

Process on Corporate Responsibility in the Field of Pharmaceuticals

Platform on Ethics and Transparency

TERMS OF REFERENCE

1. INTRODUCTION

The Platform on Ethics and Transparency is one of the work areas of the Process on Corporate Responsibility in the field of pharmaceuticals. The Platform is based on volunteer participation and is dedicated to enhancing collaboration among interested member states and all relevant stakeholders with the main objective to propose some basic principles with regards ethics and transparency in the pharmaceutical sector. The Commission Communication on Corporate Social Responsibility¹ - A renewed EU strategy 2011-14 for Corporate Social Responsibility – provides an important context on this work.

2. SCOPE

The Platform will bring together all relevant stakeholders to openly discuss a joint set of ethical and transparency principles and recommendations. The result of such an endeavour will be a List of Guiding Principles governing the interactions between healthcare professionals and patients' organisations, competent authorities, and the pharmaceutical industry. The List of Guiding Principles to be elaborated under this platform will make use of the expertise of multiple stakeholders and public administrations in a combined effort, under the coordination and with the political support of the European Commission, and will contain basic principles and serve as a starting point for future detailed practical guidelines and implementation and monitor mechanisms.

3. PROCESS - ADDED VALUE

The Drafting Committee set up on a volunteer basis with members of the Platform combines experience, expertise and knowledge in order to provide the first draft of the List of Guiding Principles. If needed external experts will be invited to contribute to the process. The European Commission will facilitate the procedure. The work will focus on three principle areas and interactions between the pharmaceutical industry and vice versa with:

- patients;

¹ http://ec.europa.eu/enterprise/policies/sustainable-business/files/csr/new-csr/act_en.pdf

- healthcare professionals; and
- competent authorities - national, regional, as appropriate.

The Guiding Principles will also reflect the relationship between the different stakeholders in the pharmaceutical sector.

There are already various codes on ethics, transparency and ethical conducts in general and they mainly regulate the relations of industry with various stakeholders.

The added value of this process would be to produce *a commonly accepted* List of Guiding Principles *that will be endorsed by and engage all involved actors*.

4. OBJECTIVES

The work of the Drafting Committee in these three areas (relations of industry, patients, healthcare professionals and competent authorities) will eventually be merged in one final document. All members of the Platform on Ethics and Transparency and all EU/EAA Member States should agree and endorse the future List of Guiding Principles by the end of 2012. An ambitious goal of the Drafting Committee is to present the first draft of by the summer of 2012.

Other industry sectors will be invited to the Platform and based on the text to be drafted for pharmaceuticals, specific guidelines for these industry sectors may have to be developed supplementary to the initial outcome.

Further work of this platform during the latter part of 2012, will aim at developing a strategy involving all participating stakeholders for implementation, dissemination, and monitoring mechanisms, to enable a robust launch of the Guiding Principles at the beginning of 2013.

3. MEMBERSHIP

EU / EEA countries plus the following stakeholders' organisations have been invited to take part to the Platform on Ethics and Transparency:

- Ø Bureau Européen des Unions de Consommateurs - BEUC
- Ø Standing Committee of European Doctors - CPME
- Ø Pharmaceutical Group of the European Union – PGEU
- Ø European Hospital and Healthcare Federation - HOPE
- Ø Association Internationale de la Mutualité - AIM
- Ø European Social Insurance Platform – ESIP
- Ø European Federation of Pharmaceutical Industries & Associations - EFPIA
- Ø European Generic medicines Association - EGA
- Ø European Self-Medication Industry - AESGP
- Ø European Association for Bioindustries - EuropaBio

- Ø European Association of Full-Line Wholesalers – GIRP
- Ø European Union of Medical Specialists - UEMS
- Ø European Patients' Forum – EPF

Experts involved in their personal capacity (academics or others) will be requested to disclose possible conflicts of interest prior to meetings.