European Federation of Pharmaceutical Industries and Associations

LEADERSHIP STATEMENT

As industry leaders, we are committed to working in partnership with all stakeholders to improve healthcare across Europe.

In doing so, we are conscious of the importance of providing accurate, fair and objective information about our medicines to allow rational decisions to be made about their use. As such, we fully respect the role that EU legislation1 plays in regulating interactions between pharmaceutical companies and healthcare professionals.

In this same spirit, we are committed to working towards greater transparency, accountability and ethical behaviour within an industry framework of self regulation.

Our companies have already adopted EFPIA Codes establishing standards for appropriate behaviour in our relations with healthcare professionals and with patient organisations2.

We believe that adherence to these Codes is essential. Breaches should not be tolerated.

Recognising however that society has particularly high expectations of our industry, we have today asked EFPIA to develop additional guidance around the following areas to ensure that our industry continues to uphold the highest standards.

1. Provision of information
2. Medical sales representatives
3. Medical samples
4. Congresses and other meetings, including exhibitions at congresses
5. Relationships with patient organisations

We have asked that this guidance be made available during the second part of 2010.

Today, we have also called for the establishment of National Ethics Groups in EFPIA's 31 member associations.3 These Groups will further ensure effective oversight of

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1 Title VIIIa of Directive N° 2001/83/CE

2 "Code on the Promotion of Prescription-only Medicines to, and Interactions with, Healthcare Professionals" (EFPIA's HCP Code) and the "Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations" (EFPIA's PO Code) – see www.efpia.eu

3 EFPIA's member associations represent (R&D-based) pharmaceutical companies operating in: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, the Netherlands, Norway, Poland, Portugal, Spain, Sweden, Switzerland, Turkey and the United Kingdom, as full members; and Albania, Bulgaria, Croatia, Cyprus, the Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Romania, Serbia, Slovakia and Slovenia, as affiliate members.

industry standards, as well as implementation of the new Guidance within one year of its issuance.

Going forward we will continue to challenge ourselves to exceed society's expectations and we welcome suggestions from others regarding how we might further strengthen confidence in our industry and our companies' behaviour.

We also invite companies that are not within EFPIA's (direct or indirect) membership to adhere to the self-regulatory rules and guidance adopted by the R&D-based industry.

Brussels, June 24th 2010

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1. Provision of information

Directive Article 88a: ... the Commission shall ... report on practice with regard to information provision ... and its risks and benefits for patients. ... the Commission shall ... put forward proposals setting out an information strategy ...	We, leaders of the industry, believe European citizens should have equal access to high-quality information on health and prescription medicines, including information provided by industry on diseases and treatments they have researched. We therefore believe that the R&D-based pharmaceutical industry has a legitimate role to play in the ongoing debate around the provision of such information. We have therefore asked EFPIA to answer any calls from the EU Institutions to contribute constructively to the debate on the provision of information.

2. Medical sales representatives

Directive Recital 49 Medical sales representatives have an important role in the promotion of medicinal products. Therefore, certain obligations should be imposed on them ... Article 17 of EFPIA HCP Code	Medical sales representatives are an important source of information to prescribers. They have a sensitive role to play in providing timely and high quality information while ensuring that their practices do not impair patients' access to healthcare professionals. All EFPIA member associations must follow high standards for the appropriate training of sales representatives in scientific matters. Medical sales representatives must also comply with industry ethical rules. Building on existing legal obligations and industry standards, we, leaders of the industry, ask EFPIA to provide guidance for defining standards and house-keeping rules for medical sales representatives.

3. Medical samples

Directive Article 96: Free samples shall be provided on an exceptional basis only ... Article 16 of EFPIA HCP Code	Medical samples are provided to health professionals so that they may familiarise themselves with the medicines and acquire experience in dealing with them. Samples of a medicine shall only be given in response to a written request from health professionals qualified to prescribe that particular medicine. Samples should however not be given for the sole purpose of treating patients. The EU Directive limits sampling to "exceptional" cases; this means that in principle, no samples should be given, except on an exceptional basis. There are still important disparities in the provision of medical samples across Europe. We, leaders of the industry, consider that it is reasonable that each healthcare professional should receive, per year, no more than 4 samples of a particular medicine he / she is qualified to prescribe; and that sampling should not extend beyond the two years after the product is first launched. Therefore, we have asked EFPIA and its member associations to support (self-)regulation moves towards this "4 x 2" standard.

4. Congresses and other meetings, including exhibitions at congresses

Directive Article 94: ... Hospitality at sales promotion events shall always be strictly limited to their main purpose and must not be extended to persons other than healthcare professionals.	Promotional, scientific or professional meetings include – but are not limited to – congresses, conference, symposia, advisory board meetings, training meetings, investigator meetings for clinical trials and non-interventional studies, etc. Through such events, pharmaceutical companies contribute to continuous medical education of healthcare professionals and scientific information exchange between the attendees and between these and industry representatives. Any practice that might create confusion about the real scientific and educational purpose of these events should not be tolerated. We, leaders of the industry, have asked EFPIA to

... Article 9 of EFPIA HCP Code	develop common standards for meetings organised / sponsored by industry and attended by healthcare professionals. We have also asked that EFPIA coordinate monitoring of European events, by setting up an on-line platform to pre-assess events in regard of EFPIA's HCP Code. Reports will be shared with corporate compliance officers, the National Ethics Groups, and congress and meeting organisers to promote compliance with industry standards. EFPIA is also asked to work with medical and scientific societies to raise awareness of the high ethical standards applying to interactions between medical doctors and pharmaceutical companies.
Articles 9 & 10 of EFPIA HCP Code	Considering that congresses are a vital forum where R&D-based pharmaceutical companies can present data and interact with scientific experts, industry leaders stress that it is critical that exhibitions at congresses do not over-shadow the main purpose of scientific events. In this respect, EFPIA HCP Code provisions relating to events and hospitality (Article 9) and gifts (Article 10) apply to exhibitions at congresses. In recognition of this, we, leaders of the industry, have asked that EFPIA coordinate the monitoring of congress activities – including exhibitions at congresses, drawing company compliance officers to problematic behaviour, exerting peer pressure through site visits at congresses. Congress organisers would receive notice of planned visits.

5. Relationships with patient organisations

EFPIA Code on Relationships between the Pharmaceutical Industry and Patient Organisations Article 5.a. (Transparency) Each company must make publicly available a list of patient organisations to which it provides financial support and / or significant indirect / non-financial support. ...	The pharmaceutical industry recognises that it has many common interests with patient organisations, which represent and / or support the needs of patients and / or caregivers. As an additional step towards increased transparency, we, leaders of the industry, have instructed EFPIA to review its PO Code with a view to requiring mandatory disclosure of financial and significant indirect / non-financial support to patient organisations. The total amounts of support provided to patient organisations should include: (i) the amount of financial support; (ii) the amount of cost invoiced to the sponsoring company for significant non-financial support; (iii) for significant indirect support not covered by invoices and for significant non-financial support, the sponsoring company will provide its best estimate established in good faith of costs incurred. EFPIA may also consider providing additional guidance on the format of disclosure of support.