

**Heads of Agreement
for
Terms and conditions for collaboration between doctors and pharmacists and
pharmaceutical companies**

Scope and purpose

Art 1. This agreement relates to collaboration between doctors and pharmacists and pharmaceutical companies (the parties) for the provision and sponsorship of professional continuity training and advertising activities by pharmaceutical companies with respect to doctors and pharmacists. The agreement further relates to collaboration between pharmacists and pharmaceutical companies on advertising activities and healthcare arrangements/activities aimed at the general public.

Sec. 2. The purpose of the agreement is to ensure, on the basis of jointly approved guidelines for collaboration, that said collaboration shall be conducted so that there are no opportunities for financial inducement and dependency between the parties, and that the parties are clearly independent of each other.

Sec. 3. Collaboration shall serve the interests of society as well as the parties for bringing existing knowledge and new developments in medical therapies to the attention of doctors and pharmacists and other healthcare personnel.

Sec. 4. In this agreement, the expression “other health care personnel” shall generally be construed as pharmacists, nurses, veterinary nurses, pharmaceutical economists and students in each of these subjects, cf. Medicines Act.

Art. 2. Each party shall be responsible for implementing collaboration in accordance with this agreement and international conventions, national legislation, including *inter alia* the Medicines Act, Marketing Act, etc. This means amongst other things that pharmaceutical companies shall not provide financial benefits to doctors and pharmacists, etc., for the direct or indirect purpose of promoting sales of medicinal products, and doctors and pharmacists, etc., shall not request or accept such services; and pharmacists and doctors shall further not, without the permission of the Danish Medicines Agency, operate or be associated with a company dealing in medicinal products, cf. Art. 3 Pharmacies Act.

Sec. 2 The prohibition in Sec. 1 shall not, however, pursuant to the provisions of the Advertising Act and this agreement, cover:

- Undertaking and sponsoring specific professional activities
- Entertainment of a reasonable nature associated with advertising activities and professional and scientific events
- Gifts (benefits in kind) of insignificant intrinsic value associated with a person’s work or given to mark a recipient’s red letter day.

Sec 3 The prohibition in Sec 1 shall further not constitute an obstacle to mutually obligating agreements between pharmacists and pharmaceutical companies on healthcare activities and advertising measures aimed at the general public.

Continuity training /Professional events

Pharmaceutical company as organizer, co-organizer or sponsor.

Art 3. In acting as the organizer or co-organizer, a pharmaceutical company may be involved in holding medical, pharmacy healthcare and scientific events for doctors and departments, institutions, etc. and for pharmacists and/or pharmacy employees. Invitations therefor shall be solely directed at doctors, pharmacists, pharmacy employees and any other healthcare personnel.

Sec. 2. As sponsor, a pharmaceutical company may further provide financial support for medical /pharmacy healthcare events arranged by doctors or pharmacists or pharmacy employees respectively. Financial support shall not be made conditional upon the sponsor gaining influence on the professional content of the event. Organisation of the event shall accordingly be independent of the financial support rendered. The organizer shall be responsible for the professional content, teachers, instructional methodology, etc.

Sec. 3. The organizer and the purpose of the event shall be clearly stated on the invitation and it shall further be stated whether financial support has been provided for the event by one or more pharmaceutical companies.

Location

Art. 4. In all cases where a pharmaceutical company is the organizer or sponsor, the choice of location for events shall take practical, financial and professional considerations into account. There shall be professional indications for choice of a foreign location.

Sec. 2. If there are professional, objective and practical reasons therefor, pharmaceutical companies shall always be entitled to opt for their Head Office/Research Centre as the location regardless of the geographic location thereof.

Sec. 3. Events shall not be held at places associated with activities without professional content, unless it can be demonstrated that such activities are not part of the event. A pharmaceutical company may in this respect bear the expenses for admission tickets of insignificant intrinsic value.

Expenses covered by a pharmaceutical company

Art. 5. The expenses of pharmaceutical companies for activities connected with events shall be kept at standard (not luxury) rates, shall be minor in comparison to the main purpose of the activity and shall only relate to doctors, pharmacists/pharmacy employees and any other healthcare personnel.

Sec. 2. Pharmaceutical companies may bear the expenses for conference facilities, lecturers, study material and the like required for undertaking professional activities in the event.

Sec. 3. Pharmaceutical companies may further bear the actual travel and subsistence expenses for delegates. Expenses shall be payable against receipt. Endeavours shall always be made for the mode of transport and accommodation standards to be reasonable.

Sec. 4. Fees for doctors, pharmacists/pharmacy employees participating as lecturers at planned events shall be reasonable considering the work associated with the lecture and shall be determined in accordance with the Danish Medical Association's teaching tariff and teaching rates with reference to AC/DJØF rates respectively.

Sec. 5. Financial support for meetings and courses should generally be given to the training centre /course organizer, not to individuals. Financial support for covering the expenses of conference facilities and lecturers may, however, be paid direct to the training centre/lecturers.

Sec. 6 Pharmaceutical companies shall always make financial support conditional upon the fact that:

- It is used for the intended purposes
- In special cases when financial support is paid to individuals, there shall be an accounting of the expenses incurred.

Entertainment and catering at events

Art. 6. Entertainment by way of accommodation, meals and other services which appear as entertainment shall only be provided as part of events with a specific professional or scientific content and shall only be provided for doctors, pharmacists/pharmacy employees and any other healthcare personnel participating in the event.

Sec. 2. Entertainment at events shall always be kept at a reasonable level in financial and timescale respects. Entertainment shall always be minor compared to the professional purposes of the event.

Sec. 3. Funding for accommodation and meals shall not be extended unnecessarily in addition to professional activities.

Sec. 4. Funding for social activities associated with professional activities shall not be permitted. If a professional or scientific event is associated with other activities such as theatre visits, outings or the like, the expenses therefor shall not be payable by any pharmaceutical company, and neither by the pharmaceutical company organizing the professional activities.

Sec. 5. Doctors and pharmacists shall not request services in contravention of Sec. 4.

Payment for companions

Art. 7. A pharmaceutical company shall not pay expenses for participation by companions at any event and shall not offer companions entertainment, gifts or other services that represent financial benefit.

Sec. 2. If a delegate makes a request to be accompanied by a companion on his/her own initiative, the organizing pharmaceutical company may accept this if all expenses are borne by the companion him/herself, cf Sec. 1.

Notification/briefing on events

Art 8. If a pharmaceutical company is the organizer or co-organizer of an event, said pharmaceutical company shall notify the event to the Self-regulation Board for the Pharmaceutical Sector (NSL). Notification shall be submitted in such good time that the secretariat of the board has the prior opportunity to make an immediate assessment of the event, and at the latest by the time that invitations are sent out. A pharmaceutical company providing financial support as sponsor to a medical or pharmacy healthcare event shall report such sponsorship to NSL. In such case, it shall be reported immediately the pharmaceutical company has made a binding promise to provide support.

Sec. 2. Similarly, a doctor or pharmacist who takes the initiative to apply to a pharmaceutical company for financial support shall brief NSL of the application. This shall be done immediately an application for support is made.

Sec. 3. All notification/briefing shall include details of the identity of the organizer and all relevant details of the nature and purpose of the event. Notification/briefing to NSL shall be done schematically on a form available from the NSL secretariat or the website.

Sec. 4. Invitations to doctors and pharmacists shall give details of the fact that:

- The event has been notified to, but not necessarily approved by, NSL and that
- The NSL secretariat has had the opportunity to review the notification, that the Board has not found cause to comment on the event on the basis of the information available, and that the event is, in the view of the organizers, in accordance with the rules of the collaboration agreement, *or*
- That NSL has not had the opportunity to review the notification but that the event is, in the view of the organizers, in accordance with the rules of the collaboration agreement.

Sec. 5. The pharmaceutical company, doctors and pharmacists responsible for the event shall ensure compliance with the requirements of Secs. 1-4 irrespective of whether planning or other (practical) tasking with respect to the event is undertaken wholly or partially by other parties.

Advertising activities aimed at healthcare personnel

Art. 9. In undertaking professional events which provide access by pharmaceutical companies to advertising and marketing, this shall be kept separately from the other professional content of the event.

Sec. 2. If pharmaceutical companies are given the option as part of professional arrangements for advertising, exhibiting, film shows, product information, etc., this shall be done on the basis of a prior agreement on the terms and conditions, including the financial terms.

Sec. 3. Modest entertainment expenses may be born as part of advertising by a pharmaceutical company, namely during calls by a medical sales representative. Entertainment expenses shall only be provided for the doctors, pharmacists or pharmacy employees at whom advertising is directly aimed.

Sec. 4 Doctors, pharmacists and pharmacy employees shall not request financial services from a pharmaceutical company for purposes that have no connection with professional or scientific events and which conflict with this agreement.

Gifts and prizes

Art. 10. Pharmaceutical companies shall not, for advertising and sales purposes, offer or promise prizes or financial inducements to doctors, pharmacists or pharmacy employees. This shall also apply to benefits in kind unless these are of insignificant intrinsic value and are related to doctors, pharmacists or pharmacy employees' practice of their business or are given to mark a recipient's red letter day.

Sec. 2. Doctors, pharmacists and pharmacy employees shall not ask pharmaceutical companies for services that conflict with Sec. 1.

Professional events and advertising aimed at the general public

Art 11. Pharmaceutical companies may sponsor healthcare activities/events by pharmacists aimed at the general public providing that the sponsoring pharmaceutical company does not actively participate in running the event. Sponsorships for such arrangements are covered by the provisions of the agreement on NSL notification/briefing, cf. Art. 8.

Art 12. A pharmacy may make advertising space available to a pharmaceutical company at the pharmacy or in advertising matter published by the pharmacy. The pharmacist shall only receive payment therefor if it is clearly stated that it refers to advertising for a medicinal product/ pharmaceutical company.

Regulation and right to complain

Art. 13. The parties shall set up NSL to monitor compliance with the provisions of this agreement by pharmaceutical companies and the healthcare personnel covered by the agreement by way of the NSL notification/briefing scheme, cf., Art 8, and by dealing with cases of complaint.

Sec. 2. The parties shall lay down rules in the statutes of NSL for the composition of and appointment of personnel to the Board, secretariat operations and funding for the Board. The Business Committee shall be unanimous with respect to appointment of the Board's chairman, members and head of secretariat and approval of budgets.

Sec. 3. NSL's tasking, competencies and duties shall be laid down in the statutes for the Board.

Sec. 4. Corporate members of Lif, IGL and PFL and companies that have acceded to NSL, doctors, pharmacists and their organizations shall be entitled to appeal to NSL.

Sec. 5. NSL tasking in connection with medical information matter shall be regulated in accordance with current Acts and Statutory Instruments, including the applicable SI on Advertising. Medical information matter shall further be regulated by the generally accepted codes for good information practice and the medico-ethical and legislative requirements laid down in NSL's guidelines and statutes.

Effective date and termination

Art. 14. The agreement shall enter into force on 1st June 2007 and may be terminated by the parties at six months' notice. The collaboration agreement between the Danish Medical Association and Lif, etc., on the terms and conditions for collaboration between the medical profession and the pharmaceuticals industry and the collaboration agreement between the Danish Pharmaceutical Association and Lif, etc., on sponsorship of professional events shall cease contemporaneously, cf. however Sec.2.

Sec. 2. The provisions of Arts. 8, 11, 12 and 13 shall only become effective when NSL has been established. In the interim period, compliance with the agreement shall be monitored by NMI, the Danish Board of Pharmacy Ethics and the Medical Ethical Board in accordance with the provisions of the collaboration agreements in force hitherto. The parties shall endeavour for NSL to be established by 1st January 2008. The parties have further agreed that there shall be an appraisal, *inter alia* of NSL operations, within twelve months of NSL's establishment.

Sec. 3. The agreement shall be subject to ongoing assessment and shall be reviewed for any revision required by 1st January 2009 at the latest. Other parties may sign up to the agreement and other organizations may actively accede to the agreement via an accession instrument with the special terms and conditions applying to their sector.

Copenhagen 31st May 2007

(Signed)

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Niels Kristensen, Danish Pharmaceutical Association

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