



Making Medicines Affordable

## EUROPEAN GENERIC MEDICINES ASSOCIATION

# PRESS RELEASE

Brussels, Wednesday, 8 July 2009

### EUROPEAN COMMISSION INQUIRY RECOMMENDS SYSTEMIC IMPROVEMENTS TO ENSURE IMMEDIATE ACCESS FOR PATIENTS TO AFFORDABLE GENERIC MEDICINES UPON PATENT EXPIRY

The EGA calls on European and national authorities for a quick implementation of the conclusions and recommendations of the sector inquiry report.

The EGA welcomes the final report on the pharmaceutical sector inquiry launched today in Brussels. The final report takes the findings of the preliminary report of 28 November 2008 to the next level, concluding that substantial reforms in European and national legislation are required to ensure timely availability of generic medicines. The final report unfolds a number of key recommendations that should enhance generic competition in the European healthcare sector and generate significant cost savings to healthcare systems, patients and tax payers. A properly functioning pharmaceuticals market will encourage pharmaceutical companies to develop innovative medicines and improve the image of the pharmaceutical industry as a whole.

The EGA and its members worked closely with the Commission throughout the inquiry, recognising this initiative as an opportunity to address loopholes in the legislative framework. These loopholes give rise to incoherent generic medicines policies in member states and allow originator companies to behave anti-competitively, thereby blocking or delaying patient access to affordable generic medicines.

"Generic medicines have been facing severe delays in getting on the market for too long now. We welcome the importance given by the European Commission to the need of high quality patents and raising the bar for patent applications. The existence of certain dubious secondary patents has indeed created a block against competition and undermined confidence in real innovation", commented Greg Perry, Director General of EGA, expressing his full support for the final report's findings and recommendations. Reiterating the EGA's longstanding plea for an urgent reform in the pharmaceutical sector, he added: "Tightening up Europe's legislative framework in the four areas of patent law, pharmaceutical legislation, price and reimbursement rules and competition law will result in a properly functioning pharmaceutical market throughout Europe."

In a press release issued this morning the European Commission also highlights that the inquiry showed that originator companies use a variety of instruments to extend the commercial life of their products without generic entry for as long as possible. Neelie Kroes, European Commissioner for Competition, said, "When it comes to generic entry, every week and month of delay costs money to patients and taxpayers. We will not hesitate to apply the antitrust rules where such delays result from anticompetitive practices. The first antitrust investigations are already under way, and regulatory adjustments are expected to follow dealing with a range of problems in the sector."

The Commission states that it is also urging Member States to:

- ensure that third party submissions do not occur and in any event do not lead to delays for generic approvals;
- significantly accelerate approval procedures for generic medicines; for example, the Commission believes that generic products should automatically/immediately receive pricing and reimbursement status where the originator drug already benefits from such status, which would allow for a faster product launch in certain cases;
- take action if misleading information campaigns questioning the quality of generic medicines are detected in their territory;
- streamline trials that test the added value of novel medicines.

[More/...](#)

Further information: Elke Grooten

EGA EUROPEAN GENERIC MEDICINES ASSOCIATION

Rue d'Arlon 50 - 1000 Brussels

Tel: +32/2-736-8411 - Fax: +32/2-736-7438

e-mail: [Imallo@egagenerics.com](mailto:Imallo@egagenerics.com)



*Making Medicines Affordable*

Companies represented within the EGA provide over 130,000 jobs in Europe. Today 50% of all medicines dispensed to patients in Europe are generic medicines but represent only 18% of pharmaceutical expenditure. Affordable generic medicines save EU patients and healthcare systems over €25 billion each year, helping to ensure patient access to essential medicines and providing urgently needed budget headroom for the purchase of new and innovative treatments.

The EGA and its members call upon the European and national authorities for quick implementation of the conclusions and recommendations of the sector inquiry report. From 2009 till 2020, a large number of pharmaceuticals are due to go off patent, representing nearly €90 billion. Immediate launch of generic alternatives for these products will bring massive savings for patients and will guarantee healthcare sustainability throughout Europe. But much of these savings will be lost if the Commission's recommendations fail to be adopted.

**More /...**



## ANNEX: Summary of EGA recommendations

### *1. On the Patent System*

- more rigorous assessment of patentability and specifically on inventive step
- more EPO resources for better assessment
- Duty of candour or Full Disclosure Statement
- No divisional patents covering same issue
- Strict timelines for oppositions

### *2. On the Litigation System*

- Strict timelines for litigation procedures
- Specialised/technical patent judges
- Addressing over-readiness of granting interim injunctions
- Community patent and unified patent court including EGA recommendations

### *3. On Pharmaceutical Legislation*

- Pharmaceutical legislation including provision prohibiting interventions or including a transparent intervention system with burden of proof on third party
- Express mention of all administrative procedures in BOLAR provision
- Distinction between incremental innovation and no added therapeutic value
- Prohibition on negative information and marketing campaigns, including comparative adverts
- Quality criteria for all information and advertisement on medicines
- Misbehaviour effectively sanctioned by authorities

### *4. On Price and Reimbursement Practices*

- Proof of added therapeutic value for obtaining price and reimbursement
- Immediate/automatic price and reimbursement approval after marketing authorisation