

Independent pharmacies are unlikely to survive Trent researchers claim

INDEPENDENT community pharmacies face a bleak future in which they are unlikely to survive, according to a report published by the Trent Institute for Health Services Research.

The report, entitled "Small pharmacies and the National Health Service", is based on interviews carried out with 20 independent pharmacy owners in 1997, with conclusions updated to take account of subsequent developments. The interviews were carried out as a pilot for a full-scale investigation of the social and economic position of independent community pharmacists, work that was then not subsequently carried out.

Professor Robert Dingwall and Pamela Watson, MRPharmS, describe their interviews as being "stories of survival". The pharmacists were "almost overwhelmed by the long hours, the low economic rewards and the general struggle for existence in serving poor and marginal communities", they say. In general, they found that being an independent pharmacy owner was "not a goal so much as something you do when other segments lose their attractions". Independents valued their professional autonomy but were paying a high price for it in terms of long hours, heavy paperwork and disruptions to family life.

The authors describe the pharmacy plan for England (*PJ*, 16 September 2000, p397), as far as independent pharmacies are concerned, as being inconsistent and incoherent. Most of the developments presaged in it would be of more benefit to the larger pharmacy chains because of economies of scale.

The authors say: "Compare the overheads of a dispensing mill [located] in an industrial park (with a low ratio of pharma-

cists to dispensing assistants and no walk-in facilities) and of a retail outlet (which has to provide private consultation space, a high ratio of pharmacists to assistants, accessible premises and the like). Relaxation of entry controls will further increase the pressure on small providers from larger predators, who can sustain the costs of competition in a way that others cannot. A large chain can absorb the low margins and predatory pricing needed to break into a market across its whole business in a way that is not open to a small chain or solo provider."

They say that the Government has been 20 years too late in trying to bring pharmacy within the NHS in the same way as general practice.

John D'Arcy, chief executive of the National Pharmaceutical Association, told *The Journal* that the researchers' conclusions echoed what the association had been telling the Government for years.

"It is difficult to get information on businesses that are close to the financial edge, because people are unwilling to admit to failure, but many economic indicators point to the conclusion that the number of pharmacies in the 'at risk' category, whichever way it is defined, must be increasing," he said.

Dr Hooman Ghalamkari, MRPharmS, owner of DG Pharmacy, Worcester, told



Pharmacy owners tell stories of survival, researchers say

The Journal that the financial and time pressures facing independent community pharmacist were the reality of running any small business.

"Economically, things are going against us, but I still see opportunities — both financially and in terms of creating new roles — for pharmacists who are proactive and who get closely involved with their local communities."

Small pharmacies and the NHS, Trent Institute for Health Services Research, Regent Court, 30 Regent Street, Sheffield S1 4DA (tel 0114 222 0703), price £15.

Continuous HRT may protect against endometrial cancer

WOMEN who use long-term continuous hormone replacement therapy (HRT) do not have an increased risk of endometrial cancer and may even be protected from the disease, results of a study suggest (*BMJ* 2002;325:239).

Of 534 postmenopausal women taking part in the study, 360 had previously taken HRT in which oestrogen and progestogen were given sequentially, 164 had not used HRT and 10 had taken oestrogen-only HRT. Subsequently, the women received continuous combined HRT and were followed up for an average of 4.4 years.

At baseline, 21 women had an abnormal endometrium but after nine months of continuous combined HRT, the endometrium had reverted to normal. In addition, no cases of endometrial cancer developed during the study.

The researchers comment that the reversal of endometrial hyperplasia seen in the study may relate to the specific HRT combination used — estradiol 2mg and norethisterone 1mg — which has a relatively strong progestogen component.

Ethics training wins funding bid

THE consortium set up for advancing the provision of pharmacy law and ethics teaching (APPLET), involving schools of pharmacy from Nottingham, Aston and De Montfort universities, has won funding of £250,000 for its three-year project from the Higher Education Funding Council for England (HEFCE).

APPLET said in its bid that the current undergraduate pharmacy law and ethics curriculum is poorly specified, with teaching largely by part-time, practice-based, non-specialist pharmacists. However, changes in pharmacists' roles such as the shift to clinical practice require a curriculum that delivers an explicit understanding and assessment at undergraduate level of health care law and bioethics.

Professor Joy Wingfield, professor of pharmacy law and ethics at Nottingham University, and the project director, said: "This funding will take the teaching of law

and ethics beyond the Medicines Act and show that there is more to it than simply controlling the supply of drugs."

The money will be put to many uses, including setting up a project team, launching a website, looking at curriculum information in disciplines related to pharmacy, running a number of pilots and making evaluations, with more than half of the fund to be spent on dissemination activities, such as providing workshops for teachers of pharmacy law and ethics.

The project, due to start on 1 October, has the support of the Society (*PJ*, 9 February, p164) and the Department of Health, both of which are nominating representatives to the project's steering group.

Professor Wingfield said that although the HEFCE money is limited to higher education institutions, the project proposal includes a strategy for the development of training support for existing pharmacists.

Big multiples get seats on NPA board

MOSS Pharmacy and Lloydspharmacy are to gain places on the National Pharmaceutical Association's board of management from September. The NPA's board has agreed to provide co-opted places for members owning 750 pharmacies or more. This means that places will be allocated to Moss and Lloyds. Boots The Chemists is the only other chain of more than 750 pharmacies, but the company is not an NPA member.

The decision to provide places is part of a review of the board's organisational structure in line with its five-year strategic plan (P7, 15 September 2001, p343). The NPA says that changes in its membership and its current system of election have left some members, particularly larger multiples, feeling disenfranchised and without a voice. Although these members may have large numbers of pharmacies, they have not had enough in any one voting area in order to gain an elected place on the board. Co-opted places will not affect the 21 directly elected places on the board.

Andrew Murdock, director of pharmacy at Lloyds, currently an elected member of the board, will give up his place and become one of the co-opted members. Companies that gain co-opted board places will lose their votes in elections to the NPA board.

The board is reviewing its composition, including representation of the NPA regions and how these should be defined; the representational needs of members of differing sizes; and how Scotland, Wales and Northern Ireland are represented.

Other matters considered at the board's July meeting are reported below.

NPA membership The number of members of the NPA has dropped from 4,859 in 2001 to 4,690 this year, although the number of pharmacies owned by members has only dropped by 18.

Modernisation response Following a presentation from the Royal Pharmaceutical Society's director of professional develop-



Moss and Lloyds will gain seats on the NPA board

ment, Philip Green, and Immediate Past-President Christine Glover, the NPA's board remains unconvinced that the Society's Modernisation Steering Group has fully explored, and promoted to the Government, options for the constitution of the Council. Board members agreed that the Society's leaders appeared to be resigned to the Society adopting a constitution similar to other regulatory bodies, where the professional majority could be as few as one. The board did not accept that the Society could perform both [regulatory and professional] roles under a constitution devised for a purely regulatory body (P7, 6 July, p4).

The NPA wants to see all pharmacist members of Council being elected by the membership as a whole. It wants to see the single transferable vote (STV) system ended and an "X" system of voting implemented in its place. Board members believe that the STV system is complex and might put members off casting their votes.

Dispensary staff The board continues to raise concerns about the Society's policy that, by 2005, staff involved in the dispensing process should be trained to a minimum of National Vocational Qualification Level 2 or equivalent. The NPA does not support this proposal and has been active in attempting to influence thinking on this matter. In particular, the NPA has highlighted two main problems with the NVQ Level 2

qualification that it considers would make it difficult to comply with this new requirement:

- 1 The level of bureaucracy involved in the NVQ process, such as the need for trained assessors, makes it impractical for this to be the standard for dispensary assistants
- 1 Many staff are part-time and do not carry out all tasks within the dispensing process and will not be able to collect evidence to demonstrate their competence over a period of time

The pharmacy sector committee (which advises the Society's Council on pharmacy practice matters) has asked for a summary of points of disagreement and suggestions for workable solutions in order that the matter can be developed with options for the Society's Council to consider. The NPA has therefore produced a document highlighting the important issues and its position.

Returned medicines The NPA is to publish advice on risk assessment and produce a protocol for dealing with the return of unwanted medicines. The NPA will discuss with the Pharmaceutical Services Negotiating Committee the need for pharmacists to be properly remunerated for accepting and sorting returned medicines.

BRIEFLY

Boots sells Halfords for £427m
THE Boots Co Plc has sold Halfords, its car parts and servicing subsidiary, to CVC Capital Partners for £410m in cash. A further £17m depends on sales targets being reached. Halfords was the final part of the conglomerate to be sold by Boots and the only part to be sold at a profit.

Reliever inhalers linked to increased asthma deaths

INCREASED risk of death from asthma is associated with excessive use of short-acting beta-agonist inhalers, according to a new study (*Thorax* 2002;57:683).

Researchers, funded by Boehringer Ingelheim, compared the risk of death among asthma patients who were taking specific drugs with that in asthma patients who were not. They included data on 96,000 asthma patients from the General Practice Research Database.

The researchers observed that increasing use of asthma medication was associated with an increased risk of death from asthma. After adjustment for confounding factors, including frequency of consultation or hospital admission for asthma, the relative risks

associated with most respiratory drugs investigated, such as long-acting beta-agonists and theophyllines, fell. However, This was not the case for short-acting beta-agonists.

Patients who had received seven to 12 prescriptions for symptom-relieving short-acting beta-agonist inhalers within the past year had a 16-fold increased risk of death compared with those not taking these drugs. The risk of death among patients who received 13 or more prescriptions for these inhalers increased by over 50-fold.

Conversely, longer-acting inhaled steroids were associated with a decreased risk of death from asthma and patients who were prescribed more than one short-acting

inhaler a month, cut their risk of death by 60 per cent if they regularly used a long-acting inhaled steroid as well.

The researchers suggest that high-risk asthma patients who over-use short-acting beta-agonists might be at increased risk because they use fewer long-acting inhaled steroids. However, their analyses show that patients who used short-acting inhalers were just as likely to use steroid inhalers for symptom prevention.

The researchers suggest that deaths due to chronic obstructive pulmonary disease could have been misclassified as asthma deaths, since this disease is more common in the elderly and 35 of the 43 asthma deaths in the study were people aged 50 years or over.

SSRI withdrawal reactions highlighted

THE Committee on Safety of Medicines and the Medicines Control Agency have received more reports of withdrawal reactions associated with the selective serotonin reuptake inhibitor paroxetine (Seroxat) than with any other drug.

Campaigning group Social Audit has reviewed data which it obtained from the CSM last month. It found that SSRIs account for five of the top six drugs for which such reactions have been reported. A total of 1,281 reports linking paroxetine and withdrawal reactions have been received by the CSM. Following paroxetine is venlafaxine (Efexor), which accounts for 272 reports. Charles Medawar, chief executive of Social Audit, has written to doctors highlighting the level of withdrawal reactions reported.

A spokesman for the MCA acknowledged that data had been supplied to Social Audit, but added that information on how to interpret the data had also been supplied, which Mr Medawar had failed to include in his letter to doctors. "The reporting of a reaction does not necessarily mean that the drug caused the problem and therefore these reactions should not be used as a list of side effects for the medicine to which it refers."

He added that reporting rates are influenced by the seriousness of the suspected reaction, its ease of recognition, the extent of use of a particular drug and also by publicity about a drug. "Numerical comparisons should not be made between reactions associated with different drugs on the basis of this information. Comparisons can be misleading unless they take account of wide a number of factors," he said.

Mr Medawar invites comments from doctors on the warnings that should be included in the summary of product characteristics and patient information leaflet for SSRIs and suggests that prescribing advice should include information about withdrawal symptoms.

However, the MCA pointed out that the product information for paroxetine and other SSRIs does contain warnings about withdrawal symptoms. "Prescribers have been reminded of the need to taper dosing when withdrawing from treatment on two occasions via *Current Problems in Pharmacovigilance* in 1993 and 2000. In addition, the British National Formulary carries a clear warning on this issue," he said.

Mr Medawar also states in his letter to

doctors that the CSM will shortly be considering reports of withdrawal reactions from patients for the first time. This, says the MCA, is incorrect. Patient reports collected by the charity MIND have been reviewed by the CSM in the past. However, the MCA does not currently have the means to collect patient reports systematically.

Nosebleeds following sildenafil use

TWO cases of nosebleeds following the use of sildenafil (Viagra) for erectile dysfunction are reported in the *Journal of the Royal Society of Medicine* (2002;95:402).

Researchers from St George's Hospital, London, describe a case of a man in his late 50s who experienced several nosebleeds after taking 50mg sildenafil. On the day of admission to hospital, bleeding had continued for six hours without stopping and resulted in a six-day hospital stay.

A second case involved a man in his early 70s who had been admitted to hospital following a nosebleed lasting five hours. He had taken sildenafil that morning. Both men

had a history of hypertension, a risk factor for heavy nosebleeds, but neither had needed to go to hospital with nosebleeds before.

The researchers comment: "There has been no obvious increase in [nosebleeds] since the introduction of sildenafil; this effect, however, might be under-reported because of the disinclination of most patients to discuss sexual matters in public, especially those relating to sexual dysfunction."

The researchers suggest that sildenafil could act at sites other than the penis, including parts of the nose, which contains erectile tissue.

Zyban safety update continues to reveal only recognised reactions

THE latest safety update for bupropion (Zyban) from the Medicines Control Agency shows that up to 24 July, a total of 7,630 reports of suspected adverse reactions have been received via the yellow card scheme in the United Kingdom. All are recognised reactions and are listed in the summary of product characteristics for bupropion.

Reports of adverse reactions with a fatal outcome have risen to a total of 60 but the MCA points out that in most of these cases an underlying condition could have been responsible. "Cardiovascular disorders, including myocardial infarction, and cerebrovascular disorders, including stroke,

were the reported causes of death in 70 per cent of these reports," the safety update states. It adds that in 14 of the reports, the individual was not taking bupropion at the time of death.

n EMEA review A review of bupropion-containing medicinal products by the European Agency for the Evaluation of Medicinal Products (EMEA) has concluded that the balance of risks and benefits of bupropion as an aid to smoking cessation remains favourable. The EMEA recommends that bupropion should be used in accordance with smoking cessation guidelines. The review was conducted following a referral by Germany in February.

Third generation pill not more risky

THIRD generation oral contraceptive pills do not carry a significantly greater risk of causing venous thromboembolism than second generation contraceptives, a High Court judge has ruled.

Dismissing a class action brought by a group of women under the Consumer Protection Act 1987 (*Pf*, 9 March, p317), Mr Justice McKay said that a paper analysing the lifetime risk of using the third generation pill showed no increased risk. He added that other studies supported this, saying: "I am not satisfied that the effect of the other investigations into the third generation pill is to show, on a balance of probability, that the risk of venous thromboembolism which it carries is more than twice that of the second generation pill. The most likely figure to represent the relative risk is around 1.7." The judge said that "the trial was almost certainly the most exhaustive examination that this question has yet received".

The action had been brought by the women against Organon Laboratories, Schering Health Care and John Wyeth & Brother. The women had claimed that use of their products had caused their thrombotic events and subsequent problems they suffered.

Evidence presented in court stated that the risk of thromboembolism for women not taking oral contraceptives was about five cases per 100,000 women per year. This rose to 15 per 100,000 for second generation pills and 25 per 100,000 for third generation but was less than the 60 per 100,000 risk from being pregnant.

Patients with Parkinson's disease should not be started on selegiline

THE use of selegiline, either alone in early stage Parkinson's disease (PD) or in combination with levodopa for more advanced disease, is not justified in new patients, concludes a review in *Prescrire International* this month.

Six years ago, a review in the same journal reserved judgement on selegiline but the latest review concludes that, on the basis of newly published data, selegiline is "not acceptable".

The reviewers say the efficacy of selegiline is at best only moderate. Although it delays the need for levodopa therapy by a few months and reduces levodopa requirements, it has no tangible effect on the course of the disease.

In addition, results from a large clinical trial and an epidemiological study suggest that selegiline may cause an increase in mor-

tality, possibly linked to its cardiovascular side effects, although the reviewers acknowledge that it is difficult to draw firm conclusions from the available mortality data. The reviewers conclude that there is no justification for starting new patients on selegiline and that patients already taking selegiline should only continue to do so if they feel a clear benefit from it and are free from risk factors associated with early mortality, especially cardiovascular disease (2002;11:108).

n Prescrire reviews The August issue of *Prescrire International* also reviews gabapentin (Neurontin) for the treatment of postherpetic pain and oral transmucosal fentanyl (Actiq) for the treatment of breakthrough pain. It concludes that for postherpetic pain, amitriptyline and desipramine remain the oral drugs of choice. However, gabapentin

may be a useful alternative given its different safety profile.

The evaluation of oral transmucosal fentanyl concludes that immediate release oral morphine is still the standard treatment of choice for breakthrough pain in cancer patients. However, in some patients oral transmucosal fentanyl may offer a slight advantage (ibid, p111 and p106).

Tirofiban similar to abciximab over long-term

THE two platelet glycoprotein IIb/IIIa inhibitors tirofiban (Aggrastat) and abciximab (ReoPro) have similar long-term beneficial effects for patients who undergo angioplasty for narrowed coronary arteries, a follow-up study has shown.

Previously, researchers had shown that abciximab was better than tirofiban at preventing death, heart attacks, and repeated surgery among 4,809 patients within 30 days of undergoing coronary-artery angio-

plasty. However, six-month data for the trial show that 14.8 per cent of the patients taking tirofiban had died, had a heart attack, or had repeat surgery, compared with 14.3 per cent of those who took abciximab (hazard ratio 1.04, 95 per cent confidence interval 0.90-1.21, $P=0.591$).

Dr David Moliterno, Cleveland Clinic Foundation, Ohio, and lead investigator, commented: "As studied, abciximab was more protective against a heart attack

occurring during, or immediately following, angioplasty. Yet the two drugs were associated with similarly low rates of death and re-narrowing of the heart's arteries at six months.

"Our conclusion is that while the more expensive drug (abciximab) is better 'up front', it provides little long-term advantage compared with tirofiban."

The study is published in *The Lancet* (2002;360:355).

Controversy over smallpox vaccine

THE Government has been accused of choosing the wrong strain of smallpox for the emergency vaccine reserve stock it has ordered from Powderject Pharmaceuticals.

Smallpox vaccine for the United Kingdom will be made using the Lister strain. American stocks will be made using the New York City Board of Health (NYCBOH) strain.

The Times newspaper on 30 July quotes Dr Steve Prior, head of the defence medical countermeasures programme at the Potomac Institute for Policy Studies, Washington DC, as saying that the NYCBOH strain is more likely to resemble the "battle-strain" believed to have been used by the former Soviet Union in its biological weapons programme. Cultures of this strain may have passed into the hands of terrorists.

However, recent guidance from the European Agency for the Evaluation of Medicinal Products suggests that either strain can be used to produce smallpox vaccines.

Varicella-zoster vaccine launched

A VACCINE containing live, attenuated varicella-zoster virus, Varilrix, has been launched this week by GlaxoSmithKline (see p155). The vaccine was previously available on a named-patient basis.

Varilrix is indicated for active immunisation against varicella in healthy adults and adolescents (13 years) who have been found to be seronegative to varicella-zoster virus and are, therefore, at risk of developing chickenpox.

The company says that the main use of the vaccine will be to vaccinate health care workers who did not have chickenpox as a child and who are not immune to the virus. It says that a policy recommending that non-immune health care workers should receive Varilrix is being considered by the Department of Health.

The Department says that the vaccine's use in the National Health Service, to protect vulnerable patients, will be considered in due course.

BRIEFLY

COX-2 safety investigated

A review has been initiated into the safety and effectiveness of the cyclooxygenase-2 inhibitors. The European Agency for the Evaluation of Medicinal Products will investigate the drugs in relation to the frequency of gastrointestinal and cardiovascular events.

Are multivitamins beneficial?

The beneficial effects of multivitamin preparations have been called into question. Current estimates of vitamin requirements relate to the prevention of diseases of deficiency. But, because deficiency is now less of a problem, Dr David Bender, University College London, believes the question has shifted to whether high levels of vitamins provide health benefits. He concludes that, apart from pregnant women and the elderly, people with healthy diets benefit little from multivitamins (*BMJ* 2002;325:173).

Vasopeptidase inhibitor is an effective treatment for chronic heart failure

OMAPATRILAT, a vasopeptidase inhibitor, is effective in treating heart failure, a new study shows. It reduces all-cause mortality and admission to hospital for chronic heart failure requiring intravenous treatment.

Omapatrilat has a dual mechanism of action and works by inhibiting two enzymes, angiotensin-converting enzyme (ACE) and neutral endopeptidase (NEP).

Dr Milton Packer, College of Physicians and Surgeons, Columbia University, New York, randomly assigned 5,770 patients to receive either omapatrilat, titrated up to 40mg once daily (n=2,886) or enalapril (n=2,884), titrated up to 10mg twice daily. Patients were eligible for the study if they had heart failure because of an ischaemic or non-ischaemic cardiomyopathy for two months or more, or had a left ventricular ejection fraction of 30 per cent or less and had been admitted to hospital for heart failure within the previous 12 months.

The percentage of patients who died or were admitted to hospital for heart failure requiring intravenous treatment was 33.7

per cent in the omapatrilat group and 31.7 per cent in the enalapril group, a result which the authors say showed non-inferiority but not superiority of omapatrilat over enalapril. The number of deaths was 477 in the omapatrilat group and 507 in the enalapril group.

They conclude that omapatrilat reduced the morbidity and mortality of patients with moderate to severe heart failure but was not more effective than ACE inhibition alone in decreasing the risk of death and admission to hospital for heart failure requiring intravenous treatment. However, secondary and *post hoc* analyses that relied on a broader definition of heart failure or focused on all cardiovascular events suggested the possibility that omapatrilat may be more effective than enalapril in these patients. They add that their inability to demonstrate that omapatrilat is superior to enalapril may have been related to deficiencies in both the effectiveness of NEP inhibition or ACE inhibition achieved by omapatrilat in the dosing regimens used.

The study is published as a rapid track publication on the *Circulation* website (www.circulationaha.org).

Bristol-Myers Squibb, the company developing the drug for both hypertension and heart failure, withdrew its marketing application for the product in the US in 2000, following questions about the risk of angioedema associated with the drug (*Pf*, 29 April 2000, p646). The company said that last week, the FDA advisory committee declined an application for omapatrilat for use in hypertension, again because of safety concerns. However, it plans to continue discussions with the FDA and evaluate options for potential use in a high-risk population.

Dr Neal Maskrey, medical director, National Prescribing Centre, told *The Journal*: "We have been interested in reports of trials of this drug for some time. If licensed it will add to the number of therapeutic options for people with heart failure, but at present it seems that ACE inhibitors and beta-blockers will remain the cornerstones of therapy for most people."

Calcium sensitiser lowers mortality

A NOVEL calcium sensitiser, levosimendan (Simdax), lowers mortality and improves cardiac function in patients with low output heart failure, a new study shows.

Levosimendan, manufactured by Orion Pharma and being developed for the treatment of acutely decompensated heart failure, has a dual mechanism of action. It binds to and sensitises troponin C, a protein that affects heart muscle contraction, increasing the contractile force on the heart and avoiding the build-up of excessive calcium which can cause arrhythmia. It also leads to vasodilation through the opening of ATP-sensitive potassium channels in vascular smooth muscle. The authors of the study say that by exerting these inotropic and vasodilatory actions, levosimendan increases cardiac output without increasing myocardial oxygen demand.

Professor Ferenc Follath, University Hospital Zürich, Switzerland, and colleagues compared the effects of levosimendan with dobutamine on haemodynamic performance in 203 patients with severe low output heart failure after a 24-hour infusion period. Eleven countries, including the United Kingdom, were involved in the randomised, double-blind trial.

They say that levosimendan improved haemodynamic performance more effectively than dobutamine. After 24 hours, haemodynamic improvement was achieved in 28 per cent of patients treated with levosimendan (n=103) compared with 15 per cent of those treated with dobutamine (n=100). Eight patients in the levosimendan group died within 31 days compared with 17

patients in the dobutamine group and after 180 days there had been 27 deaths and 38 deaths, respectively.

The researchers say that the haemodynamic effects of levosimendan, unlike those of dobutamine, were not attenuated by the concomitant use of beta-blockers. "This finding is important in view of the increasing evidence for and the usefulness of beta-blockers for the management of severe heart failure," they say. The study provided no information on the duration of infusion of levosimendan needed for optimum benefit or on how often it may be repeated in patients who do not respond initially or who relapse after an initial response.

However, they conclude: "Our results are encouraging and suggest that levosimendan could be, for several reasons, a better choice than dobutamine as inotropic therapy for patients with decompensated heart failure." (*Lancet* 2002;360:196).

Therapeutic vaccine controls HIV

A THERAPEUTIC vaccine, Remune, has been shown to stimulate HIV-specific immune responses in 243 HIV infected subjects taking antiretrovirals. The vaccine is being developed by the Immune Response Corp. Data were presented at the 14th International AIDS Conference, held in Barcelona last month.

The researchers say that Remune improves the control of the viral load, increases HIV-specific helper T-cell activity and decreases immune system activation. The three-year phase III study confirms that immunity can be boosted in chronic HIV infection, Dr Fernandez-Cruz, University General Hospital Gergorio Maranon, Madrid, lead researcher, commented.

New drug regimen effective in HIV

A DRUG regimen containing a non-peptide protease inhibitor, tipranavir, has been shown to reduce HIV-1 levels in patients who have previously received multiple protease inhibitor regimens, according to new phase IIb data.

After 48 weeks of treatment, virus from patients who had up to 20 protease inhibitor-resistant mutations at baseline were susceptible to tipranavir.

Tipranavir is being developed by Boehringer Ingelheim. Data were presented at the 11th International HIV Drug Resistance Workshop, held in Seville last month.

Fusion inhibitor vital component of new cocktail therapies for HIV infection

A FUSION inhibitor, T-20 (enfuvirtide), is expected to be a vital component of new cocktail therapies in children as well as adults with HIV infection, according to Roche and Trimeris, the two companies co-developing the new agent. T-20 works by stopping HIV from entering CD4 cells and fusing with host cells.

The companies report that in an ongoing study of 20 patients aged between three and 16 years, T-20 absorption rates were similar to those seen in adults. The patients had more than 5,000 copies of HIV RNA per ml of blood and had taken drugs from at least two of the available antiretroviral classes for three months or more. Subcutaneous injections were initially well tolerated with local reactions of redness and/or thickening at injection sites being the most common side effect. Other related side effects included diarrhoea, decreased appetite and tinnitus.

The companies also report that phase III results, of over 1,000 patients across 112 centres worldwide, have shown that levels of HIV in the blood are reduced when T-20 is used with individually chosen antiretroviral drug combinations. Twice as many patients

achieved a reduction in their viral load below detectable levels in the study arms that contained T-20 than in the study arms that only contained currently available antiretrovirals. They add that T-20 was well tolerated and that twice-daily, subcutaneous administration of the drug was well accepted.

A survey of over 500 patients taking T-20 has shown that subcutaneous self-injections of T-20 do not disrupt patients' lives. Roche and Trimeris say that, after eight weeks of treatment, 65 per cent of patients found that T-20 was either "very easy" or "easy" to use. Most patients reported little or no impact of subcutaneous delivery of T-20 on normal activities of daily living such as familiar routines of work, recreation, sleep, social life, travel, intimacy or privacy.

Data were presented at the 14th International AIDS Conference, held in Barcelona last month.

n Genetic mutations causing resistance to T-20 Researchers have identified genetic mutations in HIV that may cause resistance to T-20. Viral samples were examined from

six patients who did not respond to combination therapy with four or more drugs including T-20. Mutations occurred in regions of the gene sequence that normally remain highly conserved during viral replication, according to Visible Genetics, a pharmacogenomics company, involved in the research. Data were presented at the same meeting.

Cancer vaccine elicits appropriate immune response in patients

A GENE-BASED vaccine in development has shown promise for the treatment of colorectal cancer. The vaccine, TroVax, is being developed by Oxford Biomedica, a biotechnology company.

TroVax works by stimulating the immune system to recognise and destroy cancer cells. The gene that the vaccine contains encodes an antigen, OAB1, that exists on the surface of tumour cells. When the protein is expressed, an anti-tumour response is induced. It is this immune response that is expected to have a beneficial effect, Oxford Biomedica reports.

In a phase I/II trial of 12 patients with advanced stage colorectal cancer who had completed chemotherapy treatment, an immune response to the antigen was elicited in 10 patients. In several patients, induction of the immune response was correlated with reductions in levels of circulating markers of tumour load.

The vaccine is expected to be tested in patients with earlier stage colorectal cancer who are still undergoing chemotherapy.

Data were presented at the International Society for Cancer Gene Therapy conference, held in London last month.

New cream for eczema prevents flare-ups in infants

PIMECROLIMUS (Elidel), an anti-inflammatory cream in development, prevents flare-ups of atopic eczema in children as young as three months, according to new data presented at the 2002 World Congress of Dermatology, held in Paris, France, last month.

Pimecrolimus is expected to be launched in the United Kingdom early next year.

Novartis, the company developing the product, says that the agent works by selectively blocking the production and release of cytokines from T-cells in the skin. Two studies involving 961 children have shown that after one-year of treatment, pimecrolimus prevented flare-ups in 57 per cent of infants aged three to 23 months and in 51 per cent of children aged two to 17 years. In those treated with emollients plus topical corticosteroids as rescue treatment, flare-ups were prevented in 28 per cent of infants and 28 per cent of children.

Dr Neal Maskrey, medical director, National Prescribing Centre, said that pimecrolimus is a welcome additional therapeutic option for people with moderate to severe atopic dermatitis. However, its place in therapy remains unclear. "Fully published trials in people typical of the groups who are likely to use these agents with appropriate comparisons would be very useful to aid decisions about when to use these products," he said.

Drug that modulates glutamate levels promising for Alzheimer's disease

MEMANTINE (Axura), a non-competitive receptor antagonist that modulates levels of the neurotransmitter glutamate, looks promising for the treatment of Alzheimer's disease, new data show.

Memantine is a N-methyl D-aspartate receptor antagonist and is being developed by Forest Laboratories. It is thought to exert a neuroprotective effect on neurons and slows decay when beta-amyloid is present.

In a 52-week multicentre, placebo-controlled study of 252 patients with moderate to severe Alzheimer's disease, those switched to memantine from placebo after

28 weeks showed improvements in cognitive function compared with the projected rate of decline. Treatment with memantine was also found to reduce the costs associated with caring for an Alzheimer's disease patient.

In another study, a combination of memantine and cholinesterase inhibitors was found to be well tolerated in patients with Alzheimer's disease and vascular dementia, researchers say.

Data were presented at the Alzheimer's Association 8th International Conference on Alzheimer's disease and Related Disorders, held in Stockholm last week.