European Federation of Pharmaceutical Industries and Associations

Press Release

50 Years of EU Pharma Legislation: EFPIA Lauds Its Success and Looks to the Future

EFPIA congratulates the EU on 50 years of pharmaceutical legislation, which has served to improve the quality, safety and efficacy of medicines for the benefit of patients, while harmonizing the regulatory framework across 28 member states.

The success of EU legislation has served as a springboard for further development of the pharmaceutical sector due to new technical possibilities (IT), increasing globalisation in drug development and distribution, enhanced European and global cooperation within companies and authorities, as well as changing societal expectations.

However, new technologies and advanced knowledge of disease mechanisms, which are driving the development of targeted therapies, bring with them new challenges. The time is ripe to examine whether the current regulations, their application and interpretation are favorable to the earliest possible regulatory approval and swift access to innovative medicines after the necessary benefit-risk assessment.

This will furthermore require a comprehensive discussion on the interface between European and national rules regarding the assessment of relative effectiveness, falling under the competence of EU Member States.

The European Medicines Agency (EMA's) is also playing a significant role in seeking to speed up patient access to innovative medicines, by launching an adaptive licensing pilot project in March 2014. Several companies have already initiated pilot projects to obtain experiences in a "safe harbor" environment" granting confidentiality. The European Commission is monitoring the project and looking to analyze the experiences from a legislative perspective.

To address these complex issues and others, EFPIA is co-sponsoring a discussion event at the Representation of the Free State of Bavaria to the European Union on 18 March 2015, entitled: "50 Year Anniversary of the EU Pharmaceutical Legislation: are expectations for access to innovative medicines and science being met today?"

The event will evaluate whether the legislative framework needs revising, and/or if a more flexible interpretation of existing European rules on the authorisation of medicines to promote the earliest possible access to medicines for patients. It will also scrutinize the interface to national regulations on the assessment of relative effectiveness in the context of adaptive licensing.

EFPIA Director General, Richard Bergström said: "The EU legislative framework has served us well over 50 years, but new approaches in development and innovation mean that we must re-evaluate whether changes should be implemented to speed access to medicines for the benefit of patients."

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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 €30.6 billion on research and development per year in Europe and directly employs 690,000 people including 115,000 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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