

# Ethical rules for dialogue and negotiations with decision-makers (Lobbying Code)

## Purpose

Art. 1      Pharmaceutical companies are continually in dialogue and negotiations with politicians and regulatory authorities in order to optimize the shared interests of the parties, whilst also creating the basis for increasing access by patients and citizens to the best possible medical prevention and treatment.

The ethical rules provides a framework for dialogue between pharmaceutical companies and politicians/regulatory authorities, so as to ensure that dialogue always takes place in a open, honest, fair and credible manner. The ethical rules must at the same time ensure that the parties are financially independent of each other and that relations and dialogue are always so as to exclude the possibility of the parties pressurizing each other.

## Definitions

Art. 2      The following shall apply in these ethical rules

- a) "Politicians" refers to persons who are members of (or are candidates for) the Folketing (Danish Parliament), Regional Councils, Municipal Council (or Town Council) and European Parliament, etc.
- b) "Officials" refers to all those, whose primary occupation is as employees of a public authority that has regulatory powers or the like. These would for example be employees of:
  - 1. Ministerial departments, national agencies, directorates as well as institutes, councils and boards, etc., associated with the above,
  - 2. Regional and municipal administrations,
  - 3. A number of private associations and companies, etc., where members or owners are part of the public sector. This would apply for example to employees of the Danish Regions and Local Government Denmark, or
  - 4. The European Commission or other EU administrative body.
- c) "Decision-maker" refers to a politician or other official person, cf. Secs. a) and b) above.
- d) "Pharmaceutical company" refers to Lif's member companies or their representatives.
- e) "External consultant" refers to a third party working on behalf of the pharmaceutical company, cf. Sec. d) above, with dialogue and negotiating with decision-makers. This may for example be a PR or communication agency, legal counsel, etc.

- f) "Company representative" refers to an employee of a pharmaceutical company or an external consultant working for the company, cf. Secs. d) and e) above.
- g) "Healthcare professional" refers to doctors, dentists, veterinarians, pharmacists, nurses, veterinary nurses, pharmaconomists, midwives, bioanalysts, clinical dietitians, radiographers, social- and healthcare assistants, and students of these professions.
- h) "Dialogue" refers to all types of oral and written communication that company representatives engage in with decision-makers.
- i) "Negotiation" refers to a situation in which the company representative is in dialogue with a decision-maker to reach agreement on or to gain support for one of the company's wishes or proposals.

## Scope

- Art. 3 The ethical rules constitute a minimum set of rules which are mandatory for Lif's members. The pharmaceutical companies may therefore have their own ethical rules that go further than this set of rules.
- Art. 4 The ethical rules shall apply for company representatives' dialogue and negotiations with decision-makers at an international, national, regional or local level.
- Art. 5 If an external consultant is engaged to enter into dialogue or negotiations with decision-makers, it shall be the responsibility of the pharmaceutical company to ensure full compliance with the ethical rules by the external consultant.

## Transparency

- Art. 6 There must be full transparency on whom and what interests are represented by the company representative. Company representatives shall therefore initially, and without being so requested, introduce themselves clearly by name and by giving the name of the pharmaceutical company for whom they are working. This also applies in cases where an external consultant is used to represent the interests of several companies.
- Art. 7 The pharmaceutical company is obliged to demonstrate and ensure full transparency in instances, in which the company remunerates a decision-maker, cf. the exemption provisions in Art. 14.
- Art. 8 Every pharmaceutical company is obliged to publish a schedule on their website with the names of the PR or communication agencies, legal counsel or similar external consultants.

cies acting on behalf of the pharmaceutical company to engage in dialogue and negotiations with decision-makers.

- a) Disclosure shall be made by stating the name of the external consultant concerned.
- b) Disclosure must take place without undue delay after concluding an agreement with the external consultant and must be publicly available, while the agreement/project is in progress and at least for three months.
- c) The pharmaceutical company's schedule on its website shall further explicitly state that the pharmaceutical company has made the external agency or consultancy aware of the present set of rules and that the pharmaceutical company accepts responsibility for ensuring third party compliance therewith.

### **Requirement for information**

Art. 9 Information passed to decision-makers must be up to date and complete, and must not contain incorrect or misleading information.

### **Proper conduct**

Art. 10 In dialogue and negotiations with decision-makers, proper conduct shall be observed, which shall include, among other things:

- A) A decision-maker's integrity must never be maligned by the company representative.
- B) No misleading, false, injurious or discriminatory reference shall be made to other parties.
- C) Irrelevant personal information must never be used in an intimidating manner or as to exert pressure.

### **Confidential information**

Art. 11 The company representative must always act with discretion and must fully respect information obtained in confidence from a decision-maker, unless this would be unlawful. This must also be respected in instances where confidential information is acquired by a coincidence or error. Confidential information must not be obtained in a dishonest manner.

### **Independence**

Art. 12 There must never be any kind of financial dependency between pharmaceutical companies or their representative, on the one hand, and the decision-maker on the other. Simi-

larly, the company representative must not act in a way that may cause suspicion of bribery.

Art. 13 Company representatives must not in any way provide financial support or sponsorships to decision-makers, either individually or through organisations/associations (e.g. political parties, election funding, etc.).

a) Pharmaceutical companies may however sponsor specific professional activities, campaigns and similar events organised and held by a public authority.

Art. 14 Pharmaceutical companies or their representatives must not in any way remunerate decisions-makers performing their duties, which the company may have a direct interest in influencing. However, this is permitted exceptionally in the case of:

a) A decision-maker whose primary occupation is as a permanent employee of a pharmaceutical company and whose remuneration exclusively relates to this main occupation. If a company has employed a decision-maker who is required as part of his/her main occupation/area of responsibility to conduct dialogue and negotiations with decision-makers on behalf of the pharmaceutical company (e.g. employees responsible for public and external affairs), the company is especially responsible for ensuring:

1. That the rules and principles on conflicts of interest in the Public Administration Act are always complied with at the very least.
2. That the person engaged in dialogue and negotiations with other decision-makers is always, and without exception, fully transparent about the nature of his employment, cf. Art. 6 and 7, so there can be no doubts as to conflicts of interest.

b) A decision-maker who also acts as a healthcare professional and who, in his duties as such, exclusively undertakes professional services for the pharmaceutical company, cf. Sec. 25 in the Executive Order on Advertising of Medicinal Products. Remuneration must only be provided in relation to such professional services and shall otherwise be reasonable, compared to the services provided.

c) A decision-maker who provides a specific, limited service for the pharmaceutical company relating to teaching, lectures, etc. Remuneration must only be provided in relation to such teaching/lecturing services and must otherwise be reasonable compared to the services provided.

Art.15 Pharmaceutical companies or their representatives must not in any way offer or provide gifts, etc., to decision-makers that have a financial value for the recipient, and which have no professional purpose: for example private gifts, tickets to sporting, cultural or entertainment events, travel, vacation, extravagant visits to restaurants or the like shall not be provided.

- a) However, company representatives may provide professional information material (reports, books, analyses, films) which are intended by the company to provide relevant information and which are also included as a natural, open part of the company's dialogue with decision-makers.

Art. 16 The company representative may provide relevant hospitality at direct meetings between the company representative and the decision-maker, or when attending theme days, conferences, etc., organized and funded by the company. As part of the above meetings, the company representative may cover decision-makers' travel expenses and accommodation:

- a) The above expenditure for hospitality, travel expenses or accommodation must be reasonable and not extravagant.
- b) The permitted level of the above expenditure must follow the same strict framework for hospitality, accommodation and travel which applies for the pharmaceutical companies' relations with healthcare professionals; cf. The Danish Ethical Rules for Promotion of Medicinal Products towards Healthcare Professionals.

## Legislation

Art. 17 All activities pertaining to dialogue and negotiations with decision-makers shall comply with applicable legislation. If an opposing party makes proposals on activities or a *quid pro quo* that is contrary to the law, these shall always be refused.

- a) The company representative shall always take the initiative to act against a breach of the law when having become aware that this is happening or is being planned by a third party.

## Enforcement

Art. 18 The rules are sanctioned as outlined in the Sanctions- and fees regulations of ENLI, please refer thereto.

## Entry into force

Art. 19 This code shall enter into force on 19 February 2015 and replaces the latest published code of 10 December 2009.