



EGA *position* on the “Pharma Package”



Revised 21 January 2009

EGA Position on the EC Legislative Proposal against Falsified Medicines¹

The European Generic medicines Association (EGA) welcomes the European Commission Proposal for a Directive of the European Parliament and of the Council amending Directive 2001/83/EC as regards the prevention of the entry into the legal supply chain of medicinal products which are falsified in relation to their identity, history or source.

Falsified medicines can put the health and life of patients in jeopardy. Among falsified medicines, counterfeit medicines represent a high risk of harm to patient. Counterfeiting is without doubt a criminal act which deserves adequate measures to prevent it.

Generic medicines represent today nearly 50% of all medicines dispensed in the European Union (EU) and, although there are no reported cases of counterfeited generic medicines in the EU, the EGA has been quick to engage in the fight against the counterfeiting and falsification of medicines. EGA members see this European Commission initiative as an encouraging step forward.

Quality Compliance

The EGA supports the EC proposal regarding quality aspects as it provides a pragmatic way to further increase the efficiency of the EU system as regards the quality of medicines. EGA members welcome the clarifications and strengthening of the current quality legal framework as proposed by the EC.

Similarly, we support the EC proposal to apply the same and unique rules to all operators of the production and distribution networks, both in the EU and worldwide, and for medicinal products and active substances entering the EU territory, regardless of their geographic origin or end-destination. This measure targets the elimination of potential “weak links” and creates a level playing field for medicines through the introduction of the concept of equivalence of quality standards and the involvement of regulators from exporting third countries. The EGA also supports the principles of enhanced transparency measures proposed by the Commission for the production and distribution networks as facilitators for traceability.

Having analysed the EC proposal in detail, the EGA believes that it adequately addresses the concerns outlined in the European Parliament’s Written Declaration on pharmaceutical active principles² (Sept 2006) in a way that circumvents the risk of delaying generic medicines access to market without compromising on medicines quality: the unavailability of EU GMP certificates for active substance exporters, linked to the limited number of EU inspectors, will not constitute an administrative hurdle for registration. Manufacturers remain responsible for ensuring the quality compliance of their suppliers.

Making Medicines Affordable

Wholesale Distribution and Safety Features

It must be reiterated that the use of seals and traceability systems as proposed by the European Commission are expensive measures that will not stop the counterfeiting of medicines nor prevent a falsified medicine from reaching patients.

The EGA believes that new technical solutions serve other purposes related to reimbursement fraud or recall systems, for instance, but will not add value to the fight against counterfeiting. In addition, over-reliance on technology will provide a false sense of security.

Furthermore, there is a substantial risk that new rules requiring the use of seals or mass serialisation could substantially increase the manufacturing costs of generic medicines, potentially reducing the ability of the generic medicines industry to provide affordable medicines without increasing security for patients.

The EGA supports the EC proposal to employ a risk-based assessment of medicines using available data on price and past incidents. This approach will focus efforts on the fight against counterfeiting where the risk is the highest and most necessary, ie with lifestyle drugs and expensive branded medicines.

Further Information

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1- European Commission proposal for a Directive of the European Parliament and of the Council amending Directive 2001/83/EC as regards the prevention of the entry into the legal supply chain of medicinal products which are falsified in relation to their identity, history or source: http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/pharmpack_12_2008/counterfeit/counterfeit-dir_en.pdf

2- European Parliament Written Declaration on pharmaceutical active principles, 0061/2006, 4 Sep 2006, by Amalia Sartori, John Bowis, Françoise Grossetête, Cristina Gutiérrez-Cortines and Thomas Ulmer.

Conclusion

In conclusion, any additional rules and requirements proposed, whether they relate to quality compliance or traceability, should be shown to adequately address the problems at stake (ie, the counterfeiting of medicines or the introduction of substandard active substances or medicines onto the community market) and to lead to the enhanced protection of patients.

Attention should be paid to avoiding and increase in the administrative and financial burden to companies and organisations which already comply with the set requirements.

More specifically, consideration should be given to the resources needed for implementation, from both the industry and the authorities. Accordingly, effective measures which have been identified should receive priority.

The EGA is the official representative body of the European generic and biosimilar 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.