

EUROPEAN FINE CHEMICALS GROUP RATIFIES FDA'S PROPOSED GENERIC DRUG USER FEES ACT (GDUFA)

Brussels, 9th September, 2011:

The Board of the European Fine Chemicals Group (EFCG) is delighted to announce that today it agreed to ratify the proposal of the US Food and Drug Administration (FDA) to put forward a legislative package, designed with the help of EFCG and US industry representatives, to deliver into US law a new Generic Drug User Fees Act (GDUFA).

GDUFA requires the FDA to commit to significantly improve and enhance its regulatory activities for the benefit of global generic drug providers and US generic drug users, in exchange for the global generics industry providing FDA with \$299 million in user fees each year over the next 5 years.

The key benefits for drug providers will be faster and more predictable regulatory review times, including dealing with the backlog of applications, and parity of inspections between domestic and foreign sites for both finished dosage form (FDF) and active pharmaceutical ingredient (API) manufacturers.

Guy Villax, CEO of Hovione and an EFCG Board member, who led the EFCG negotiating team, commented "the outcome of these negotiations are epoch-making for our industry and, if adopted, will go a long way to deliver on EFCG's major objective to level the playing field for its members. Regulators' weak enforcement has made non-compliance a major competitive advantage. We congratulate FDA for leading the way to find solutions that both protect the patient and stop unfair competition."

Notes for editors:

Generic drugs are those containing off-patent APIs made available to patients via a doctor's prescription. Over the counter (OTC) drugs available to patients without prescription are excluded from GDUFA.

For public minutes of industry meetings with the FDA see the FDA website at <http://www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees/ucm256662.htm>

For further information, contact Tony Scott, Adviser to EFCG on tscott@tsassoc.eu

The European Fine Chemicals Group was formed in 2004 as a sector group of the Brussels-based European Chemical Industry Council (Cefic) and represents fine chemical manufacturers in Europe, including those who make generic APIs. See www.efcg.cefic.org