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Ethical rules for the pharmaceutical industry's donations and grants to hospitals.

Preamble

The pharmaceutical industry's professional and scientific donations and grants to hospitals support initiatives that result in real value for patients. There must be no doubt about proper ethical standards for relations between pharmaceutical companies and hospitals. Accordingly, Lif has set clear ethical rules to ensure independence between the pharmaceutical industry and hospitals. These ethical rules also create openness about the pharmaceutical industry's donations and grants to hospitals.

This code is supplementary to, and in some areas stricter than, the EFPIA Code on the promotion of prescription-only medicines to, and interactions with, healthcare professionals, Art. 11 "Donations and grants that support healthcare or research" and the Pharmaceutical industry's code on advertising, etc., for medicines aimed at healthcare professionals, Art. 14 "Donations and grants for health services and research". It is always the most stringent rules in the area that must be complied with. All the codes of ethical rules are available at: www.enli.dk.

Art. 1. The ethical rules shall be binding on all members of Lif and cover donations and grants given to Danish or foreign hospitals.

Art. 2. The ethical rules do not regulate pharmaceutical companies' sponsorship of healthcare professionals to attend national or international events, offers to attend information meeting/continuity training events arranged by the pharmaceutical industry, collaboration on clinical research or gifts of negligible value to professionals as these items are otherwise covered in national and international ethical rules or Danish legislation.

Art. 3. The ethical rules define "grant" and "donations" as any kind of support given for projects or activities, equipment, units, etc. (*such as databases, research projects, patient information leaflets, patient training programs, medical equipment, PhD training or other education*) for which the hospital /hospital department has applied for assistance in funding. Donations and grants may be either in-kind or pecuniary.

Art. 4. Members of Lif may give donations or grants to hospitals / hospital departments if they have a professional and/or scientific purpose, including the provision of grants/donations for health services or research, or other professional activities that benefit patient care or hospitals.

Art. 5. No donations or grants such as gifts, benefits in kind or pecuniary advantage shall be offered or given to hospitals/ hospital departments if they do not have a professional or scientific purpose.



Art. 6. It shall not be permitted for donations and grants to hospitals to be given to individual healthcare professionals, associations of healthcare professionals or members of the hospital administration. Small private hospitals /clinics owned by one or more healthcare professionals shall also be covered by the prohibition.

Art. 7. Companies shall ensure and shall make it a condition that grants or donations are only used for the intended professional /scientific purposes. Provided that the intended professional /scientific purposes are complied with, the company shall not seek to influence specific operations at the hospital, business processes, tasking or how funding is actually used. It shall be a precondition that it shall be up to the hospital /hospital department to manage and decide how to make use of the grant or donation from the pharmaceutical company.

Art. 8. Donations or grants provided for a project, an activity, a purpose or a unit at the hospital shall be approved by a hospital employee who is competent to do so. Before a donation or grant is transferred to a hospital account (money) or hospital unit (benefit in-kind), the transfer shall itself be approved by a hospital employee who is competent to do so.

Art. 9. The company providing a donation or grant shall ensure that donations or grants are always accompanied by a written and signed document specifying at the very least the following:

- 1) Name of the activity, project, equipment or unit the donation or grant is to support.
- 2) Name(s) of the hospital/ department, etc., responsible for the activity, project, equipment or unit.
- 3) Name(s) of the person(s) at the hospital responsible for the activity, project, equipment or unit.
- 4) Name(s) of the person(s) at the hospital responsible for the account (money) or unit (in-kind) to which the donation or grant has been transferred.
- 5) Name of the competent person, manager, director, etc., at the hospital who has given approval for the hospital/department to receive the donation or grant.
- 6) Types of activity/project/equipment/unit for which the donation or grant is being given.
- 7) The purpose of the activity/project/equipment/unit for which the grant or donation is being made.
- 8) Timeframe (if available).
- 9) The amount of funding provided.
- 10) Scope, content and estimated value of benefits in-kind.

Art. 10 (a). As part of every donation or grant, pharmaceutical companies shall be required to publish a schedule on their website containing the information covered by Art. 9 (1, 2, 6-10). The schedule is to be published when the donation or grant has been made, and shall remain on the website for at least two years subsequently.

10 (b). Copies of the schedule must be supplied on request when no longer available on the pharmaceutical company's website. The requirement shall not apply to donations or grants made more than 10 years previously.

10 (c). Members of Lif shall provide Lif with an annual schedule of all their donations and grants to hospitals during the preceding year. The schedule is to contain the information listed under Art. 10 (a). The schedule is to be submitted after the end of each calendar year and will be published on Lif's website.

Art. 11 (a). Art. 8, Art. 9 and Art. 10 (a), (b) and (c) do not apply to grants and donations of a total value of maximum DKK 5000 per calendar year for a specific purpose or specific activity. The value is calculated in proportion to the company's costs in connection with giving the grant or donation for instance the size of the amount of the financial grant or the company's expenses for benefits in kind.

Art. 11 (b). Art. 8, Art. 9 and Art. 10 (a), (b) and (c) do not apply to grants and donations of a total value of maximum DKK 20,000 within a calendar year in case the grants or the donations are comprised of a plurality of identical benefits in kind in form of patient material / equipment that individually represents a minor value (for instance cool bags for a specific medicinal product, patient information leaflets regarding a specific medicinal product, injection needles for patient related injection equipment or the like).

Art. 12. The provisions of this code shall apply to donations and grants made to hospitals after 1 September 2011.