



International
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News Release

IFPMA, EFPIA, JPMA & PhRMA Agree Joint Position on Publication of Clinical Trial Results in Scientific Literature

Industry Commits to Submit for Scientific Journal Publication the Results of all its Phase III Clinical Trials

Geneva, 10 June 2010 - The International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) today approved a "Joint Industry Position on the Publication of Clinical Trial Results in the Scientific Literature"¹, previously approved by the European Federation of Pharmaceutical Industries and Associations (EFPIA), the Japanese Pharmaceutical Manufacturers Association (JPMA) and the Pharmaceutical Research and Manufacturers of America (PhRMA).

Through the Position, the above associations and their member companies and associations commit, as a minimum, to submit for publication as a manuscript in a peer-reviewed journal, the results of all their industry-sponsored phase III clinical trials, as well as the results of other trials of significant medical importance. The new Joint Position requires submission for publication of the results of all trials within its scope, regardless of whether the outcome was positive or negative.

Mr. Haruo Naito, President of the IFPMA and President and CEO of Eisai, said: "Our earlier Joint Position on Disclosure of Clinical Trials² already requires members to disclose the trials they are undertaking and to publish summary results in online registries. This new Joint Position on publication is a logical extension of that approach, requiring members to seek scientific journal publication of the results of the specified trials."

Submission of manuscripts should occur ideally within 12 months and no more than 18 months after approval of the product concerned or the decision to discontinue the trial. In the case of trials of a product which is already marketed, submission should ideally be within 12 months of the completion of the trial and not more than 18 months after that date.

The Position also lays down guidelines which enhance transparency regarding the authorship of manuscripts. An authorship credit requires a substantial contribution to the design of the trial, data acquisition or interpretation, plus drafting or revision of the text, plus final approval. The roles of medical writers, statisticians and other who contribute to a manuscript but who do not meet the authorship criteria should be mentioned appropriately. Company involvement in both the research and publication should be disclosed, and sponsors should encourage authors to disclose all relevant interests. The primary publication for a particular trial should provide an accurate report of its findings, including adverse events, and there should be a discussion of the strengths and limitations of the study.

Online registration details and summary results of members' clinical trials can be located easily, using the IFPMA Clinical Trials Portal, which can be found at www.ifpma.org/clinicaltrials.

(Ends)

¹ IFPMA, EFPIA, JPMA & PhRMA Joint Industry Position on the Publication of Clinical Trial Results in the Scientific Literature, 10 June 2010

² IFPMA, EFPIA, JPMA & PhRMA Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases, 10 November 2009

About the IFPMA:

The International Federation of Pharmaceutical Manufacturers & Associations is the global non-profit NGO representing the research-based pharmaceutical industry, including the biotech and vaccine sectors. Its members comprise 25 leading international companies and 45 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 Directory (www.ifpma.org/HealthPartnerships) help make the industry's activities more transparent. The IFPMA supports a wide range of WHO technical activities, notably those relating to medicine efficacy, quality and safety, and coordinates industry participation in the WHO IMPACT initiative to combat counterfeit medicines. It also provides the secretariat for the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).

For further information, please contact:

Guy Willis
Director of Communications
E-mail: g.willis@ifpma.org
Tel: +41 22 338 32 00
Fax: +41 22 338 32 99
Web: www.ifpma.org