



# EGA *fact sheet* on generic medicines



## Assured Quality, Safety and Efficacy of Generic Medicines

*A generic medicine must meet the same stringent standards as an originator product to gain approval from the medicines regulators.*

No medicine, originator or generic, can be marketed in the EU unless it has been approved by one of the national or the European medicines regulators: this is the patient's guarantee of pharmaceutical quality which applies equally to all medicines.

The national medicines agencies and the European Medicines Agency in London (EMA) are responsible for safeguarding public health by assessing the quality, safety and efficacy of medicines available to patients in Europe. For generic medicines, as with all pharmaceutical products, ensuring scientifically controlled quality, safety and efficacy is of paramount importance.

Generic medicines account for more than two thirds of all applications made under Europe's Mutual Recognition Procedure and Decentralised Procedure.<sup>1</sup>

Generic medicines applications can also now be made using the Centralised Procedure giving marketing authorisation applicable in all EU Member States.

A generic medicine must meet the same stringent standards as an originator product to be approved by the medicines regulators. To gain approval, a generic medicine must<sup>2</sup>:

- contain the same active ingredients as the originator reference product,
- be identical in strength, pharmaceutical form (eg, tablet/capsule, injectable, liquid, etc), and route of administration ,
- be bioequivalent to the originator reference product,
- meet the same batch requirements for identity, strength, purity, and quality,
- be manufactured under the same high standards of good manufacturing practice (GMP) regulations that are required for all pharmaceutical products.

## Data Required for Market Authorisation Originator Product vs Generic Medicine

Generic medicines are approved on 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
<b>Administrative data</b> concerning Marketing Authorisation Holder	■	■
<b>Summary of Product Characteristics (SmPC)</b> , Patient Information Leaflet, labelling and packaging	■	■
<b>Expert Summaries</b>	■	■
<b>Composition of medicinal product</b>	■	■
<b>Description of manufacturing process</b> - Good Manufacturing Practice (GMP) required	■	■
<b>Control of starting materials</b>	■	■
<b>Control of finished product</b>	■	■
<b>Stability tests</b> on active substance and finished product	■	■
<b>Dissolution profile</b> comparing generic product with the reference product	■	■
<b>Non-clinical documentation</b>	■	■
<b>Clinical documentation</b>	■	■
<b>Results of bioequivalence study</b>	■	■

<sup>1</sup> The **Mutual Recognition Procedure** is where a Marketing Authorisation is assessed and granted by a National Authority (the reference member state or RMS). The applicant then applies in selected Member States, who recognise the original assessment following a 90-day procedure. If agreed, the National Authorities (the concerned Member States or CMS), grant national marketing authorisations.

The **Decentralised Procedure** was introduced in October 2005 to streamline the authorisation procedure. It follows the same principles as the Mutual Recognition Procedure, except that the applicant applies in the reference Member States (RMS) and the concerned Member States (CMS) at the same time. The reference Member State takes the lead in the assessment, and national authorities grant national marketing authorisations once the procedure is successfully concluded.

The detailed Marketing Authorisation (MA) procedures with all the relevant guidelines are described in the Notice to Applicants available on the websites of the **European Commission**: [www.ec.europa.eu/enterprise/pharmaceuticals/eudralex/homev2.htm](http://www.ec.europa.eu/enterprise/pharmaceuticals/eudralex/homev2.htm), the **National Medicines Agencies**: [www.heads.medagencies.org](http://www.heads.medagencies.org) and the **European Medicines Agency (EMA)**: [www.emea.europa.eu](http://www.emea.europa.eu).

<sup>2</sup> **Regulation 726/2004 and Directive 2001/83/EC**. Article 10, paragraph 2, point (b) of this Directive defines a generic medicine in the European Union in the following terms:

“**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.”

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.