

WHO to unveil global clinical trials register

WHO will unveil the world's first global clinical trials register in November in a transparency drive that has gained momentum after recent accusations that drug companies suppressed vital data.

Dr Tikki Pang, Director of WHO's Research Policy and Cooperation department said that, initially, registration under the new scheme would be voluntary but that a legal requirement may be necessary later to ensure that all clinical trials are centrally registered.

"Eventually, some sort of enforcement procedures may be essential," Dr Pang said.

The plan is to unveil plans for the global register at the Ministerial Summit on Health Research to be held in Mexico City, 16-20 November.

Health research councils in countries like Brazil, India and South Africa could assist in ensuring that trials in their countries be incorporated into the register, he said.

He rejected the notion that the monitoring of clinical trials in developing countries was less advanced than in the developed world.

Dr Pang said WHO had the potential to establish binding international procedures because it represented 192 governments: "Our advantage is our official link with national governments".

Earlier this year, a lawsuit against pharmaceuticals giant GlaxoSmithKline (GSK) filed by New York State attorney-general Eliot Spitzer propelled the issue of missing trial data to centre-stage.

In the lawsuit, GSK was accused of suppressing negative trial data on anti-depressant paroxetine in children, conducted by SmithKlineBeecham before its 2000 merger with GlaxoWellcome.

The lawsuit underscored the wider problem of how to ensure that all clinical data are published and easily accessible to the public.

In response, the Pharmaceutical Research and Manufacturers of America adopted new voluntary guidelines in June urging members to "commit to the timely communication of all meaningful results of clinical trials, whether those results are positive or negative".

But Kay Dickersin, Director of the Center for Clinical Trials and Evidence-Based Healthcare at Brown University, said US regulators, the

Food and Drug Administration (FDA), already had legal requirements for drug companies to register trials on a government database.

"There's an obscure 1997 law and an even more obscure law from 1993, but neither have ever been enforced", Professor Dickersin said, adding: "The FDA lacks teeth. It's a regulatory agency, not an enforcement body".

FDA spokesperson Susan Cruzan confirmed that the FDA had never enforced existing provisions on clinical trials but said regulators were now considering whether to ask legislators for new enforcement powers.

Dr Pang said he hoped WHO's register could play a key role in making the registration of clinical data legally binding globally.

He said the Framework Convention on Tobacco Control which was adopted at the World Health Assembly in 2003 could provide a precedent and legal model for clinical trials, as countries which ratify the convention are obliged to enforce its provisions.

Dr Pang said WHO was also looking to national health research organizations, research funders, consumer organizations and publishers for help.

"For example, ethics review boards in the United States and other countries might insist that a trial be assigned a registry number. We've talked to the Rockefeller Foundation, Bill and Melinda Gates Foundation, the Canadian Institutes of Health Research, the Wellcome Trust and the Medical Research Council in Britain, among others," Dr Pang said.

WHO plans to use an existing numbering system, the International Standard Randomized Controlled Trial Number Register (ISRCTN), for the new global clinical trials register.

At present the register contains all WHO-sponsored trials in reproductive health and childhood diseases. Those in

tropical diseases will be next, and vaccine trials are likely to follow.

With its global launch, the register will be open to any organization conducting clinical trials.

Dr Pang said the register in the form of a database administered by the British publishing house Current Controlled Trials Ltd may not be a long-term solution because it is run by a private company which could in theory go bankrupt, and because it charges a fee.

"A few hundred dollars may be trivial to a pharma giant, but it matters more to researchers from the South. For that reason, we are considering using our own numbering system, something like the ISBN number used in book publishing," Dr Pang said.

"The service must be free to users.

In particular, we want the database to be used by members of the lay public," he said, citing an inquiry he received from a person whose son had a rare, fatal disease, and who was desperate to find a trial to enrol him in. "We could fill that need."

WHO scientist Dr Metin Gülmezoglu said companies would be offered incentives in the form of access to WHO research, but enforcement is an unresolved problem. "We're hoping national governments will help on that."

GSK spokeswoman Mary Anne Rhyne said the company was now leading the way in disclosure of data, and intends to cooperate with a future trials registry, but "the devil is in the detail" of the disclosure rules.

Currently, the company often publishes summaries of trial results, not raw data. Vera Hassner Sharav of the US Alliance for Human Research Protection said the practice of summarizing trials has caused "an erosion of science into pseudoscience."

"Companies are agreeing to go along with this process," she said, "because they think they can control it." ■

Owen Dyer, *London*

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