



# EGA *fact sheet* on generic medicines



## Pharmacovigilance and Generic Medicines: Ensuring On-going Patient Safety

*All European pharmaceutical companies are legally required to monitor the use and effect of a given medication according to the science of pharmacovigilance.*

All European pharmaceutical companies are legally required to monitor the use and effect of a given medication and to detect, assess, understand and prevent any adverse reactions or any other medicine-related problem that may arise. This science, and its related activities, make up what is called 'pharmacovigilance'.

Because generic medicines can only be marketed after the originator product has been available to patients for many years, the effects of the active substances they contain are very well documented and their safety profiles are well established. As a result, unexpected adverse events are extremely rare for these well known substances.

Nevertheless, it is important to assess on a permanent basis that the risk-benefit of a given medicine remains positive during its entire life cycle. Therefore monitoring the use and effect of medicines is an essential part of the activities of a pharmaceutical company.

In order to achieve the goal of maintaining the highest safety standards, the newly adopted legal

framework for pharmacovigilance clearly sets out the roles and the responsibilities of pharmaceutical companies in this area<sup>1</sup>. Companies must ensure that:

- an appropriate system of pharmacovigilance is in place in order to assume the responsibility and liability for their medicines;
- appropriate action can be taken when and where necessary;
- all information impacting the risk-benefit balance of a medicine is reported to the authorities;
- a person responsible for pharmacovigilance is permanently and continuously at their disposal in the EU.

Generic companies together with all other stakeholders are committed to meeting all these requirements and to ensuring that patients only receive safe and effective medicines.

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<sup>1</sup> For further information, please refer to the following EU legislation on pharmacovigilance:

- Title IX Pharmacovigilance (Articles 101- 08) of EU Directive 2001/83/EC as amended.
- *The Rules Governing Medicinal Products in the European Union, Volume 9A - Pharmacovigilance for Medicinal Products for Human Use*. Available from the EudraLex website: [ec.europa.eu/enterprise/pharmaceuticals/eudralex/](http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/)

*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.*