WHO Launches Initiative to Standardize Clinical Trial Data

BY KERRI WACHTER
Senior Writer

The World Health Organization has launched a major initiative to standardize the way that information on clinical trials is made available to the public.

In an attempt to address growing public concerns about the transparency of medical research involving human participants, WHO is recommending 20 key details that all clinical trial registries should include.

"Registration of all clinical trials and full disclosure of key information at the time of registration are fundamental to ensuring transparency in medical research and fulfilling ethical responsibilities to patients and study participants," Dr. Timothy Evans, assistant director-general of the WHO, said in a written statement.

WHO's International Clinical Trials Registry Platform is not itself a registry but provides standards for all clinical trial registries. These standards require information about sources of monetary or material support, primary and secondary sponsors, contacts for public and scientific queries, countries of recruitment, health conditions or problems studied, interventions, key inclusion and exclusion criteria, study design, date of first enrollment, target sample size, recruitment status, and primary and secondary outcomes.

The voluntary initiative is part of a growing movement toward greater accessibility to clinical trial information, prompted in part by high-profile cases involving the suppression of data by pharmaceutical companies.

In the European Union, all clinical trials conducted in member states are required to be registered in the EudraCT database, supervised by the European Medicines Agency.

In the United States, www.ClinicalTrials.gov (developed and run by the National Institutes of Health) enrolls publicly and privately funded clinical trials worldwide. However, there are several hundred other national and private clinical trial registries around the world. The Registry Platform seeks to bring participating registries together in a global network to provide a single point of access to the information stored in them, according to a WHO statement.

The WHO has acknowledged the need to balance increased transparency with the protection of competitive advantage. It may come down to a question of the timing of disclosure. In comments submitted to a WHO formal consultation on disclosure timing policy in April, the Pharmaceutical Research and Manufacturers of America noted "there may be infrequent instances where companies may regard certain data elements as sensitive for competitive reasons and wish to delay public disclosure." In particular, the organization said that companies may wish to delay the disclosure of the official scientific title of the study, specific mechanism or molecular identifiers of the intervention, target sample size, primary outcome, and key secondary outcomes.

The WHO Registry Platform is expected to launch a Web-based search portal later this year that would allow interested individuals to search among participating registries for clinical trials taking place or completed throughout the world.

For more information on the registry platform, visit www.who.int/ictrp/en. ■

Unapproved Drugs: FDA Announces Crackdown

BY ALICIA AULT
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The Food and Drug Administration announced that it is renewing efforts to ensure that all drugs currently sold by prescription either go through its formal approval process or be taken off the market.

The agency has periodically targeted some of these products using its existing authority. Now, the FDA has issued more formal guidance that spells out for manufacturers how it will prioritize enforcement, and what route they can take to prove safety and efficacy of their products.

There are many reasons why unapproved products are on the market, said Dr. Steven Galson, director of the FDA's Center for Drug Evaluation and Research, at a press briefing.

Most were marketed before passage of the 1962 Food, Drug, and Cosmetic Act, which required formal proof of safety and efficacy. Or their makers may simply have begun selling the products without seeking the agency's approval, he said. In very few cases, the products are grandfathered in under existing laws, agency officials said.

Many of the unapproved drugs are listed in the Physicians' Desk Reference. Some are advertised in medical journals.

If the manufacturers don't seek approval, they will be subject to enforcement action, Dr. Galson said. But in most cases, the FDA will not remove a drug from the market if it has been shown to have some medical utility. Examples include some levothyroxine and phenobarbital products.

Many of the drugs are cough and cold preparations that include pheniramine maleate and dexbrompheniramine maleate, or single-ingredient narcotics such as codeine phosphate and oxycodone HCl. Sedatives like chloral hydrate are also unapproved.

The agency recently announced that it is requiring makers of carbinoxamine-containing products to seek approval by late September. Any unapproved products still on the shelves at that date will be ordered off the market, said Deborah M. Autor, FDA associate director for compliance policy. Carbinoxamine is used in cough and cold treatments, mostly for children, that have been associated with 21 reported deaths since 1983.

Interested parties can go to the FDA's Web site (www.accessdata.fda.gov/scripts/cder/drugsatfda) to determine if a drug is approved. The database includes only approved medications. ■