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**For the attention of the European Commission-Enterprise and Industry Directorate General – Consumer goods -Pharmaceuticals**

Antibioticos is a privately owned Italian Company producing APIs and advanced intermediates , exporting products all over the world for originators and generic drug producers

The Company has three Manufacturing Sites in Europe , two in Italy and one in Spain with more than one thousand employees.

Antibioticos is one of the major manufacturer in Europe of semisynthetic Penicillins and Cephalosporins. Production of APIs is fully integrated with the production of the key intermediates like 7 ACA and 6 APA of fermentation origin.

The company is fully committed with GMP respect and all the European Sites are regularly inspected by FDA and National Health Authorities.

During the years the competition of manufacturers of non EU countries, maily China and India became stronger and stronger, and often the GMP compliance of these manufacturers are not verified by competent health authorities against the same GMP standards .

For the above reason Antibioticos shares the European Commission's concerns related to the introduction into the market of APIs, especially coming from extra-EU countries, that can jeopardize the human health, if not produced in compliance with the quality GMPs standard, applied in the Community (i.e. ICHQ7A).

Therefore Antibioticos strongly supports the preparation and the putting in force of a legislation, at Community level, which rules the matter.

The rule should take into consideration what is requested with the Written Declaration on active pharmaceutical ingredients, approved on November 30th 2006 by European Parliament, that is:

- a) mandatory inspections performed by European regulatory Authority on production sites that export APIs into the EU;
- b) traceability of APIs (i.e. the possibility to locate the source).

Hoping this proposal will soon be implemented , we remain

Faithfully yours

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