

PGDs for pharmacy supply in event of biological incidents released by DoH

THE Department of Health has issued a set of patient group direction (PGD) templates that will enable pharmacists to supply treatment to people exposed to biological agents in mass casualty situations.

The templates include PGDs for the supply, by pharmacists and nurses, of ciprofloxacin tablets and doxycycline capsules to people known or suspected to have been exposed to anthrax, plague or tularaemia (a disease caused by the bacillus *Francisella tularensis*). There is also a PGD for registered health care professionals to supply potassium iodate tablets to people thought to have been, or expected to be, exposed to radioactive iodine.

The Journal understands that the templates were developed by the Department some time ago but that they have been released to primary care organisations now that emergency planning is being co-ordinated at a local level.

Sonia Colwill, pharmaceutical adviser for South East London Strategic Health Authority, was made aware of the PGDs last week and told *The Journal* that she has sent them to PCT pharmacy advisers. "I have suggested that as a minimum they should take them to the appropriate committees and get them signed off and then deploy them in whatever local plans they have."

She added that PCTs would need to think about how the PGDs will be used and

who will administer them.

Ms Colwill is also assistant director of pharmaceutical public health at Lambeth Primary Care Trust. The PCT is about to send information to local community pharmacists about what they should do in the event of an incident, such as if a contaminated person walks into the pharmacy. Although she could not give details of what pharmacists would be told, Ms Colwill said the information would be presented in a practical way. She added that Lambeth PCT was now involving pharmaceutical advisers and a community pharmacist in planning at a strategic level. "I think pharmacists will be involved in a reactive way," she said.

The PGDs for ciprofloxacin and doxycycline suggest that, if exposure to a biological agent has occurred or is suspected, an initial three days supply of treatment should be given as prophylaxis. The PGD gives information about who can be treated using the PGD (in both cases adults and children over 12 years). It also includes information



A supply of ciprofloxacin can be made by pharmacists under one of the PGDs released by the Department of Health

about patients in whom the benefits of using either drug are likely to outweigh the potential risks.

PGDs for administration of atropine and pralidoxime by paramedics and nurses to patients with nerve agent poisoning have also been published on the Department's website. Others will be published as they are developed. A link to the webpage, from which the PGDs can be downloaded, can be found on the *Pf Online* links page (www.pfonline.com/links).

Confusion over Scottish pharmacy regulations and competition

THE Government has failed to confirm whether pharmacy regulations in Scotland are a health matter devolved to the Scottish Parliament or a matter of competition policy over which the Westminster Parliament rules.

Asked for advice on the legal position, the Advocate-General for Scotland (Dr Lynda Clark) said: "In general terms, competition policy is reserved, while health matters are devolved, but the situation can be extremely complex when those matters meet and intersect."

Dr Clarke's statement came in the Westminster Parliament on 8 April in response to a request for clarification of whether the Scottish Parliament has power to reject the Office of Fair Trading's call for pharmacy regulations to be scrapped.

Following the exchange, Annabelle Ewing (SNP, Perth) said: "The question remains to be answered. Was the Scottish Executive announcement made in good faith after checking the legal position or was it just an attempt by Labour to kick this extremely important and sensitive issue into touch for the duration of the Scottish Parliamentary election campaign?"

Although doubt remains among lawmakers, Frank Owens, chairman of the Scottish Pharmaceutical General Council, is confident that the Scottish Executive cannot be overruled.

"The devolution settlement is not a matter of opinion, it is a matter of fact," he said. "The right of the Scottish Executive to make its own decision on Scotland's health care is unambiguous. Devolution means that the directly elected Scottish Government has the power to decide the path that is right for Scotland. The Department of Trade and Industry has explicitly recognised the power and the right of the Scottish Executive to reject the OFT proposal for Scotland's health care system."

"The will of the Scottish Parliament is clear — SPGC has not found a single MSP who supports the OFT recommendation. Revoking the control of entry system would require a vote by the Scottish Parliament and such a proposal currently has no support whatsoever. Centralisation of services by supermarkets is very unpopular with Scotland's decision-makers when it comes at the expense of local provision," he added.

Safeway rejects OFT

SAFeway has broken ranks with the other supermarkets and rejected the Office of Fair Trading's call for pharmacy deregulation.

Instead, Safeway wants the regulations to be improved. Control over new pharmacy contracts should rest with strategic health authorities, it says.

ROYAL PHARMACEUTICAL SOCIETY NEWS

Modernisation

The Council has adopted further recommendations concerned with modernisation of the Society. The 30 decisions are mainly concerned with eligibility to serve on the Council, its constitution, the register and registration (p521).

Special general meeting

A special general meeting has been requested to debate planned changes to the organisation of the Society. The meeting would also consider motions calling for lay membership of the Society's Council to remain at its current ratio and for a referendum of members on any proposed new Charter (p525).

UK backing for American call to make greater use of bar codes on packaging

ORGANISATIONS in the United Kingdom are backing a call by the United States Food and Drug Administration for the greater use of bar codes on pharmaceutical packaging.

Last month, the FDA proposed that all prescription medicines and some non-prescription medicines, vaccines and blood products should carry bar codes on their packaging. The FDA wants the bar codes to use the EAN.UCC (European Article Number.Uniform Code Council) system and carry, as a minimum, the product's US national drug number which identifies its strength and dosage form. The FDA is also asking whether additional information such as batch numbers and expiry dates should be included within the bar code.

The FDA says that the use of bar codes on medicines, together with bar codes on patient identification bracelets and comput-

erised medical records, would allow health care professionals to check the appropriateness of all medicines before they are administered to the patient.

Kevan Wind, National Health Service London and Eastern drug procurement specialist pharmacist, told *The Journal* that with a rise in automated dispensing and increasing use of patient packs in hospital and community pharmacy, greater use of bar codes would bring benefits in terms of patient safety and supply chain management.

He said that at present around 80 per cent of pharmaceutical products carry a bar code. Products from smaller manufacturers may lack a bar code and parallel imports may carry one that is not in the UK format.

Mr Wind is a member of the committee of PharmEDI, a group for parties interested in the use of information technology in the pharmaceutical supply chain. PharmEDI is

keen to see greater use of bar codes to improve transparency — “so that we are all talking about the same thing” — and wants to see the National Health Service Information Authority and the Purchasing and Supply Authority take a lead.

In terms of adding batch specific information, Mr Wind pointed out that this would result in additional costs for manufacturers. Bar codes would have to be printed on individual packs rather than printed on mass on packaging designed to hold many different batches of a product.

The FDA's proposals are also being supported by e.centre, the UK authority for the EAN.UCC system. Steve Coussins, e.centre's chief executive, said there is limited use of the codes in pharmacies and that it will be campaigning “to ensure that this important ruling by the FDA will pave the way to improved patient safety in the UK”.

Lay members appointed to health regulation body

EIGHT lay members have been appointed to the Council for the Regulation of Health Care Professionals, which is to oversee the health care professions' regulatory bodies.

Six members have been appointed by the National Health Service Appointments Commission to represent lay interests in England. They are:

- Sue Leggate — a consumer affairs specialist and a Consumers' Association council member
- Peter North — a retired Royal Air Force officer and lay assessor for the General Medical Council
- Hugh Ross — programme director for the Bristol Health Services Plan and former NHS trust chief executive
- Lois Willis — a member of the Motor Neurone Disease Association care centres review panel

- Kieran Walshe — reader in public management and director of research for the Manchester University Centre for Healthcare Management
- Sally Williams — an independent health policy adviser and a lay member of the Royal College of Surgeons of England Patient Liaison Group

Two further lay members appointed by ministers in Scotland and Wales are:

- Dr Frances Dow — vice-principal at the University of Edinburgh
- David Smith — a lecturer and food policy adviser in Wales

The council's chairman is Jane Wesson (*P7*, 15 February, p216). The Royal Pharmaceutical Society's representative is its President, Marshall Davies.

Medicine imports and exports rising

IMPORTS and exports of medicines to and from the United Kingdom rose sharply last year, according to figures from the Association of the British Pharmaceutical Industry.

Imports rose by around £1bn to £7.44bn in 2002 while exports rose by a similar amount to £10.03bn, giving a balance of trade of £2.59bn, slightly lower than last year. The ABPI says that Government initiatives such as national service frameworks are driving an increased use of pharmaceuticals by the National Health Service with an estimated 707 million prescription items dispensed in England last year, an average of 11.7 items per person a year. This is still under 13 per cent of NHS spending, the ABPI says.

The amount spent by pharmaceutical companies on research and development rose to £3.17bn.

ABPI annual review 2002, ABPI, 12 Whitehall, London SW1A 2DY (tel 020 7930 3477).

Switching statins leads to theoretical drug interactions

DELIBERATELY switching hospital patients to simvastatin (Zocor) from other statins raises theoretical problems of drug interactions that are not seen in practice, hospital pharmacists told participants at the American College of Cardiology meeting in Chicago last week.

The number of patients with theoretical recorded drug interactions rose from 6.1 per cent to 16.4 per cent when most patients admitted to five hospitals had their statin therapy switched to equivalent doses of simvastatin. However, no increase in side effects was noted. Most of the increase was related to a potential interaction between simvastatin and diltiazem that is not included in either the American or United Kingdom summary of product characteristics for Zocor.

Peter Dumo, PharmD, of Harper University Hospital, Detroit, and Wayne State University presented data on a therapeutic intervention policy (*Journal of the American College of Cardiology* 2003;41[Suppl A]:525A). He explained to *The Journal* during the meeting that the intervention policy had been agreed by the hospital group pharmacy and therapeutics committee. The proportion of patients taking simvastatin rose from around one-third to nine-tenths after the policy started in March 2002. Only patients on the highest dose of atorvastatin (Lipitor) or those where the prescriber specifies "dispense as written" are not switched. Prescriptions for other products received in the pharmacy are changed automatically. A note is sent to the prescriber and a sticker placed in the patient's notes.

Professor Dumo said that the most important thing about the therapeutic intervention process,

a common formulary management approach in the United States, is to evaluate the changes made afterwards. "A lot of people are making changes, but not many are looking at the effects," he said. "When doing therapeutic intervention with any drug there is a potential risk of reduced efficacy. Safe processes are the key and there must be a review to see that these are working."

The hospital group has carried out a similar intervention switching patients to amlodipine (Istin) from other dihydropyridine calcium channel blockers, again without any major adverse events being recorded. Professor Dumo was unable to give any figures for the savings made or costs incurred by the pharmacy department for either of the interventions.

Other research presented at the ACC meeting is reported on page 506 of the week's *Journal*.

Prescriber training to start by summer

UNIVERSITIES in England are set to offer training in supplementary prescribing for pharmacists, with courses expected to start by the summer.

Keele University is planning a supplementary prescribing course that will run alongside its existing postgraduate programme in prescribing studies. Those taking the supplementary prescribing course will be able to earn credits towards a master of science degree. Professor Stephen Chapman, head of medicines management at Keele, said that some of the course sessions will be run jointly with nurse prescriber training. The first pharmacists are expected to start training in the summer.

The School of Pharmacy, University of London, and St Bartholomew school of nursing and midwifery, City University, London, are creating a joint lecturer post in prescribing in health care. The post holder will teach prospective supplementary prescribers at both institutions, starting this spring. The two universities collaborated on an extended nurse prescribing course and have a joint lecturer post in medicines risk management together with the academic pharmacy unit at Barts and the London NHS Trust. The new prescribing lecturer will also be associated with the academic pharmacy unit.

Regular use of aspirin and ibuprofen protects against breast cancer

REGULAR use of ibuprofen and aspirin protects women against breast cancer, say researchers from Ohio State University.

They used data from the Women's Health Initiative, which enrolled 80,741 postmenopausal women aged between 50 and 79 years with no reported history of any cancer. Of those enrolled, 1,392 were later diagnosed with breast cancer.

The researchers estimate that women taking two or more non-steroidal anti-inflammatory drugs per week for five to nine years reduced their risk of breast cancer by 21 per cent. Use for 10 or more years was associated with a risk reduction of 28 per cent.

The researchers adjusted the estimated probability of developing breast cancer for age and other breast cancer risk factors (eg, body mass, oestrogen use, family history and exercise) and found that the risk remained stable. Ibuprofen was more effective than aspirin in preventing breast cancer (49 per cent vs 21 per cent) and that regular use of low-dose aspirin (<100mg) had no effect.

The data are published in the Proceedings of the 94th Annual Meeting of the American Association for Cancer Research (www.aacr.org).

Which? calls for independent body for patient information and group support

PATIENT organisations should publish details of who their sponsors are and should make their funding policies widely available, says a report in this month's *Which?*. It adds that organisations should avoid direct sponsorship and calls for a central, independent body for patient information that could, in the long term, provide financial support for patient organisations.

The Consumers' Association, publisher of *Which?*, is critical of the amount of funding that comes from the pharmaceutical industry and suggests that companies use patient organisations to promote their own messages. "Accepting funds from drug manufacturers inevitably raises questions about an organisation's independence," it says.

Which? contacted various patient groups and found that many receive funding or sponsorship from pharmaceutical companies. It gives examples of cases that it suggests raise questions about the independence of particular organisations. For example, it points out that the National Eczema Society (which receives donations from 14 drug manufacturers) has run a successful campaign to have eczema guidelines removed from general practitioners' computer-based prescribing systems. The NES had concerns that guidelines did not include details of the most up-to-date treatments. However, *Which?* suggests that this campaign has left GPs without consistent guidance and says that some of the treatments

not listed in the guidelines were likely to have been made by the sponsors of the NES.

A spokesman for the NES said the charity was disappointed that *Which?* had produced such a "superficial and misleading account" of pharmaceutical company funding of patient support organisations. "The NES has always been clear in its outright refusal under any circumstances to endorse or promote specific products. This is made clear in all publications and on our website." He added that people with eczema would rightly expect the NES to provide them with information about any new treatment with proven clinical efficacy. "The Consumers' Association, by adopting a writing style which implies a lack of independence and which might be seen by many as suggesting some sinister motives on the part of those involved, is at best mischievous," he said.

The *Which?* report also looked at patient organisation websites to find out how transparent their funding policies are. Of 125 patient organisations, 32 list their donors and only two of these — the Alzheimer's Society and Diabetes UK — explain their funding policy.

The Long-term Medical Conditions Alliance has published guidelines for patient groups about working with the industry and suggests that all patient groups should adopt a policy setting out their position on corporate support.

David Pink, chief executive of the LMCA, told *The Journal* that the report raised an important issue but he did not think that patients had reason to be concerned. "Patient organisations in the UK are fiercely independent. Most are wary about bias being brought to their activities by pharmaceutical companies."

Live lecture sessions on the internet

LECTURES and discussions are to be broadcast live on the internet by the Royal College of Physicians for doctors, pharmacists and nurses who want to see them. Viewers will also be able to send in questions and have them answered in real time. Called

RCPlive, the broadcasts start with two talks on epilepsy from 8pm to 9pm on 29 April. The second topic — multiple sclerosis — will be covered on 4 June.

Users need to register in advance at www.rcplive.ac for access to the broadcasts.

Internet pharmacies put people at risk, researchers say

BUYING non-prescription and complementary medicines via the internet is not safe. That is the stark conclusion of research conducted from Australia in the summer of 2001 (*Quality and Safety in Health Care* 2003;12:88).

The quality of information about two products — Sudafed (pseudoephedrine) and a preparation of St John's Wort — was assessed on 104 e-pharmacy websites in 13 countries and the products ordered from sites that offered delivery to Australia.

The researchers say that 21 of the 25 websites that offered information about pseudoephedrine provided useful information about its benefits, but that only 13 of them included useful information on risks associated with the drug.

Nineteen websites published information about St John's Wort, with 17 and 18 of them respectively giving useful information on benefits and risks.

"This study shows that consumers who self-select non-prescription medicines from e-pharmacies are at risk of medication misadventures," the researchers say.

PJ Online

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

Severe acute respiratory syndrome

Links to information from the Chief Medical Officer, WHO, Public Health Laboratory Service, Department of Health and *The Journal*.

www.pjonline.com/topics

Hay fever

Articles on pharmacy management of hay fever and pollen count links.

www.pjonline.com/links/hayfever

Botanical dermatology database

Information on plants and plant products as causes of adverse skin reactions.

www.pjonline.com/links/dermatology

Clinical leaders of thrombosis

An anti-coagulation and deep vein thrombosis special interest group for health care professionals including pharmacists.

www.pjonline.com/links/thrombosis

Pharmaceutical companies

A growing list of pharmaceutical companies and pharmacy chains, with a link to ABPI member organisations.

www.pjonline.com/links/companies

Diary

- Local/branch meetings
- Future events/Society meetings
- Conferences
- Reunions
- Health events

www.pjonline.com/diary

Care needed over use of obesity drug in teenagers

DESPITE showing that sibutramine (Reductil) can help teenagers lose weight, the authors of a new study say that drugs used for weight loss should only be used for this age group as part of a clinical trial.

Dr Robert Berkowitz, of the University of Pennsylvania school of medicine, Philadelphia, and colleagues conducted a double-blind trial involving 82 obese adolescents aged 13 to 17 years. All of the teenagers in the study received the same family-based behavioural weight loss programme but half were randomised to receive 5mg of sibutramine daily while half received placebo. The dose of sibutramine was increased to 10mg daily after three weeks and to 15mg daily after seven weeks.

The researchers found that after six months' treatment, teenagers in the sibutramine group had lost 7.8kg (± 6.3 kg) equal to an 8.5 per cent reduction in body mass index (BMI). In contrast, adolescents treated with placebo lost 3.2kg (± 6.1 kg) equal to a 4.0 per cent reduction in BMI. In addition, more than twice as many sibutramine-treated teenagers than placebo-treated teenagers had their initial BMI reduced by 10 per cent and 15 per cent ($P=0.02$ for both).

The researchers comment that adolescents who adhered closely to the behavioural programme and who were treated with sibutramine achieved the greatest decrease in BMI during the first six months. "The behavioural and pharmacological treatments appeared to have additive effects that maximised weight loss," they say.

Despite their findings, the researchers are cautious about recommending the use of weight loss drugs for the treatment of obe-

sity in children and adolescents. They point out that patients taking sibutramine must be carefully monitored to control increases in blood pressure and pulse rate. "Until more extensive safety and efficacy data are available . . . weight-loss medications should be used only on an experimental basis for adolescents," they say (*JAMA* 2003;289:1805).

Authors of an accompanying editorial (*ibid*, p1851) comment that improvements seen in co-morbid conditions associated with obesity, such as insulin resistance and dyslipidemia, were no different in adolescents receiving sibutramine or placebo. In addition, they point out that it is unknown whether sibutramine will continue to be effective for reducing body weight in the long term.

Reductil is not licensed for use in children and adolescents under 18 years or in adults over 65 years.

Launch of triptan with long half-life for acute migraine

A NEW triptan, frovatriptan (Migard), for the acute treatment of headaches in migraine with or without aura has been launched by Menarini (see p510).

Vernalis, which developed frovatriptan and has licensed it to Menarini, says that the 5-HT_{1B/D} agonist differs from other triptans in that it has a half-life of 26 hours, four to eight times longer than other drugs in the same class. The company adds that this attribute, together with data from clinical studies, suggests that frovatriptan has a particular benefit for patients with long-lasting migraine attacks.

Phase III data presented at the American Academy of Neurology annual meeting held in Reading, Berkshire, earlier this month confirm that frovatriptan is effective in preventing menstrual migraine when administered for six days during menstruation.

Training package for schizophrenia guideline launched

AN INTERACTIVE electronic training package to help health care professionals use the National Institute for Clinical Excellence schizophrenia guideline was launched recently by the National Collaborating Centre for Mental Health.

The launch of the training package coincided with publication of "Schizophrenia: full national clinical guideline on core interventions in primary and secondary care", which contains all the evidence considered in the production of the shorter NICE guideline published in December 2002 (*Pfj*, 7 December 2002, p799).

The training package is available via the internet (a link to the guideline appears on *Pfj Online* at www.pjnline.com/links) and as a CD-ROM (available from the NHS response line, tel 0870 1555 455, quote reference N0203).

BRIEFLY

Pegfilgrastim launched this week

A long-acting form of filgrastim (Neupogen), pegfilgrastim (Neulasta), has been launched by Amgen this week (see p510). The new formulation contains a polyethylene glycol (PEG) molecule bonded to the filgrastim molecule and can be administered once per chemotherapy cycle rather than by daily injections, as is the case with filgrastim.

Corona virus main cause of SARS

A new virus belonging to the Coronaviridae family is likely to be the main cause of severe acute respiratory syndrome (SARS), researchers suggest. They studied 50 patients with SARS from five separate outbreak clusters and found evidence of the virus in 90 per cent of patients. The new corona virus was not present in any patients belonging to a control group. The research is published on *The Lancet's* website (www.thelancet.com).

H pylori and reflux disease

Helicobacter pylori infection is less prevalent among patients with gastro-oesophageal reflux disease than among those without the disease, a systematic review has shown. Researchers looked at 20 studies involving 4,134 patients and found that the average prevalence of *H pylori* infection in patients with reflux disease was 38.2 per cent compared with 49.5 per cent for the comparator group. There was substantial heterogeneity between studies with patients from the Far East with reflux disease having a lower prevalence of infection than patients from western Europe and North America (*BMJ* 2003;326:737).

Sickle cell drug prevents deaths

Adults with moderate to severe sickle cell anaemia who take hydroxyurea have a lower mortality than those patients not taking this drug, a new study shows (*JAMA* 2003;289:1645). Researchers estimated that the overall reduction in mortality after nine years of follow-up was 40 per cent. They add that over this period, no unexpected serious adverse effects of the treatment were observed.

DHEA of no benefit in Alzheimer's

Dehydroepiandrosterone (DHEA), a supplement available from internet websites, does not improve cognitive performance in patients with Alzheimer's disease, say researchers. They conducted a randomised trial of DHEA versus placebo in 58 patients over six months and found that although a transient improvement in cognitive performance was seen at three months in the DHEA group, it narrowly missed statistical significance. No effect on cognitive function or global improvement was seen at six months (*Neurology* 2003;60:1071).

Rowlands pharmacies to be rebranded

ROWLANDS pharmacies, part of the chain owned by the Phoenix wholesaling group, are to receive a new look with the aim of emphasising their group identity.

Kenny Black, commercial director, Rowlands, said a recent survey showed that customers of the chain are confused by the dual Rowlands and Numark branding carried by many of its pharmacies.

As part of the new look, "Rowlands" is more prominent, overlying "Numark" on the fascia alongside the group's version of the pharmacy cross (see picture, right).

Rowlands is the largest shareholder in Numark.



New education centre facility to be opened in London pharmacy

NEW education facilities are to be introduced by Greenlight Pharmacy in north London.

Pharmacist Tim O'Donoghue told *The Journal* that he currently offers seminars in the evenings after the pharmacy has closed. "This means after 7.30pm, which might not be a good time for the community," he explained. So, to overcome the problem, the pharmacy's basement is to be made into an educational centre with consulting rooms.

The idea is that different groups of people will be able to use the educational centre: it will not just be reserved for pharmacist-run sessions. Because the centre has been given this community focus, the scheme has been granted £75,000 of funding by the West Euston Partnership. The pharmacy is situated in a deprived area and the West Euston Partnership aims to regenerate the local area.

Funding for hospital manufacturing

HOSPITAL manufacturing units in England are set to receive £42m over the next three years, according to Dr Jim Smith, chief pharmaceutical officer, speaking at the Guild of Healthcare Pharmacists annual meeting in Bristol on 5 April.

Dr Smith said that it was established that the service was fragmented and an effective infrastructure was lacking. He added that guidance is to be released soon on how the money should be used to support hospital manufacturing, and that emphasis will be placed on aseptic preparations and oncology services.

Dr Smith also commented on how unusual it was for someone like himself, a civil servant, to make this sort of announcement. He had stepped in at short notice to take the place not only of Lord Hunt, who had resigned as health minister over the invasion of Iraq, but also his replacement who was unable to attend the meeting.

The scheme involves not only the refurbishment of the basement but also installing lift access for wheelchairs and a second entrance to the basement to allow independent access without going through the pharmacy. Building starts this month.

Mr O'Donoghue comments that the centre demonstrates the pharmacy's active role in the community and will encourage the public to appreciate the educational role pharmacists can provide.

Greenlight Pharmacy was featured in *The Guardian* newspaper on 9 April as a model community pharmacy. It highlights the pharmacy's clinical focus, such as not selling cosmetics and photographic goods, and the fact that the pharmacists spend 80 per cent of their time in front of the counter. A regular patient is quoted as saying: "Half the time, I think my doctor doesn't have time, whereas here they listen."

Glucosamine daily doses vary widely

WIDE variation in the recommended dose of glucosamine sulphate has been identified by *Health Which?*

An article in the April issue of the magazine says that some suppliers of glucosamine suggest a daily dose below 1,500mg a day — the amount most commonly used in clinical trials. Recommended daily doses varied between 500mg and 2,000mg.

In addition, the price per gram of glucosamine varied from 11.1p to 60.6p. The price differences did not appear to be linked to the amount of glucosamine in the supplement, the article adds.

Holland & Barrett's supplement was subjected to particular criticism. It inaccurately described the content of glucosamine sulphate in its product, says the magazine.

Health Which? concludes: "Our advice is to choose the cheapest brand, which will deliver 1,500mg of glucosamine sulphate a day."

Prescriptions from hospitals cause problems in the community

HOSPITAL doctors receive inadequate training in writing outpatient prescriptions, according to preliminary research presented by Mike Wilcock, Royal Cornwall Hospital, Truro, speaking on 7 April at the launch of the 2003 joint National Pharmaceutical Association and Guild of Healthcare Pharmacists award, sponsored by Merck Sharp & Dohme.

Mr Wilcock, who won the 2002 MSD award with colleague Ros McLaughlin, also suggested that community pharmacists find it difficult to contact hospital-based prescribers to query items on FP10(HP) prescription forms.

The final results from the project, which is examining how community pharmacists can help secondary care prescribers, will be presented at the British Pharmaceutical Conference in Harrogate in September.

The MSD award aims to promote partnership between pharmacists working in primary and secondary health care in order to improve patient care.

Notice-Board, p511

BRIEFLY

Call for 24-hour pharmacies

A substantial increase in health care delivery by pharmacists, accompanied by prescribing powers, is needed in London.

So says a joint report on primary care produced by the London Assembly and the Mayor of London, Ken Livingstone. The report, "Access to primary care", says that each primary care trust should ensure that 24-hour pharmacy services are available in at least one place to match the 24-hour services provided by general practitioners and hospitals.

Cholesterol absorption inhibitor adds to reductions in heart disease marker

ADDING ezetimibe (Ezetrol), a cholesterol absorption inhibitor, to low-dose simvastatin (Zocor) gives an additional reduction in C-reactive protein (CRP), an important independent marker for cardiovascular events and atherosclerosis.

Dr Philip Sager, cardiovascular clinical project director, Schering Plough, told *The Journal*, that when added to simvastatin at doses of 10mg, 20mg, 40mg or 80mg, ezetimibe 10mg produces further reductions in lipid levels.

In a trial of 668 patients, low-density lipoprotein cholesterol was reduced by 49.9 per cent in the ezetimibe plus simvastatin group compared with an average of 36.1 per cent in those given simvastatin alone ($P<0.01$). In addition, there were further reductions in CRP (34.8 per cent vs 18.2 per cent, $P<0.01$). The reductions in CRP seen with ezetimibe plus 10mg simvastatin were the same as those for 80mg simvastatin alone (*Journal of American College of Cardiology* 2003;41[Suppl A]:316A).

Dr Sager, speaking during the ACC meeting in Chicago last week, said that doc-

tors are often not good at titrating patients to higher doses of statins and there are concerns about adverse effects of taking high doses. Adding a second drug might be seen as an easier way of achieving lower lipid targets. He noted that in the United States combination products have become more popular for treating hypertension in order to improve

patient compliance. A combination of ezetimibe and a statin is under development.

In trials, ezetimibe monotherapy had an adverse event profile similar to that of placebo and when combined with statins and adverse events were similar to those seen with statins. Dr Sager said that reversible episodes of elevated liver enzymes had been seen, but such rises had also been seen with non-systemic treatments such as resin binding agents and aggressive low-fat diets.

In order to see if the effects of ezetimibe on CRP lead to atherosclerotic regression, a phase III study in Europe, under the acronym ENHANCE, will look at the effects of ezetimibe 10mg and simvastatin 80mg in comparison with simvastatin 80mg alone on carotid artery wall thickness in patients with high cholesterol levels. Other ongoing trials are looking at combination therapy in patients with hyperlipidaemia and either chronic kidney disease (SHARP trial) or aortic stenosis (SEAS trial).

Ezetimibe is expected to be launched in the United Kingdom later this year by a Merck Schering-Plough joint venture.

Nesiritide shortens hospital stay in heart failure

NESIRITIDE (Natrecor), a recombinant form of human B-type natriuretic peptide, significantly shortens the time patients with acutely decompensated heart failure stay in hospital, new data show. However, other results suggest that the drug may increase the risk of death compared with current treatments.

When administered intravenously, nesiritide causes dilation of arteries and veins without increasing heart rate. In a study of 130 patients consecutively discharged from the coronary care unit at Loma Linda University Medical Centre, California, 58 patients received nesiritide. Although the patients who received nesiritide had worse clinical symptoms on admission, they had shorter hospital stays (2.87 vs 3.79 days, respective-

ly, $P=0.002$) (*Journal of American College of Cardiology* 2003;41[Suppl A]:161A).

Results of another study suggest that nesiritide might be a higher risk treatment for acutely decompensated heart failure than existing diuretic and vasodilating drugs. Researchers from St Luke's-Roosevelt Hospital, New York, calculated the risk of death at 30 days and six months using data from two published trials which used nesiritide.

Using crude mortality data, they found a trend towards higher mortality from using nesiritide in 735 patients followed for 30 days (7.2 vs 3.6 per cent, odds ratio 1.97, 95 per cent confidence interval 0.98-3.95, $P=0.057$). At six months, on an intention-to-treat basis, there was still a trend towards a

higher risk of death for patients taking nesiritide (33 per cent for adjustable dosing, 22 per cent for fixed dosing and 20 for existing treatment, $P=0.068$).

The researchers comment: "Although effective at reducing symptoms compared with placebo, the modest acute clinical benefit compared with [existing therapy] (when including intravenous nitroglycerin) coupled with possible long-term risk need to be considered prior to widespread clinical use." (*Ibid*, p161A).

The drug, developed by Scios Inc, is currently being submitted for marketing authorisation in Europe where it will be marketed by GlaxoSmithKline. Data were presented at the American College of Cardiology meeting in Chicago last week.

Aldosterone blocker improves survival in heart failure after MI

ADDING eplerenone (Inspra), a selective aldosterone blocker, to optimal treatment in patients with left ventricular dysfunction after a myocardial infarction reduces deaths due to cardiovascular events, according to data presented at the American College of Cardiology meeting in Chicago last week.

The study, which used the acronym EPHEsus, randomised 6,642 patients to receive either eplerenone 25-50mg or placebo daily. After an average of 16 months of follow-up, there were 478 deaths in the eplerenone group and 554 in the placebo group (relative risk 0.85, 95 per cent confidence interval 0.75-0.96, $P=0.008$). Of these deaths, 407 in the active group and 483 in the controls were attributed to cardiovascular causes (relative risk 0.83, CI 0.72-0.94, $P=0.005$). There was also a 15 per cent reduction in the risk of being

admitted to hospital for heart failure in the eplerenone group and 23 per cent fewer episodes of hospital admission for heart failure.

Dr Bertram Pitt, University of Michigan, Ann Arbor, lead investigator for the EPHEsus trial, said at the ACC conference that eplerenone was beneficial in patients who were already receiving optimal therapy, including angiotensin-converting-enzyme inhibitors, beta-blockers and lipid-lowering agents. This trial shows that on top of what we currently have we can do better, he said.

He added that the lack of a spironolactone control arm in the study was due to there having been no data to show that spironolactone was effective post-MI at the time the trial was designed.

The trial was published last week in *The New England Journal of Medicine* (2003; 348:1309).

The Pharmaceutical Journal attended the American College of Cardiology congress courtesy of Merck/Schering-Plough Pharmaceuticals

Monoclonal antibody may provide protection for peanut allergy sufferers

AN EXPERIMENTAL monoclonal antibody may provide protection against the effects of accidental peanut ingestion in peanut allergy sufferers, researchers report.

Dr Donald Leung, National Jewish Medical and Research Centre, Denver, and colleagues say that for patients with peanut allergy there is currently no adequate treatment for, or protection against, accidental ingestion of peanuts other than avoidance, although adrenaline modulates the reaction and can be lifesaving.

However, the researchers have found a humanised IgG1 monoclonal antibody against IgE, TNX-901, that, at a dose of 450mg administered subcutaneously every four weeks, substantially increases threshold peanut antigen sensitivity to a level that should provide at least partial protection against most unintended peanut ingestion. TNX-901 recognises and masks an epitope in a region of IgE responsible for binding to high-affinity receptors for IgE on mast cells and basophils.

Data were analysed for 82 patients with a history of peanut allergy manifested by urticaria, angioedema, lower respiratory tract symptoms or hypotension. Subjects were randomly assigned to receive TNX-901 150mg, 300mg or 450mg or placebo subcutaneously every four weeks for four doses. Threshold doses of encapsulated peanut flour were established at screening.

THX-901 450mg increased the threshold of peanut sensitivity from a level equivalent to approximately half a peanut to one equal to almost nine peanuts (the average amount of peanut consumed in an accidental exposure is believed to be not more than one or two peanuts, although this has not been accurately quantified, the researchers say). A total of 21 per cent of patients in the 300mg group (n=19) and 24 per cent in the 450mg group (n=21) were effectively desensitised and able to ingest about 24 peanuts, the final dose in the food challenge, before having a reaction.

The researchers conclude that, although the results are encouraging,

“TNX-901 is still an experimental drug and approval for general use will require confirmation of these results in additional studies” (*New England Journal of Medicine* 2003; 348:986).

Molecule promising for alleviating symptoms in Parkinson's disease

A NATURALLY occurring molecule injected directly into the brains of patients with Parkinson's disease may help alleviate symptoms, a new study shows.

The molecule, glial cell line-derived neurotrophic factor (GDNF), is involved in the development and maintenance of dopamine neurons in the substantia nigra and has restorative effects in rodent and primate models of Parkinson's disease. However, penetration into brain tissue from either the blood or the cerebrospinal fluid is limited.

In a phase I trial, researchers delivered GDNF directly into the brains of five patients with idiopathic, L-dopa-responsive Parkinson's disease who were poorly controlled on optimal medical therapy. GDNF

was infused directly into a region of the brain most severely depleted of dopamine in Parkinson's disease.

They found that GDNF led to increases in dopamine storage and that symptoms improved in all five patients after three months of treatment. Reductions in many of the rating scores for Parkinson's disease were seen. GDNF can be tolerated for one year.

However, the researchers point out that precise functional effects of GDNF delivery have not yet been determined because of the open nature of the trial and the small number of patients. The study warrants careful examination of GDNF as a treatment for Parkinson's disease, they say. The study is to be published in the May issue of *Nature Medicine*.

New antifungal for oesophageal candidiasis

AN ANTIFUNGAL agent in development, anidulafungin, is as effective as fluconazole in the treatment of oesophageal candidiasis, new data show. Anidulafungin, which is being developed by Vicuron Pharmaceuticals, belongs to a class of antifungals known as echinocandins.

The company says that, in preclinical studies, anidulafungin has been shown to destroy more than 99 per cent of candida, including fluconazole-resistant strains.

In a phase III trial, researchers randomly assigned around 600 patients to receive one of two regimens: anidulafungin 100mg intravenously plus oral placebo on day one followed by anidulafungin 50mg intravenously

plus oral placebo daily for 14 to 21 days; or fluconazole 200mg orally with intravenous placebo on day one followed by fluconazole 100mg with intravenous placebo daily for 14 to 21 days.

Oesophageal candidiasis was cleared in 97.2 per cent of patients treated with anidulafungin (n=249) and in 98.8 per cent of patients treated with fluconazole (n=255). However, a higher relapse rate occurred in patients treated with anidulafungin than in those treated with fluconazole.

Vicuron Pharmaceuticals plans to file for a licence in the United Kingdom, as part of European approval, during the second half of this year.

BRIEFLY

Antiepileptic drug for obesity

Antiepileptic drug zonisamide plus a hypocaloric diet results in more weight loss than placebo plus a hypocaloric diet when used in the treatment of obesity, researchers report in *JAMA* this week (2003;289:1820). Zonisamide has serotonergic and dopaminergic activity and weight loss is an adverse effect associated with the drug. Zonisamide is manufactured by Elan Pharmaceuticals.

Benefit of new antiviral continue

The benefits of adding enfuvirtide (T-20, Fuzeon), an HIV type-1 fusion inhibitor, to an optimised antiretroviral regimens in patients who had previously received multiple antiretroviral drugs has been reported online in *The New England Journal of Medicine* (www.nejm.org). Enfuvirtide, which is being developed by Roche and Trimeris, is expected to be launched in the United Kingdom in the next few months.

New basal insulin analogue

A new basal insulin analogue, insulin detemir (Levemir), provides more predictable glycaemic control than current basal insulins, according to data presented at a Diabetes Dialogue conference held in Geneva last week. It has also been found to be associated with fewer episodes of hypoglycaemia and less weight gain than other basal insulins. Novo Nordisk expects to launch insulin detemir in the United Kingdom later this year.