

EFPIA Calls for Collaboration in the Implementation of Clinical Trials Regulation Following Vote in the European Parliament

(Brussels – 3 April 2014): The global market for clinical trials is becoming increasingly competitive and Europe runs the risk of losing its status as an attractive environment for clinical trials research in the face of strengthening competition. The European Federation of Pharmaceutical Industries and Associations (EFPIA) thus welcomes the decision reached by the European Parliament in yesterday's plenary vote towards the adoption of the new Clinical Trials Regulation. EFPIA believes the new legislative framework will facilitate a more harmonised approach to clinical trials in the EU, with a single submission and overall streamlined assessment process. EFPIA also welcomes the legislation's approach to transparency, which respects the need to protect personal patient data and commercially confidential information.

While EFPIA sees the vote as a positive step forward in improving the European framework surrounding clinical trials, it believes that some of the initial objectives of the Regulation's revision have been only partially achieved. The revision of the Clinical Trials legislation aimed to improve the efficiency of the process for authorising and conducting clinical trials and, in turn, to boost EU competitiveness as a clinical research hub, encouraging more efficient patient access to innovative medicines in the EU. It is critical that the Commission and EMA interpret the Clinical Trial Regulation in a manner that respects patient privacy, the integrity of regulatory decision-making, and incentives for companies to make long-term investments in biomedical research.

Richard Bergstrom, Director General of EFPIA, stated: "The revised legislation is a good step towards more streamlined processes surrounding clinical trials in Europe, as well as towards a responsible transparency surrounding clinical trials -- one that I see as in line with [EFPIA-PhRMA Principles for Responsible Data Sharing](#). There is still work to be done. The success of this legislation will depend on how it is applied in practice. It will be essential to collaborate with relevant stakeholders and ensure they have the opportunity to provide input. This is a must if we are to achieve a system that will foster the innovation we need to improve patient outcomes."

In EFPIA's view, success in achieving this objective now depends on the legislation's implementation at Member State level, so that collaboration between ethics committees is promoted and efforts are made to enable assessment of clinical trial applications in the shortest time frame possible. A key pillar of success will be the efficient operation of the European Medicines Agency's European Clinical Trials Database. EFPIA also looks forward to seeing the European Clinical Trials electronic portal and database fully operational within the mandated timeline, the responsibility of the European Medicines Agency, and is ready to contribute as a strong stakeholder partner to support its development and implementation.

While EFPIA sees the positive plenary vote as progress towards a more streamlined scientific and ethical process for clinical trials approval, it recognises the difficulties faced by some Member States in implementation. EFPIA believes collaboration is necessary if we are to successfully implement a system that will foster the innovation



needed to improve patient outcomes. EFPIA looks forward to continuing the discussion with MEPs and other relevant stakeholders towards this end.

About EFPIA

EFPIA represents the pharmaceutical industry operating in Europe. Through its direct membership of 33 national associations and 40 leading pharmaceutical companies, EFPIA provides the voice of 1,900 companies committed to researching, developing and bringing new medicines to improve health and quality of life around the world. The pharmaceutical industry invests 30 billion on research and development per year in Europe and directly employs 700,000 people including 116,000 in R&D units in Europe.

EFPIA members are committed to delivering innovative medicines to address unmet needs of patients and reducing the burden of chronic diseases for Europe's ageing population. EFPIA believes in close cooperation with its stakeholders to help create sustainable healthcare systems and to develop prompt responses to health threats in Europe.

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