



# EGA *fact sheet* on generic medicines

## The Overall Contribution of Generic Medicines to Healthcare & Enterprise

*Generic medicines ensure patient access to quality, safe and effective pharmaceuticals while saving EU healthcare systems some €20 billion each year.*

In an era when increasing demands are being made on Europe's health services, affordable generic medicines provide a major benefit to society by ensuring patient access to quality, safe and effective pharmaceuticals while saving EU patients and healthcare systems over €25 billion each year.

The European generic pharmaceutical industry is at the forefront of providing these high-quality affordable medicines to millions of patients throughout Europe and other regions of the world.

Generic pharmaceutical producers are now becoming the principal suppliers of medicines for Europe's patients. Taking Europe as a whole, close to 50% of all medicines<sup>1</sup> dispensed to patients are generics.

Competition from generic medicines provides an important incentive to originator companies to develop innovative products. Moreover, the savings from using generics help to provide urgently needed budget headroom to allow governments to pay for the costly new innovative treatments.

Generic medicines are equivalent to the originator reference product in terms of quality, safety and efficacy. They contain the same active substance and have the same pharmaceutical form as the originator reference product, and their therapeutic interchangeability with the reference product has been scientifically demonstrated through bioequivalence studies. Generic medicines are approved on the basis of their own data. With the exception of clinical trials results, the data requirements submitted for the approval of products is the same for a generic manufacture as for an originator company.

Generic medicines account for more than two thirds of all applications made under the EU's Mutual Recognition Procedure and Decentralised Procedure. Generic medicines applications will also increase under the EU's Centralised Procedure as originator reference products registered under this procedure lose their market exclusivity.

While generic pharmaceutical companies principally develop, produce and market affordable, high quality off-patent equivalent medicines, they also invest in improving production processes, resulting in better products and lower prices. Several generic pharmaceutical companies also develop new formulations, methods of delivery, and dosage regimes for well-known medicines. Some generic pharmaceutical companies have also researched and

developed their own NCEs (New Chemical Entities).

As this dynamic EU growth sector increases its share of the global generic pharmaceutical market and establishes its leadership in the field of new bio-similar medicinal products, it creates new sources of enterprise and employment in the EU, and actively contributes to Europe's overall competitive position on the world stage.

However, for the industry to maximise the benefits for healthcare systems and patients, EU Member State governments, and the EU as whole, must create the right environment for effective generic competition.

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<sup>1</sup> 2006 Market Review, *The European Generic Pharmaceutical Markets*, EGA internal document, June 2006.

*Formed in 1993, the EGA is the official representative body of the European generic pharmaceutical industry, which is at the forefront of providing high-quality affordable medicines to millions of Europeans and stimulating competitiveness and innovation in the global pharmaceutical sector.*