



Making Medicines Affordable

EGA

Myths and Realities

of the pharmaceutical industry

Myth

European Generics companies merely copy originator products using originator company data.

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Reality

Generic medicines are approved on the *merits* of their own data under the same stringent EU requirements as originator products.

Data Required for Market Authorisation

Originator Product vs Generic Medicine

Generic medicines are approved on the merits of their own data. With the exception of the pre-clinical data and clinical trials results, this is the same as the data that originator companies must submit for the approval of their products.

REGISTRATION DATA REQUIRED	Originator	Generic
Administrative data <i>Concerning Marketing Authorisation Holder</i>	■	■
Summary of Product Characteristics (SmPC) <i>Patient Information Leaflet, labelling and packaging</i>	■	■
Expert Summaries	■	■
Composition of medicinal product	■	■
Description of manufacturing process <i>Good Manufacturing Practice (GMP) required</i>	■	■
Control of starting materials	■	■
Control of finished product	■	■
Stability tests <i>On active substance and finished product</i>	■	■
Dissolution profile <i>Comparing generic product with the reference product</i>		■
Non-clinical documentation	■	
Clinical documentation	■	
Results of bioequivalence study <i>(see note other side)</i>		■

Definition of a Generic Medicinal Product

Regulation 726/2004 and Directive 2001/83/EC Article 10, paragraph 2, point (b)

“Generic medicinal product shall mean a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies. The different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance shall be considered to be the same active substance, unless they differ significantly in properties with regard to safety and/or efficacy. In such cases, additional information providing proof of the safety and/or efficacy of the various salts, esters or derivatives of an authorised active substance must be supplied by the applicant. The various immediate-release oral pharmaceutical forms shall be considered to be one and the same pharmaceutical form. Bioavailability studies need not be required of the applicant if he can demonstrate that the generic medicinal product meets the relevant criteria as defined in the appropriate detailed guidelines.”

Bioequivalence studies

Bioequivalence studies demonstrate equivalence between the generic test product and the reference product. The generic medicine and the reference product are considered to be bioequivalent (and therefore interchangeable) when the bioequivalence study demonstrates that the two formulations have no significant differences in the rate and extent of absorption in the human body.

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.