



EGA *fact sheet*

on generic medicines

Innovation, Affordable Healthcare and a Competitive Pharmaceutical Industry

Pharmaceutical innovation is important for improving both the healthcare provision of EU citizens and the overall development of the EU pharmaceutical industry.

Pharmaceutical innovation is important for improving both the healthcare provision of EU citizens and for the overall development of the EU pharmaceutical industry. Innovation takes place in the form of small, incremental improvements to existing pharmaceuticals, and as major scientific breakthroughs leading to new medicines or treatment regimes.

There are three types of innovation.

The Three Types of Pharmaceutical Innovation

- **Incremental Innovation:** new dosage forms and new formulations.
 - **Stepwise Innovation:** different molecules of one chemical family offering some differences in properties, such as indications, side effects, and drug metabolism.
 - **Breakthrough Innovation:** a genuine new approach to a disease, or a New Chemical Entity (NCE).
-

The EGA endorses and encourages pharmaceutical innovation. But while recognising the existence of both incremental and breakthrough advances, the

generic medicines industry is concerned that certain product changes, which claim to bring innovation, in fact offer little added benefit to patients. Instead, modifications such as these are designed to prolong the life cycle of the originator product and to prevent competition from generic alternatives without enhancing the effectiveness of existing treatments.

To be valuable, innovation must be able to demonstrate added therapeutic benefit to patients when compared to therapeutic alternatives. In other words, it must show an increase in “relative efficacy”.

As many medicines are currently being developed and brought to market, it should be clear that only those products that bring real added therapeutic value and increased benefits to patients – and which are truly cost-effective in comparison to established pharmacotherapies – should be adequately reimbursed.

In order to promote innovation in pharmaceuticals in Europe, the EU should focus its energies on:

- Creating an EU equal to the US National Institutes of Health to encourage EU-based pharmaceutical research;
- Establishing better links between science and business;
- Implementing reimbursement structures to reward added value of innovation;
- Improving the quality of patents by insuring a proper enforcement of the criteria especially of inventive step;
- Facilitating faster access to the market for new approved medicines;
- Promoting stronger generic competition in Europe.

If the EU is to enhance its competitive position in relation to the United States – the world leader in pharmaceutical innovation – it must adopt the kinds of measures which seek to encourage both competition and innovation.

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.

EUROPEAN GENERIC MEDICINES ASSOCIATION

Rue d’Arlon 15 · B-1050 Brussels · Belgium
Tel: +32-02/736-8411 · Fax: +32-02/736-7438
www.egagenerics.com · info@egagenerics.com