



Lif's ethical rules

for dialogue and negotiations
with decision-makers



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Purpose

Art.1

Pharmaceutical companies are in on-going dialogue and negotiations with politicians and the regulatory authorities in order to optimise 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 provide a framework for dialogue between pharmaceutical companies and politicians /regulatory authorities, so as to ensure that dialogue is always conducted with openness, honesty, probity and credibility. The ethical rules are also intended to ensure that the parties are economically independent of each other, and that relations and dialogue are always so as to preclude the possibility of the parties pressurizing each other.

Definitions

Art.2

The following shall apply in these ethical rules

A) "Politicians" shall be taken to mean persons who are members of (or are candidates for) the Danish Parliament, Regional Council, Municipal Council (or Town Council) and European Parliament, etc.

B) "Officials" shall be taken to mean 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:

- Ministerial departments, national agencies and directorates and institutes, councils and boards, etc., associated with the above;

- Regional and municipal authorities
- Miscellaneous 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;
- EU Commission or another EU administrative body.

C) "Decision-maker" shall be taken to mean a politician or other official person, cf. Secs. A and B above.

D) "Pharmaceutical company" shall be taken to mean Lif's member companies or their representatives.

E) "External consultant" shall be taken to mean a third party working on behalf of the pharmaceutical company with dialogue and

negotiating with decision-makers. This may for example be a PR or communication agency, legal counsel, etc.

F) "Company representative" shall be taken to mean an employee of a pharmaceutical company or an external consultant working for the company, cf. Secs. D and E above.

G) "Health professional" shall be taken to mean doctors, dentists, veterinarians, pharmacists, nurses, veterinary nurses, pharmaconomists and students of these professions.

H) "Dialogue" shall be taken to mean all types of oral and written communication that company representatives engage in with decision-makers.

I) "Negotiating" shall be taken to mean 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 comprise a minimum set of rules which are mandatory for Lif's members. The pharmaceutical companies may therefore have their own sets of 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 (politicians and officials) at the 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 said third party.

Openness

Art.6

There shall be full openness about who 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 shall also include instances when an external consultant is used to represent the interests of several companies in the same case.

Art.7

A pharmaceutical company shall be required to show and ensure full openness in instances

where in the company remunerates a decision-maker, cf. the exemption provisions in Art. 14 A, B and C.

Art.8

All pharmaceutical companies shall be obliged to publish a schedule on their website with the name of the PR or communication agency, legal counsel or similar external consultancies acting on behalf of the pharmaceutical company to engage in dialogue and negotiations with decision-makers.

Disclosure shall be made by stating the name of the external agency /consultancy/legal counsel concerned.

The timescale for disclosure shall be without undue delay after making an agreement with

the external consultant and this shall be placed in the public domain while the project is in progress and at least for three months.

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 rules and that the pharmaceutical company accepts responsibility for ensuring third party compliance therewith.

Requirement for information

Art.9

Information passed to decision-makers shall be kept up-to-date and complete and shall 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 that:

- A)** A decision-maker's integrity shall not be maligned by the company representative.

- B)** No misleading, false, injurious or discriminatory reference shall be made to other parties.

- C)** Irrelevant personal information shall never be used in an intimidatory way or as so as to exert pressure.

Confidential information

Art.11

The company representative shall always act with discretion and shall fully respect information obtained in confidence from a decision-maker unless this would be unlawful. Confidences shall also be respected in instances where confidential information is acquired by chance or in error. Attempts shall never be made to obtain confidential information by dishonest means.

Independence

Art.12

There shall never be any kind of financial dependency between pharmaceutical companies or their representative on the one hand and the decision-maker on the other. Similarly, the company representative shall not act in such a way as to cause suspicion of bribery.

Art.13

Company representatives shall not in any way provide financial support or sponsorships to officials or politicians individually or via organisations/ associations (e.g. political parties, election funding, etc.).

A) Pharmaceutical companies may however sponsor specific professional activities, campaigns and similar events arranged and held by an official body.

Art.14

Pharmaceutical companies or their representatives shall not in any way remunerate officials or politicians performing duties which the company may have a direct interest in influencing. This shall however be permitted exceptionally in the case of:

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 shall be especially responsible for ensuring:

a) That the rules and principles on conflicts of interest in the Public Administration Act are always complied with at the very least.

b) 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 shall be no doubts as to conflicts of interest.

B) A decision-maker who also acts as a health professional and who in his duties as such, exclusively undertakes professional services for

the pharmaceutical company, cf. s. 23 Advertising Order. Remuneration shall only be provided with respect 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 shall only be provided with respect to such teaching/lecturing services and shall otherwise be reasonable compared to the services provided.

Art.15

Pharmaceutical companies or their representatives shall not in some other 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, holidays, extravagant visits to restaurants or the like shall not be provided.

A) However, company representatives may provide professional information matter (reports, books, analyses, films) which are intended by the company to provide appropriate 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 themed days, conferences, etc., organised and funded by the

company. As part of the above meetings, the company representative may cover decision-makers' travel expenses and overnight accommodation.

A) The above expenditure for provision of meals, travel expenses or overnight accommodation shall be reasonable and not extravagant.

B) The permitted level for the above expenditure shall follow the same strict framework for provision of meals, overnight accommodation and travel as that applying for the pharmaceutical companies' relations with health professionals.

Legislation

Art.17

All activities relating to dialogue and negotiations with decision-makers shall comply with current legislation. If a counterparty proposes 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.

