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LEWIS WHYLD/PA WIRE

The High Court upheld NICE's decision against using the drug donepezil in mild to moderate cases

High Court backs NICE's decision on Alzheimer's drugs

Owen Dyer LONDON

Campaigners and drug makers failed last week in their High Court bid to overturn guidance recommending only limited coverage on the NHS of drugs to treat Alzheimer's disease.

This was the first major legal challenge to guidance issued by the National Institute for Health and Clinical Excellence (NICE), the body that recommends which drugs are available on the NHS in England and Wales.

Mrs Justice Dobbs ordered NICE to amend the existing guidance, having ruled that its diagnostic criteria breached the Disability Discrimination Act and the Race Relations Act. NICE undertook to make the relevant changes within 28 days—but the core of the guidance will remain unchanged.

The guidance recommends against the use of donepezil (Aricept), rivastigmine (Exelon), and galantamine (Reminyl) in patients with mild to moderate Alzheimer's disease and against the use of memantine (Ebixa) in moderately severe to severe disease.

The court's decision means that the NHS will not typically cover the costs of acetylcholinesterase inhibitors for patients who are given a new diagnosis of Alzheimer's disease. Patients already

The core of the guidance will remain unchanged

taking the drugs, however, will continue to receive them under an arrangement made in 2006, when NICE reversed its previous recommendation that the drugs be covered.

The judge rejected claims by the Alzheimer's Society that NICE's deliberative process failed to take adequately into account the potential benefits to carers and failed to reflect the full costs of long term care.

The court also dismissed a claim from the manufacturer of donepezil, Eisai, and its UK distributor, Pfizer, alleging that NICE acted unfairly in releasing a "read only" version of its economic model document in which changes could not be tracked.

Mrs Justice Dobbs also rejected a claim that NICE's assessment of data from research into Alzheimer's disease was irrational.

But she upheld the claim of the Alzheimer's Society that the questionnaire NICE recommends for diagnosing the severity of Alzheimer's disease, the mini-mental state examination, potentially discriminates against non-English speakers and people with learning disabilities.

The claimants were ordered to pay 60% of the case's legal costs and were denied leave to appeal.

NICE delays decision on drugs for macular degeneration

Caroline White LONDON

The National Institute for Health and Clinical Excellence (NICE) has had to delay its final decision on two drugs for age related macular degeneration after mounting pressure from charities and healthcare professionals.

NICE, which advises health authorities in England and Wales on the treatments to use on the NHS, issued preliminary guidance in June on the use of ranibizumab (marketed as Lucentis) and pegaptanib (Macugen) for the treatment of the disease. Both drugs are already available in Scotland.

It argued that pegaptanib should not be used at all and that ranibizumab should be prescribed only to the one in five people with the neovascular or "wet" form of the disease and only where both eyes were affected and in the better seeing eye only.

Both drugs target vascular endothelial growth factor, high concentrations of which can prompt excess blood vessel formation and fluid leakage in the eye.

Around 26 000 people develop the wet form of age related macular degeneration every year in the United Kingdom, and 245 000 people are blind or visually impaired as a result.

NICE's conclusions sparked a wave of protest from patients and healthcare professionals that continued after the statutory consultation period closed, following a campaign spearheaded by the Royal National Institute for the Blind (RNIB).

The Royal College of Ophthalmologists and the Royal College of Nursing had both pressed for the drugs to be made available to NHS patients. The *Drug and Therapeutics Bulletin*, published by the BMJ Publishing Group, called NICE's stance "unacceptable."

The institute said at the time of its initial decision that both drugs were very expensive and that most people with age related macular degeneration sought help only once their second eye was affected. But last week it decided to postpone its deliberations until the autumn while it reviews the figures for the projected costs to the NHS.

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Audit Scotland wants more effective care for long term illness

Bryan Christie EDINBURGH

Decisions on managing long term medical conditions in Scotland are being made on limited evidence of what works for patients, says a report from the public service watchdog, Audit Scotland.

The report calls for better information to be provided urgently on the cost, quality, and scope of such services to ensure the best use of resources and the most appropriate service provision in the future.

The report says that managing long term conditions is one of the biggest challenges facing healthcare systems worldwide. In the United Kingdom these conditions account for 80% of all GP consultations and 60% of hospital bed days. The number of people with long term conditions is expected to rise markedly over the next 20 years, in line with the ageing of the population.

The watchdog looked in particular at two diseases: chronic obstructive pulmonary disease and epilepsy. The report found that services are improving but that progress could still be made.

The current policy is to develop community based services to look after people with long term conditions. This requires the redesign of existing care and the transfer of resources from hospital to community services. The report says, however, that decisions on the best use of resources are currently being made on limited evidence and that there is little information at a national or local level on activity levels, costs, and effectiveness of services. "This gap urgently needs to be filled," it says.

The report recommends that the Scottish Executive Health Department, NHS boards, and local authorities should collect better information and should agree targets on the development of community based services. They should also evaluate different ways of providing services to ensure cost effectiveness and to promote the sharing of good practice. Audit Scotland's report also finds that patients want better information about their conditions and more say in their own care.

Barbara Hurst, director of public reporting at Audit Scotland, said, "The Scottish Executive, health boards, and councils need to do more to make improvements nationwide and to create joined-up services."

Managing Long-Term Conditions is available at www.audit-scotland.gov.uk.

GMC looks into complaints about overseas trained doctors

Peter Moszynski LONDON

The General Medical Council has commissioned new research to establish why UK doctors who trained overseas seem to be disproportionately represented at its fitness to practise hearings.

Figures released by the GMC last month show that of the 3086 complaints lodged against doctors in 2006 where the doctor's country of training was known, nearly 40% referred to overseas trained doctors—roughly in proportion to their numbers in the NHS workforce—but the percentage of overseas trained doctors who were then referred to hearings was twice that among UK graduates (34% versus 16%). However, in a further 1279 complaints made about doctors the doctor's place of training was not given.

Overseas trained doctors seemed more likely to be struck off

Of those 3806 inquiries, 2334 related to UK trained doctors, 1143 were "international," 309 from the European Union, and 20 were "other European." Overseas trained doctors also seemed more likely to be struck off: of the 54 doctors removed from the medical register last year, 35 of them had trained abroad.

The figures only refer to whether a doctor graduated abroad (either within the European Union or in other countries) or in the UK so do not give details of nationality, language, or ethnicity. A British doctor who trained in Australia would appear as an overseas graduate, while an Iraqi who trained in the UK would appear in the British statistics.

Paul Philips, the GMC's director of standards and fitness to practise, said, "The number of fitness to practise cases we deal with is going up year on year. Doctors with a primary medical qualification from overseas or within the EU are disproportionately represented, and more are being referred to us than we should be seeing, without a good explanation."

The GMC began to investigate the issue last November after similar findings from the 2005 statistics, and the Economic and Science Research Council, the UK's leading research funding and training agency, has initiated a number of research projects into the implications of these findings as part of a larger programme examining the links between career transitions and medical performance.

The GMC says that the studies are "designed to help understand the experiences of doctors from different backgrounds and the contexts within which concerns about doctors are referred to us."

The GMC says "recent international research points to performance problems occurring as a result of the transition process, from . . . one country to another, from one stage of training to another, and so on."

PAVEL RAHMAN/ASSOCIATED ORESS

A Bangladeshi woman pulls a makeshift raft, carrying drinking water

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NOZIZWE MADLALA-ROUTLEDGE/ASSOCIATED PRESS

Nozizwe Madlala-Routledge speaking to the press after her dismissal

South African health minister sacked after attending AIDS conference

Pat Sidley JOHANNESBURG

President Thabo Mbeki of South Africa last week fired his outspoken deputy minister of health, Nozizwe Madlala-Routledge. The sacking unleashed an unusually vigorous wave of support for her among opposition parties, trade unions, doctors, and AIDS activists as well as a torrent of criticism against the minister of health, Manto Tshabalala-Msimang, and the president.

Ms Madlala-Routledge had flown to an AIDS conference in Madrid in June, which Mr Mbeki says she did not have permission to attend. She told a radio station after being sacked that she had been invited to address the International AIDS Vaccine Initiative (IAVI) meeting and believed she had permission to go before leaving. When told she did not have permission she flew back to South Africa without delivering her speech.

Much of the criticism of the sacking has its background in the president's views on HIV and AIDS—he has questioned the link between the virus and AIDS (bmj.com, 14 Oct 2006, News Extra).

The president was eventually forced to release the letter of dismissal to her giving reasons for her firing. It referred to her previous stint as deputy minister of defence and said, in part, "I have, during the period you served as deputy minister of defence, consistently drawn your attention to the concerns raised by your colleagues about your inability to work as part of a collective, as the constitution enjoins us to." It continued: "You travelled to Madrid despite the fact that I had declined your request to undertake this trip. It is clear to me that you have no intention to abide by the constitutional prescriptions that bind all of us."

Extreme weather affects half a billion people

Peter Moszynski LONDON

In the wake of unprecedented flooding across the world, humanitarian agencies are appealing for immediate help and warning that serious planning efforts must be made to mitigate disasters, given the likelihood of increasing devastation from the effects of global warming.

The International Federation of the Red Cross and Red Crescent Societies said, "Severe flooding has affected tens of millions of people around the world in recent weeks and months, including Bangladesh, China, Colombia, India, Indonesia, Nepal, Pakistan, and Sudan. From Dhaka to Khartoum, officials say they are seeing the heaviest rains in decades and, in some cases, recent memory."

The federation estimates that 35 million people have been affected in South Asia, while a "staggering" 200 million people have been affected by the floods in China.

It is feared that a lack of clean drinking water will result in widespread outbreaks of waterborne diseases, such as diarrhoea, skin infections, and malaria.

Cholera is reported to be spreading in Bangladesh, where local authorities report that more than a million homes have been destroyed by floodwaters in recent weeks. In India doctors have been asked to forgo their August holidays to help cope with the consequences of record monsoon rainfall across wide areas.

See www.oxfam.org.uk and www.reliefweb.int.

UK heart surgeons improve patients' survival rates

Toby Reynolds BMJ

Heart surgeons in the United Kingdom have raised the standards expected of them, figures published last week by the Healthcare Commission show.

The data on survival of patients after heart surgery, issued by the independent healthcare regulator in England, cover 38 of the 39 hospitals in the UK that carry out major heart surgery (St Mary's Hospital, London, was unable to supply the data in the format required). The figures show that 96.5% of the 35 064 patients who underwent any kind of heart surgery in the year to March 2006 survived (left the hospital alive).

The commission looked in particular at survival of patients after the two most common heart operations: heart bypass and aortic valve replacement.

Survival after heart bypass operations remained better than expected, said the commission. In the UK 20 773 such operations were performed between April 2005 and March 2006. Of these patients 98.4% survived, above the expected range of 97.7% to 98.3%.


AJ PHOTO/SPL

Prosthetic heart valve

The survival rate of 98% among the 3504 patients undergoing aortic valve replacement operations was within the expected range of 96.6% to 98.2%.

The overall survival rate was similar to the 96.6% seen in the previous year.

The main change this year is in what the website shows as an expected standard alongside the actual survival data for individual hospitals. The site compares actual survival with a predicted rate calculated from patients' characteristics, so that hospitals or surgeons who take more difficult cases are not disadvantaged. This year a new and more exacting UK algorithm that gives higher expected survival rates has been added to the Euroscore model that was used last year.

The Healthcare Commission first published cardiac surgery survival data on its website last year to help patients make more informed choices about their care.

The UK rates of survival after heart surgery are at http://heartsurgery.healthcarecommission.org.uk

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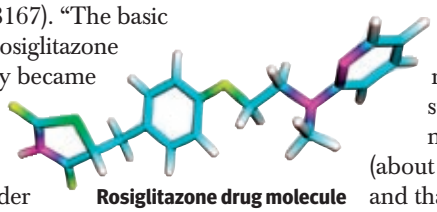
FDA needs more funding, journal says, amid questions about antidiabetes drug

Janice Hopkins Tanne NEW YORK

The US Food and Drug Administration needs more funding to do its job, say two articles in the *New England Journal of Medicine* (*NEJM*) related to reports of an increased cardiovascular risk associated with rosiglitazone (marketed as Avandia), used to treat type 2 diabetes.

Earlier this year the FDA placed its most serious "black box" warnings on rosiglitazone, which is made by GlaxoSmithKline, and pioglitazone (Actos), made by Takeda, saying that they increased the risk of congestive heart failure (*BMJ* 2007;334:1237).

Clifford Rosen, who chaired the FDA advisory committee that looked into the drug, has written a commentary in the *NEJM* (doi: 10.1056/NEJMp078167). "The basic plot of the rosiglitazone story quickly became obvious to the . . . committee: a new 'wonder drug,' approved prematurely and for the wrong reasons by a weakened and underfunded government agency subjected to pressure from industry, had caused undue harm to patients."



Rosiglitazone drug molecule

Earlier this month the committee recommended keeping rosiglitazone on the market, because it might help patients, but that it should carry stronger warnings (*BMJ* 2007;335:223, 4 Aug). Dr Rosen said that the rosiglitazone studies were mostly short (about six months) and that adverse events might be classified differently in some studies. The committee lacked information about the other glitazone drug, pioglitazone, because the FDA had not completed reviewing the manufacturer's data.

Dr Rosen, an endocrinologist, is a senior staff scientist at St Joseph Hospital in Bangor, Maine, and the Jackson Laboratory in Bar Harbor, Maine. He told the *BMJ* that the FDA needed more funding and should undergo a "sea change" in the way it evaluates drugs.

Instead of relying on surrogate end points such as glycaemic control or lipid concentrations it should look at clinical events such as myocardial infarction, he said. More funding would enable the FDA to increase its staff and design longer studies that would yield better results, such as two year, prospective, randomised controlled trials, he added.

DR TIM EVANS/SPL

Skin cancer is on the increase—but lung cancer is falling

Adrian O'Dowd MARGATE

The incidence of some cancers is rising in the United Kingdom because of people's lifestyle choices, says Cancer Research UK.

The charity has published new statistics showing steady rises in the numbers of cases of some types of cancer that are linked to excessive exposure to sun, alcohol consumption, smoking, and obesity.

The number of new diagnoses of malignant melanoma—the most dangerous form of skin cancer—rose from 5783 in 1995 to 8939 in 2004, making it the fastest rising cancer in the UK. This represented an increase in incidence per 100 000 people, adjusted for age, of 43%.

ROMAN PODERNY/REX

Lung cancer is still a bigger killer than skin cancer

The incidence of oral, uterus, and kidney cancers has also risen in the 10 years to 2004, says Cancer Research UK. And it adds that around half of all cancers could be prevented if people modified their lifestyle.

The new figures, published by the charity and the UK Association of Cancer Registries, show that:

- From 1995 to 2004 the number of new diagnoses of oral cancer rose from 3696 to 4769 (six cases in every 100 000 people in the UK population), an increase in age standardised incidence of 23%
- Cancer of the uterus rose from 5018 to 6438 (16.8 per 100 000), a 21% increase in age standardised incidence, and
- Cancer of the kidney rose from 5636 to 7044, a 14% increase in age standardised incidence.

Together these four types of cancers account for almost 10% of all the 284 560 new diagnoses of cancer in the UK in 2004.

Over the same period, however, the incidence of cervical cancer fell, as a result of the national screening programme, and the incidence of lung cancer continues to fall, thanks in part to successful smoking cessation campaigns.

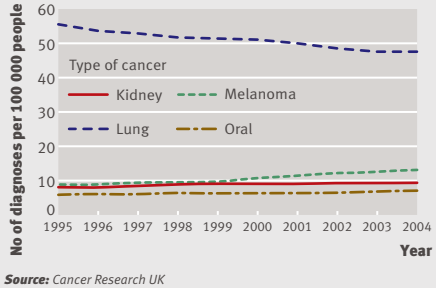
The number of new diagnoses of cervical cancer fell from 3478 in 1995 to 2726 cases in 2004 (a fall in age standardised incidence of 24%) and those of lung cancer fell from 40 787 to 38 313 (13%). However, lung cancer, with an incidence of 47.6 per 100 000 in 2004, is still the commonest cancer.

Ian Fentiman, professor of surgical oncology at Guy's, King's and St Thomas' School of Medicine, London, said the new statistics were important but had to be considered in context.

"These are certainly not the biggest cancers out there," he said. "The things we should still be panicking about are things like smoking, because lung cancer is still a mega-killer."

Details of the incidence of cancers in the UK in 2004 are at http://info.cancerresearchuk.org/cancerstats/incidence/.

UK INCIDENCE OF KIDNEY, LUNG, AND ORAL CANCERS AND MALIGNANT MELANOMA



Source: Cancer Research UK

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