.

Mr Davies added that independent pharmacists may be disadvantaged through lack of time, expertise and resources to broker complex multi-party deals. "Mawdsleys new contract protection programme will address this imbalance," he said.

# No long-term benefit from HIV treatment interruption

“Structured treatment interruption” in which highly active antiretroviral therapy (HAART) is intermittently stopped is a practice which does not appear to provide long-term benefit to patients infected with HIV.

Researchers hypothesised that this approach might boost immune responses to control HIV infection better. Evidence from earlier research, published in *Nature* in 2000, suggested that treatment interruptions worked for patients during the earliest stages of acute infection. Viral loads in newly infected patients remained suppressed for a median of six months after therapy had been stopped. However, the same research group, led by

Bruce Walker of Massachusetts General Hospital, Boston, has now shown that for most patients this effect was transient — viral load rebounded in eight of 14 patients by one year.

The patients underwent successive treatment interruptions after an initial treatment period of at least eight months. Treatment was restarted if viral load exceeded 50,000 RNA copies/ml plasma on a single occasion or 5,000 copies/ml for three consecutive weeks. Of the 14 patients in the study, 11 achieved virologic control for at least 90 days. However, for most patients there was a subsequent rise in viral load. Only three patients maintained control for more than two years.

“We . . . now have about five years of follow-up on some of the patients,” says Dr Walker. “Although we were able to use early treatment and structured treatment interruption to boost immunity and have 11 of 14 patients control their virus, most of the persons ultimately ‘broke through’, meaning that they had a recurrence of viraemia.”

The researchers conclude that treatment interruptions should probably be avoided outside the setting of controlled clinical trials. They suggest that data from the study could be used to inform current efforts to develop a therapeutic AIDS vaccine (*PLoS Medicine* 2004;1:e36).

# Analgesic use in pregnancy linked to increased risk of schizophrenia

Children born to women who took analgesics in the second trimester of pregnancy may have an increased risk of developing schizophrenia, say Danish researchers.

They studied data from almost 8,000 people from two registers, the Copenhagen Perinatal Cohort and the Danish Psychiatric Central Register, to investigate the relationship between prenatal exposure to analgesics and admission to psychiatric hospital later in life.

Data on medicines taken for at least five days during pregnancy were analysed, and both prescribed analgesics and those bought over-the-counter were included.

After adjusting the results for possible confounding factors, such as parental history of schizophrenia, viral infections in the second trimester and concomitant drug treatment, the researchers found the estimated risk of schizophrenia to be over four times greater in those who were exposed to analgesics in the second trimester than in those who were not (adjusted odds ratio 4.75, 95 per cent confidence interval 1.9–12.0). The association was slightly stronger in females than in males. In the first trimester the risk was only significant for the third month and it was not significant in the third trimester.

The researchers suggest that the second trimester of pregnancy may be a period when the developing brain is particularly sensitive to a range of environmental influences and that chemical substances may disrupt fetal neurodevelopment. However, they also note that women who took analgesics during this period were also more likely to take medicines for psychiatric conditions.

They suggest that a larger cohort study is needed to separate the effects of prenatal exposure to analgesics from the somatic or psychosomatic conditions prompting their use (*British Journal of Psychiatry* 2004;185:366).

## Correction

Vantage Pharmacy says that its dispensing assistant course is in the process of being accredited by the College of Pharmacy Practice but has not already been accredited (p673).