



Making Medicines Affordable

## EGA GENERAL POSITION PAPER ON PHARMA FORUM ISSUES

(June 2007)

### 1. Pricing and reimbursement

Within the Pharmaceutical Forum the EGA would like to see Member States adopt a generic medicines programme consisting of:

1. A coherent generic medicines policy
2. Automatic pricing and reimbursement approvals and substitution status for generic medicines once they have obtained a market authorisation (MA).
3. Reimbursement systems structured according to the clinical relevance and pharmacotherapeutic value of a product over another and which preclude switching to non-added value higher-priced patented products away from lower-priced generic medicines or existing alternatives.
4. Prices of generic medicines not linked to a constant set percentage of the originator product (eg, always 25-50% lower than the originator), since this is anti-competitive and endangers security of supply. Such linkage enables originators to force generic competitors out of the market by constantly lowering prices to the point where generics (forced to sell at a fixed percentage below the originator) cannot afford to enter or remain on the market.
5. Adequate incentives for physicians to prescribe generic medicines, in addition to validated prescription guidelines and a system where doctors are rewarded for following the protocol and held accountable for non-rational prescribing practices.
6. The removal of disincentives for pharmacists to dispense generic medicines. Countries should introduce pharmacist remuneration systems that are neutral or which favour the delivery of generic medicines.
7. Information to patients about generic medicines and incentives to demand and accept them. Authorities should provide information on generic medicines highlighting the quality, safety and efficacy of generic medicines.

The EGA also stresses that whilst it is necessary to ensure that pricing systems encourage price competition and more affordable quality healthcare to patients, it is equally important that pricing systems are managed with the objective of ensuring the long-term sustainability of the EU-based generic medicines industry so it can compete effectively on EU and global markets.



## 2. Innovation and Relative Effectiveness

The EGA fully endorses pharmaceutical innovation and recognises incremental as well as breakthrough innovation. However, the generic medicines industry is concerned that certain product changes which claim to bring innovation in reality offer little added benefit to patients and are, in fact, less advantageous for patients due to their higher prices. Such products are merely designed to prolong the life cycle of the originator product and to stop competition from generic alternatives. Part of the responsibility for this problem lies with the patent system which may not be strict enough when assessing patent applications. Moreover, even though patents should always have an inventive step in technical terms, they do not always bring added therapeutic value.

The EGA recognises three forms of innovation:

- **“Incremental innovation”** - new dosage forms and new formulations.
- **“Stepwise innovation”** - different molecules of one chemical family offering some differences in properties, eg, indications, side-effects, and drug metabolism.
- **“Breakthrough innovation”** - real new approach to a disease / new chemical entity (NCE).

In all cases, however, innovation is only valuable if it can demonstrate added therapeutic benefit to patients (compared to therapeutic alternatives) ie, relative efficacy.

In the case of pricing and reimbursement systems, there is clearly a major role to be played in the assessment of product changes, especially incremental innovation. It should be clear that only products that bring real added therapeutic value or benefits to patients, and which are truly cost-effective compared to established pharmaco-therapies, should be reimbursed.

## 3. Patient Information.

The EGA recognises that the major problem facing patients in the EU is the multitude of unregulated information on the Internet both on products and diseases. Moreover, this information is usually only in English and is very much targeted at audiences in the USA. Patients should be able to access information that is unbiased, guaranteed in terms of quality and independence, and readable in their own language. Patients should also have the opportunity to acquire a greater understanding of diseases and the various therapy options available for treating them.

Pharmaceutical companies should not be allowed to publish information on their individual medicines via sources other than their own websites. Direct Information from industry to patients on individual products via newspapers, magazines, TV, etc (PUSH principle) is currently forbidden and should remain forbidden in future, too due to the possibility of this being used as a form of individual product promotion and the possibility of undue influence over patients.

The EGA sees no need for expanding European Legislation<sup>i</sup>, but sees rather a need for clarifying and enforcing legislation in the various Member States.

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<sup>i</sup> Legislation on Information to Patients is covered by Directive 2004/27/EC and Regulation (EC) No 726/2004.



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The EGA proposes a 3-layered approach to meet this challenge:

- Firstly, the European Union should establish a comprehensive and detailed online European Directory on Diseases, Prevention and Medicines. This should be available in all languages of the EU, free of charge and hosted by the European Commission, EMEA and the Heads of Medicines Agencies. Medicines should at all times be mentioned by their international non-proprietary name (INN). This directory should contain links to other certified websites.
- Secondly, all EU national medicines agencies should develop comprehensive and freely accessible information for patients on all products on their market via the Internet and other sources. The information provided would include approved registration documents such as the patient leaflet itself, EPARs and SMPCs. In addition, each agency should provide information on generic medicines highlighting the quality, safety and efficacy of generic medicines, similar to current procedures carried out by the FDA and some EU agencies.
- Thirdly, pharmaceutical companies should be allowed to place the approved PILs, EPARs and SmPCs which refer to their products on their websites (PULL principle: available for patients actively looking for information). Any other form of information published by companies on their own individual medicines must be strictly based on the above approved documents, must be in line with the quality criteria<sup>ii</sup> agreed in the Pharmaceutical Forum, and must be pre-approved by the competent authorities (not by a self regulating body). The authorities should establish a fee system to finance the resources needed for carrying out this activity.

The EGA is the official representative body of the European generic pharmaceutical and biosimilar medicines industry, which is at the forefront of providing high quality affordable medicines to millions of Europeans and stimulating competitiveness and innovation in the pharmaceutical sector. The EGA's membership consists of generic medicine companies and national associations, representing the industry in 34 European countries.

<sup>ii</sup> The quality principles for good information as defined by the Working Group of the Pharma Forum are supported by the EGA: objective and unbiased, patient-oriented, evidence-based, up-to-date, reliable, understandable, accessible, transparent, relevant and appropriate, consistent with statutory information