Drug companies agree to make clinical trial results public

Susan Mayor *London*

Pharmaceutical companies around the world have agreed to make results from clinical trials of new prescription medicines publicly available, it was announced last week.

The voluntary agreement has been drawn up by the world's main pharmaceutical industry trade associations and agreed by key companies. It states that summary results of completed, industry sponsored clinical trials will be publicly disclosed on free and publicly accessible databases, regardless of outcome, for any medicine approved for marketing in at least one country.

The results will be published in a standard, non-promotional summary that will

include a description of trial design and methods, results of primary and secondary outcome measures described in the protocol, and safety results. Each company can select the website where they publish trial results, but if they are published in a peer reviewed journal, the database will include a link to the relevant article.

For medicines not yet approved or for trials not yet completed, companies agreed that the results should normally be published within one year of approval or, for post-approval trials, within one year of trial completion. In addition, details of all clinical trials, other than exploratory trials, will be

publicly registered within 21 days of starting patient enrolment, with information on how to enrol for patients and clinicians.

The agreement says that the pharmaceutical industry is "committed to increasing the transparency of the clinical trials our member companies sponsor."

Four key international pharmaceutical associations, including the European Federation of Pharmaceutical Industries and Associations, and the Pharmaceutical Research and Manufacturers of America, signed up to the agreement, which will be adopted later this year.

The agreement follows several serious problems with prescription medicines associated

with lack of open access to clinical trial results—including the increased risk of cardiovascular deaths resulting in the recent withdrawal of rofecoxib (*BMJ* 2004;329:816).

Wendy Garlick, principal policy adviser in health to Which?, a UK consumer organisation and publisher of *Drug and Therapeutics Bulletin*, said, "We support the agreement but consider that it should be mandatory—enforced by legislation—and not voluntary." □

The agreement, *Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases*, is available at www.efpia.org/4_pos/sci_regu/Clinicaltrials2005.pdf

Parents should restrict children's use of mobile phones, report says

Madeleine Brettingham *London*

Parents need to be more cautious about allowing their children to use mobile phones, said a report launched by the National Radiological Protection Board this week.

The report is a continuation of work published in 2000 by the UK Independent Expert Group on Mobile Phones (*BMJ* 2000;320:1358), and although this latest report denies there is decisive evidence to support the view that mobile phones are hazardous to health, the board's chairman, Sir William Stewart, admits that he is "more concerned" by the evidence presented to the panel this time around.

"In relation to radiation it often takes a long time for things to become obvious," said Sir William. "We have five years more information, and some of it suggests that 10 years down the line things may be

beginning to show through."

The group acknowledges that members of the public are worried about the effects of exposure to radiation from mobile phones and masts, and although its findings do not wholeheartedly endorse these, it says that some studies suggest that prolonged exposure to mobile phone energy may affect cognitive functions, increase susceptibility to cancer, and damage DNA. The implications are sufficiently serious for the group to advocate caution until these findings can be properly consolidated and examined.

The report urges particular vigilance in relation to groups who may be more vulnerable, such as younger children. "Parents have a serious responsibility in this field," said Sir William. "They may want to ensure that children use text messages where possible and use a phone

with a low SAR [specific absorption rate] value." The specific absorption rate is the rate at which electromagnetic energy is imparted from headset to user.

Most mobile phone manufacturers now supply information relating to the specific absorption rate value of newly purchased phones. The government, through Ofcom

(the independent regulator and competition authority for the UK communications industries), also measures the radiation emitted by mobile phone base stations. □

Mobile Phones and Health, Report of an Independent Expert Group on Mobile Phones is available online at www.iegmp.org.uk

STEVE MEDDALES

Parents may want to encourage children to use text messages where possible, to reduce exposure to radiation, report says