



EGA *position* on the “Pharma Package”



Revised 21 January 2009

EGA Position on the EC Legislative Proposal on Pharmacovigilance¹

The European Commission’s legislative proposals on Pharmacovigilance have been well received and generally accepted by the European Generic medicines Association as the proposed measures support the strategy to better protect public health by strengthening and rationalising EU Pharmacovigilance.

The EGA recommends supporting the EU Commission pharmacovigilance proposal in that it ensures that:

- reporting is proactive and proportional to the likelihood of harm;
- medicines safety transparency and communication are increased and reporting is facilitated;
- EU decision-making on important safety issues is rationalised and harmonised.

In addition, we believe that the proposals remove national disparities and substantially improve the overall operation of the Community pharmacovigilance rules while at the same time increasing public health protection.

The EGA has, however, a major concern with the introduction of the new ‘summary of the essential information necessary to use the medicine safely and effectively’ which is to be included in the summary of product characteristics (SmPC) and the package information leaflet (PIL). The EGA rejects this new section as this summary will shift the focus away from other important information stated in the product information and may lead to confusion and serious consequences for public health (eg, patient non-compliance) and may entail issues of liability. Furthermore, this new summary would imply that the resource intensive user testing on target groups, as required by Community law, is not ensuring that the package leaflet is legible, clear and easy to use. Such a critical change to the SmPC and PIL template has not been tested to ensure that it will achieve the objective of the exercise, which is to minimise the risks and to maximise the benefits of medicines.

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¹ The European Commission proposal for a Directive of the European Parliament and of the Council amending Directive 2001/83/EC as regards the pharmacovigilance and the European Commission proposal for a Regulation 726/2004 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency amending, as regards pharmacovigilance of medicinal products for human use:

- http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/pharmpack_12_2008/pharmacovigilance/pharmacovigilance-dir_en.pdf
- http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/pharmpack_12_2008/pharmacovigilance/pharmacovigilance-reg_en.pdf

Making Medicines Affordable