

Chloramphenicol eye drops approved as pharmacy medicine for treatment of bacterial conjunctivitis

Chloramphenicol 0.5 per cent eye drops have been reclassified as a pharmacy medicine.

The Medicines and Healthcare products Regulatory Agency announced the POM to P switch earlier this week and the move has been applauded by pharmacy organisations.

David Pruce, the Royal Pharmaceutical Society's director of practice and quality improvement, said: "Making chloramphenicol eye drops available without a prescription is a safe, effective and convenient route to treatment for the many patients who visit pharmacies every day with acute bacterial conjunctivitis."

The National Pharmaceutical Association welcomed the announcement. Colette McCreedy, the NPA's director of pharmacy practice, said: "We are confident that this will be an extremely useful product and will increase patients' access to an effective treat-

ment." She added that the NPA had hoped for a lower minimum age limit, given the frequency of infective conjunctivitis in young children. The OTC products, which went through the reclassification process concurrently, are indicated for acute bacterial conjunctivitis in adults and children aged two years and over.

MHRA chief executive Kent Woods said that the case for making chloramphenicol eye drops available over the counter, both in terms of patient safety and the risk of emergent bacterial resistance, had been debated thoroughly. "We are convinced that the potential health benefits outweigh any risks to patients, or to the community at large," he said.

Chairman of the Committee on Safety of Medicines Gordon Duff added: "Allowing patients quick access to this treatment will help to speed their recovery, lower the risk of spreading infections, of infection returning or of further complications developing. As such, I welcome this move and believe there is a clear public health benefit to be gained from making this important medicine available through pharmacies."

John Blenkinsopp, a senior research fellow at Keele University, worked as a switch consultant for Galpharm. He told *The Journal* that the switch process for OTC chloramphenicol had been notable. "The MHRA attempted to



Patients with conjunctivitis will have quicker access to treatment

ensure the companies made their applications consistent with each other," he said. This included the training packages that have been prepared for pharmacists and pharmacy counter assistants.

Practice guidance for pharmacists has been produced by the Society and is available online (www.rpsgb.org/practice). The guidance outlines indications for supplying the medicine without a prescription as well as points to consider when counter prescribing. It provides information on whom to refer, how to administer, how chloramphenicol works, cautions, adverse effects and interactions.

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OTC products

Three companies submitted switch applications to the MHRA. Optrex Ltd launched Optrex Infected Eyes earlier this week (see p705). It is expected to become available in the last week of June. A Galpharm product will be launched later this year. The Boots product has yet to receive MHRA approval.

The Society

Election of Officers

In the new Council's first election of Officers, Hemant Patel has been elected President and Gerald Alexander Vice-President. John Jolley has been re-elected Treasurer (p715).

Past presidents' advice

Three past presidents of the Society have bowed out from the Council with words of advice for their successors (p716).

CD changes post-Shipman

The Society has produced a guide to planned regulatory changes arising from the Government's response to the fourth report of the Shipman Inquiry (p718).

Branch representatives' meeting

We report this week the debate on the 18 motions considered by the branch representatives' meeting held on 24 May (pp719-722).

Pharmacy guidance on CD regulations published by Society

Guidance on what pharmacists should be doing to comply with current and planned Controlled Drugs regulations has been published by the Royal Pharmaceutical Society.

The document "What does the Government's response to the fourth report of the Shipman Inquiry recommendations mean in practice?" describes the things that pharmacists should be doing in terms of their practice as it relates to CDs. It also lists whether the actions are good practice, whether they fall under current law or whether they are covered by regulations that have yet to be implemented.

The guidance provides information on receipt of stock, record keeping, storage, dispens-

ing and supply, patient returns, destruction of stock and inspection of pharmacies. An edited version appears in the Society section of this week's issue (see p718).

Heidi Wright, the Society's head of quality improvement, said: "The Society, together with other pharmacy bodies and the Department of Health, will be issuing further guidance around various aspects outlined in the document."

Pharmacists can obtain a copy of the guidance, which is available on the Society's website (www.rpsgb.org/practice), by contacting the Society's practice and quality improvement directorate (tel 020 7572 2208, e-mail qualityimprovement@rpsgb.org).

National Pharmaceutical Association's image lacks impact

The National Pharmaceutical Association's carboy logo is old-fashioned, is not well recognised and lacks impact, a design agency told the chairman and board members at their May board meeting.

Market research showed that the NPA's name has drug company associations and fails

to communicate the NPA's representation of community pharmacy and pharmacy owners, the agency said.

Proposals and recommendations on changing the name of the NPA will be discussed and ratified at the NPA's board meeting and annual general meeting on 28 June.

Stop-smoking training should focus on counselling

Smoking cessation training programmes for pharmacists should focus on counselling skills, rather than facts about smoking, research by the Health Development Agency, in conjunction with PharmacyHealthLink, suggests.

The HDA examined training programmes and resources available in England and consulted professional organisations about what training should be offered and by whom. It found that, although pharmacists are knowledgeable about smoking cessation and nicotine replacement therapy (NRT), they need additional support in understanding how smoking cessation training translates into offering a service, and how they actually deal with smokers and their various problems. Pharmacists also need encouragement to expand their role in smoking cessation beyond the sale of NRT and to consider that counselling and the behavioural side of smoking cessation, as well as referral of patients to primary care trust services, is relevant to them.

The research suggests that since pharmacists' success in smoking cessation pro-



Smoking behaviour should be taken into consideration in pharmacists' training

grammes grows with increased practical experience, establishing confidence in pharmacists new to the service is crucial to its success. Pharmacists therefore need support to help them cope with low success rates as

well as training to help them recognise those who are seriously trying to quit.

The survey found that the training available to pharmacists varies considerably both locally and nationally. Commenting on the research, Miriam Armstrong, chief executive of PharmacyHealthLink, said: "While we recognise that many pharmacists provide excellent specialist smoking cessation services, the standard of training is by no means consistent. Training programmes are currently multifaceted and fragmented, with many different providers and consequently considerable variation in the amount and type of training that any individual pharmacist or staff member may receive."

She added that one of the remaining issues is whether there should be a pharmacy-specific training standard for smoking cessation or whether the same training standard should apply to all health professionals. She invited feedback on the report, by e-mail, to info@pharmacyhealthlink.org.uk.

The report is available via *PJ Online* (www.pjonline.com/links/pj).

Nicotine myths prevent smokers from quitting

Misconceptions about the role of nicotine are preventing smokers from using nicotine replacement therapy (NRT) when they attempt to quit, data due to be presented at the UK National Smoking Cessation Conference in London this week suggest.

More than two-thirds of UK smokers (71 per cent) believe that the nicotine in cigarettes causes lung cancer, 62 per cent believe that it causes heart attacks and heart disease and 69 per cent believe that nicotine in smoking cessation aids is as harmful as smoking cigarettes, the study found. And only 14 per cent of those who believed that nicotine in smoking cessation aids is as harmful as

smoking cigarettes planned to use NRT during their next quit attempt, compared with 38 per cent of those who thought NRT was less harmful than cigarettes.

Commenting on the findings, Graham Phillips, who runs a smoking cessation service at his pharmacy in Letchworth, Hertfordshire, said: "Pharmacists should explain to smokers that when they light up, it is the nicotine that gives them the hit and the rest of the smoke that can cause cancer. It is vital that customers are educated about the comparative safety of NRT versus continuing smoking and NRT's proven effectiveness in helping people to quit successfully."

More women than men get their blood pressure checked

Twice as many women as men are taking advantage of free health monitoring services such as diabetes screening and blood pressure monitoring at Lloydspharmacy, the community pharmacy chain announced this week.

Lloydspharmacy has offered free blood pressure tests since June 2003. Of the 225,000 who have been tested, only 14 per cent (31,961) have been men. And of the 550,000 people who have used Lloydspharmacy's diabetes screening service, only 136,768 (24 per cent) have been men.

Andy Murdock, pharmacy director for Lloydspharmacy, commented: "Given the accessibility of pharmacists in the local community, we are disappointed that men don't seem to be taking advantage of the services they offer."

Men's Health Week runs from 13–19 June. This year the event focuses on obesity.

Patient knowledge of diabetes does not improve disease control, researchers say

Patients with diabetes who have a better understanding of their condition do not necessarily have better disease control, research suggests.

In a recent study, researchers assessed the diabetes-related knowledge and clinical data of 200 patients who had been admitted to hospital with an acute coronary syndrome. Six months later the patients' clinical measurements were reassessed.

The researchers found no correlation between how much the patients knew about their condition and their blood sugar control, cholesterol levels, or weight management, even after adjusting for factors such as age,

duration of diabetes and years of education. Nor was an association found between rates of death and myocardial infarction and patient knowledge.

They say that despite a belief that poor patient understanding impedes self-management of the condition and thus accelerates cardiovascular complications, they found no such relationship.

Although educating patients about their condition may be important, the researchers say that new strategies are needed to translate understanding of disease into better risk factor modification in these patients (*American Journal of Cardiology* 2005;95:1290).

News in brief

Diabetes roadshows

LifeScan, a manufacturer of blood glucose monitors, will be holding a series of patient roadshows in conjunction with Diabetes UK to coincide with diabetes week (12–18 June). The roadshows will be located next to supermarket pharmacies so that patients can be directed to a pharmacist when appropriate. Details are available via *PJ Online* (www.pjonline.com/links/pj).

New oxygen contract is a risk to patients, says PSNC

The introduction of new arrangements for the supply of oxygen to patients at home could compromise patient care, according to the Pharmaceutical Services Negotiating Committee.

Commenting on the new contracts awarded to four companies across England and Wales, announced this week, PSNC chief executive Sue Sharpe said: "We have strong reservations about the decision to introduce new arrangements for the supply of domiciliary oxygen. We welcome the introduction of more technically advanced equipment that can increase mobility and ease of use for patients, but we have expressed forcefully our view that the service will become far less easy and convenient for patients to use than the present arrangements."

Mrs Sharpe said that the advantages of the present system have been ignored by the Government and added: "There is a real risk that patient care will be compromised as the service transfers to the new contractors unless comprehensive measures are introduced to facilitate the handover."

The National Pharmaceutical Association also expressed concerns about the new arrangements. Colette McCreedy, director of pharmacy practice, NPA, said: "Not only have the advantages of the present systems been ignored by the Government but no acknowledgement has been given of the excellent job pharma-

cists have done over many years — even with less technically advanced equipment."

She said that the new service's 24-hour, seven-days-per-week coverage will be difficult to achieve in all circumstances, particularly in rural areas. "We need reassurance that neither patients nor pharmacists will be compromised during the transition and implementation of these new arrangements," she added.

The PSNC has written to the Department of Health asking for urgent resolution of outstanding issues, including the arrangements for terminating the current community pharmacy-based service.

One unresolved issue centres on who will pay for equipment needed by patients who need to start treatment with domiciliary oxygen before the new contracts come into operation. Although pharmacy contractors are likely to be partly compensated for oxygen headsets they lend to existing patients, the DoH has no intention of fully reimbursing them for any new headsets they have to buy for new patients.

The DoH view is that any new headsets required are the responsibility of primary care trusts, which should either broker the transfer of spare sets from other contractors or buy them themselves. Because of this, the PSNC has told contractors that they should not buy any new headsets, but should ask PCTs to provide them.



Domiciliary oxygen: advantages of the present system have been overlooked

Under the new contracts, both hospital doctors and GPs will be able to order oxygen treatment, which will have to be provided within a set response time. Currently, hospital doctors cannot order home oxygen treatment. The new regional contract holders are Air Products, Allied Oxycare/Medigas, BOC and Linde.

Health minister Jane Kennedy said that the new arrangements will give patients round-the-clock access to expert advice and support and the latest equipment, including lighter cylinders, smaller, more efficient concentrators, liquid oxygen and, for the first time, portable systems.

Experts to tackle violence against NHS staff

Local security management specialists will be based at every NHS hospital trust and primary care trust by June 2006, the NHS Security Management Service announced this week. These specialists will work in partnership with the police to investigate assaults on staff and ensure appropriate action is taken.

Stephen Lutener, head of regulation at the Pharmaceutical Services Negotiating Committee, said: "The PSNC welcomes the attention being drawn by the NHS Security Management Service to the concerns about violence against NHS staff. The deterrence of violence, by effectively pursuing prosecution

of those who commit violence towards people working within the NHS, is an important part of protecting the service given by community pharmacies and other health workers within the NHS."

The NHS Security Management Service is currently running pilot projects in which community pharmacists report all incidents of violence or threats of violence to their PCT (*PJ*, 19 March, p325). The pilots will allow the Security Management Service to assess the incidence of violence in community pharmacies as well as the effectiveness of the reporting system.

NHS24 needs to improve, independent review team says

Improvements that NHS24 should make were set out last week by an independent review team.

The Scottish Executive asked the review team to examine NHS24's performance in response to criticism of the service.

In an interim report, the team recommends that the feasibility of two or three mini-centres across Scotland is considered, the use of call-back is reviewed and that NHS24 should work more closely with health boards.

The review notes that NHS24 faced a particular challenge of peaks in calls at weekends and during public holidays after nearly 90 per cent of Scotland's GPs opted out of 24-hour care. Staff management needs to be tackled, with the report stating that an "extreme family friendly" culture has left NHS24 with more than 300 shift patterns.

A final report that will set out how to improve service efficiency, respond to the needs of rural areas and deliver a seamless patient journey is expected in September.

Floor space exemption should exclude added mezzanines

Pharmacies under 15,000 square metres should not be allowed to have mezzanines added in order to extend their floor space and become exempt from the NHS (Pharmaceutical Services) Regulations 2005, the Pharmaceutical Services Negotiating Committee has said.

Responding to the Office of the Deputy Prime Minister's consultation "Planning control of mezzanine and other internal floor-space additions", the PSNC said it believes that proposals to create more than 200 square metres of additional retail floor space should require planning permission.

The National Pharmaceutical Association accepts, in its response, that a threshold is required to exclude small internal mezzanine developments from requiring planning permission, but sees 200 square metres as a low threshold.

The NPA is urging the Office of the Deputy Prime Minister to treat each case individually and to consider the impact on the community pharmacy network of mezzanine extensions that increase floor space above 15,000 square metres.

The consultation document and the PSNC and NPA's responses are available via *PJ Online* (www.pjonline.com/links/pj).

OTC simvastatin response mix up

The Medicines and Healthcare products Regulatory Agency has this week admitted that only a third of the responses to the consultation on the change of simvastatin to an over-the-counter medicine were favourable.

The MHRA had originally said that “about two thirds of respondents were in favour of the proposal”. In April, the *Drug and Therapeutics Bulletin* claimed that the MHRA exaggerated the proportion of favourable responses to the public consultation. The MHRA refuted the claim of misrepresentation saying that the Committee on Safety of Medicines had full access to all responses to the consultation.

However, in a correction to information on its website, the agency has said that, in fact, a third were in favour, a third against and a third were not opposed, but raised issues to be considered. The in-

correct information was, the agency says, “due to an administrative error”.

In a statement issued this week, the MHRA said: “We apologise for any confusion caused by this error.

“We in no way intended to misrepresent the results and can assure the public and other interested parties that the correct findings were given to the Committee on Safety of Medicines who made their recommendations with the full facts in front of them.”

The MHRA has published a listing of all consultation responses on its website, together with the full text of all responses other than those where the respondent has not given consent for public disclosure. “We are now adopting this model for all future switch consultations, so as to avoid any further confusion,” the MHRA added.

Management restructured at Boots The Chemists

Commercial management of Boots The Chemists is to be restructured, Richard Baker, chief executive of Boots The Chemists, announced this week.

David Kneale, chief commercial officer, will leave the company and his role will be split. He will stay at the company until the end of July to help manage the transition.

Pharmacist Alex Gourlay, acting retail director, will take the new role of health care and store development director. He will be responsible for the “Healthcare first” initiative and the future development of store formats. Ian Filby, commercial director, lifestyle, has been appointed to the new role of beauty and lifestyle director and will also be responsible for marketing. Mr Gourlay and Mr Filby will take up their new roles on 1 July and will report to Mr Baker.

A spokesman said that the changes will have little effect on the company’s pharmacy business, except that health care will now be directly represented on the company’s executive.



Pharmacist Alex Gourlay: new health care and store development director

Investigation by *The Sun* prompts Society action

The Royal Pharmaceutical Society has asked *The Sun* newspaper to share evidence that some pharmacists allegedly unlawfully sold prescription-only medicines to an undercover investigator without following the proper procedures for emergency supply.

According to *The Sun*, the investigator visited five pharmacies in the London area posing as an illegal immigrant without a prescription and was sold prescription drugs in three of them. The drugs reported to have been sold are temazepam, atenolol, amitriptyline, ranitidine, amoxicillin, flucloxacillin and diazepam.

In some cases a month’s supply is reported to have been sold, and in one case the reporter claims to have been sold the drugs by the owner of the shop who was not a pharmacist.

David Pruce, director of practice and quality improvement at the Society, said: “We are

concerned about some of *The Sun*’s findings and would ask the paper to share any evidence with us so that we can investigate.

“In an emergency, pharmacists are legally allowed to sell or supply a maximum of five day’s treatment of a prescription-only medicine under certain restrictions. However, temazepam, a Controlled Drug, is not allowed to be supplied in this way.” He added that the Society was “particularly concerned that one of the sales was made without a pharmacist being present. In supplying prescription-only medicines in emergencies a pharmacist must personally handle the request and be satisfied that the patient has an immediate need for the medicine and also that the patient has been prescribed the medicine before.”

He added: “We would want to investigate any supply which falls outside of these restrictions.”

Drug for chemotherapy-induced nausea and vomiting launched

A new single-dose drug for the treatment of chemotherapy-induced nausea and vomiting was launched this week by Cambridge Laboratories.

The company says that palonosetron (Aloxi), a second generation 5HT₃ antagonist, has a longer half-life — about 40 hours compared with four to nine hours for first generation drugs — and a greater ability to bind to the 5HT₃ receptors than the first generation drugs in its class.

Palonosetron is licensed for the prevention of acute nausea and vomiting associated with highly emetogenic and moderately emetogenic cancer chemotherapy. It is given as a single intravenous bolus of 250µg 30 minutes before chemotherapy. Repeated dosing within a seven-day interval is not recommended.

In two randomised controlled trials comparing palonosetron with dolasetron and ondansetron for the prevention of acute and delayed nausea and vomiting, palonosetron



Palonosetron is given as a single IV bolus 30 minutes before chemotherapy

was at least as effective as the comparators. The side effect profile is similar to that of first generation 5HT₃ antagonists, with headache and constipation being the most common.

Notice-board p705

Docetaxel increases breast cancer survival

Survival among women with operable, node-positive breast cancer is higher with adjuvant docetaxel therapy than with adjuvant fluorouracil therapy, according to new data.

In the breast cancer international research group trial, 1,491 women with axillary node-positive breast cancer were randomised to receive six cycles of treatment with either docetaxel plus doxorubicin and cyclophosphamide (TAC) or fluorouracil plus doxorubicin and cyclophosphamide (FAC).

According to interim results, at median follow-up of 55 months, the estimated rates of disease-free survival at five years were 75 per cent among patients receiving TAC compared with 68 per cent among those receiving FAC. This represents a 28 per cent reduction in the risk of relapse with TAC

therapy ($P=0.001$). Estimated rates of overall survival at five years were 87 per cent in the TAC group versus 81 per cent in the FAC group, and mortality was reduced by 30 per cent with TAC therapy ($P=0.008$). Incidence of neutropenia and infections were greater in the TAC group.

The researchers conclude that adjuvant chemotherapy with TAC has a therapeutic advantage over FAC, but at the expense of increased toxic side effects (*New England Journal of Medicine* 2005;352:2302).

Last month, a trial in which women with breast cancer were being treated with docetaxel plus doxorubicin was terminated because the regimen was associated with a high risk of life-threatening complications (*PJ*, 21 May, p605).

Dispensing robots installed

Three new dispensing robots have been installed in the Ipswich Hospital NHS Trust, as part of a £1.79m programme that includes building a new pharmacy manufacturing unit.

Meanwhile, in Wales, an automated dispensing system at the Princess of Wales Hospital in Bridgend was officially opened this week by health minister Brian Gibbons. Funding has also been provided to install robots at the Royal Gwent Hospital in Newport and the Royal Glamorgan Hospital in Llantrisant.

Daily ibuprofen use linked to increased breast cancer risk

Long-term daily use of ibuprofen may be associated with an increased risk of breast cancer, results of a study involving 114,000 women suggest (*Journal of the National Cancer Institute* 2005;97:805).

The study also found an association between aspirin and ibuprofen use and increased risks of oestrogen receptor and progesterone receptor-positive breast cancer. Women completed a questionnaire detailing their use of non-steroid anti-inflammatory drugs and cancer cases were reported through the California Cancer Registry.

Long-term users of ibuprofen were found to have a 51 per cent higher risk of breast cancer compared with non-users. The researchers say that if causality were subsequently proven, 16 of the observed 2,391 breast cancer cases and eight of the 713 non-localised breast cancer cases would be attributable to long-term daily use of ibuprofen. They point out, however, that it is not clear whether the observed association is causal, and say that their observations warrant further investigation.

“A more detailed understanding of the tissue-specific effects of NSAIDs, particularly in the context of the complex biological mechanisms involved in the development of different cancers, is also needed,” they add.

News in brief

Patient information records

The NHS Information Standards Board has launched a set of standards for documenting patient information. The standards are based on best practice from the Nursing and Midwifery Council, General Medical Council and Health Professions Council, and aim to provide a single model for recording patient records throughout the NHS in England.

HPA vaccine report

The Health Protection Agency has published a report on the current status of UK vaccine programmes. The report, “Protecting the health of England’s children; the benefit of vaccines”, provides information and data on the different diseases against which the routine national childhood vaccination programme currently offers protection.

E111 campaign

A campaign to promote use of E111 cover for European travel has been launched by the Department of Health. The E111 form will become known as the European Health Insurance Card from September.

PJ Online

Access to *PJ Online* is free to all

Treasures of the Royal Pharmaceutical Society

The series aims to raise awareness of key historical pharmacy-related material maintained by the Society. www.pjonline.com/series

Brain drain

Various articles on the emigration of health care professionals from developing to developed countries. www.pjonline.com/braindrain

Pharmacist-led company provides PIL user-testing

A pharmacist-led University of Leeds spin-out company, LUTO, has been set up to provide a patient information leaflet (PIL) testing service to the pharmaceutical industry. The company was developed in response to regulations making user testing of PILs mandatory. The regulations come into force in the UK on 1 July and in other EU member states on 31 October.

LUTO (Leeds University Testing Organisation) is led by Theo Raynor, professor of pharmacy practice at the university, who has worked for over 20 years in the field of patient-focused research into medicines labelling and leaflets.

He is joined by two other pharmacist directors — Burrinder Grewal, who brings commercial expertise, and John Blenkinsopp, a consultant to the pharmaceutical industry.



Mark Gibson, Burrinder Grewal, John Blenkinsopp, Theo Raynor and Peter Knapp

The team is completed by two directors from other disciplines at the University of Leeds — Peter Knapp, a psychologist, and Mark Gibson, a socio-linguist. LUTO provides

user testing of PILs, packs and other written material for patients to pharmaceutical companies and manufacturers of generic and over-the-counter products in the UK and Europe.

Google is primary health resource for 1 in 8

Google, the internet search engine, is the first port of call for 12 per cent of people looking for information on illness, a survey of 1,000 consumers has found. Medical practitioners, the first port of call for 52 per cent of consumers, are the only source of information more popular than Google.

A third of consumers (35 per cent) say they self-diagnose and tell a medical practitioner which conditions they believe they have before their consultation and a fifth (22 per cent) already have a treatment in mind before consulting a medical practitioner.

Commenting on the findings, Colette McCreedy, director of pharmacy practice at the National Pharmaceutical Association,

said: "Health care professionals all have to accept that the internet will become an increasingly important source of information and be aware of the risk that a patient will misdiagnose. As a result, we will become interpreters as well as providers of information about medicines and illness and we also need to ensure that patients use the internet in addition to, rather than as a replacement for, information from health care professionals."

"The lack of accreditation for internet sites is a problem as patients cannot tell which sites are authoritative and which are unreliable," she added. "Pharmacists can help patients by directing them to reliable sources of information, such as NHS Direct."

News in brief

British Library articles

The British Library has launched a pay-as-you-go service, giving access to the past five years of articles from the top 20,000 research journals. Articles can be ordered from <http://direct.bl.uk>.

UK PubMed Central

A group of major funders of science research, including the Wellcome Trust and the Medical Research Council, is planning to set up a free, open access, online database of peer-reviewed papers arising from research they have funded — a UK version of the US PubMed Central.

POEM

Chondroitin ineffective for pain relief in severe knee osteoarthritis

Clinical question Is chondroitin sulphate effective for pain relief or for preventing progression of osteoarthritis of the knee in patients with severe disease?

Bottom line After two years of treatment, chondroitin sulphate had no effect on comfort in patients with severe degenerative arthritis of the knee. Compared with placebo, however, it appears that chondroitin may have a small protective effect on the joint. The clinical relevance of this effect is not known.

Synopsis Patients between the ages of 40 and 85 years with clinically symptomatic knee osteoarthritis (OA) according to American College of Rheumatology criteria were eligible to participate in this study unless they had severe changes on x-ray (severely narrowed joint space with sclerosis of subchondral bone). The authors excluded patients with secondary OA and those with the most severe symptoms. The patients were randomly assigned (concealed allocation) to receive 800mg chondroitins 4 and 6 sulphate (n=150) or placebo (n=150) for two years. The main outcomes, assessed via intention to treat, were radiographic progression and symptom relief as measured by the WOMAC Index (Western Ontario and

McMaster Universities Osteoarthritis Index). Participants and study personnel did not know to which group the patients were assigned until the conclusion of the study. Even though only 219 patients of the 300 (73 per cent) completed the two-year study, the researchers carried forward the last observation (a debatable approach) and did an x-ray at the time of dropping out. At the end of two years, the patients taking chondroitin experienced no change in their joint space width from baseline; the patients taking placebo had narrowing of their joint space by an average 0.14mm (\pm 0.57mm; $P=0.04$). So it looks as if chondroitin may protect the joint from further deterioration. It had no effect, however, on pain.

Level of evidence 1b (individual randomised controlled trial with narrow confidence interval).

Reference Michel BA, Stucki G, Frey D, et al. Chondroitins 4 and 6 sulfate in osteoarthritis of the knee: a randomized, controlled trial. *Arthritis and Rheumatism* 2005;52:779–86.

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Trial vaccine reduces shingles pain in older people

Older people at risk of developing shingles (*Herpes zoster*) and associated neuropathic pain may benefit from a vaccine currently under investigation, new data suggest.

US researchers randomised 38,546 adults aged over 60 years to receive either a live attenuated varicella-zoster vaccine or placebo, and monitored them for the development of shingles. Among those vaccinated, 315 cases of shingles were confirmed compared with 642 among those given placebo.

Following positive diagnosis, the patients' pain and discomfort were measured repeatedly for six months, and the researchers used the incidence, severity and duration of the associated pain and discomfort to calculate the "burden of illness" in each group. They found that administration of the vaccine reduced



Dr P. Marazzi/SPL

Shingles rash: often followed by pain

the burden of illness by 61.1 per cent ($P<0.001$). The incidence of postherpetic neuralgia, the neuropathic pain syndrome that persists or develops after the rash has

healed, was also reduced by 66.5 per cent through use of the vaccine ($P<0.001$). The vaccine reduced the overall incidence of *Herpes zoster* by 51.3 per cent ($P<0.001$).

The incidence and severity of shingles and postherpetic neuralgia increase with age as a person's immunity to the varicella-zoster virus decreases. The researchers say that the vaccine boosts immunity to the virus, reducing the morbidity of the condition. Low rates of adverse effects were reported in the study.

However, since the investigational vaccine was at least 14 times more potent than the current vaccine licensed to prevent varicella (Varivax; Merck) the researchers say that the licensed vaccine cannot be recommended to protect against the virus (*New England Journal of Medicine* 2005;352:2271).

Novel tyrosine kinase inhibitor improves survival in patients with Glivec-resistant GIST

Survival in patients with gastrointestinal stromal tumours (GIST) who had become resistant to imatinib (Glivec) was improved by treatment with a new oral, multi-targeted tyrosine kinase inhibitor, SU11248. Treatment also achieved response in late-stage kidney cancer.

In a study, 312 patients with GIST who were resistant or intolerant to imatinib were randomised to SU11248 (25–75mg/day) or to careful observation, and switched to active treatment if their cancer progressed. Results showed that SU11248 more than quadrupled duration of disease control, with a median time to tumour progression of 6.3 months compared with 1.5 months (hazard ratio 0.335; $P<0.00001$). It also reduced the risk of death by approximately 51 per cent (hazard ratio 0.491; $P=0.00674$).

George Demetri, assistant professor of medicine, Dana Farber Cancer Institute, Boston, Massachusetts, said: "These results substantiate the concept that multi-targeted drugs such as SU11248, which blocks the tyrosine kinase enzymes controlling production of several molecular signals involved in tumour growth, can overcome resistance to other targeted drugs such as Glivec in cancer."

He explained that GIST was a key disease for investigating the effects of these inhibitors because it has mutations that cause the enzymes to become overactive. Two further studies in metastatic renal cell carcinoma showed a response rate of 40 per cent with SU11248.

The data were presented at the American Society of Clinical Oncology meeting in Orlando, Florida, last month.

New drug for skin infections

A novel lipoglycopeptide antibiotic, telavancin, has been shown to be beneficial for treating skin infections including methicillin-resistant *Staphylococcus aureus*.

Researchers randomised 167 patients with complicated skin infections to intravenous telavancin (7.5mg/kg per day) or standard therapy (either anti-staphylococcal penicillin four times daily or vancomycin twice daily).

Of those patients with *S aureus* infection at baseline 80 per cent of those treated with telavancin were cured compared with 77 per cent of those receiving standard therapy. And 82 per cent of patients infected with MRSA were cured with telavancin therapy compared with 69 per cent in the standard group. (*Clinical Infectious Diseases* 2005;40:1601).

Drug designed for lung cancer shrinks breast tumours

A drug that was originally designed for the treatment of lung cancer may be beneficial for patients with breast cancer, say researchers.

The European marketing application for gefitinib (Iressa) was withdrawn earlier this year after the drug failed to demonstrate increased survival in the overall population of lung cancer sufferers. However, the drug has now been shown to reduce the size of breast tumours when used alone or in combination with anastrozole (Arimidex) before surgery.

In a double-blind trial researchers randomised 56 postmenopausal women with early breast cancer to gefitinib 250mg daily plus anastrozole 1mg daily or to gefitinib 250mg daily plus placebo, for four to six weeks before surgery.

The breast cancers were all oestrogen-receptor positive and epidermal growth factor-receptor positive.

Tumour cell proliferation was reduced in both groups. Tumour size was reduced by 30–99 per cent in 14 out of the 28 patients taking gefitinib plus anastrozole and in 12 out of the 22 patients assigned gefitinib alone.

The researchers say that neoadjuvant hormonal therapy helps avoid the toxic effects of cytotoxic treatment and that reducing the size of large primary breast cancers may enable patients to undergo more conservative surgery. "Gefitinib, combined with an aromatase inhibitor, might have a role in the neoadjuvant treatment of breast cancer by reducing the size of the tumour more rapidly," they add.

They add that the treatment was well tolerated and that large scale studies of the use of gefitinib before breast cancer surgery are now being designed.

The study was published early online in *The Lancet Oncology*.

Gene therapy for arthritis

A therapeutic gene can be safely transferred into human rheumatoid joints, say researchers. They introduced a gene encoding the IL-1 receptor antagonist into synovial cells of nine women with rheumatoid arthritis, using an inactivated retrovirus. The cells expressing the transduced gene produced less inflammatory cytokines than cells not treated (*PNAS* 2005;102:8698).

News in brief

Growth factor may help Crohn's

Severity of Crohn's disease may be decreased by a haematopoietic growth factor. Researchers found that administering sargramostim 6µg/kg/day to patients with active Crohn's disease decreased disease severity and improved the patients' quality of life (*New England Journal of Medicine* 2005;352:2193).

Correction

Palonosetron (Aloxi) is licensed for the prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy, not just acute nausea and vomiting (p701).