

## WHO warns of a polio epidemic in Africa

Fiona Fleck *Geneva*

Africa could be on the brink of a major poliomyelitis epidemic after a child in Sudan's crisis-ridden Darfur region was found to have been paralysed by the disease last month, World Health Organization officials warned on Tuesday.

It was the first confirmed case of polio, which mainly affects children under the age of five, in the country for three years.

Sudan is the tenth African country in which the disease has

reappeared since Nigeria's Islamic states suspended immunisation last August. WHO officials believe that the virus travelled from Nigeria across Chad to Sudan.

"The virus is spreading at an alarming pace," said David Heymann, the WHO epidemiologist in charge of the global polio eradication campaign.

"African countries have worked rapidly and effectively to eradicate polio; now the tragedy is that many of them are becom-

ing reinfected," Dr Heymann said.

Nigeria's failure to participate fully in the programme has been a major setback to achieving WHO's goal of eradicating polio globally by the end of 2004 and the main reason why the number of polio cases has nearly doubled globally to 333 from 183 this time last year.

The other reason for the increase is low coverage of the vaccine in the 10 previously polio free countries, which besides Sudan are Benin,

Botswana, Burkina Faso, Cameroon, the Central African Republic, Chad, Côte d'Ivoire, Ghana, and Togo.

When the eradication initiative was launched in 1988 polio was endemic in 125 countries. Today it is endemic in Nigeria, Niger, Egypt, Pakistan, Afghanistan, and India.

Islamic states in Nigeria that suspended immunisation claimed that the vaccine caused sterility and was a US plot to spread HIV infection. □

## GlaxoSmithKline to publish clinical trials after US lawsuit

Liza Gibson *London*

The world's second largest pharmaceutical company, GlaxoSmithKline, is to publish summaries of the results of all its clinical trials on its website once a product has been launched.

GlaxoSmithKline said it has been considering the move for several months now, but it follows on the heels of a US lawsuit, filed by Eliot Spitzer, New York state's attorney general, earlier this month.

Mr Spitzer alleged the company engaged in "repeated and persistent fraud" for concealing the results of clinical studies for its antidepressant paroxetine; these suggested the drug was ineffective and unsafe in treating depression in children and adolescents (12 June, p 1395).

Mr Spitzer also had an internal memo (dated 1998) from GlaxoSmithKline's predecessor company, SmithKlineBeecham, which said that it would be "commercially unacceptable" to admit the results. This document was published in the Canadian Medical Association's

journal, *CMAJ*, earlier this year and reported in the *BMJ* (21 February, p 422).

A GlaxoSmithKline spokesperson said the company decided to undertake the move now to increase transparency in clinical trials and to restore trust in research undertaken by the pharmaceutical industry.

A few days before the announcement, GlaxoSmithKline had already published full reports (including raw data) of eight trials of paroxetine in children on its website. Although paroxetine is not licensed for use in children, it has been used off label. Last year, the United Kingdom contraindicated its use in these groups while the United States issued warnings.

Mr Spitzer described GlaxoSmithKline's actions as a "positive step": "The availability of this information is in the best interest of the consumer. We will continue our efforts to change industry practice in this area." However, he added that it would not resolve all of the issues in the lawsuit.



Tadataka Yamada of GlaxoSmithKline said the trial register "will be a major advance"

The lawsuit has also raised an old topic—publication bias towards negative trial results, which has long been debated by academic circles—and brought it into the mainstream. Last week the American Medical Association urged the US Department of Health and Human Services to set up a public registry on clinical trials after the Spitzer lawsuit.

The database, to be called the GSK Clinical Trial Register, will be accessible to doctors and

the public in the third quarter of this year. It will be gradually built, as the company has some 49 products, but it is envisaged that it will include all clinical trials (phase I to phase IV) and data on efficacy and safety.

Tadataka Yamada, GlaxoSmithKline's chairman of research and development, said: "The GSK Clinical Trial Register will be a major advance in providing online access to information to support patient care, facilitating access to study summaries by putting them on a single internet site."

Other companies have not been so forthcoming. In May 2003 the UK trade body, the Association of the British Pharmaceutical Industry (ABPI), launched its own clinical trial register, which publishes basic information on trial protocols, but no data on trial results. However, fewer than 10 pharmaceutical companies participated in this project (GSK did not take part).

Separately, the UK parliamentary health select committee has announced an inquiry into the influence of the pharmaceutical industry on health policy, research, prescribing practice, and use of drugs by patients. □