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Client Alert

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Pharmaceutical Industry Extends Commitment to Register Clinical Trials

Over the past several years, the public health benefits associated with making clinical trial information more widely available to healthcare practitioners, patients, and others have been recognized and supported on both public and private fronts. The scope and timing of such disclosures have varied, however. In November 2009, the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) released a Joint Policy that enhances the commitment to disclosure. The new policy calls for the registration of "all clinical trials in patients conducted on a medicinal product" and the disclosure of results from those trials. The policy extends the range of clinical trials about which pharmaceutical companies should disclose information to include *all* clinical trials in patients at a minimum. Last year the IFPMA had agreed to the registration of all *confirmatory* clinical trials and all exploratory efficacy trials. This 2008 policy, thus, excluded Phase I studies from registration.

The 2009 policy addresses this limitation by defining a clinical trial as "an interventional trial involving human subjects from Phase I and beyond." The term "clinical trial", however, does not include the use of a medicinal product in the normal course of medical practice or in non-clinical laboratory studies.

The new policy has been approved by the IFPMA's participating pharmaceutical associations—the Pharmaceutical Research and Manufacturers of America, the European Federation of Pharmaceutical Industries, and the Japanese Pharmaceutical Manufacturers' Association.

Under the new policy, pharmaceutical companies are to disclose all clinical trials (from Phase I forward) in patients in a manner consistent with applicable national laws and rules governing protection of intellectual property. The disclosure should be made no later than 21 days after the initiation of patient enrollment. The registrations are to made on one of a number of free, publicly accessible, internet-based registries, such as the National Library of Medicine in the United States (www.clinicaltrials.gov). Each registered trial should contain a unique identifier (e.g. a company-assigned study ID) to ensure transparency and avoid multiple postings of the same trial. This unique identifier will allow users to track the trial through multiple databases, including clinical trial results databases.

The registry should contain basic information about each trial sufficient to:

- Inform interested patients (and their physicians) of the existence of a trial
- Provide a public reference point to enable trials to be tracked to publication, and

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- Reduce unnecessary duplication of trials on marketed medicines.

The aim of the registry is to include the Minimum Trial Registration Data Set published by WHO in May 2006 (http://www.who.int/ictrp/network/trds/en/).

The new policy also commits to disclosure of results of all clinical trials conducted on a medicinal product that has been approved for marketing and is commercially available in at least one country. These results are to be posted no later than one year after approval and commercial availability. Moreover, the policy states that if trial results from an investigational product that has failed in development have significant medical importance, the study sponsors are encouraged to post the results.