

# Pharmacists expected to play key role in Ask About Medicines Week activities

PHARMACISTS will play a key role in the multidisciplinary approach to Ask About Medicines Week (AAMW), according to one of the week's organisers. AAMW kicks off on Sunday 12 October.

The national week has been organised by Developing Patient Partnerships (formerly the Doctor Patient Partnership), the Task Force on Medicines Partnership and PECMI (Providing Excellence in Consumer Medicines Information).

Joanne Shaw, director of the Medicines Partnership, told *The Journal* that focusing the week on medicines puts patients rather than professionals at the heart of the campaign. "But pharmacists will gain from being at the centre of a multidisciplinary approach during the week," she said.

The aim of the week is to encourage people to make better use of their medicines. Both medicine users and health care professionals are being encouraged to create opportunities to ask about medicines.

In addition, new sources of useful and reliable information about medicines are being provided. A guide to health and medicines information is being launched and patients can pick up cards, already distributed to pharmacies, suggesting questions to ask about their medicines.

The week will have a series of daily themes around which organisations and



*Pharmacists can give out cards with questions patients should be asking about medicines*

health care staff taking part are structuring their activities. The themes are:

- **Monday** Babies and children
- **Tuesday** Women's health, including emergency contraception
- **Wednesday** People with mental health problems, including depression
- **Thursday** Men's health and medicines
- **Friday** Older people and medicines
- **Saturday** People living with long-term or chronic illnesses, specifically HIV, diabetes, asthma, arthritis and epilepsy

NHS Direct Online is one of the organisations taking part in AAMW. The service

will be updating the information on medicines that it provides and linking with the themes of the week.

Datapharm, the company that publishes the compendia of patient information leaflets and summaries of product characteristics, has developed new medicines guides for patients and these will be placed on a website once they are approved by a multidisciplinary advisory panel. Direct links to the guides will be made from the NHS Direct site.

Anne Joshua, national pharmacy adviser for NHS Direct, told *The Journal* that NHS Direct Online has a health encyclopaedia section offering treatment guides. Under the "medicines" heading of the guides there will be an alphabetical listing of branded and generic medicines for each condition. As guides become available, direct links will be established.

"This is a way of providing information on medicines for patients that is outside the existing regulations and which can be tailored to patients' needs," Mrs Joshua said. "In the future, the guides could also be available in print or on television."

The first guides will cover medicines for epilepsy, one of the AAMW themes, and for colds and influenza, a current NHS Direct Online hot topic.

**Concordance section, pp493-519**

## New report supports expanded pharmacist roles

THE public should "reap the benefits" of pharmacists redefining their roles, a *Health Which?* report has concluded.

A special investigation, including a survey of over 1,500 people, gauged public opinion on the changing role of pharmacists. The findings are published in the October issue of *Health Which?*

Obtaining repeat prescriptions from pharmacists rather than doctors was described as "a clear winner" with 78 per cent of people thinking it is a good idea. Most people — 87 per cent — also thought that medicines management was a good idea. Nearly 60 per cent liked the idea of supplementary prescribing by pharmacists but people who take medicines regularly were most resistant to this change.

The introduction of more e-pharmacy services split public opinion. Only 46 per cent were in favour of being able to buy medicines via mail order or over the internet, but 59 per cent supported the idea of on-line advice from pharmacists. Better information about pharmacy opening hours and provision of support for smoking cessation were viewed favourably.

Altogether, 74 per cent of people thought that pharmacists are a trustworthy source of advice about medicines. But fewer people sought general health advice from

pharmacists. Only 11 per cent had asked for such advice or for an opinion on whether or not they needed to see a doctor and just 2 per cent had sought advice on point of care tests available at pharmacies or for lifestyle advice. The report says that although people think pharmacists are qualified to give health advice, certain barriers exist. Chief of all is privacy. "A big factor that deters some people from seeking a pharmacist's advice is concern about being overheard by other customers — a third of people told us that this put them off," the report notes.

Better access to pharmacy services was of high priority to many people. A third of people surveyed wanted their medicines delivered to their homes. Longer opening hours were wanted by 32 per cent of people. "If pharmacists are to become an integral part of the primary care team then their opening hours need to better reflect modern lifestyles," the report concludes.

In a second part of the investigation, a team of 20 researchers across the UK searched for an open pharmacy at 7.30pm on a weekday and at 2pm on a Sunday. They were successful in two-thirds of their attempts. Of the 28 times that an open pharmacy was found, 12 of the pharmacies were in supermarkets, nine were part of multiple chains and seven were independent pharma-

cies. Researchers were more likely to find an open pharmacy in urban than rural areas.

The researchers identified a particular problem with finding out which pharmacies are open. Few pharmacies displayed information about the nearest out of hours pharmacy, information was not always available in local newspapers and the advice from NHS Direct was inconsistent.

### Pharmacy priorities

Respondents to the *Health Which?* survey identified the following priorities for pharmacy:

#### More important

- Home delivery of medicines
- Longer opening hours
- A need for all pharmacies to have private consultation areas
- More point-of-care tests

#### Less important

- Telephone or e-mail advice from pharmacists
- Opening of new pharmacies
- Improving the quality of advice
- More lifestyle advice

# Parents need information about minor ailments and self-limiting conditions

MANY parents are unsure to which health care professional they should turn when their children are ill, a new survey has revealed.

The survey of 304 parents, conducted by the Consumer Health Information Centre (CHIC), which is operated by the Proprietary Association of Great Britain, and Developing Patient Partnerships showed that one in four parents would take a child to accident and emergency or would dial 999 if the child had a high temperature, and 3 per cent of parents would take a child to accident and emergency or dial 999 if he or she had a cough. If their child had a headache, 12 per cent of parents would take the same action. The results suggest that parents have difficulty deciding whether children need emergency treatment or a visit to the general practitioner or when the pharmacist could help.

Parents also tend to overestimate the seriousness of minor conditions. For example, 64 per cent of parents surveyed said

they would consult their GP if a child had worms, although most GPs would advise a parent to visit their pharmacist for treatment and advice. Almost half of parents were not aware you could get a treatment for worms from pharmacies. However, 99 per cent of parents said that with appropriate guidance they would be happy to treat a child's minor ailments themselves with over-the-counter products. CHIC and DPP are now launching a "managing minor ailments" campaign that includes an information booklet called 'Caring for kids — a self-care guide to childhood ailments', designed to explain the symptoms of the most common minor ailments and how they should be treated. The campaign will be run through DPP member GP practices and primary care trusts.

Despite continuing drives to promote self-care, GPs still spend 20–40 per cent of their time consulting on minor ailments for the general population, and currently 46 per cent of prescriptions from out-of-hours pri-

mary care services are for over-the-counter medicines.

□ Free copies of the booklet on childhood ailments can be obtained from CHIC on 020 7761 1803, or at [www.chic.org.uk](http://www.chic.org.uk).

## Director of self-care appointed at DoH

A DIRECTOR for self-care issues in England has been appointed by the Department of Health. The new director will be the chief nursing officer Sarah Mullally.

The announcement was made at a conference about self-care held by the Proprietary Association of Great Britain on 7 October. Health minister Rosie Winterton said that more needs to be done to support self-care development and that the appointment will ensure that the DoH takes a co-ordinated and comprehensive approach.

"Sarah Mullally will bring both a clinical perspective and — as the Department's management board member with responsibility for improving patient and public involvement in health — a patient focus," said Ms Winterton.

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## New contract ballot papers go out

NEW contract ballot papers are to be sent to pharmacy contractors in England and Wales by the Pharmaceutical Services Negotiating Committee next week.

If contractors vote to accept the proposed framework for the new National Health Service community pharmacy contract (P7, 19 July, p77), they will have a chance to vote on the details of the contract and its financial arrangements at a later date.

Steven Williams, chairman of the PSNC's contract planning subcommittee, said: "The aim of this preliminary ballot is to demonstrate to the Government that, given adequate funding and incentives, community pharmacies are ready and willing to increase their role in NHS primary care. A mandate from contractors at this stage is very important prior to us entering into the negotiations on funding."

The PSNC believes that the possibility of a new contract provides an unprecedented opportunity to create a secure and healthy future for pharmacy contractors.

□ **PSNC changes** Reform of the PSNC will see three places allocated for representatives of the Association of Independent Multiple pharmacies (AIMp), less than two years after the group was established. The committee will expand to 31 members, with an additional three nominees from the Company Chemists Association. The PSNC is also pursuing becoming a company limited by guarantee as a way of protecting committee members from liability.

AIMp chairman Peter Cattee told *The Journal* that he is pleased to see official recognition for the independent multiple sector, with three places being "fair representation" for them.

## MEP welcomes opening of the new school of pharmacy in East Anglia

THE new school of pharmacy at the University of East Anglia, which opened last month, has been welcomed by Bashir Khanbhai, a pharmacist and MEP for the East of England. "I am absolutely delighted to see the new school of pharmacy up and running and I wish it every success," he said at a symposium held at the school last week.

Mr Khanbhai represents the counties of Cambridgeshire, Bedfordshire, Essex, Suffolk, Norfolk and Hertfordshire in the European Parliament.

"I have been arguing for the need for such a school here in Norfolk since 1995 and now, taken alongside the new hospital and medical school, health care provision and training in the Eastern region is in an extremely strong position," said Mr Khanbhai.

"The east of England currently has the highest vacancy rate for pharmacists across the United Kingdom and I hope this new degree course will help to address the acute shortage," he added.

### ROYAL PHARMACEUTICAL SOCIETY NEWS

#### Views sought on new draft Charter

The Council has approved a completely revised draft Royal Charter for the Society, with major changes made to reflect the views expressed by members and others in the consultation during the summer. It has also agreed that the revised draft should be issued for further consultation (p521).

The consultation paper will be published as an eight-page centre pull-out in *The Pharmaceutical Journal* next week.

# Revised chemotherapy guidance must be implemented by end of November

UPDATED guidance on the administration of intrathecal chemotherapy has been issued by the Department of Health.

The revised guidance, which replaces guidance issued two years ago (*PJ*, 17 November 2001, p707), sets out key requirements for National Health Service trusts providing an intrathecal chemotherapy service. It also covers action to be taken by trusts that do not normally provide such a service. The updated recommendations must be implemented throughout the NHS by 30 November.

Most of the guidance is unchanged. However, additions include the need to identify a single "designated lead" to oversee compliance with the guidance. This could be a doctor, pharmacist or nurse. The guidance also makes clear what trusts with either a low-volume or high-volume case-load should do to ensure the safety of the service.

One requirement laid down in the guidance is for a register of designated personnel who have been trained and certified compe-

tent for a particular task associated with the intrathecal chemotherapy service. Staff moving from one hospital to another should take a record of their training certification. However, automatic inclusion on the new hospital's register should not occur.

In terms of dispensing, the guidance states that it is acceptable to dispense batches of intrathecal chemotherapy drugs for high volume paediatric services as long as each dose within the batch is signed for separately.

At the point of administration, each dose must be removed from the lockable container or refrigerator individually, never as a batch, it adds.

Tim Root, London specialist pharmacist, Chelsea and Westminster Hospital, who was involved in developing the guidance, told *The Journal* that it also announces publication of an associated training resource pack. Also included is a suggested checklist for use by trusts and strategic health authorities for monitoring compliance, he added.

The full updated guidance is available from the Department of Health, PO Box 777, London SE1 6XH. It can also be downloaded from the internet via *PJ Online* ([www.pjonline.com/links/pj](http://www.pjonline.com/links/pj)).

## Medicines governance increases incident reporting

MEDICATION incident reporting has increased ninefold in Northern Ireland's acute hospitals since a pharmacy-based medicines governance team was established.

Tracey Boyce, Northern Ireland medicines governance team leader, said that the increased level of reporting has enabled the team to remedy some common medicine-related problems.

For example, some patients were routinely receiving pneumococcal vaccine twice, due to an unwitting clash of primary and secondary care policies, and developing severe site reactions. In another example, reports of serious adverse reactions due to intravenous administration of undiluted vancomycin led to the discovery that the

package information contained no instructions for dilution.

The medicines governance team, comprising six pharmacists and an administrator, serves the 16 acute trusts in Northern Ireland. During the first year of operation the team developed a reporting culture questionnaire that was sent to more than 14,000 members of staff. One key finding was that many staff were not reporting incidents because they did not know what constituted an adverse medication incident, said Ms Boyce. The full results of the survey will be published soon.

Ms Boyce, who was speaking at a European Foundation for the Advancement of Healthcare Practitioners conference on

medication errors, held in London last week, attributes much of the team's success to "getting out there and talking to people." Awareness of the importance of reporting medication incidents has been raised progressively through the introduction of a uniform reporting system, personal contacts, safety memos and a quarterly newsletter. Safety memos are brief, to the point and deal with common problems that have been identified through the reporting system.

A medication safety website has also been set up to help to share the team's information as widely as possible.

The National Patient Safety Agency's incident reporting scheme for England and Wales is due to go live in November.

## Correction issued for BNF 46 relating to indinavir dosing

THE British National Formulary has issued a correction to the 46th edition relating to the dosing of indinavir.

The printed version of BNF 46 shows incorrect units for the dose of indinavir for children and adolescents (p305). The dose should read as follows: "Dose: 800 mg every 8 hours; child and adolescent 4–17 years, 500 mg/m<sup>2</sup> every 8 hours (max 800 mg every 8 hours); child under 4 years, safety and efficacy not established."

Digital versions of BNF 46 show the dose correctly.

## Data confidentiality review starts for yellow card reporting scheme

A WIDE ranging review of the confidentiality of data on adverse drug reactions (ADRs) held by the Medicines and Healthcare products Regulatory Agency has begun (*PJ*, 26 July, p110).

The aim of the review, led by Dr Jeremy Metters, a former Department of Health deputy chief medical officer, is to consider whether ADR data can be made more widely available and, if so, for what purposes and under what conditions. It has been prompted partly by increasing numbers of requests for access to ADR data by researchers in academic and clinical institu-

tions. There is also potential for the data to be used for researching any genetic basis for ADRs that could result in their reduction.

A concern that the review intends to address is how to guarantee that increasing access to the data does not reduce ADR notifications, and thus put public health at risk because contributors become concerned about potential breaches of confidentiality.

Comments can be sent to Review of Access to Yellow Card Data, Room 14-111, Market Towers, 1 Nine Elms Lane, London SW8 5NQ until 9 January 2004.

## BRIEFLY

**Topical gentamicin corrects cystic fibrosis mutation**

Applying topical gentamicin to the nasal epithelium of patients with cystic fibrosis can correct one of the mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that causes the disease. Researchers found that, after treatment, electrophysiological abnormalities caused by the CFTR defect resolved in 21 per cent of patients and chloride or sodium transport was restored in 68 per cent (*New England Journal of Medicine* 2003;349:1433).

**Hepatitis A offers asthma protection**

Exposure to hepatitis A virus (HAV) may protect some people from asthma and other atopic diseases, according to American researchers. They found that people who carry a variant of the gene that encodes TIM-1 (the cell-surface receptor used by HAV to infect human cells) are protected against allergic disease. They suggest that the altered version of the gene may enable the virus to enter cells more efficiently and thereby influence the allergic response. The researchers add that their finding could provide a molecular explanation to the suspected link between atopic disease and hygiene (*Nature* 2003;425:576).

**Imatinib has bigger molecular effect**

Imatinib (Glivec) has a greater effect on the main molecular abnormality of chronic myeloid leukaemia (CML) than does interferon alfa plus cytarabine, new data show. Researchers measured levels of transcripts of the BCR-ABL gene (which characterises CML) in patients who were considered to be in complete cytogenetic remission after treatment with either imatinib or interferon alfa plus cytarabine. Those in the imatinib group were much more likely to have a profound reduction in BCR-ABL transcript levels, they say (*New England Journal of Medicine* 2003;349:1423).

**Anbesol reclassification**

Seton Products Ltd has asked the Medicines and Healthcare products Regulatory Agency to reclassify Anbesol Adult Strength Gel as a general sale list medicine. The product is currently a pharmacy medicine. Details available via *Pfj Online* ([www.pjonline.com/links/pj](http://www.pjonline.com/links/pj)).

**GSL application for cetirizine syrup**

Galpharm has applied for its hayfever and allergy relief syrup (cetirizine hydrochloride 1mg/1ml) and tablets (cetirizine hydrochloride 10mg) to be reclassified as general sale list medicines. Comments on Medicines and Healthcare products Regulatory Agency consultation document ARM 12 (available via *Pfj Online* ([www.pjonline.com/links/pj](http://www.pjonline.com/links/pj))) can be made until 23 October.

# New Boots boss spends time working in pharmacy



Mr Baker (right) was accompanied by superintendent pharmacist Digby Emson for his visit

RICHARD BAKER, the new chief executive of the Boots Co Plc, spent a day working in a Boots The Chemists branch in Leicester last week. The purpose of the day was for him to see what happens behind the pharmacy counter and to talk directly to pharmacy staff and customers.

Mr Baker said: "Pharmacy is an integral part of Boots. Our history, our heritage and

our future all have pharmacy stamped through them."

Mr Baker, who was formerly chief operating officer at Asda, took up his new post in September.

"There are no tills or customers at head office, so I want to spend as much time as possible out in the field because that is where I will learn the most," he added.

## Levocetirizine offers no benefits according to French reviewers

LEVOCETIRIZINE (Xyzal), the active enantiomer of cetirizine, is a commercial novelty that offers no benefits for patients, according to a review in the French drug bulletin *Prescrire International* (2003;12:171).

The bulletin examines the clinical trial evidence available for levocetirizine, which is made by UCB Pharma. It concludes that the drug has exactly the same effects as cetirizine, but at half the daily dose. "UCB Pharma chose the active enantiomer trick to replace cetirizine," the bulletin states.

However, UCB Pharma has hit back at the French review. A spokesman for the company pointed out that a significant amount of published data was not examined

by *Prescrire*. "This new data effectively renders the *Prescrire* review both inaccurate and in some instances incorrect." He pointed out that pharmacodynamic studies have shown levocetirizine to be superior to loratadine, fexofenadine, mizolastine and desloratadine in terms of inhibition of histamine-induced weal and flare surface area.

The *Prescrire* review adds that the classification of cetirizine and levocetirizine as non-sedative non-anticholinergic antihistamines is questionable. Trial data show that of 538 patients who received levocetirizine, 5.6 per cent experienced drowsiness and 2.6 per cent reported dry mouth (versus 1.3 per cent for each for those given placebo).

## Therapy can stop after *H pylori* eradicated

FOR patients with bleeding peptic ulcers that have healed following successful *Helicobacter pylori* eradication therapy, maintenance anti-ulcer treatment is not necessary to prevent ulcer recurrence, say Taiwanese researchers.

After *H pylori* eradication had been achieved (using a one-week proton pump inhibitor-based triple therapy plus three weeks of omeprazole), 82 patients were ran-

domised to receive one of four maintenance anti-ulcer treatments (antacid suspension, colloidal bismuth subcitrate, famotidine or placebo). During the 56-month follow-up no evidence of ulcer relapse or bleeding recurrence was found in any patient.

"Successful eradication of *H pylori* drastically changes the natural history of bleeding peptic ulcers," they say (*Archives of Internal Medicine* 2003;163:2020).

# Hormone replacement treatments link with asthma and respiratory allergy

HORMONE replacement therapy (HRT) appears to increase a woman's risk of developing asthma or a respiratory allergy, according to research reported at the 13th annual congress of the European Respiratory Society in Vienna last week.

Norwegian researchers, led by Dr Cecilie Svanes, Bergen University, examined data from 16,190 women aged between 26 and 54 years who were taking part in the European community respiratory health survey study. The women, who were living in northern Europe (Norway, Sweden, Denmark, Estonia and Iceland), were sent a questionnaire 10 years ago and then contacted again between 1999 and 2002.

Analysis of the responses returned by 2,589 women aged over 45 years showed that women who had used HRT were 40 to 50 per cent more likely to suffer from asthma or to exhibit asthma symptoms. The risk for atopic, or allergic, asthma was even greater at 60 per cent.

"These findings could alter our understanding of asthmatic disease and open up new avenues of research into its causes. However, so far they are based on an epidemiological study, and therefore need to be confirmed," Dr Svanes said.

The same study also considered a possible link between asthma and oral contraceptives. Data extracted from replies received from 6,512 women aged under 45 years suggested that asthma and hay fever increase by about a third among women who take oral contraceptives.

□ **Antibiotics linked with allergies** Another study, presented at the ERS congress in Vienna, indicates that children who receive antibiotics before six months of age have an increased risk of developing allergies. The study author, Dr Christine Cole, of Henry Ford Hospital, Detroit, suggests the use of antibiotics may affect the gastrointestinal tract and alter development of the child's immune system.

## Templates issued for 18 PGDs for use in emergency care of patients

PHARMACISTS will be able to administer a range of medicines, including adrenaline, emergency hormonal contraception and glucagon, under patient group directions (PGDs) for emergency care issued by the Department of Health this week.

The DoH has issued 18 national template PGDs that trusts can adopt and adapt. The PGDs could be used in any emergency or first contact care setting. This could include general practice, out-of-hours services, accident and emergency or minor

injury departments and walk-in centres, or other settings. The DoH says that it is up to local trusts to decide where it is appropriate to use them.

The templates have been placed in the National Electronic Library for Health.

The Royal Pharmaceutical Society welcomed the templates, with its President, Dr Gill Hawksworth, saying that they "will offer speedier care to patients as well as more choice over who treats them and where they are treated".

### BRIEFLY

#### First male cancer centre

The United Kingdom's first male cancer centre has opened at the Western General Hospital, Edinburgh. The centre will provide support and information for men with testicular, prostate and penile cancer. Scotland's First Minister, Jack McConnell, commented: "I am proud that the UK's first male cancer clinic is in Scotland. But it should also serve as a strong reminder to every Scottish man of our awful record on men's health and that prevention is better than cure."

#### Portable oxygen on the NHS

Community pharmacies in Scotland will be able to supply portable oxygen cylinders on the National Health Service from April next year.

At the same time, the threshold for prescribing oxygen concentrators, rather than cylinders of gas, is to be cut from 15 hours daily usage to eight hours. Portable cylinders will be prescribable to both cylinder and concentrator patients.

#### New primary care funding

Additional funding for primary care services in Scotland was announced last week. A sum of £3m has been granted for this year and £7.5m for next year will be spent in agreement with local health care co-operatives and will be a boost to the development of community health partnerships. The funding will be aimed at improving services and access to health, in particular for the management of chronic diseases and promoting mental health and wellbeing.

### PJ Online

*PJ Online* contains the editorial contents of *PJ* publications.

#### What's new

*PJ Online* is continually being updated. Details of recent changes can be found on the "What's new" page or via the various "New on this site" links.

[www.pjonline.com/whatsnew](http://www.pjonline.com/whatsnew)

#### Health events

Current and forthcoming health and health awareness events.

[www.pjonline.com/diary](http://www.pjonline.com/diary)

#### Reports

Links to reports of various organisations' meetings and conferences, including the British Pharmaceutical Conference, the Commonwealth Pharmaceutical Association, the International Pharmaceutical

Federation and others. Also included are links to reports of Royal Pharmaceutical Society Council meetings and Statutory Committee reports.

[www.pjonline.com/reports](http://www.pjonline.com/reports)

#### Medicines requiring storage at low temperatures

A list of temperature-sensitive medicines prepared by the Royal Pharmaceutical Society's technical information centre, together with storage advice and contact details for further help.

[www.pjonline.com/pip](http://www.pjonline.com/pip)

#### Translators and dictionaries

Links to both translator and dictionary web sites for European and world languages. Part of the "Information" section on the notice-board.

[www.pjonline.com/noticeboard](http://www.pjonline.com/noticeboard)

# Strains identified for cervical cancer human papillomavirus vaccine

RESEARCHERS have identified strains of human papillomavirus (HPV) that could be used to prevent up to 84 per cent of cervical cancer cases, participants at the recent European Cancer Conference in Copenhagen heard.

Dr Xavier Bosch, Institut Catala d'Oncologia, Barcelona, explained that persistent infection with high-risk types of HPV increases the risk of cervical cancer. These types are detected in 90–100 per cent of cases, as opposed to 5–20 per cent of controls. Their role in the cause of cervical cancer provides a strong rationale for their use in screening and for the development of anti-HPV vaccines.

Dr Bosch studied a pool of evidence on HPV and cervical cancer collected by the International Agency for Research on Cancer based in Lyon, France.

His group estimated that a vaccine including HPV 16 and 18, the most common high-risk types of the virus, would prevent 72 per cent of cervical cancer cases among those vaccinated in Europe and North America. A vaccine containing types 16, 18, 33, 31 and 45 would cover 84 per cent of cases, he added.

Dr Bosch reported that, in Europe, around 65,000 new cases of cervical cancer are diagnosed each year, of which 21,000 eventually lead to death. "HPV vaccinations are still in the experimental stage, and the

vaccine would be expensive at introduction. But the gains in the longer term would be huge both in terms of health care costs and in women's quality of life," Dr Bosch said.

Meanwhile, a Cancer Research UK project has found that a vaccine against HPV 16 and 18 acts against a pre-cancerous disease of the vulva. Scientists at the charity's Paterson Institute, Manchester, in collaboration with doctors at St Mary's Hospital, tested a vaccine called TA-HPV, which was developed by Xenova Research Ltd and is a modified version of the smallpox vaccine.

They gave the vaccine to 18 women with vulval intraepithelial neoplasia (VIN) — a condition in which precancerous lesions appear on the lining of the vulva and are difficult to treat.

Thirteen women developed a specific immune reaction to HPV and, in eight, the diameter of the lesion shrunk by at least 50 per cent. This is the first time scientists have used vaccines of this type in women with VIN.

Lead researcher Professor Peter Stern of Cancer Research UK said: "Our results were encouraging . . . although I think vaccines will prove most useful as part of a combination of treatments." He added that the vaccines appeared well tolerated, with less impact than one of the current mainstays of treatment — surgery. It appeared that the vaccine was more effective in women with

high levels of immune cells in their lesions before vaccination.

"It could be that we will need to test women beforehand, to identify a group who are most likely to benefit from vaccination. It is also possible that repeated vaccination may build up the immune response against cancer, in which case it might be necessary to give women a number of shots of vaccine during a course of treatment," Professor Stern added.

## Hope for pancreatic cancer vaccine

EARLY trial results for a pancreatic cancer vaccine used as treatment have raised hope for the development of this therapy.

At last month's European Cancer Conference in Copenhagen, Dr Robert Maki, Memorial Sloan-Kettering Cancer Center, New York, reported a phase I study of the vaccine in 10 patients with pancreatic cancer.

Surgeons first operated to remove the primary tumour completely. The vaccine was then administered within eight weeks of surgery. No patients had chemotherapy or radiotherapy. The overall survival for the 10 patients was, on average, two-and-a-half years. The typical survival after surgery for pancreatic cancer is 14–15 months. One patient out of the 10 in the trial was still alive and without disease after five years. Two more were alive and disease-free after more than two years.

Dr Maki reported that the trial screened out people who had evidence of tumour spread, "so we may be biased in who we selected". However, statistics show that mortality is still about 90 per cent within two years, even for those who have complete removal of their cancer.

The vaccine was created from a heat-shock protein taken from the patients' own tumours. It was too early to tell whether it

would be possible to create a vaccine that could be used on all patients, Dr Maki said. A method for purifying the vaccine overcame the problem of pancreatic enzymes attacking the vaccine after administration.

However, Dr Maki warned that a larger study was needed to "get a better picture of the efficacy of this vaccine".

### BRIEFLY

#### Cannabis reduces sleep disturbance

The cannabis extract mouth spray, Sativex, reduces both neuropathic pain and sleep disturbance in patients with multiple sclerosis compared with placebo, according to recent data. A five-week trial in 66 patients, showed participants on active treatment were almost four times more likely to report an improvement than those on placebo. Patients involved in the trial had been diagnosed with MS for an average of 11.5 years and remained on existing medication. Sativex is currently being reviewed for licence in the United Kingdom by the Medicines and Healthcare products Regulatory Agency.

## Pro-drug improves lung function

ASTHMA patients attain greater improvements in lung function with ciclesonide, a new inhaled corticosteroid pro-drug, than with budesonide, results from a 12-week trial have shown. The multi-centre study was reported at the European Respiratory Society congress, held in Vienna, last week.

On average, patients who received a once daily treatment of ciclesonide (320µg) during the study period recorded greater improvements in their forced expiratory volume and vital capacity compared with budesonide (400µg).

Dr Dieter Ukena, from University Hospital, Homburg, Germany, whose department spearheaded the trial, explained that ciclesonide is metabolised into active drug in the lungs. As a result, it has less potential than other inhaled corticosteroids for inducing local side effects, he said. He claimed that any drug entering the bloodstream rapidly bound to plasma protein and was inactive until cleared by the liver.

A second study conducted by researchers from Imperial College, London, revealed no significant changes in urinary cortisol levels in asthma patients receiving ciclesonide for 12 weeks, with some suppression of cortisol in budesonide treated patients.

# Promising male hormone contraceptive

RESULTS of an Australian study of a male hormonal contraceptive tested in 55 couples report no pregnancies over 12 months.

"This is the first time a reversible male contraceptive, that will suppress sperm production reliably and reversibly, has been fully tested by couples," said principal investigator, Professor David Handelsman of the ANZAC Research Institute, Australia.

Male partners received the progestin DMPA by injection every three months. This turns off the brain signals that stimulate sperm production. As this also turns off testosterone production temporarily, the men were given a hormonal implant to replace testosterone every four months.

At the beginning of the study, hormone doses were adjusted to ensure that testosterone levels stayed normal.

The researchers saw no serious side effects over the 12-month period, allowing larger trials to proceed.

"This shows the way for a final product to be a single injection containing testosterone and a progestin which will easily be given by doctors on a three to four monthly basis and still maintain male sexual health," Professor Handelsman said. The researchers say that collaboration between two large international companies is now under way to develop such a product.

The study was funded by an American family planning agency and carried out at the ANZAC Research Institute in New South Wales and Prince Henry's Institute in Victoria. There were two phases of the trial. In the first phase 95 per cent of men showed enough sperm suppression to enter the second phase — the 12-month effectiveness period.

The researchers add that studies from both developing and developed countries show that women who are in stable relationships are happy to trust men to use a contraceptive.

## Depression relapse rate decreases with new dual re-uptake inhibitor

PATIENTS with major depressive disorder taking duloxetine hydrochloride, a serotonin and norepinephrine re-uptake inhibitor, have a lower risk of relapse compared with patients on placebo, findings presented at the annual congress of the European College of Neuropsychopharmacology in Prague last month indicate.

In a randomised, double blind controlled trial, 533 patients suffering from major depressive disorder were treated with 60mg duloxetine daily for 12 weeks. Patients who responded to treatment (n=278) were then randomised to either continue with the duloxetine or to placebo for a further 26 weeks. It was found that 17.4 per cent of patients receiving duloxetine suffered a relapse, compared with 28.5 per cent of the placebo group ( $P=0.042$ ).

Furthermore, in a pooled analysis presented at the American Psychiatric Association's annual meeting in San Francisco earlier this year, patients with a Hamilton rating scale for depression (HAMD<sub>17</sub>)  $\geq 19$  taking duloxetine (80–120 mg daily) had significantly higher rates of remission compared with patients taking paroxetine (20mg daily) or placebo. The HAMD<sub>17</sub> threshold for entry to the studies was  $\geq 15$  and remission was defined as a score of  $\leq 7$ . Patients with depression who achieve full remission are less likely to suffer a relapse.

*The Journal attended the European College of Neuropsychopharmacology congress courtesy of Eli Lilly*

### BRIEFLY

**GABA-A agonist in trial for insomnia**  
Gaboxadol, a gamma-aminobutyric acid type A receptor agonist has entered a phase III clinical trial for treating insomnia. The trial is a randomised, double blind, multi-centre (100 sites in Europe and Canada) study in 650 patients with primary insomnia. In previous trials, sleep efficiency and night awakenings were found to be improved, with no signs of abuse potential compared with other hypnotic agents.

**Anxiety now target for new drug**  
Aprepitant, the substance P receptor antagonist approved by the United States Food and Drug Administration in March 2003 for treating chemotherapy induced nausea and vomiting, is in phase III trials as a treatment for anxiety.

## New class of anxiolytics

THE anxiolytic effect of pregabalin, a novel agent that also demonstrates efficacy for epilepsy and neuropathic pain, is apparent after one week according to a poster presented at the annual congress of the European College of Neuropsychopharmacology in Prague.

In a four- to six-week trial, early improvement was found in 48 per cent of patients with generalised anxiety disorder given 200mg daily of pregabalin (n=78) compared with 29 per cent of patients given a placebo (n=414). Early improvement was defined as at least a 30 per cent improvement in Hamilton anxiety rating scale by week one. This indicates that pregabalin has an earlier onset of action than serotonergic anxiolytics and venlafaxine, say researchers. Pregabalin's mechanism of action involves selective binding to the alpha-2-delta subunit of voltage-gated calcium channels. The agent has no significant effects at gamma-aminobutyric acid type A or type B receptors or at benzodiazepine receptors. It appears to be well tolerated, with the most frequently reported adverse effects being somnolence and dizziness.

## Alzheimer's vaccine hope

ALTHOUGH a phase II multi-centre trial of a vaccine for Alzheimer's disease was suspended last year, because of cases of aseptic meningoencephalitis in 6 per cent of participants, an independent follow-up study of a cohort (n=30) in Zurich has found that the vaccine did slow disease progression in 20 cases.

Patients in the phase II trial were given prime and booster injections of beta-amyloid to encourage the body to produce antibodies against beta-amyloid plaques, which are associated with age-related memory impairment and Alzheimer's disease.

Reporting on the follow-up study at the annual congress of the European College of Neuropsychopharmacology in Prague last month, Professor Christoph Hock, division of psychiatry research, University of Zurich, called the antibody response that was observed "remarkable". Patients also showed significantly slower rates of decline in daily activities and cognitive function, indicated by mini mental-state examinations, disability assessments and the Wechsler memory scale.