



International Federation of Pharmaceutical Manufacturers & Associations

Fédération Internationale de l'Industrie du Médicament

Federación Internacional de la Industria del Medicamento

NEWS RELEASE

GLOBAL INDUSTRY POSITION ON DISCLOSURE OF INFORMATION ABOUT CLINICAL TRIALS

Geneva, January 6, 2005 – Today the research-based pharmaceutical industry is announcing principles of disclosure of clinical trial information through clinical trial registries and databases. The International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) has jointly developed these principles together with three other industry associations: the European Federation of Pharmaceutical Industries and Associations (EFPIA), the Japanese Pharmaceutical Manufacturers Association (JPMA) and the Pharmaceutical Research and Manufacturers of America (PhRMA).

The *Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases*¹ demonstrates the innovative pharmaceutical industry's commitment to increasing the transparency of clinical trials sponsored by their member companies. "The industry recognises that there are important public health benefits, including increased confidence, associated with making clinical trial information more widely available to healthcare practitioners, patients and others", said Dr. Harvey E. Bale, Director General of IFPMA. Beginning mid 2005, the industry will make the results public of trials that have taken place – whether positive or negative – but also information on those that are just being initiated.

Under the proposals, drawn up by the world's major pharmaceutical industry trade associations and agreed by major companies, summary results of industry-sponsored clinical trials completed from today onwards on a medicine that has been approved for marketing, will be publicly disclosed via free, publicly accessible databases, regardless of outcome. Also, details of ongoing clinical trials being performed to determine a medicine's therapeutic benefit will be publicly registered at initiation so that patients and clinicians will have information about how to enrol. Both requirements will be adopted by the worldwide pharmaceutical industry during 2005.

"The industry is committing itself to making available information on all clinical trials of importance to patients' health. These include all such trials except exploratory trials – and even those results will be published if they have significant medical importance", Dr Bale added.

Trial results will be published in a standard, non-promotional summary that will include a description of trial design and methodology, results of primary and secondary outcome measures described in the protocol, and safety results. If the results are published in a peer-reviewed medical journal, the database will include a link to the relevant article

The results will be published within one year after the medicine is approved or, for post-approval trials, within one year of them being completed.

End

The International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) is a non-profit, non-governmental organization (NGO) representing national industry associations and companies from both developed and developing countries. Member companies of the IFPMA are research-based pharmaceutical, biotech and vaccine companies. In the current research and development pipeline, our industry is working on more than 700 new medicines and vaccines for infectious diseases including HIV/AIDS, Tuberculosis, and Malaria.

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¹ Joint Position on the Disclosure of Clinical Trial Information via Clinical Trials Registries and Databases, available on-line at: http://www.ifpma.org/Issues/issues_reg.aspx