



To the attention of:
European Commission

Origgio, 8th May 2008

**Ref: GMP – Public Consultation of European Commission to counterfeit Medicines
for Human Use**

Archimica owned by TowerBrook Capital Partners, L.P. TowerBrook, a private equity firm, is manufacturer of bulk active ingredients (API's) and advanced intermediates for life-science industry. A global organization with a strong manufacturing and service presence in Europe and the United States, as well as in all the major pharmaceutical markets of the world.

Archimica is regularly inspected by AIFA and FDA.

Archimica fully agrees with the European Commission's concerns about the introduction into the market of APIs coming from extra-European countries, where the compliance to cGMPs quality standards is not verified by an European Regulatory Authority.

For this purpose, Archimica is asking to consider what it is requested with the Written Declaration on Active Pharmaceutical Ingredients, approved on November 30th 2006 by European Parliament, in more detail:

- 1) mandatory inspections performed by European regulatory Authority on production sites that export APIs into EU;
- 2) traceability of APIs in order to identify the source

In conclusion, Archimica strongly recommends preparing a legislation to avoid such potential risk for human health.

Best Regards,

A handwritten signature in black ink, appearing to read "Stefan Scherer", is written over a horizontal line.

Dr. Stefan Scherer
Managing Director

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Societa con Unico Socio: Archimica Group Holdings B.V. - Soggetto esercitante l'attivita di direzione e coordinamento.

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