**FOR IMMEDIATE RELEASE**
**August 31, 2016**

**EFCG supports the USA’s Generic Drug User Fee Act**

**Brussels, 31st August 2016** – The European Fine Chemicals Group (EFCG) - a sector group of Cefic, the European Chemical Industry Council - has agreed on terms reauthorising the US Food and Drug Administration’s (FDA’s) Generic Drug User Fee programme (GDUFA) for generic pharmaceutical substances from FY2018 to FY2022.

The conclusion of the agreement demonstrates the strong cooperation between industry and regulators in ensuring public safety. During negotiations with the FDA, European API producers were represented by EFCG as well as stakeholders such as the US-based associations GPHA, BPTF and PBOA.

States Guy Villax, EFCG Board Member, *“We thank the FDA for inviting us to participate in these negotiations, and for valuing the contribution the European API industry makes to the USA’s generic medicines industry. We are pleased with the agreement we were able to reach on this important public safety issue. The continued funding of enforcement activities is key to safeguarding the supply chain that delivers high quality generic medicines to patients”.*

GDUFA is designed to speed access to safe and effective generic drugs for the public as well as reducing unnecessary costs for industry. It also ensures that Active Pharmaceutical Ingredients (APIs) being used are compliant with regulations and filings and that non-compliant producers are excluded from the market. EFCG members support GDUFA since fees paid by industry to the FDA enable the funding of additional review and inspections resources. Since its inception in 2012 GDUFA has delivered concrete improvements in inspection and enforcement, for example with the opening of FDA offices in India and China.

Since 2004, EFCG has been raising red flags on matters such as data integrity failings and the use by some of non-compliance as a competitive advantage. These decade-old efforts are now bearing their fruits.

***About EFCG***

*EFCG was formed in 2004 to be the focus, the forum and the voice of the European fine chemicals manufacturers. We are a non-profit international sector group within Cefic - the Brussels-based European Chemical Industry Council - and represent over 100 organisations with over 200 manufacturing sites.*[*http://www.efcg.cefic.org/*](http://www.efcg.cefic.org/)

***About Cefic***

*As the forum and the voice of the chemical industry in Europe, Cefic is a committed partner to EU policymakers, facilitating dialogue with industry and sharing our broad-based expertise. We represent 29,000 large, medium and small chemical companies in Europe, which directly provide 1.2 million jobs and account for 17% of world chemical production.* [*www.cefic.org*](http://www.cefic.org)

***About SOCMA***
*Since 1921 SOCMA has represented a diverse membership of small, medium and large chemical*
*companies located around the world.* [*www.socma.com*](http://www.socma.com)

***About BPTF***
*SOCMA’s Bulk Pharmaceuticals Task Force (BPTF) is an industry trade organization for U.S.*
*manufacturers of active pharmaceutical ingredients (APIs), their intermediates and excipients. Created in 2002 as an affiliate organization of SOCMA, its objective is to seek clarification of current regulatory requirements and to interact with governmental agencies on emerging issues that may impact SOCMA members.* [*www.bptf.us*](http://www.bptf.us)

***About GPhA***

*GPhA represents the manufacturers and distributors of finished generic pharmaceuticals,*

*manufacturers and distributors of bulk pharmaceutical chemicals, and suppliers of other goods and services to the generic industry. Generic pharmaceuticals fill 88 percent of the prescriptions dispensed in the U.S. but consume just 28 percent of the total drug spending. Additional information is available at* [*www.gphaonline.org*](http://www.gphaonline.org)

***About the PBOA***

*Founded in 2014, the Pharma & Biopharma Outsourcing Association (PBOA) is a nonprofit trade association dedicated to advancing the regulatory, legislative and general business interests of Contract Manufacturing Organizations (CMOs) and Contract Development and Manufacturing Organizations (CDMOs). PBOA members provide the services that help the pharma and biopharma industry develop and manufacture drugs, biologics, vaccines, and other treatments safely and cost effectively. For more information about the PBOA, its members, and its mission, please visit* www.pharma-bio.org.