



European Chemical Industry Council

# NEWS RELEASE

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## **Cefic asks for enforcement of mandatory inspections to increase safety of medicines**

**Brussels, 17 November 2009** - Last December, the Commission issued a draft amendment to the current directive aimed at preventing the entry into the legitimate supply chain of falsified medicines.

The impact assessment study carried out by the Commission recognises that the entry into the EU market of fake medicines not complying with GMP (Good Manufacturing Practice) standards can have a severe impact on citizens' health.

It concludes that the best option lies in the actual enforcement of the current directive, namely the conducting of mandatory inspections throughout the legal supply chain with a focus on Active Pharmaceutical Ingredient (API) manufacturing sites in third countries, especially Asia.

At an event hosted by the European Voice on Wednesday 18 November, these issues will be debated by representatives of EU institutions and various stakeholders.

In order to prevent fake medicines to enter the EU market, Cefic recommends to inspect the 400 to 500 Asian sites included in approved Marketing Authorization Applications in the EU and to enhance international cooperation with other relevant drug agencies. .

According to Cefic this is a reasonable number for mandatory inspections and should impact neither on the 'time to market' nor on the price of medicines.

"Cefic would like to stress that mandatory inspections of registered API manufacturing sites worldwide are essential and feasible. The two co-legislators need to reinforce this aspect to help guarantee the safety of medicines throughout the supply chain because patient safety should always come first", declared Cefic Director General Hubert Mandery.

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