

Hot weather no risk to medicine stocks

THE recent spell of unusually hot weather in the United Kingdom poses no significant risk to medicines stored at ambient temperatures, say pharmaceuticals experts.

Most medicines are tested to meet the requirements of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (see www.pjonline.com/links/pi) which demand stability in more challenging conditions than seen in the UK.

In general, products that meet the international requirements must remain within their specifications after storage for six months at 40C. Products which have to be stored in a refrigerator are expected to be stable for six months at 25C. More detailed stability testing is only needed if these conditions are not met. Products are also expected to tolerate "short term excursions outside the label storage conditions, such as might occur during shipping."

One academic expert commented: "There's nothing to worry about. Most medicines are tested up to 40C. Most dosage forms are formulated for a worldwide market and may sit on airport tarmacs for a few days at up to 50C."

He added that short-term high temperatures were not a problem for solid dosage forms, provided they were not also exposed to high humidity. But semi-solids, such as ointments, could be expected to soften.

An Association of the British Pharmaceutical Industry spokeswoman said that

manufacturers printed storage guidance on medicine labels and everyone should adhere to that guidance. Pharmacists who were concerned about individual products should contact their manufacturers for advice.

Boots The Chemists has hired air-conditioning units for some of its stores that are not air-conditioned. In addition, stores have been told to take appropriate action, including using cool boxes to protect more vulnerable lines.

A Royal Pharmaceutical Society spokesman said that the Society's guidance to pharmacists was set out in the section on stock in the Code of Ethics and Standards. This says that pharmacists must exercise their knowledge of stability of materials to segregate for disposal any substances that are likely to have deteriorated.

□ **Society warning** The Royal Pharmaceutical Society issued a press release on 11 August warning members of the public that the summer heat could damage their medicines. People should keep medicines out of direct sunlight and away from heat, light and moisture, it said.

The Society's science secretary, Dr John Clements, said: "Gelatin capsules can stick together and soften, ointments and creams



Fans might make dispensary staff feel better but only air-conditioning units can reduce the temperature

can change in consistency and become runny, making them less easy to apply, and suppositories can melt." The Society advised people who were unsure about the condition of their medicines to speak to their pharmacists.

NPA says appliance contractors hold NHS to ransom

APPLIANCE contractors should stop holding the National Health Service to ransom and receive the same payment for dispensing as community pharmacies rather than fund "free" services through excessive on-cost remuneration, the National Pharmaceutical Association says.

The Department of Health is currently consulting on possible changes to the way in which appliance contractors are remunerated. At present, appliance contractors receive an on-cost of up to 25 per cent (plus a dispensing fee of 2p) on items they dispense. They are not subject to a discount clawback. The NPA has made a strongly worded submission to the consultation, even though it was not invited to do so.

The NPA says that for many years appliance contractors have "enjoyed profits far higher than community pharmacies for providing what is, in effect, the same service". NPA director of practice Colette McCreedy said: "Appliance contractors appear to have held the DoH to ransom with their sponsored stoma care nurse positions and 'additional services' such as home delivery, flange cutting and helplines."

The NPA calls the additional services provided by appliance contractors and their higher levels of remuneration a "chicken or egg" situation. Appliance contractors fund

up to 70 per cent of all stoma care nurse positions in the NHS. They can afford to do this because of the higher remuneration and because one of the main roles of the nurses is to ensure that appliance prescriptions are routed to the sponsor's dispensing service, the NPA claims. The proportion of stoma appliances dispensed by appliance contractors rose from 37 per cent in 1993 to 64 per cent in 2001. "If the DoH did not reward appliance contractors so freely, it would discover that it could afford its own independent stoma care nurses," the NPA says.

The NPA also expresses concern that the DoH consultation document makes invidious comparisons between pharmacy and appliance contractors. The NPA says that pharmacies can, and do, provide home delivery, flange cutting and face-to-face advice on appliances and on medicine-related problems, even without the funding that appliance contractors receive.

The DoH is proposing setting standards for appliance dispensing. These include home delivery within two working days, measuring and fitting at home, flange cutting, telephone helplines and supply of disposal bags and wipes. Appliance contractors meeting these standards would be remunerated at the current high level. If the standards are not met, or not required, then

remuneration "should be at the same rate as for pharmacies".

The NPA suggests that instead there should be a tiered fee-based approach to remuneration with additional services being commissioned locally as required. This would remove current incentives towards prescribing large quantities of expensive items. Any accessories required should be listed in the Drug Tariff so that they can be prescribed in the normal way. It adds that appliance contractors should be subject to discount clawback and a global sum in the same way as pharmacies.

The Pharmaceutical Services Negotiating Committee has set up a working group and will be making a formal submission to the consultation before the closing date of 31 August.

Ray Hodgkinson, director general of the British Healthcare Trades Association, which represents 90 per cent of dispensing appliance contractors, told *The Journal* that much of the cost of looking after stoma patients in the NHS, both pre- and post-operatively, is borne by appliance contractors. "It can be shown that this cost exceeds the remuneration received by [them]," he said. The needs of patients with stomas are different from the rest of the population that might consult a pharmacist, he added.

Social and health services back new medicines support scheme in Norfolk

PHARMACISTS in Norfolk are joining forces with social services to improve medicines use in older people. The scheme involves three main elements: a pharmaceutical assessment, provision of compliance aids and training of social services care workers.

Denise Farmer, head of prescribing policy, Southern Norfolk Primary Care Trust, told *The Journal*: "We have had involvement and co-operation from the Norfolk local pharmaceutical committee, social services and all six PCTs in Norfolk." She stressed how important it has been for different organisations in Norfolk to work together in the scheme. "We have had a positive response, with excellent attendance at meetings and everyone has been extremely interested," she said.

The scheme involves health professionals and social service staff referring older people for a pharmaceutical assessment. A community pharmacist, Ian Charles, is being employed by social services from September. "We believe he is one of the first pharmacists to be specifically employed by social services," said Mrs Farmer. He will be undertaking some of the assessments; others will be carried out by pharmacists and pharmacy technicians paid on a sessional basis.

The scheme allows the assessor to recommend, where appropriate, that the patient is given either a compliance aid or help from social services. Monitored dosage systems (MDS) will be supplied by community pharmacists on a weekly basis. Prescriptions for MDS devices are expected to be for no longer than 28 days and the cost of the devices is covered by the scheme. If the patient needs more help, and is receiving

social services support, then a chart will be produced to help the social services care worker to administer the patient's drugs from original containers.

The PCT has produced a specific, standardised version of a medication administration record (MAR) chart. "This ensures care workers only see one type of chart," said Mrs Farmer. Charts will be supplied to community pharmacists who have to fill them in and, when the items are dispensed, stick duplicate labels onto the chart.

Social care workers will receive training as part of the scheme. A training package has been developed by the University of East Anglia academic pharmacy department. Mrs Farmer explained: "It will be delivered by pharmacists or other suitably qualified people to 50 care workers each month." They will be trained in a half-day workshop. It will include topics about medicines, repeat prescribing, how to use the MAR chart and issues such as crushing tablets and opening capsules. The care workers will also be given a reference booklet containing information about medicines.

Pharmacists who supply the charts or compliance aids also need to be accredited as part of a service level agreement. This involves a one-evening training course.

The scheme has been granted £230,000 funding for the first year. Pharmacists will be paid £50 for carrying out an assessment that is expected to take two hours: one-and-a-half-hours with the patient and another half-an-hour to complete relevant paperwork. For filling compliance aids, and carrying out any necessary follow-up monitoring, pharmacists are paid £12 per month per patient (or £3 per week). A sum of £5 per

patient per month is paid for providing charts.

It is expected that 850 referrals will be made to the scheme in its first year.

The scheme will start in October and is still in the process of recruiting pharmacists. All pharmacies providing services to patients registered with general practitioners in the PCTs in Norfolk are eligible to participate. Further information is available from Denise Farmer at Southern Norfolk PCT (tel 01353 669519).

NPA warns Shipman Inquiry to avoid overburdening pharmacists

A HEAVY additional burden in the management of Controlled Drugs might result in community pharmacists choosing not to stock them, according to the National Pharmaceutical Association. And this would not be beneficial to patients.

The NPA made its views clear to the Shipman Inquiry in advance of a consultation on the use of CDs (*PJ*, 9 August, p171). Although the NPA accepts that there is a need to examine the ways that CDs are managed, it stresses that "any additional burden on pharmacists must go no further than is absolutely necessary to protect the public in a way that is proportional to the risk". The introduction of any new administrative requirements would emphasise the need for pharmacies to have a proper information technology infrastructure, it adds.

The NPA is against suggestions that pharmacists should keep a running balance

of CDs until the introduction of electronic CD registers that can automatically calculate balances. Keeping running balances "would not assist in highlighting the activities of an ill-intentioned GP who wanted to use CDs to harm patients", it says.

Entry plans are "deregulation by stealth"

THE New Economics Foundation (NEF) has described Government proposals to inject greater competition into the pharmacy market as "deregulation by stealth" and is warning that they could trigger the slow death of traditional high street pharmacies (our Lobby correspondent writes).

The think-tank says that compromise proposals, announced by Trade and Industry Secretary Patricia Hewitt last month in response to the Office of Fair Trading

BRIEFLY

Pharmaceutical care trial website

A trial of pharmaceutical care offered through community pharmacies now has a website giving details of the study and progress to date (www.respect-trial.co.uk). The trial, funded by the Medical Research Council, is already underway in East Yorkshire Primary Care Trust.

report on control of entry, "benefit no-one, least of all pharmacy users." In a new report, the NEF says that the proposals, opening the way for more competition, are "simply deregulation by stealth".

NEF head of public affairs Molly Conibee said: "The Government had a chance to stand up for principles and not big business profits on the issue of community pharmacies. Instead, it has opted for deregulation-lite — a middle way that benefits no-one."

Anticoagulation self-testing to launch in Sheffield community pharmacies

A PILOT project to move anticoagulation testing from secondary care to community pharmacies is about to start in Sheffield.

The project involves patients self-testing, but doing this in a pharmacy. The idea for the scheme came from Andrew Hartley, a community pharmacist in Sheffield who sits on both the local pharmaceutical committee and the professional executive committee of the primary care trust in south west Sheffield. "Secondary care has got a crisis with no capacity to deal with the growing number of people who need monitoring," he told *The Journal*.

The pilot will take place in five community pharmacies. Both pharmacists and pharmacy staff have been trained so that they can assist patients who are carrying out the tests. The pharmacies have been supplied with CoaguChek S machines and other material, such as laminated reminder cards to which patients can refer.

To participate, each pharmacy needs an area where a patient can sit and carry out a test. But Mr Hartley stresses that various approaches to this have been taken and it is not just for pharmacies that already had consultation areas. For example, one phar-



Patients will use CoaguChek S testing machines in community pharmacies to measure INR levels

macy has put a testing area into a back office that is separate from the dispensary.

When patients come for a test, they will be asked to fill in a form that contains some questions about recent illness and changes to medicines or supplements they are taking. The international normalised ratio (INR) test result will be added to this form and the pharmacist faxes a copy of it to the local surgery. The INR will also be recorded in the patient's yellow book (INR record). Pharmacists also have to carry out quality assurance tests on the machine.

It is expected that each of the five pharmacies will see 50 patients a month during

the pilot. These 250 patients account for 21 per cent of the total number of people requiring anticoagulation services in the area: this is about the figure by which secondary care services in Sheffield said they wanted their workload to be reduced. Looking to the future, Mr Hartley said that capacity could be increased if the pilot is rolled out. "The five sites could comfortably handle a couple of hundred patients each," he said.

Pharmacists in the pilot will be paid a professional fee of £4 per patient for each test, and are also given an additional sum, of around £25 each month, to cover the costs of using the space in the pharmacy. "This project is extremely economic," commented Mr Hartley.

Patients are currently being recruited to the pilot. Each of the pharmacies has links with a local surgery, and patients are being identified at these practices. A patient training session will be held in September where pharmacists and pharmacy staff, working with Roche (the manufacturer of the testing machine being used), will show patients how to self-test. In the longer term, it is hoped that as new patients join the scheme, they will be trained in the pharmacy.

Low-intensity warfarin therapy fails to impress

DEBATE about the intensity of warfarin therapy that should be used to prevent recurrent venous thromboembolism may have been settled this week with publication of a study in *The New England Journal of Medicine* (2003;349:631).

Dr Clive Kearon, McMaster University, Hamilton, Ontario, and colleagues hypothesised that extended treatment with low-intensity anticoagulant therapy (target international normalised ratio [INR] of 1.5 to 1.9) might be as effective as conventional-intensity therapy (target INR of 2.0 to 3.0)

but with a lower risk of bleeding. However, in a study of 738 patients, they found that not only was conventional treatment more effective, it was also no more likely to cause bleeding episodes than low-intensity therapy.

The researchers conclude that low-intensity therapy reduces the risk of recurrent thrombosis by about 75 per cent, whereas conventional-intensity therapy reduces this risk by over 90 per cent.

The authors of an accompanying editorial point out that a recent study comparing

low-intensity warfarin with placebo had shown the active treatment to be "a highly effective method of preventing recurrent venous thromboembolism" (*Pf*, 1 March, p292). The rates of thrombosis recurrence and bleeding were similar to those observed in the current study and so when considered together suggest that conventional therapy is preferable. "It appears the debate about the intensity of warfarin therapy for venous thromboembolism is now settled. The target INR should be 2.0 to 3.0," they conclude (*ibid*, p702).

Measles is becoming more contagious

THE rate of spread of the measles virus in the United Kingdom is increasing, a study suggests.

Researchers used data from recent measles outbreaks in England and Wales to measure the reproductive number of the virus, which is the average number of new infections that an infected person causes.

They report that the reproductive number has risen from a value of 0.47 for the years 1995–98 to a value of 0.82 for the years 1999–2002. The researchers point out that if the reproductive number exceeds a value of one, then the virus will not disappear after each outbreak, but may become a self-sustaining or endemic disease. "We are

approaching the danger zone where measles could once again become an endemic disease in the United Kingdom. We are not yet there, but it may be going that way," said Dr Vincent Jansen, one of the authors of the paper.

It is not known whether the drop in infant measles, mumps and rubella (MMR) vaccination uptake is responsible for this phenomenon, although the reproductive number is approximately proportional to the fraction of the population that is not immunised. "Of course the coincidence is suggestive of a causative connection, but we cannot draw this conclusion from our data," Dr Jansen added (*Science* 2003;301:804).

ROYAL PHARMACEUTICAL SOCIETY NEWS

Regulation of pharmacy premises

The Society is to seek broader powers in relation to the registration of retail pharmacy premises in order to address problems resulting from the limitations of the current statutory framework (p217).

Statutory fees

The Society is to ask for a general increase in the statutory fees of 5 per cent, with some fees rising by a larger amount to reflect more accurately the costs of the activities to which they relate (p220).

Lifting advertising ban could lead to more switches to pharmacy medicines

MORE medicines are likely to be switched to pharmacy medicine status next year as a result of plans to lift the current ban on advertising non-prescription medicines for a range of chronic diseases.

The Department of Health announced on 11 August that it plans to amend the Medicines (Advertising) Regulations 1994 (see Panel). This will allow a much wider range of medicines to be advertised to the public. New regulations are expected to be put in place by the end of the year. The Medicines and Healthcare products Regulatory Agency said that of 53 responses to its consultation document MLX 288, 31 were broadly in favour of removing the restrictions, although eight of these mentioned specific areas of concern. Thirteen responses opposed the proposal or expressed significant concern.

Sheila Kelly, director of the Proprietary Association of Great Britain, told *The Journal* that lifting the advertising ban will remove another hurdle facing pharmaceutical companies that want to have their products reclassified. "If companies can't advertise their products then switching is not going to happen," she said. Last year, a Royal Pharmaceutical Society working group produced a list of around 30 therapeutic areas in which it believed there were products that could be reclassified as pharmacy medicines (*P7*, 2 February 2002, p131). Mrs Kelly said that without changes to the regulations, advertising would only



A wider range of pharmacy medicines could be available next year

have been permitted for about five of these categories.

The Medicines and Healthcare products Regulatory Agency has already revised its procedures for reclassifying medicines and companies can now make applications at a time of their choosing rather than waiting for designated slots every six months.

"There is a lot of work going on behind the scenes at companies," Mrs Kelly said. "The switches that are likely to occur will be complex and will be accompanied by a range of information for patients and pharmacists."

The PAGB will be leading the development of new therapeutic area guidance on

what can and cannot be said when advertising products in specific categories. The new regulations will be put forward once this guidance is finalised. Guidance will be developed first for Government priority areas such as cardiovascular disease. The promotion of 75mg aspirin for the prevention of heart attacks or strokes could be an early candidate under the new rules.

Lord Warner, Parliamentary Under-Secretary of State for Health, stressed when making the announcement that the ban on advertising prescription medicines directly to the public will remain in place.

He added that a European ban on advertising products for chronic insomnia, diabetes and other metabolic diseases, malignant diseases, serious infectious diseases (including HIV and tuberculosis) and sexually transmitted diseases to the public will not be changed.

Areas where restrictions are to be lifted

- Bone diseases
- Cardiovascular diseases
- Diseases of the liver, biliary system and pancreas
- Endocrine diseases
- Genetic disorders
- Joint, rheumatic and collagen diseases
- Psychiatric diseases
- Serious disorders of the eye and ear
- Serious gastrointestinal diseases
- Serious neurological and muscular diseases
- Serious renal disease
- Serious respiratory diseases
- Serious skin disorders

CoMedis aims for 4,000 online users

COMEDIS, an online ordering service for non-prescription medicines, is aiming to have around 4,000 independent community pharmacies using its service by early 2004.

Speaking to *The Journal* last week, CoMedis director Mike Owen said that the number of registered pharmacy users has risen from 1,200 at the time of launch in March to 1,700 at present. Further marketing through the National Pharmaceutical Association and tie-ups with wholesalers and buying groups in the autumn is planned with the aim of doubling this number. Of those registered, around half are using the

system regularly to gain information about non-prescription medicines or to place orders, usually once or twice a fortnight. Around 50 different pharmacies use the system each day and average order values are around £150 to £200.

CoMedis has been formed by the Proprietary Association of Great Britain together with seven consumer health care suppliers; Crookes, Johnson & Johnson MSD, Novartis, Pfizer, Roche, Schering-Plough and SSL. These represent about 45 per cent of the total non-prescription medicines market by volume.

Levonorgestrel to change to stat dose

LEVONELLE (levonorgestrel) is expected to become simpler to use for emergency contraception next year.

Schering Health Care, which markets Levonelle in the United Kingdom, has applied to the Medicines and Healthcare products Regulatory Agency to change the instructions for using the product from two 750mg doses of levonorgestrel 12 hours apart, to a single dose of 1.5mg levonorgestrel.

The application was considered by the Committee on Safety of Medicines in June. A Schering spokeswoman said that it is not known when the change would be licensed, but the company expects to launch the new dose by 2005.

A World Health Organization research group showed at the end of last year that a single dose of levonorgestrel was just as effective as two successive doses (*P7*, 14 December 2002, p838).

Women face dilemma over HRT use

FOR many women taking hormone replacement therapy (HRT) the benefits of short-term use will outweigh the risks, according to the Committee on Safety of Medicines. Women using HRT in the longer term must be made aware of the increased incidence of breast cancer and other adverse effects, it says.

The CSM's advice follows publication of the Million Women Study in *The Lancet* last week (P7, 9 August, p169), which revealed the levels of risk associated with different types of HRT (see Panel).

Use of HRT containing oestrogen plus progestogen was shown to double a

woman's chance of developing breast cancer. This means that for every 1,000 women who use combined HRT continuously for five years, there will be an extra six cases of breast cancer diagnosed. For oestrogen-only products the risk is lower, with an extra one or two cases of the disease being diagnosed for every 1,000 women who use this type of HRT for five years.

The study also examined the risk associated with tibolone (Livial), another type of drug used to relieve menopausal symptoms. The investigators found that tibolone use was associated with an increased risk of breast cancer, although the risk was not as high as with combined HRT.

Dr Nuttan Tanna, specialist pharmacist at Northwick Park menopause clinical and research unit, North West London NHS Trust, told *The Journal* the study confirmed much of what is known about the breast-cancer risk associated with HRT. "Women considering using HRT need to decide how bad their menopausal symptoms are and should have an individualised risk benefit evaluation, with the opportunity to consider their increased risk of breast cancer with time," she said. What the study did not do, however, was clarify the length of time that women can safely use HRT. "We need further research before we can give patients a definite time scale," she added.

Commenting on the study, Professor

Gordon Duff, chairman of the CSM, said: "We . . . realise that these findings may present women and their doctors with a dilemma about long-term HRT treatment. However, what this study clearly shows is that, in all cases, the additional risk of breast cancer begins to decline when HRT is stopped and by five years reaches the same level as in women who have never taken HRT. The new findings mean that it is even more important that each decision to start HRT is made on an individual basis, and is reassessed at least annually."

Million Women Study

The Million Women Study recruited 1,084,110 women aged 50–64 years between 1996 and 2001. Half had used HRT. Incidence of breast cancer was increased for current users of combined HRT (adjusted relative risk 2.00, 95 per cent confidence interval 1.88–2.12, $P < 0.0001$), oestrogen-only HRT (1.30, 1.21–1.40, $P < 0.0001$) and tibolone (1.45, 1.25–1.68, $P < 0.0001$).

The relative risks were increased separately for oral, transdermal and implanted oestrogen-only formulations.

More research into reducing and preventing chronic illness needed

MORE research needs to be done on ways of preventing and reducing ill-health, according to the Health Development Agency, the Government's public health promotion body.

Only 0.4 per cent of public health research published in the United Kingdom between 1995 and 2001 related to illness prevention, the HDA reveals in a new report.

Professor Mike Kelly, director of research and information at the HDA, said

that an interest in short-term, politically high-profile "quick hits" could be inhibiting research into longer-term health benefits.

The HDA report, "Public health intervention research: the evidence", suggests that there should be a national research framework to lead development and that universities should be given incentives to carry out this type of work. A national public health database should be established, it adds.

Research into research started

AN INVESTIGATION into how the results of research should be communicated has been launched this week by the Royal Society.

The reason behind the investigation is criticisms of the process of peer review, which scientists almost exclusively rely on to check the quality of their research before it is made public. The vice-president of the Royal Society, Professor Sir Patrick Bateson, commented: "It is evident that peer review is not perfect, and some scientific papers were approved by referees and published in leading journals but later shown to have been based on false or poorly inter-

preted results." He added: "At the same time, researchers can still attract publicity for highly questionable results even when they offer no evidence that their research has been checked."

The investigation will examine the process of peer review, how it might be improved and whether there are any suitable alternatives to it.

□ **Scottish research** The Scottish Executive has published a new strategy to give patients greater say in health research funding. Steering groups comprising patients, clinicians and researchers will be set up to identify areas where money needs to be spent.

BRIEFLY

Diphtheria vaccine replaced

The current single adsorbed diphtheria vaccine for adults is being replaced by the combined tetanus/low dose diphtheria vaccine for adults and adolescents for all routine uses. This is because the manufacturer has not supplied necessary paperwork to the Medicines and Healthcare products Regulatory Agency confirming that the single diphtheria vaccine complies with European legislation.

MS risk reduced by sun exposure

Exposure to the sun during childhood and early adolescence may protect against the development of multiple sclerosis. A study conducted in Tasmania found that the risk of developing the disease was inversely proportional to the amount of sun exposure when aged 6–15 years. Higher exposure in winter was particularly important (*BMJ* 2003;327:316).

Psoriasis treatments similar

Methotrexate and ciclosporin are similarly effective for the treatment of moderate-to-severe chronic plaque psoriasis, say researchers. In a study involving 88 patients, the two therapies were found to reduce the severity of disease by a similar amount and were both well tolerated (*New England Journal of Medicine* 2003;349:658).

Warn patients treated for Parkinson's disease about gambling behaviour risk

PATIENTS with Parkinson's disease should be warned that treatment could be associated with an increased risk of gambling, suggest American researchers (*Neurology* 2003;61:422).

After a review of 1,884 patients with Parkinson's disease who were seen at the Muhammad Ali Parkinson Research Centre, Barrow Neurological Institute, Phoenix, Arizona, over a 12-month period, Dr Mark Stacy and colleagues found that seven men and two women showed signs of pathological gambling.

Of these nine patients, eight were being treated with pramipexole (Mirapexin, mean dose 4.3mg/day, range 2 to 8mg/day) and one was being treated with pergolide (Celance, 4.5mg/day) when they started gambling.

The researchers report that the overall incidence of gambling among the patients was 0.05 per cent. The incidence of this behaviour among pramipexole-treated patients was 1.5 per cent and 0.3 per cent for pergolide-treated patients. The researchers point out that the rate of pathological gam-

bling found in subjects taking pramipexole is only slightly higher than the reported rate in the general population (0.3 to 1.3 per cent) and other factors could have contributed to the development of this behaviour.

"However, this clinical observation suggests that higher dosages of dopamine agonists may be a catalyst to bringing out this destructive behaviour," said Dr Stacy.

He added that it might be appropriate to inform patients of this potential risk, "particularly patients taking relatively high dosages of a dopamine agonist, and with a documented history of depression or anxiety disorder".

The patients identified as pathological gamblers had been taking pramipexole or pergolide for between six and 64 months. Seven patients started gambling within one month of an increase in their dopamine agonist dose.

For six of the patients the gambling was controlled by switching treatment to ropinirole (Requip). Another patient, who did not tolerate a change in dopamine agonist ther-

apy, improved after the pramipexole dose was reduced from 8mg/day to 3mg/day with a concurrent increase in the levodopa dose.

Pfizer, manufacturer of Mirapexin, said that long-term, controlled clinical trials of pramipexole involving nearly 1,000 patients with Parkinson's disease did not suggest an association between the product and excessive gambling or other impulsive behaviours.

NICE consults on ninth work wave

THE National Institute for Clinical Excellence is consulting on a ninth wave of technology appraisals.

The topics proposed are adefovir dipivoxil (Hepsera) for chronic hepatitis B, atrasentan for prostate cancer, cetuximab (Erbix) for head and neck cancer, erythropoietin (Eprex/NeoRecormon) for chemotherapy-induced anaemia, etanercept (Enbrel) and infliximab (Remicade) for ankylosing spondylitis, inhaled insulins, melagatran and ximelagatran (Exanta) for (a) treatment of venous thromboembolism and (b) prevention of stroke after atrial

fibrillation, natalizumab (Antegren) for multiple sclerosis, nesiritide (Natrecor) for acute decompensated heart failure, pegaptanib (Macugen) for age-related macular degeneration, prasterone (dehydroepiandrosterone, DHEA) for systemic lupus erythematosus, thrombophilia screening in patients at risk of deep vein thrombosis, clinics for assessing and preventing falls, and HealOzone for tooth decay.

Comments on the proposed programme can be sent to Catriona Gregory (tel 0113 254 5636, e-mail catriona.gregory@doh.gsi.gov.uk) by 5 September.

Scotland endorses new arthritis drug

THE Scottish Medicines Consortium has given the green light to valdecoxib (Bextra) to be used for osteoarthritis and rheumatoid arthritis within the National Health Service in Scotland.

The SMC says valdecoxib should be considered for patients at high risk of gastrointestinal adverse effects, although it adds that there is no evidence of any advantages or disadvantages compared with other selective cyclo-oxygenase inhibitors.

The SMC has ruled on three other drugs this month. The antiretroviral agent enfuvirtide (Fuzeon) was given a cautious welcome but adefovir dipivoxil (Hepsera) for chronic hepatitis B and memantine (Ebixa) for Alzheimer's disease were not recommended for use.

Details of the SMC rulings are available online (www.htbs.co.uk/smc).

PJ Online

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Online journals

A selection of over 100 online journals, including *BMJ*, *JAMA*, *New England Journal of Medicine* and *The Lancet*. There are links to the relevant homepages and the access (free or subscription) is also summarised.

www.pjonline.com/links/journals

Health sites

The links section lists hundreds of health websites, in over 50 categories. Further information can be found on the medical notes section of the BBC website and NHS National Electronic Library.

www.pjonline.com/links

Health events

Awareness campaigns are listed on the Diary page. Logos are only used with the permission of the relevant organisation. There are also links to other lists of awareness events including the Department of Health and Health-news, plus a link to the health sites section.

www.pjonline.com/diary

Recalls

Product recalls and drug alerts, from 2001 to date, are listed here.

www.pjonline.com/recalls

Posters

Tips on preparing and presenting posters, including links to various universities.

www.pjonline.com/bpc

BRIEFLY

Study supports pharmaceutical care

A United States study provides new evidence to support the concept of pharmaceutical care. Researchers reviewed therapeutic decisions made by pharmacists and found them to be clinically credible. By the end of the pharmaceutical care programme patients' drug therapy problems had been resolved in 89 per cent of cases (*Archives of Internal Medicine* 2003;163:1813).

Using NRT to cut down helps long-term

NICOTINE replacement therapy (NRT) can help smokers unable or not ready to stop smoking to reduce the number of cigarettes smoked, according to a study reported at the World Conference on Tobacco or Health in Helsinki last week. Results showed that this approach helped 10 per cent of smokers stop completely after two years.

The study, carried out in Denmark, followed up 411 people smoking an average of 24 cigarettes a day who were not ready to stop completely. They were randomised to NRT gum or placebo plus smoking cessation advice and were advised to quit after six months. More people randomised to gum achieved a sustained reduction in their smoking levels — 8.8 per cent of those using the gum had reduced their daily cigarette consumption by more than 50 per cent at one year compared with only 1.5 per cent of those given placebo gum. Nearly three times as many people using NRT had stopped smoking completely at one year compared with the placebo group (11.2 per cent vs 3.9 per cent), with 10 per cent maintaining cessation at two years.

Martin Jarvis, principal scientist with Cancer Research UK's Health Behaviour

Unit and professor of health psychology, University College London, said: "Current approaches to nicotine addiction, which focus on abrupt cessation, motivate only a small number of smokers who are ready to quit. A lot of people lack confidence in their ability to stop smoking." He added: "If they can be encouraged to use medicinal nicotine to reduce their smoking without immediate pressure to quit, this will improve their confidence in their ability to stop. This strategy offers a positive way to help smokers to quit in the longer term."

"Pharmacists have a central role in educating people about nicotine replacement therapy," Professor Jarvis pointed out. He suggested that it might be appropriate to tell smokers not ready to stop: "NRT will make it easier for you to reduce how many cigarettes you smoke — reducing your addiction, helping you to move on to quitting altogether." He said that the idea that someone who has smoked for 20 years can stop immediately is generally unrealistic. "Cutting down using NRT offers a more rational approach to breaking the addiction, on the way to stopping completely."

□ *Pharmacists against tobacco* A global network of pharmacists against tobacco was

set up by national and international pharmaceutical organisations at the Helsinki conference. The network's activities will be co-ordinated by the International Pharmaceutical Federation (FIP). Details are available online (www.pharmacistsagainsttobacco.org).

NSAIDs increase miscarriage risk

NEW research shows that taking non-steroidal anti-inflammatory drugs (NSAIDs) or aspirin during pregnancy increases risk of miscarriage. Therefore, it might be prudent for women who are planning to become pregnant to avoid using these drugs, according to researchers at the Kaiser Foundation Research Institute in California.

The researchers examined whether prenatal use of painkillers is associated with miscarriage in 1,055 women at 20 weeks gestation. They found that using NSAIDs during pregnancy increased risk of miscarriage by 80 per cent. The risk was highest when NSAIDs were taken around the time of conception (hazard ratio, 5.6) or for longer than a week (hazard ratio, 8.1).

A similar association was found for aspirin. However, use of paracetamol during pregnancy was not associated with increased risk of miscarriage regardless of when it was used or for how long.

The reason for this difference is that paracetamol has a different pharmacological effect, the researchers suggest. All three inhibit the production of prostaglandin. However, NSAIDs and aspirin do this in

most of the body's organs whereas paracetamol only has this effect in the central nervous system.

They comment that animal studies have shown that prostaglandins are needed for successful implantation of an embryo into the uterus wall. So inhibition of prostaglandin synthesis could lead to abnormal implantation and subsequent miscarriage. Another possible effect of prostaglandin suppression in pregnancy is through an adverse effect on placental perfusion and circulation.

Current guidance in the BNF states that most manufacturers advise that NSAIDs should be avoided in pregnancy.

Although the researchers say that their findings will need to be confirmed, they comment: "If NSAID use during pregnancy, especially around conception, is associated with miscarriage it will have wide clinical implications because many women are likely to be prescribed NSAIDs during the periconceptional period." They add that women planning to become pregnant should be aware of the risk and avoid using NSAIDs around conception (*BMJ* 2003;327:368).

All old people to have pneumococcal immunisation

OLD people are to be targeted in a new pneumococcal immunisation campaign to be rolled out over three years, the Department of Health has announced.

This follows a recommendation from the Joint Committee on Vaccination and Immunisation that all people aged 65 years and over should be vaccinated against pneumococcal disease. Initially, all people aged 80 years and over will be offered vaccination with the 23-valent pneumococcal polysaccharide vaccine, starting from 20 August. This will be followed by all those aged 75 years and over from April 2004 and all those aged 65 years and over from April 2005.

The DoH has suggested offering pneumococcal vaccination at the same time as influenza vaccination, the policy for which remains unchanged for 2003-04.

Supplies of pneumococcal polysaccharide vaccine can be ordered directly from Pasteur Merieux MSD.

Re-immunisation with polysaccharide vaccine is not generally recommended.

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