



EGA *position* on the “Pharma Package”



8 January 2009

EGA Position on the EC Legislative Proposal on Industry Information to Patients¹

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 in an attempt to harmonise the current framework of industry information to patients throughout the Member States. The EGA sees this as a constructive step forward, also as the proposal introduces the use of quality criteria for information to patients.

However, the EGA is concerned over the possible misuse of information as a marketing tool. It is crucial to the EGA that the proposal ensures **better – rather than simply more – information** to patients in order to avoid any form of direct marketing and exerting undue commercial influence over consumers.

Therefore, the EGA initial conclusions on the proposal are:

- There is no need to expand the scope of the current European legislation, but rather a need for harmonising the legislation in the various Member States;
- The pharmaceutical industry should be allowed to provide patients, who are actively searching for information, with the approved format of the patient information leaflet for their own authorized medicines via their own website.
- Any other form of information published by companies on their own individual medicines must be strictly based on the approved documents listed above, must be in line with the quality criteria as listed in the proposal, and must be preapproved by an independent body.
- Pharmaceutical companies should not be allowed to publish information on their individual medicines via sources other than their own website. Direct information from industry to patients on individual products via newspapers, magazines, TV (PUSH principle) is currently forbidden and should remain forbidden in future due to the possibility of this being used as a form of individual product promotion and the possibility of undue influence over patients.

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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 information to the general public on medicinal products for human use subject to medical prescription 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 information to the general public on medicinal products for human use subject to medical prescription.

- http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/pharmpack_12_2008/patients/patients_dir_en.pdf
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Making Medicines Affordable