

Second counterfeit medicine discovered in UK

Pharmacists who discover they have unwittingly dispensed counterfeit Reductil should contact patients to alert them to check their medicines, according to official advice from the Royal Pharmaceutical Society.

The advice follows confirmation from the Medicines and Healthcare products Regulatory Authority that fake Reductil (sibutramine) found its way into the official medicines supply chain last week.

The counterfeit packs look similar to the authentic product manufactured by Abbott Laboratories Ltd, but the key difference is in batch numbers.

Genuine Reductil has a numeric batch number with a one-letter alphabetic suffix. The batch reference on supplies of counterfeit Reductil contains only numbers.

Pharmacists in either community or hospital are advised to contact the MHRA if they suspect any counterfeit Reductil has found its way into their dispensaries. And if they are worried about the authenticity of any other medications they should contact their local Society inspector or the MHRA for advice.

The Society's director of practice and quality improvement David Pruce said: "As far as pharmacists are concerned they just need to be aware of counterfeit drugs as an issue and have a slightly higher degree of suspicion such as if there is something [wrong] with the packaging or if a batch number doesn't look right."

The counterfeit drug was spotted by a wholesaler last week after it became suspi-

cious of the batch number and contacted the MHRA.

It is the second case of counterfeit drugs in the UK's legitimate drugs supply chain in 10 days. The first case involved counterfeit supplies of the drug Cialis (tadalafil) (*PJ*, 28 August, p277).

The MHRA was unable to say when its two investigations into the matter would be completed.

The counterfeit drugs which are being recalled by the MRHA are Reductil 15 mg capsules batch number 65542 and Cialis 20mg tablets lot numbers A031410 expiry date 06/2006 and A041410 expiry date unknown.

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Advice from the Society, p361

MHRA repeats warning on unsafe TCMs

A warning that there can be no guarantee of the safety or quality of traditional Chinese medicines (TCMs) has been reissued by the Medicines and Healthcare products Regulatory Agency.

The MHRA issued a similar warning three years ago (*PJ*, 6 October 2001, p452).

The warning is being circulated again in the light of clear evidence that problems with TCMs containing toxic, and often illegal, ingredients persist, with the ingredients not always being declared on labels.

The MHRA says: "There is no reliable way for the public to identify those TCMs which could be unsafe. In the light of this evidence we are unable to give the public any general assurances as to the safety of TCMs on the UK market. When buying TCMs people should always be aware of the possibility of low quality or illegal products. They should not take them if they are not labelled and [do not] include a list of ingredients in English. Even then, clear labelling is not in itself a guarantee of good quality standards."

It explains that unlicensed products with potent and/or illegal ingredients can reach the UK market in a number of ways. These can include a lack of quality control and quality assurance in manufacturing, and in the international supply chain, a failure of con-



Dangerous traditional Chinese medicines continue to be found

cerned parties to check what is permitted in UK law, or intentionally criminal activity.

□ Safety and effectiveness of herbal medicines were among the topics covered in a session sponsored by the Royal Pharmaceutical Society "Can herbs improve your health?" at the British Association Festival of Science held in Exeter this week. Speakers included Peter Houghton, professor of pharmacognosy at King's College London, who said that people taking herbal medicines in conjunction with conventional medicines could be at risk of unknown interactions.

Imports fracture confidence, claims Patients Association

Patients are beginning to lose confidence in the integrity and safety of medicines dispensed by community pharmacies because of parallel importing, according to the Patients' Association (PA).

Roger Odd, a PA trustee, pharmacist and former head of the Royal Pharmaceutical Society's practice division, said: "We've got a problem with patients being worried about what they're getting. The problem is parallel imports from foreign countries being over-labelled. Some of them are wrongly labelled and some are expired."

Such mistakes mean that faulty or counterfeit medicines could be difficult to recall from the market.

Steven McNamara, of the Irish Patients' Association, said: "If they're making this sort of error, how can we trust them to keep the records necessary to be able to recall medicines."

Don Macarthur, general secretary of the European Association of Euro-Pharmaceutical Companies, responded: "Parallel trade in pharmaceuticals is heavily regulated. All products are checked twice — once by the regulatory authorities and again by the original manufacturer — before parallel import licences are issued."

The Independent to publish pharmacy careers supplement

For the second time this year, a special supplement promoting careers in pharmacy is to be circulated with *The Independent*.

The Royal Pharmaceutical Society has joined forces with the newspaper to publish the supplement on 23 September. The earlier supplement was published on 23 February (*PJ*, 21 February, p229).

The new supplement, published to coincide with the British Pharmaceutical

Conference, will reach more than 500,000 readers.

It will highlight career opportunities across pharmacy and focus on topical issues that are shaping the future of the profession. The supplement will also include a contribution from the Society's President, Nicholas Wood, and preview BPC 2004, which takes place in Manchester from 27 to 29 September.

Counterfeit medicines advice

We reproduce the Society's advice for pharmacists on counterfeit medicines found in the UK supply chain (p361).

Council response to BRM motions

A two-page article sets out the Council's response to the resolutions passed at the Society's 2004 branch representatives' meeting (p362).

The Society

Hospital chief pharmacists set to earn over £80,000

Hospital chief pharmacists whose jobs fall into band 9 of the new pay arrangements under Agenda for change will receive salaries of between £66,063 and £83,546.

The salary for pay band 9 has been published in the final draft of the Agenda for change proposed agreement. It sets out the details that support a recent joint statement on Agenda for change (*PJ*, 21 August, p245).

Chief pharmacists' jobs were evaluated at pay band 8c, 8d or above, ie, outside Agenda for change earlier this year.

The recent announcement of the introduction of band 9 at the top end of the scale brings all pharmacy job profiles within Agenda for change. Salaries for bands 8c and 8d have been previously announced.

The new salary will apply from 1 October.

A chief pharmacist allocated to band 9 whose current salary is substantially below the proposed new salary will be initiated on a transitional salary of £57,539 to £62,867. The salary will then be increased over a couple of years until it reaches the pay band level.

The Agenda for change proposed agreement is available via *PJOnline* (www.pjonline.com/links/pj).

Discrimination act deadline approaches

Community pharmacists must make their premises accessible to disabled customers or face potentially expensive legal claims, the Pharmacy Mutual Insurance company has warned.

From 1 October, service providers are required by the Disability Discrimination Act 1995 to make reasonable adjustments to any physical barriers that might stop disabled people making use of their services. Examples of the type of change that might be required include installing ramps or handrails where there are steps leading to a building entrance and replacing door handles with ones that are easier to grip.

Malcolm Jack, general manager of PMI, said: "Pharmacists, as service providers, must

adhere to these requirements and start planning any required adjustments now."

In most cases, the adjustments that need to be made are minimal and will not incur a great cost. In a pharmacy, for example, it will be important to ensure that the aisles between shelving units are wide enough to accommodate wheelchair users.

□ The Department for Work and Pensions will reward best practice in accessibility in the second annual "Access all areas awards" in November. Smaller businesses that provide goods and services to the public and have taken imaginative steps to open up their services for disabled people can enter the awards scheme until 30 September via *PJ Online* (www.pjonline.com/links/pj).

News in brief

Welsh prescription charges

On 1 October prescription charges in Wales will be reduced from £6 to £5, in the first step towards abolishing all prescription charges by 2007, as pledged by the Welsh Assembly Government. The cost of prepayment certificates will be reduced from £31.40 to £26.16 for a four-month certificate, and from £86.20 to £71.83 for a 12-month certificate.

Mental health bill published

Major reform of mental health legislation looks certain following the publication of the revised draft mental health bill on 8 September. More details next week.

News in brief

Pharmacy staff organisation

A new professional association has been formed for pharmacy staff. The Association of Professional Pharmacy Staff aims to give recognition to the qualifications held by pharmacy staff and to assure customers about the standard of advice given by pharmacy staff. For further information, tel 01284 718913.

Breast cancer study

The Breakthrough Generations study, which will investigate the genetic, environmental, behavioural and hormonal factors influencing risk of breast cancer, is seeking to recruit more than 100,000 UK women. The study is expected to last 50 years. For details tel 0870 242 4485, www.breakthroughgenerations.org.uk.

SMC on risperidone

Risperidone has been accepted for use within NHS Scotland by the Scottish Medicines Consortium for the treatment of episodes of mania in bipolar disorder. It says that the drug has similar efficacy to haloperidol in improving symptoms, with fewer extrapyramidal side effects.

MPs investigate pharmaceutical industry's influence on DoH

Members of Parliament began hearings this week to investigate the influence the pharmaceutical industry is able to exert over the Department of Health (*PJ*, 26 June, p791).

The inquiry began on 9 September, after *The Journal* went to press, with officials from the DoH and the Department of Trade and Industry being questioned by the House of Commons Health Select Committee.

The committee has already taken written evidence on the industry's influence over innovation, medical research, regulatory review, product evaluation and information, in-service training and education.

Richard Baker, director-general of the Association of the British Pharmaceutical Industry, said: "The UK-based industry makes an enormous contribution to Britain's health and wealth and it would be reprehensible if we were not in constant communication with everyone involved in the health care process, from the regulators to the NHS on the ground and from politicians to patients. However, there is always room for improvement and the industry hopes that the select committee will encourage a positive dialogue to identify ways in which we can all improve this two-way partnership."

Public health minister visits community pharmacy in Leeds



Melanie Johnson (centre), the public health minister, is pictured with pharmacists, GPs and staff from Leeds North East Primary Care Trust during a visit to Cohen's Pharmacy to find out more about the PCT's minor ailments scheme

Patients with COPD are missing out on treatment

Patients with chronic obstructive pulmonary disease (COPD) may be missing out on appropriate treatment, according to a primary care study presented at the European Respiratory Society meeting in Glasgow this week.

The study recruited 597 patients aged 40 or older with prior diagnoses or taking medicines consistent with COPD though not previously diagnosed with this condition.

David Price from Aberdeen University said that 40 per cent of these patients were found to have COPD. Half had been diagnosed with asthma only and 10 per cent had no prior diagnosis of obstructive lung disease. "The level of misdiagnosis and underdiagnosis

seen in this study is concerning," he remarked. "It is time for primary care professionals to rethink their approach to COPD to ensure patients receive an early, correct diagnosis and appropriate effective treatment," he stated. The study was supported by Boehringer Ingelheim and Pfizer.

The ERS conference also heard that more than half of COPD patients were failing to notify their GPs of an exacerbation. Investigator John O'Reilly, University Hospital, Aintree, said: "By not reporting their exacerbations, COPD patients are not receiving treatment needed to manage their condition and help prevent further episodes."

Spirometry is used to diagnose COPD

Superdrug pharmacists to offer spirometry to target COPD

Pharmacists at 20 Superdrug stores across the UK will be offering spirometry tests to about 1,000 smokers in the week of 15 November, as part of British Lung Foundation activities to mark World COPD Day.

Pharmacists will be targeting long-term smokers of 20 cigarettes or more per day, who are over 35 years. Those whose results suggest they have or are at risk of COPD will be advised to see their doctor.

The initiative will be funded by Boehringer Ingelheim and Pfizer, and the spirometers provided by Vitalograph.

□ The benefits of spirometry screening for symptomatic smokers were highlighted last week at the Primary Care Conference part of the European Respiratory Society meeting in

Glasgow. During a 12-month spirometry screening project at a Lancashire GP practice, at least a third of 56 symptomatic smokers who were found to have significant airway obstruction quit smoking. Of those with mild COPD, 57 per cent were motivated to give up cigarettes. This compared with around a third of patients with either more severe disease or whose symptoms put them at risk of COPD, but who had normal lung function.

Kay Holt, nurse practitioner at Cleveleys Group Practice, Wyre, concluded that targeting intensive smoking cessation support at patients in the earliest stages of airway obstruction could prevent COPD or at least reduce its potential severity. She now plans to carry out a further study in local pharmacies.

Rosuvastatin improves lipid profile in metabolic syndrome

Low-dose rosuvastatin achieves major reductions in LDL-cholesterol and increases HDL-cholesterol in patients with metabolic syndrome, according to results from an AstraZeneca-sponsored study reported at the European Association for the Study of Diabetes meeting in Munich this week.

The COMETS study randomised 397 patients with metabolic syndrome (a cluster of three or more cardiovascular risk factors) to treatment with rosuvastatin (10mg daily), atorvastatin (10mg daily) or placebo for six weeks. The dose of the statins was then doubled for a further six weeks, and the placebo group transferred to rosuvastatin (20mg daily).

Results showed that LDL-cholesterol was reduced by 41.7 per cent in the rosuvastatin group at six weeks, compared with 35.7 per cent in the atorvastatin group ($p < 0.001$). Levels of HDL-cholesterol increased by 9.3 per cent after six weeks' treatment with rosuvastatin, compared with 4.8 per cent with atorvastatin ($p < 0.001$). These differences were maintained at 12 weeks.

A second study showed similar results in type 2 diabetes. Results after eight weeks' treatment showed that 10mg rosuvastatin achieved greater improvements in the lipid profile than 10mg atorvastatin and similar effects to a 20mg dose of atorvastatin.

Old sulphonylureas have higher MI risk than newer agents

Treatment with "older" sulphonylureas is associated with twice the risk of a myocardial infarction than "newer" agents in this class (such as glimepiride and gliclazide), according to data presented at the European Association for the Study of Diabetes meeting this week.

The Danish case-control study matched 6,738 people having a first MI with age- and sex-matched controls, and assessed the rate of MI and deaths in relation to use of sulphonylureas. Results showed that the risk of MI was

nearly three times as high in people using older sulphonylureas (odds ratio, 2.07) than newer agents (odds ratio, 1.36). The overall 30-day mortality rate was 24.6 per cent, reduced to 9.5 per cent in patients taking gliclazide.

The researchers suggested that older sulphonylureas block ATP-sensitive potassium channels in the heart, which prevents the myoprotective effects of ischaemic preconditioning — a process that can reduce damage to the heart during an MI.

Treatment hope for urinary incontinence with multiple sclerosis or spinal cord injury

Two new treatments — cannabinoids and botulinum toxin — have been shown to have some clinical benefit in treating urinary incontinence related to multiple sclerosis or spinal cord injury.

The cannabinoid data come from the Medical Research Council-funded CAMS (cannabinoids in multiple sclerosis) trial. The main trial, assessing effects on spasticity, was published last year (*PJ*, November 13, 2003, p672). The investigators have now reported data from a sub-study assessing whether treat-

ment has any effect on lower urinary tract symptoms, a common problem in patients with longstanding multiple sclerosis. They report a significant reduction in urge incontinence episodes in the cannabinoid group compared with placebo, but no changes in quality of life measures.

The botulinum study was a placebo-controlled European trial in 59 patients with incontinence caused by neurogenic detrusor overactivity associated with multiple sclerosis or spinal cord injury.

Treatment involved a single treatment of botulinum toxin type A (Botox) or placebo, given as 30 injections into the detrusor muscle. Patients were followed up for 24 weeks. There was a rapid and sustained reduction in incontinence episodes in the botulinum-treated patients, and low incidence of side effects. Urodynamic tests also showed improvements in bladder function.

Both studies were reported at the International Continence Society conference in Paris at the end of August.

BP targets unachievable in most patients

Current blood pressure targets are unachievable in most patients, primary care specialists say. They suggest that it is more important to find out what patients want from treatment than to strive to achieve the targets.

Writing in the *BMJ* (2004;329:523), Neil Campbell and Peter Murchie, from the department of general practice and primary care, University of Aberdeen, comment on the two new hypertension guidelines issued this year by the National Institute for Clinical Excellence and the British Hypertension Society.

They say that although there is plenty of evidence of the benefits of lowering blood pressure, treatment targets are less evidence based. Further, to reach current targets (systolic blood pressure of 140mm Hg [or 130mm Hg, eg, in diabetics]), most patients will require up to four drugs. "Some [patients] will judge blood pressure lowering as vital

James Holmes/Read Nurse/SPL

Hypertension: find out what patients want

and will tolerate inconvenience and discomfort to achieve a lowered cardiovascular risk. Others will not and we should accept this."

They conclude: "Appropriate management of blood pressure should therefore be guided by an informed dialogue between patients and doctors and not by blind pursuit of blood pressure targets."

Strong evidence to treat systolic hypertension in the over-60s

There is strong evidence of the benefits of treating systolic hypertension in patients aged 60 years and over, according to a review which identified over 1,000 studies and selected 36 for inclusion.

The authors define systolic hypertension (SH) as 160mm Hg or more. They say that, in older patients, SH is a much more important risk factor for cardiovascular disease than diastolic hypertension. Poor control of SH is increasing, they add.

There is firm evidence from clinical trials to support the treatment of this condition, the review finds. The studies support the use of thiazide diuretics and long-acting calcium channel blockers as first line therapy.

The evidence available to support treatment of patients to the level of 140mmHg or those with baseline systolic blood pressure of 140–159mmHg is less strong. Thus decisions on therapy for these patients should be more sensitive to patient preference and tolerance of therapy, the authors suggest.

"Many questions remain unresolved in the treatment of SH in older persons, leaving patients and clinicians uncertain about how best to balance risks and benefits. In addition, in this age group, decisions about treatment invariably involve trade-offs of substantial risk," say the US researchers (*JAMA* 2004;292:1074–80).

Benefit of beta blockers in elderly heart failure patients

A trial has, for the first time, confirmed the benefit of beta-blockers in elderly patients with heart failure.

The trial involved 2,135 patients. It was designed to evaluate the effects of the beta-blocker nebivolol versus placebo on top of background therapy. Patients were aged 70 or older and had clinically stable chronic heart failure, with or without systolic dysfunction. Patients were randomised to receive either nebivolol or placebo once daily.

The drug reduced the combined endpoint of mortality and cardiovascular hospital admission by 14 per cent compared with placebo.

Investigator Andrew Coats, University of Sydney, Australia, said: "We know that there is underuse of beta-blockers in heart failure patients. This is especially the case for those aged 70 and over. Doctors have been concerned that the trials to date have not recruited patients like the ones they see in routine practice. The SENIORS study addresses this concern, and hopefully, as a result, will change clinical practice so that every elderly patient that could benefit from optimal heart failure treatment will get it."

Results were reported at last week's European Society of Cardiology meeting in Munich.

Can vessel endothelium predict cardiovascular risk in children?

Changes in children's small blood vessel function may predict future heart disease. So said Dr Faisal Khan, of Dundee university, speaking at this week's British Association science festival in Exeter.

In a conference session on the microcirculation, Dr Khan highlighted his previous work testing microvascular function in children. His group had studied 145 normal, healthy children aged 11 to 14.

They found that about 20 per cent of the children tested had signs of endothelial dysfunction, though none had symptoms of heart disease. Endothelial dysfunction is recognised to have a key role in atherosclerosis and is related to many risk factors associated with the development of cardiovascular disease in later life. The group found that microvascular function was poorer in those with higher body fat and signs of insulin resistance, both cardiovascular risk factors.

Dr Khan suggested that, with indicators of cardiac risk apparent in childhood, lifestyle interventions should be made at this age. Unhealthy lifestyle factors should be identified and physical activity, weight management and a healthy diet promoted, he added.

New guide to NHS modernisation launched

A definitive guide to modernising the NHS was launched this week by the NHS Modernisation Agency.

The guide sets out 10 key principles of modernisation, called "The 10 high impact changes for service improvement and delivery". They are evidence-based, and take a "systems" approach rather than focussing on different sectors or professions.

The guide offers a number of opportunities for pharmacists. In particular, around discharge from hospital, chronic disease management and role redesign.

Variation in discharge from hospital is a problem identified by the guide. It says that length of patient stay is highly variable and unpredictable. However, it notes that the discharge process is in the health service's control so there is significant opportunity to redesign the system. Some of its suggestions include establishing regular decision-making ward rounds, identifying and planning around lead-in times for discharge (eg, for test results,

medicines and transport), and matching the time of discharge with the time that beds are required (*PJ*, 4 September, p307).

How patients with chronic conditions are managed needs to be changed, the guide states. Instead, a more pro-active, systematic approach underpinned by good prevention is

needed. This includes recognising the role that self-care plays, providing systematic disease management and care planning, and providing case management for those at high risk of deterioration.

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

The 10 high impact changes

- Treat day surgery rather than inpatient surgery as the norm for elective surgery
- Improve access to key diagnostic tests
- Manage variation in patient discharge from hospital
- Manage variation in patient admission to hospital
- Avoid unnecessary follow-ups for patients and provide necessary follow-ups in the right care setting
- Increase the reliability of performing therapeutic interventions through using a "care bundle" approach
- Apply a systematic approach to care for people with long-term conditions
- Improve patient access by reducing the number of queues
- Optimise patient flow through service bottlenecks by using "process templates"
- Redesign and extend roles to attract and retain an effective workforce

Medicines management guide launched for PCTs and NHS trusts

How the medicines management aspects of national service frameworks should be implemented is set out in a new resource published this week by the Department of Health.

The guide is designed to provide practical support for primary care trusts and NHS trusts to implement the diabetes NSF, the renal services NSF and the forthcoming NSF on long-term conditions. It includes existing guidance, published evidence and examples of innovative practice.

The handbook describes why medicines management is needed, and the evidence for

it, and then sets out a framework for action. The aim of the framework is to help local implementation teams identify and prioritise areas for action.

The resource also describes what a good medicines management programme should include; from the processes that should be in place in GP practices, to those at PCTs and hospitals. It states that a successful programme should have the following outcomes:

- Improved patient experience and satisfaction

- Better patient health outcomes
- Reductions in unused waste medicines returned to community pharmacies
- Intended medicines usage as described in NSFs
- Improved patient understanding about their medicines so that patients are able to state what medicines they are taking and what they are taking them for, resulting in improved compliance

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

£6m cancer project

Nine areas of England are to pilot schemes to improve the quality of care for cancer patients. The two-year pilots will cost £6m.

Patients in the nine areas will be monitored to see how earlier diagnosis and better service co-ordination can help them find their way through the NHS more easily, reduce uncertainty and improve well being.

FIP launches pharmacists' HIV/AIDS network

The International Pharmaceutical Federation (FIP) has launched an online HIV/AIDS network for pharmacists. It is intended to help pharmacists obtain resources on HIV/AIDS in order to serve their patients and the public better and to combat the discrimination and stigma related to the illness.

The network, accessible via *PJ Online* (www.pjonline.com/links/pj), is in English and French and includes a discussion forum

to facilitate communication between pharmacists working in the field. It will also be used to disseminate HIV/AIDS training modules being prepared jointly by FIP and the World Health Organization.

The network was launched during the World Congress of Pharmacy and Pharmaceutical Sciences, which took place this week in New Orleans, Louisiana.

Congress reports, p355-9

PJ Online

International Pharmaceutical Federation (FIP)
Reports from the 2004 congress, taking place this week, are now online. Earlier reports are also available.
www.pjonline.com/reports/fip

Pharmacy around the world
Articles on pharmacy, from America to Zimbabwe
www.pjonline.com/series

Patient information on the internet is too complicated

Websites giving information for diabetes patients are too complicated for most people.

One of the most difficult to understand is NHS Direct, which demands a reading age of 16.8 years. The UK average reading age is nine years.

Dr Maged Boulos, of the University of Bath's School for Health, looked at 15 inter-

net websites and found that the easiest to understand included one aimed primarily at health professionals (NHS Prodigy) and the BMJ Publishing Group "Best treatments" site.

Dr Boulos said: "Public and patient health information that is difficult to understand or liable to misunderstanding by the lay consumer could result in serious consequences."

Osteoarthritis patients may benefit from new drug

Lumiracoxib, a cyclo-oxygenase 2-selective inhibitor due to be launched in the UK next year, has been shown to cause fewer ulcer complications in patients with osteoarthritis than naproxen or ibuprofen, without increasing the rate of serious cardiovascular events.

In the Therapeutic Arthritis Research and Gastrointestinal Event Trial (TARGET), sponsored by Novartis, over 18,000 patients with osteoarthritis were randomised to lumiracoxib 400mg daily versus naproxen 500mg twice daily or ibuprofen 800mg three times daily, for 52 weeks, in two identical substudies. Low dose aspirin was also being taken by 24 per cent of patients. Patients were assessed for upper gastrointestinal ulcer complications, such as bleeding, perforation and obstruction, and for adverse cardiovascular events (myocardial infarction, stroke or cardiovascular death).

In patients not taking aspirin, the cumulative one-year incidence of ulcer complica-

Patients with osteoarthritis may benefit from treatment with lumiracoxib

tions was 1.09 per cent with the non-steroidal anti-inflammatory drugs versus 0.25 per cent with lumiracoxib ($P < 0.0001$). This is equivalent to a four fold reduction (79 per cent). In patients taking aspirin, reductions in ulcer complications were not significant. In the overall population (aspirin and non-

aspirin), ulcer complications were reduced by about three fold (66 per cent) with lumiracoxib compared with the NSAIDs.

The incidence of overall adverse cardiovascular events was not found to differ significantly between treatment groups. Patients taking lumiracoxib experienced smaller changes in blood pressure than those taking the NSAIDs. Liver function test abnormalities occurred in 2.6 per cent of patients taking lumiracoxib, compared with 0.6 per cent taking the NSAIDs. The authors say that this effect was reversible on discontinuation of the drug and point out that the lumiracoxib dose used was two or four times more than the recommended chronic dose for osteoarthritis.

The authors conclude that lumiracoxib is an appropriate treatment for patients with osteoarthritis, who are often at high cardiovascular risk (*Lancet* 2004;364:665 and 675).

Lumiracoxib, manufactured by Novartis, is due to be marketed as Prexige in 2005.

Sinclair Stammers/SPL

Gene therapy slows prostate cancer growth

The development and progression of prostate cancer could be slowed by a new gene therapy technique.

The androgen receptor (AR) has been shown to play a key role in the development of prostate cancer by regulating genes important for progression of the disease. A team of researchers from Imperial College London, Cancer Research UK and Hammersmith Hospital, London, were able to stop this action by fusing a repressor protein called PLZF with the AR. They transduced PLZF-AR into prostate cancer cell lines using a virus as a vector, and found that PLZF-AR silenced the AR-regulated genes and inhibited the androgen-regulated growth of the cancer cells.

Jonathan Waxman, one of the researchers from Imperial College, said: "We hope to combine, using this repressor, with existing

cancer treatments to help develop newer, more effective methods to treat cancer." The study appeared in an advance online publication of *Oncogene* (www.nature.com/onc).

Prostate cancer gene identified

Researchers have identified a gene that they believe may have an important role in determining how aggressive a patient's prostate cancer will be. They found that the E2F3 gene was present in 67 per cent of human prostate cancer cells but it was not detected in the cells of men who had not been diagnosed with prostate cancer. Furthermore, the higher the levels of E2F3 that were detected, the poorer the patients overall survival was found to be ($P = 0.0022$). The researchers say that over-expression of E2F3 is an independent prognostic marker of poor clinical outcome (*Oncogene*, as above).

Genetic markers may predict response to DMARDs

Patients with early rheumatoid arthritis who are likely to benefit from treatment with disease-modifying anti-rheumatic drugs (DMARDs) may be identified by genetic tests, new research suggests.

By analysing genetic and clinical data from 457 subjects taking part in a previous trial comparing methotrexate and etanercept, US researchers have found variations in two particular gene regions that are associated with response to the drugs.

They found that patients who had two copies of a particular allele (HLA-DRB1) encoding the shared epitope were three to four times more likely to achieve 50 per cent improvement in disease activity after 12 months treatment with etanercept compared with methotrexate than patients with one or no copies of the alleles.

The researchers also found that patients who had specific HLA genes in addition to particular genetic variations in the tumour necrosis factor gene region had better responses to both drugs (*Arthritis and Rheumatism* 2004;50:2750).

Leptin injection may be useful in amenorrhoea

Injection of recombinant human leptin has successfully treated hypothalamic amenorrhoea in a recent, small US study.

Hypothalamic amenorrhoea occurs typically in athletes or underweight women. Leptin is the hormone thought to be linked to the suppression of reproductive function in such women in response to low energy stores.

Researchers from Harvard Medical School studied eight women with hypothalamic amenorrhoea for one month before and three months after treatment with recombinant human leptin. The women self-administered the subcutaneous injection at a dose of 0.08mg/kg/day: 40 per cent of the dose was given at 8am and 60 per cent at 8pm to

mimic normal diurnal leptin levels. Five of the eight subjects, whose periods had stopped a mean of five years beforehand, went on to start menstruating. In three of these women ovulation occurred and, in the other two, pre-ovulatory follicles developed.

Leptin administration increased the levels of reproductive, thyroid and growth hormones without apparent adverse effects. The authors of the study say that the current treatment of hypothalamic amenorrhoea, oestrogen, may have side effects and does not address underlying infertility. They add that further studies are warranted to determine the safety and efficacy of this agent (*New England Journal of Medicine* 2004;351:987).

News in brief

Liraglutide trial results positive

New data have shown that liraglutide, a long-acting analogue of GLP-1 hormone currently under investigation by Novo Nordisk for type 2 diabetes, can provide improved blood glucose control without associated weight gain. The data were reported at the European Association for the Study of Diabetes in Munich this week.

Correction

The director-general of the Association of the British Pharmaceutical Industry is Richard Barker, not Richard Baker (p336).