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News Release

New Joint Industry Clinical Trials Transparency Position Requires Companies to Disclose All Clinical Trials in Patients

Geneva, 10 November 2009 – The Council of the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) has approved an updated *Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases*[(1)]. This extends the range of clinical trials that member companies[(2)] should provide information on to include all clinical trials in patients, as a minimum. The scope of this new Joint Position will include early stage safety trials of medicines for life-threatening conditions, which are typically not done in healthy volunteers.

"This new Joint Position will provide increased clinical trial transparency for the benefit of patients and medical professionals" said Mr. Haruo Naito, IFPMA President and President and Chief Executive Officer of Eisai Co., Ltd.

The new Joint Position, which has already been approved by the other participating pharmaceutical 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), will enter force in 6 months time, when its provisions will supersede those of the previous one, dated 18 November 2008. The first such Joint Position was established in January 2005.

When the new Joint Position enters force, member companies should post registry details of all new trials in patients on a publicly accessible website within 21 days of the start of patient enrollment. Thereafter, they should also post summary results of any trial falling with the scope of the new Joint Position within one year of the medicinal product concerned being first approved and made commercially available in any country.

To facilitate patients' and health professionals' access to clinical trials registry details and summary results of completed trials, the IFPMA Clinical Trials Portal (www.ifpma.org/clinicaltrials) was launched in September 2005. The Portal has been subsequently refined to improve its performance and ease of use, notably providing interfaces in French, German, Japanese and Spanish. More recently, the *my*Portal facility has been added, which to allow users to request e-mail alerts when new trials are posted which correspond to criteria that they have defined. The IFPMA is committed to a process of ongoing improvement of the Portal.

(ends)

(1) *Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases,* dated 10 November 2009, available online at www.ifpma.org/clinicaltrials .

(2) Companies which are direct members of the IFPMA or members of an IFPMA member association.

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About the IFPMA:

The International Federation of Pharmaceutical Manufacturers & Associations is the global non-profit NGO representing the research-based pharmaceutical, biotech and vaccine sectors. Its members comprise 25 leading international companies and 44 national and regional industry associations covering developed and developing countries. The industry's R&D pipeline contains hundreds of new medicines and vaccines being developed to address global disease threats, including cancer, heart disease, HIV/AIDS and malaria. The IFPMA Clinical Trials Portal (www.ifpma.org/ClinicalTrials), the IFPMA's Ethical Promotion online resource (www.ifpma.org/EthicalPromotion/) and its Developing World Health Partnerships information (www.ifpma.org/HealthPartnerships) help make the industry's activities more transparent. The IFPMA strengthens patient safety by improving risk assessment of medicines and combating their counterfeiting. It also provides the secretariat for the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).

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