

Boots launches private PGD service to supply Viagra

Four pharmacists in the north west of England this week became the first in the UK to offer the erectile dysfunction drug sildenafil (Viagra) to patients through a private patient group direction (PGD). The pharmacists, who are employed by Boots at three of its stores in Manchester and Salford, have signed up to the pilot, which is being run as a private health care service.

If the pilot is successful Boots plans to roll it out to other branches, although this decision is unlikely to be made before the end of the year.

The local pharmaceutical committee is disappointed that it knew nothing about the scheme until it appeared in the media last weekend. Manchester LPC secretary Pauline Thickett said: "It just seems that Boots is going off on its own way and not involving

other pharmacists locally. It would have been nice as LPC secretary to have known about this beforehand, rather than having to find out about it on the news."

Under the erectile dysfunction programme the Boots pharmacists will only be able to offer patients Viagra. If they decide a patient would benefit from an alternative erectile dysfunction drug they have to refer the patient to their GP. Pharmacists have been trained over the past nine months to work to a protocol developed by an advisory expert panel.

The programme, which is only available to men aged between 30 and 65 years who are registered with a GP in the UK, has taken two years to develop. Manchester was chosen as the pilot area because the company can trial the initiative in three distinctly different Boots stores. Boots is confident that the



Boots pharmacies will offer sildenafil to men through a private PGD

rigour of the pharmacist consultation and the protocol will prevent the service being abused by men who want sildenafil for lifestyle, rather than clinical, reasons.

Kevin Reilly, Boots's health care development manager, said: "The bottom line here is that PGDs are very strict and patients will be screened for the service. If you were a fraud and wanted four tablets of Viagra (for lifestyle reasons) there are much easier ways of doing that than going through this programme."

Boots is hoping that its initiative, being marketed under the banner "Boots Pharmacy+ ED Programme", will help reach the 90 per cent of men whom it estimates have erectile dysfunction but go untreated.

How the programme will work

Men interested in obtaining sildenafil will be able to telephone to book an appointment for a consultation with the pharmacist. Consultations, which will take place in the pharmacy, are expected to take between 45 minutes to an hour. The pharmacist will take the patient's medical history, assess his symptoms of erectile dysfunction as well as check his cholesterol, blood pressure and glucose levels before deciding whether to issue a packet of four tablets. The pharmacy consultation and medicine will cost £50.

The pharmacist will also inform the patient's GP about the consultation and its outcome. If a patient wants further packets of sildenafil he will have to agree to a consultation with a Boots-nominated private GP. The consultation will cost £37.50 and the Viagra £21.25.

Bar too high for private PGDs

The burden of regulation is frustrating pharmacists who want to supply prescription medicines via private patient group directions, according to the National Pharmacy Association.

"Currently, [regulations] require registration with the Health Care Commission and the involvement of a medical agency when wishing to set up a private PGD service. This is on top of current mandatory regulation of all pharmacies and pharmacists by the Royal Pharmaceutical Society, not to mention additional oversight [by primary care organisations] required through the NHS contractual framework," the NPA said in a statement issued this week. It added that regulatory streamlining could be done without adversely affecting patient safety.

An NPA spokesman commented: "The process of registration is time consuming and costly, effectively [excluding] some providers. NPA members are telling us that when they try to innovate using this route they are stymied at the first hurdle. The Government has committed to reduce the burden of regulation across all of their departments; we look forward to discussing a way forward with officials."

He added: "At a time of NHS deficits, there is an opportunity to equip pharmacists with an alternative method of medicine supply, further encouraging self care."

Opinion varies on uptake of Pfizer accounts

More than 80 per cent of pharmacies have now opened a Pfizer/UniChem account ahead of the 5 March start date for Pfizer's new distribution system, *The Journal* can reveal.

The figure, given by a spokeswoman for UniChem, includes England, Scotland and Wales but not Northern Ireland where, she said, uptake has not been as speedy because pharmacists there received sign-up packs only recently. And she made clear that the figure incorporates existing UniChem customers.

Pfizer was not able to give *The Journal* a regional breakdown of accounts signed up or the actual percentage figure because, a spokeswoman for Pfizer explained, the situation is changing all the time. "Only a small minority have yet to open a Pfizer account but we are confident that most of them will have opened one by the time we go live," she added.

Pfizer this week urged pharmacists to sign up to the scheme. In a statement the manufacturer confirmed that it would no longer supply UK wholesalers with prescription medicines after 5 March. "After this point we do not believe UK wholesalers will have sufficient stocks in order to guarantee to supply the full range of Pfizer prescription medicines beyond a short period of time," it states.

In response to Pfizer's statement, Harry McQuillan, Scottish Pharmaceutical General

Council chief executive officer, stated: "The result of a recent SPGC straw poll of community pharmacy contractors in Scotland showed that a significant percentage has not yet opened up an account with Pfizer. It also showed that many who have opened an account did so under duress and are not happy with Pfizer's distribution proposal."

The Journal made contact with Gavin Dobson, a community pharmacy manager in Errol, Kinross-shire, who has not signed up to the Pfizer scheme. He told *The Journal* that he believes Pfizer's plans will not go through and that he has decided to do without a Pfizer account throughout March in the hope that the Office of Fair Trading will intervene.

His chosen buying group, Albapharm, confirmed that fewer than five of its 182 members have opened a Pfizer account. None of Albapharm's 26 members in Northern Ireland has signed up to the scheme, a spokesman for the company added.

"I am stocking up on Pfizer products as we speak and I've now got enough Pfizer medicines to last me through March. This is costing me dearly," Mr Dobson said. However, he admits: "If the situation doesn't resolve by the end of March, I will probably have to open a Pfizer account — obviously my patients come first."

Threshold triggers antivirals for seasonal influenza

GPs in England have been told to consider prescribing antiviral drugs to at-risk patients who have been in close contact with someone with flu-like symptoms or who have developed flu-like symptoms themselves. The advice comes as surveillance data show that the overall rate of influenza reports has exceeded the threshold at which National Institute for Health and Clinical Excellence guidelines on the use of antiviral drugs are triggered.

In a letter to prescribers, David Salisbury, the Department of Health's director of immunisation policy, monitoring and surveillance, summarises the NICE guidance, incorporating recent changes to oseltamivir's licence. He reminds GPs that oseltamivir (Tamiflu) should be prescribed for the prevention of influenza in members of at-risk groups who have not been vaccinated against flu this season (or who were vaccinated too recently to be protected or who received a vaccine that does not match the circulating virus) and who have been in close contact

with someone with flu-like symptoms. Another requirement is that the person must be able to start taking oseltamivir within 48 hours of being in contact with the person with flu-like symptoms. Dr Salisbury points out that since publication of the NICE guidance, which refers to patients aged 13 years and over, oseltamivir has received a licence for prophylactic use in children aged one year and above. "In the interim, until NICE completes its review, it would be appropriate to use oseltamivir for prophylaxis in persons aged 1 year and above according to the other conditions laid out by NICE," he writes.

Another licence change means that post-exposure prophylaxis is now 10 days as opposed to seven.



Patients with flu-like symptoms may now get antivirals

In terms of treating flu, prescribers are asked to consider use of zanamivir (Relenza) and oseltamivir but only in those who can start treatment within 48 hours of the onset of symptoms.

NICE does not recommend amantadine for either the prevention or treatment of influenza.

More pharmacies in England claim for MURs

Over 4,000 contractors in England are now claiming payments for medicines use reviews, and the number of MURs claimed for by each pharmacy has also increased, official figures show.

The latest data from the NHS Business Services Authority Prescriptions Pricing Division show that in November 2006 4,107 pharmacies claimed payments for MURs (6 per cent increase on the previous month) and contractors made claims for a total of 63,455 MURs (up 13 per cent on the figure for October 2006). An average of 15 MURs per month were carried out by each pharmacy.

Alastair Buxton, head of NHS services at the Pharmaceutical Services Negotiating

Committee, welcomed the rise in uptake of MURs.

"Contractors are now recognising that the future of the community pharmacy service lies in developing what we offer to patients," he said.

"The month-on-month growth in MURs conducted is pleasing to see and demonstrates that the profession is getting to grips with this service," he added. "Contractors, local pharmaceutical committees and the pharmacy bodies have put a lot of effort into supporting pharmacists to provide MURs. It is essential that we all continue to work towards a situation where MURs are 'business as usual' for community pharmacies and their patients."

Treating pandemic flu

It is impossible to predict which drugs will be active against a new pandemic strain of influenza, infectious disease experts argue in the online version of the *BMJ* (9 February, www.bmj.com). They suggest that governments should follow the lead set by the UK, US and Greece and stockpile both M2 ion channel inhibitors (amantadine and rimantadine) and neuraminidase inhibitors (oseltamivir and zanamivir).

Conceding that ion channel inhibitors can have unacceptable side effects and that they are associated with resistance, they argue that these can be reduced if they are used in combination with neuraminidase inhibitors. Activity can be preserved by not using them alone or for inappropriate prophylaxis.

APPG inquiry takes evidence from Department of Health officials

The All-Party Pharmacy Group is a step closer to drafting its report on the future of pharmacy, following the seventh and penultimate evidence session of its inquiry last week. Witnesses at the session, held at the Palace of Westminster, included Jeanette Howe, deputy chief pharmaceutical officer for England, Keith Ridge, chief pharmaceutical officer for England, and David Colin-Thomé, national clinical director for primary care.

According to Mrs Howe, the community pharmacy contract has "widened the range of services available from pharmacy", but it was criticised by APPG chairman Howard Stoate (*PJ*, 10 February, p154). "There is no mechanism to sell services to anyone," he said. Mrs Howe partly attributed the modest uptake of

enhanced services to the financial problems in the NHS. However, competition and lack of integration are other likely barriers.

Dr Colin-Thomé said that although the general medical services and community pharmacy contracts were designed to sit alongside each other, integration is going to take time. "For professions to be able to collaborate and not to compete requires a step change," Mr Ridge said.

Dr Stoate said: "If practice-based commissioning is led by GPs, they are pretty unlikely to commission their own services from somebody else." He added that the conveyor belt had to move, so GPs take on secondary care work, pharmacists take on primary care work and technicians take on dispensing and checking.

Pharmacist MP Sandra Gidley (LibDem, Romsey) said she could not see anything coming from the DoH to help joint working and understanding across the professions. The DoH said it recognises the need to make practice-based commissioning multidisciplinary and will be concentrating on that in 2007-08, bringing together commissioners, primary care trusts and pharmacists.

Other issues on the agenda included NHS IT and the current control of entry review, which the DoH said would be conducted quickly to minimise the length of uncertainty for pharmacists.

The final session of the inquiry will hear evidence from Lord Hunt, the minister with responsibility for pharmacy, in March.

Written information of little value, say patients

Patients believe the written medicines information they receive is of little value and fails to increase their knowledge, according to the results of research published this week. However, changes to the way information is now presented are likely to make it more useful.

Patients also think that the main purpose of statutory patient information leaflets (PILs) that accompany medicines is to highlight side effects rather than, as thought by some health professionals, to promote concordance.

Patients would prefer side effects to be listed in the order of the likelihood of them occurring, because they believe this would give a more accurate indication of probability, the researchers' report reveals.

Some patients also questioned the credibility of PILs because they were written by the drug manufacturers.

Patients are keen to be given medicines information before any prescribing decision is taken but they do not want written information to replace a conversation with a health professional about the prescribing decision, the researchers discovered.

The findings come from a review of 70 quantitative and qualitative research papers on the role and effectiveness of written information available to patients about individual medicines. Researchers also sought advice from designers, patients and patient organisations who attended two workshops in the year-long study.



Saturn Skills/Science Photo Library

Patients questioned the credibility of PILs

The research, conducted on behalf of the Department of Health's NHS technology assessment programme, was carried out by a team led by Theo Raynor, professor of pharmacy practice at the school of health care at the University of Leeds.

He said: "Despite what we found there are reasons to be optimistic because since 2005 all leaflets for medicines in the EU have to be tested on patients first before the manufacturer can gain a licence. Although this was too late to have an impact on our study, that is

bound to make a difference, and from the work we are doing at the moment, we can see that this is happening."

The study concluded that there was a gap between "currently provided leaflets and information that patients would value and find more useful".

Patients said it was important to them that they could easily understand the written information they were given and that the leaflets were well designed so they were easy to read.

The researchers said: "The challenge is to develop methods of provision flexible enough to allow uptake of varying amounts of information on a variety of aspects, depending on needs at different times in an illness."

The way to achieve that, they recommend, is to involve patients more in the decisions around information leaflets, to design leaflets according to key principles so that the information is presented in a way that is easily and clearly understood, and to present risk information in numerical order.

But Professor Raynor pointed out there is also the need for more research that focuses on web-based patient information. He said: "We found hardly any research on how patients used and valued web-based information, which is becoming much more important as people increasingly go to the web for this kind of information."

Generics manufacturers collaborate on PILs

A scheme to ensure that patients receive similar patient information leaflets (PILs) from all manufacturers of the same generic medicine has been launched by the British Generics Manufacturers Association. As well as increasing the uniformity of information provided, the scheme will also reduce the regulatory burden on the generics industry and the Medicines and Healthcare products Regulatory Agency.

Participating companies will be given access to a library of user-tested PILs that they may then submit to the MHRA as part of

their own new product applications or for existing licences. Participants will also be able to undertake "bridging" — using information from an approved PIL and applying it to closely related products.

June Raine, director of post licensing at the MHRA, said: "We welcome this innovative initiative from the generics manufacturers. Patients need consistent and high quality information about their medicines. This scheme will help to make a real difference to the many patients who rely on BGMA member companies for their medicines."

Copy patients into letters

Patients should be automatically copied into letters sent between health professionals so that they are kept informed about their condition and may make better decisions about their care. Health minister Rosie Winterton will write to various professional bodies and voluntary organisations to draw attention to the benefits of patients seeing these letters and asking them to meet to discuss implementation of the policy. The Royal Pharmaceutical Society is not included in this initiative.

"Keep well" scheme expands

A Scottish health check initiative that aims to tackle health inequalities is being expanded. The "Keep well" programme (previously known as "Prevention 2010") is currently offered in five sites, including a project in Glasgow that involves pharmacy (*PJ*, 20 January, p64).

This week, the Scottish Executive announced the initiative will be extended to sites in south Glasgow, Aberdeen, Fife, North and East Ayrshire, Inverclyde and West Dunbartonshire later this year.

Preregistration update

Funding for hospital preregistration placements in Scotland has been announced this week by the Scottish Executive. An NHS circular states that the level of funding per placement is now £23,632.

It also lists the number of preregistration placements in each health board this year. These total 160 placements: 42 in hospitals and 118 in community pharmacy. The circular states that this information will now be used to calculate the funding for community pharmacy placements.

PJ Online

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Tomorrow's Pharmacist

This year's *Tomorrow's Pharmacist* is now online. Articles cover a diverse range of subjects including

- Preregistration training
- Career options
- Practice around the world
- CV writing

www.pjonline.com/tp

Hospital Pharmacist

The February issue is now online. The special feature is statistical analysis.
www.pjonline.com/hp

Donepezil orodispersible tablets approved for use in NHS Scotland

Donepezil orodispersible tablets have been accepted for the treatment of mild to moderate Alzheimer's disease by the Scottish Medicines Consortium.

In its latest set of approvals, the SMC endorsed donepezil (Aricept Evess; Eisai) orodispersible tablets for use in NHS Scotland for the symptomatic treatment of mild to moderately severe Alzheimer's dementia in patients who have difficulty in swallowing solid formulations and for whom donepezil is appropriate. In England and Wales donepezil is not recommended for people with mild Alzheimer's disease and, on the basis of this, Eisai has launched legal proceedings against the National Institute for Health and Clinical Excellence (*PJ*, 15 January, p42).

The SMC also accepted deferasirox (Exjade; Novartis) for the treatment of chronic iron overload associated with the treatment of rare acquired or inherited anaemias requiring recurrent blood transfusions, although it is not recommended for patients with myelodysplastic syndromes.

In addition, tacrolimus (Prograf; Astellas) has been accepted for the prophylaxis of transplant rejection in heart allograft recipients; human fibrinogen and human thrombin medicated sponge (TachoSil; Nycomed) has been accepted for supportive treatment in surgery for the improvement of haemostasis where standard techniques are insufficient;

and propiverine hydrochloride (Detrunorm XL; Amdipharm) modified release capsules have been accepted for the treatment of urinary incontinence and of urgency and frequency in patients with overactive bladder.

The SMC rejected four medicines in this latest batch of assessments: rimonabant (Acomplia; sanofi-aventis) as an adjunct to diet and exercise for obese or overweight patients with associated risk factors; sunitinib (Sutent) for the treatment of advanced or metastatic renal cell carcinoma after failure of interferon-alfa or interleukin-2 therapy; pemetrexed (Alimta; Eli Lilly) as monotherapy for the second-line treatment of patients with locally advanced or metastatic non-small cell lung cancer; and interferon beta-1b (Betaferon; Schering) for patients at high risk of developing multiple sclerosis who have a single demyelinating event with an active inflammatory process severe enough to warrant treatment with intravenous corticosteroids.

□ **SIGN** Last week the Scottish Intercollegiate Guidelines Network published guidelines on acute coronary syndromes, cardiac arrhythmias, management of chronic heart failure, management of stable angina and risk estimation and the prevention of cardiovascular disease. The guidelines are available from the SIGN website (www.sign.ac.uk) and via *PJ Online* (www.pjonline.com/links/pj).

Dutch pharmacy established to supply medicinal cannabis

A Dutch pharmacy is claiming to be the first in the world to be established exclusively for dispensing medicinal cannabis on prescription. Last month it served its first customer, a multiple sclerosis patient who uses cannabis to control pain and spasms.

The Cannabis Pharmacy in Groningen in the north of the Netherlands operates to the same professional standards as other pharmacies but dispenses only one product.

It was set up by the non-profit patients' group the Foundation for Medicinal Cannabis in order to provide pharmaceutical quality cannabis at prices comparable to the city's many so-called coffee shops — €6 (£4) a gram.

Since 2003 patients in the Netherlands have been able to receive medicinal cannabis on prescription from an ordinary pharmacist. However, it is relatively costly at €9 (£6) per gram and health insurers have increasingly excluded it from their cover. Many chronic users have turned to the coffee shops, whose cannabis may contain impurities.

By contrast prescription cannabis is produced under laboratory conditions to a standardised quality, strength and content, containing no pesticides, heavy metals or bacteria. The Dutch ministry of health supervises production through a company, Bedrocan, based in Veendam, near Groningen.

Pharmacist Lisette Wijnkoop, who works at the Cannabis Pharmacy, says it was set up to guarantee low cost and high quality by buying in bulk. It also helps many patients who may not like to go to a coffee shop for medicine. In addition she argues it can offer specialist "know how about the application and the best way to use" cannabis and "information on side effects and use with other medication".

She estimates there are 150 patients in the city. Throughout the Netherlands an estimated 15,000 mainly multiple sclerosis, cancer and rheumatism patients use medicinal cannabis.

The Cannabis Pharmacy is being run as a pilot project by the Dutch ministry of health's office for medicinal cannabis.

NICE to look at obesity, cancer and arthritis

New drugs for the treatment of obesity, cancer, rheumatoid arthritis and Crohn's disease are being looked at by the National Institute for Health and Clinical Excellence for future use in the NHS in England and Wales, it was announced last week.

New clinical guidelines for the treatment and management of acute diarrhoea and vomiting in children and another, devoted to the treatment of adults with rheumatoid arthritis, are also being developed as part of the institute's 13th work programme, according to details revealed by the Department of Health.

New drugs which are being appraised for the NHS on the grounds of their cost and clinical effectiveness are: adalimumab for patients with moderate to severe Crohn's disease; certolizumab pegol for the treatment of rheumatoid arthritis; lapatinib plus capecitabine for advanced, metastatic or recurrent breast cancer; and bevacizumab for the treatment of lung cancer.

The suitability of rimonabant in the treatment of obesity in conjunction with exercise and diet is also being appraised.



Obesity treatments will be assessed

The latest programme also involves NICE looking at the clinical and cost effectiveness of infliximab for patients with ulcerative colitis, and new rapid clinical guidelines on the care of acutely ill patients in hospital are also being developed. NICE is also going to focus on the most effective way to store and preserve donated kidneys.

Omega-3s for depression

There is no convincing evidence that long-chain omega-3 fatty acids are an effective single treatment for depression, according to a review of evidence in February's issue of *Drug and Therapeutics Bulletin*. Limited evidence suggests a possible benefit in patients receiving fish oil products containing eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) omega-3 fatty acids in combination with their existing anti-depression medicines. However, the *DTB* says that this needs to be confirmed before the routine use of such supplements can be recommended for patients with depression.

Ranibizumab launched for macular degeneration

A second inhibitor of vascular endothelial growth factor (VEGF) has been launched for the treatment of neovascular (wet) age-related macular degeneration (AMD) — a condition that results in loss of central vision. Ranibizumab (Lucentis; Novartis), a monoclonal antibody which binds to all isoforms of VEGF-A, is administered by intravitreal injection like last year's newcomer, pegaptanib sodium (Macugen), licensed for the same condition.

Writing in this week's *BMJ*, Usha Chakravarthy, professor of ophthalmology and vision sciences, Queen's University Belfast, and Jennifer Lim, associate professor

of ophthalmology, University of Southern California, compare treatments for wet AMD (2007;334:269). They say: "Different isoforms of the growth factor probably contribute to leakiness, abnormal morphology, and fragility of the neovascular complex [features of the disease]. Thus, ranibizumab has better outcomes than pegaptanib sodium, which inhibits VEGF₁₆₅ alone."

They add: "Low dropout rates in the vascular endothelial growth factor inhibition trials suggest that patients accept the potential long-term risks associated with such treatment so that they can maintain vision in the short term."

The authors add that another monoclonal antibody, bevacizumab, currently only licensed for treatment of metastatic colorectal cancer, is reported to provide visual outcomes similar to ranibizumab, but would cost much less. They suggest that "a controlled clinical trial of bevacizumab versus ranibizumab should be a priority for health services already struggling to meet the demands of ever aging populations".

Ranibizumab is administered monthly for three consecutive months. Patients are reviewed monthly thereafter for further visual deterioration, and treated with further monthly injections as needed.

Notice-board p185

Upper GI safety of etoricoxib superior to that of diclofenac for arthritis, study suggests

Using etoricoxib (Arcoxia) rather than diclofenac reduces the number of uncomplicated upper gastrointestinal events in patients with arthritis, a new analysis of data from the MEDAL study suggests.

The cardiovascular results of the MEDAL (multinational etoricoxib and diclofenac arthritis long-term) programme, which includes 34,701 patients with osteoarthritis or rheumatoid arthritis, were announced last year (*PJ*, 18 November 2006, p599; *Lancet* 2006; 368:1771). Last week saw publication of an assessment of the upper gastrointestinal safety of etoricoxib and diclofenac in the MEDAL patients (*Lancet* 2007;369:465).

The new analysis shows that overall upper gastrointestinal clinical events were less common with etoricoxib than with diclofenac,

due to a decrease in uncomplicated events (hazard ratio 0.59, 95 per cent confidence interval 0.45–0.74; $P < 0.0001$), but that there was no difference in the number of complicated events.

The authors of an accompanying editorial (*ibid*, p439) argue that the results could have important ramifications, because the use of these drugs in a susceptible population is often limited by gastrointestinal toxicity. However, the editorial also highlights the shortcomings of the findings. "We would need to treat 259 patients with etoricoxib to prevent one uncomplicated gastrointestinal event in one patient," the authors say. "So, although the effect might well be statistically significant, the effect is certainly not large and might not be clinically relevant."

Public health minister backs pharmacy condom campaign



Making condoms easier and less embarrassing to buy for young people is an important part of tackling increasing rates of sexually transmitted infections. This was the message from public health minister Caroline Flint (pictured front) when she visited the Co-op Pharmacy in Rossington, near Doncaster, to back its support for the Department of Health's "condom essential wear" campaign.

Evidence for switch to aromatase inhibitor strengthened

Evidence supporting the benefits of switching to exemestane (Aromasin) after treatment with tamoxifen for breast cancer has been reinforced with publication of the full results of the intergroup exemestane study this week (www.thelancet.com, 13 February).

The initial results of the study, which showed improvements in disease-free survival in postmenopausal breast cancer patients switched to exemestane after two to three years' treatment with tamoxifen, were an-

nounced at the American Society of Clinical Oncology last year (*PJ*, 10 June 2006, p673).

In addition, a separate study published online in *Cancer* this week has shown that switching to an aromatase inhibitor after two or three years of tamoxifen therapy significantly improves survival for postmenopausal breast cancer patients, compared with two or three years' additional tamoxifen treatment (www.interscience.wiley.com, 12 February).

Reports focus on local health needs of developing nations

A powerful, co-ordinated international response to the health staffing crisis in developing nations is necessary, particularly in sub-Saharan Africa, according to Nigel Crisp, former NHS chief executive, in his report "Global health partnerships", published this week. The report highlights an absence of any means for spreading good practice and learn-

ing between development projects, agencies and countries, and a need for better sharing of information. It follows publication of a BMA International report, which found that health professionals undertaking work placements in the developing world need to have better long-term assistance that takes into account local conditions and knowledge.

Extra benefit from extended anticoagulation unlikely

Patients with deep vein thrombosis or pulmonary embolism who have no known risk factors for recurrence are unlikely to gain extra benefit from six, rather than three, months of anticoagulation, the authors of a study published online conclude (www.bmj.com, 8 February). The researchers found that, among 749 patients with deep vein thrombosis or pulmonary embolism, there was no significant difference in the rate of adverse outcome in patients allocated to three or to six months' anticoagulation with heparin and warfarin.

Interleukin antibody for psoriasis

The safety and efficacy of human interleukin-12/23 monoclonal antibody for the treatment of psoriasis has been demonstrated in a phase II study, published in *The New England Journal of Medicine* (2007; 356:580).

The authors explain that aberrant type 1 immune responses have been linked to the pathogenesis of psoriasis, and cytokines that elicit these responses may represent appropriate therapeutic targets. A fully human interleukin-12/23

monoclonal antibody was developed, which binds with high affinity to the p40 subunit of human interleukin-12 and -23, neutralising their bioactivity by blocking interactions with their cognate cell surface receptors.

To assess the antibody, 320 patients with moderate-to-severe plaque psoriasis were randomised to receive one 45mg subcutaneous dose of interleukin-12/23 monoclonal antibody, one 90mg dose, four weekly 45mg doses, four weekly 90mg doses or placebo. At week 20, patients in the placebo group crossed over to receive one 90mg dose of interleukin-12/23 monoclonal antibody.

The results show that there was at least 75 per cent improvement in the psoriasis area and severity index at week 12 in 52 per cent



Plaque psoriasis may be treated with a monoclonal antibody against interleukin-12/23

of patients who received 45mg of antibody, in 59 per cent who received 90mg, in 67 per cent who received four weekly 45mg doses and in 81 per cent who received four weekly 90mg doses, compared with 2 per cent who received placebo ($P < 0.001$ for each comparison).

More patients treated with antibody than with placebo experienced adverse events and serious adverse events, although the differences were not significant. However, the authors say the trial was not large enough to detect differences in uncommon serious adverse events. They suggest that additional studies are needed to characterise the antibody's safety and efficacy and to determine a suitable dose schedule.

Muscular dystrophy improved by losartan

Losartan improves muscle regeneration and repair in mice with Duchenne muscular dystrophy (DMD), a new study reveals.

Researchers tested the drug in a mouse model of the disease following studies of Marfan syndrome, another condition characterised by muscle wasting. Previous work by the researchers has shown that Marfan syndrome is the result of excessive activity of transforming growth factor (TGF)-beta in muscles. Blocking TGF-beta with losartan leads to muscle regeneration, and normal architecture and function.

In the current study, published this month in *Nature Medicine* (2007;13:204), the re-

searchers show that TGF-beta is implicated in the muscle damage seen in DMD as well. Mice treated with losartan were able to regenerate muscle after injury, whereas untreated mice had large patches of scar tissue in place of muscle.

The research was partly funded by the US National Institute of Arthritis and Musculoskeletal and Skin Diseases. Its director Stephen Katz is cautiously optimistic about the findings. "But we need to do clinical studies first. If they are successful, this therapy has the potential to help many people with devastating diseases for which there has really been no good treatment," he said.

Orexin antagonist shows promise as insomnia treatment

An antagonist of the orexin OX_1/OX_2 receptor — ACT-078573 — being developed by Actelion may prove useful for people suffering from sleep disorders.

The company reports that a study involving 39 patients with primary insomnia indicates that the compound improves sleep efficiency as measured by polysomnography. The study

follows research published in *Nature Medicine* this month that shows an increase in sleep in animals and healthy volunteers (2007;13:150).

Actelion says that ACT-078573 is the first oral orexin receptor antagonist that penetrates the blood-brain barrier and is capable of inducing transient and reversible blockade of the OX_1 and OX_2 receptors.

Cannabinoid system proposed as target for Parkinson's drugs

Using drugs to modulate endocannabinoid production in the brain could lead to the development of new treatments for Parkinson's disease, a study published in *Nature* last week suggests (2007;445:643).

An imbalance in the neural activity in two neural pathways has been suggested as a basis for the motor deficits seen in Parkinson's disease and the researchers showed that endocannabinoids had different effects on these two pathways.

They were also able to demonstrate that motor deficits in animal models of Parkinson's disease could be improved by treatment with inhibitors of endocannabinoid degradation (reserpine and 6-hydroxy-dopamine).

Lead author Robert Malenka, of Stanford University, California, commented: "This study points to a potentially new kind of therapy for Parkinson's disease. . . . We have identified a new way of potentially manipulating the circuits that are malfunctioning in this disease." However, the researchers warn that human trials are a long way off and that any such therapies may only treat a part of the complex pathophysiology of Parkinson's disease.

Lavender oil and gynaecomastia

Repeated topical exposure to lavender and tea tree oils has been proposed as the likely cause of three cases of prepubertal gynaecomastia reported in *The New England Journal of Medicine* earlier this month. US researchers performed studies using human cell lines to investigate the observed association between use of the oils and the condition in three boys. The *in vitro* studies indicate that the oils have oestrogenic and anti-androgenic activities (2007;356:479).

R&D news in brief

Transdermal Alzheimer's vaccine

Vaccination with a transdermal beta-amyloid peptide against Alzheimer's disease has shown positive results in animal studies. Researchers tested the vaccine in transgenic mice, designed to develop amyloid plaques at eight months of age. The plaques were cleared from the brains of treated mice, which showed no signs of aseptic meningitis — a serious side effect observed in clinical studies of an intraperitoneal vaccine (*Proceedings of the National Academy of Sciences* 2007;104:2507).