



Making Medicines Affordable

EGA RESEARCH PROJECT - REQUEST FOR PROPOSALS

Submission Deadline: Friday 22 December 2006

REPORT ON BARRIERS TO GENERIC PHARMACEUTICAL COMPETITION IN EUROPE

The European Generic Medicines Association is the official representative body of the European generic pharmaceutical 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. Formed in 1993, the EGA represents companies employing over 100,000 in Europe, and plays an important consultative role in European healthcare policy-making. It works with European national governments and the EU institutions to develop affordable solutions, ensuring patient access to essential medicines and budgetary headroom for new innovative treatments.

The EGA has a history of publishing high quality research reports on issues germane to the generic pharmaceutical industry in Europe. Its 2 most recent reports are "Sustaining Generic Medicines Markets in Europe" by Prof. Dr. S. Simoens of Katholieke Universiteit Leuven; and the internally produced 2006 Market Review of the European Generic Markets.

Objective

It now wishes to commission a wide-ranging report on perceived barriers to the market entry of generic medicines in Europe. As guidance, although not intended to be an exhaustive list, the report is likely to cover the following issues:

1. Failings in the system for the assessment and granting of patents, especially by the European Patent Office.
2. Uneven enforcement of IP law by national courts
3. The use of evergreening/life cycle management strategies, affecting both product protection and pricing/reimbursement systems.
4. Abuse of EU regulatory approval regime
5. Possibilities for misuse of legislation.
e.g. Effects of Directive 2004/48/EC on the enforcement of IP rights; Paediatric extensions

(A more detailed outline is available on request)

The report is to have an executive summary at the front. It will be launched at a high-profile EGA Workshop in Brussels to which target audiences will be invited.



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Proposals

Proposals should be in English up to a maximum of 10 pages, and forwarded to Mrs. V. A. Lowe at Veronica.Lowe@auxilium.freeserve.co.uk

Your proposal should include:

- 1) Name of organisation; address; and contact details including web address
- 2) Name; qualifications; experience; and contact details of project leader
- 3) An indication of qualifications and expertise of team members
- 4) Approach to be adopted; method of data collection; and validation
- 5) An indication of the level and extent of work envisaged to complete the project

Guidelines

The EGA looks for proposals which:

- 1) Set out the proposer's experience and credentials for undertaking the project
- 2) Meets the brief as outlined
- 3) Gives a clear indication of how data will be obtained and what sources will be interrogated
- 4) Indicates any potential problems, and suggests solutions

Timetable: By end June 2007

Funds Available: 100,000 Euro

Selection and Project Management

The EGA will review the proposals and invite selected proposers to discuss the research outline by teleconference or if practicable, at a meeting. Mrs. V. A. Lowe, Chairman of the Steering Group, will act as project manager. Liaison will be by Email or telephone, and there will be scheduled regular teleconference calls.

EGA Steering Group

The report is being co-ordinated by the EGA's Legal Affairs Committee, chaired by Dr. Gyorgy Thaler.

Mrs. V. A. Lowe (Steering Group Chair)
Ms. I. Gryglicka
Ms. Z. Ulusoy
Mr. V. Afenliev
Mr. K. Mager

Mayne Pharma plc
Polfarmed
Nobel Ilac
Actavis
Sandoz International