Collaboration agreement between Lif and Capital Region of Denmark on knowledge-sharing, professional advisory services and funding for continuity training for healthcare professionals:

Introduction and purpose

This collaboration agreement sets out the mandatory framework for cooperation between pharmaceutical companies and the Capital Region of Denmark's hospitals for communicating and sharing professional knowledge and continuity training for healthcare professionals. The agreement shall be subject to the framework of applicable legislation, the industry's ethical rules, the eligibility rules in the Administration and Medicines Acts, and the Danish Region's joint regional policies for continuity training and skills development dated 8 February 2018.[1] See Appendix 1 for a description of the legislation and industry's ethical rules.

The collaboration agreement determines that the Capital Region of Denmark is to approve and select healthcare professionals for participation in continuity training activities provided by pharma companies in a transparent, independent manner clearly anchored in management. Professional meetings shall be prearranged and agreements between pharma companies and healthcare professionals employed by hospitals for participation on advisory boards are to be subject to management approval.

This is so as to ensure that:

- The prescription of medicinal products and other forms of treatment shall only be done as result of a medical assessment.
- Employees shall not be subjected to subjective or financial influences.
- Procurement of medicinal product, etc. shall be done on the basis of objective and financial criteria.
- Maintenance of confidence that hospital and hospital pharmacy personnel are not acting on the basis of personal or financial interest.

The agreement has been drawn up on the basis of the fundamental consideration that collaboration on sharing medical knowledge and continuity training for healthcare professionals is both necessary and in the interest of both parties, since it supports:

- Building strong professional competencies and mutual skills.
- Communicating and sharing new knowledge of new research results, new therapeutic progress, adverse reactions, etc.
- Optimal medicine usage and treatment of patients.
- Research and development of new, improved medicinal products.
- The Danish health service as an attractive place for life science companies to invest in research.

[1] The ethical rules have been drawn up by the independent Ethical Committee for the Pharmaceutical Industry in Denmark (ENLI). ENLI's purpose is to ensure professional, objective and independent collaboration between associated pharma companies and other parties in the health service and to ensure transparency in associated companies' relations with stakeholders.

Art. 1. Efficient administration

Sec. 1. Hospitals, healthcare professionals and companies are all interested in the framework for collaboration being effective and flexible. Accordingly, the parties acknowledge a shared responsibility for ensuring flexible administration of the rules (formal requirements) of the collaboration agreement in daily routines that ensure due consideration of the practical planning of professional events, including relevant timetables and deadlines.

Formal requirements for ensuring managerial competencies and 'arm's length' between the healthcare professionals and the pharma company

Art. 2. Requirements associated with planning and holding meetings

Sec. 1. Meetings must have a professional purpose.

a) Meetings between company representatives and hospital personnel shall always have been agreed with the healthcare professional(s) and the purpose of meetings must have been pre-arranged. Unannounced company calls and meetings shall not be permitted.
b) Appointments must be made in writing (possibly as e-mail correspondence).
c) The content and format of larger meetings (>3 participants) shall have been pre-approved by departmental management.
d) Company representatives shall register their presence in hospitals in accordance with hospitals' current procedures and requirements.

Art. 3. Requirements for participation on advisory boards

Sec. 1. Pharmaceutical companies shall submit any draft agreements between them and healthcare professional employed at the hospital for participation in company-initiated advisory boards to the head of department (although their immediate manager if participation relates to heads of department themselves) so as to obtain the manager's written approval of an agreement between the company and the healthcare professional in advance. Please see Appendix 2 for a more detailed description of advisory boards.

Sec. 2. The participation of healthcare professionals employed by hospitals on company-initiated advisory boards must always have a relevant scientific, research or similar professional purpose. In contrast, advisory boards intended to contribute to corporate marketing activities, etc., shall not be permitted.

Sec. 3. Doctors, pharmacists and dentists shall also be obliged to apply in advance to the Danish Medicines Agency for permission to participate on a corporate advisory board, cf. legal provisions thereon.[2]

[2] Order No 1154 of 22/10/2014 on the affiliation of healthcare professionals to pharmaceutical and medtech companies and special medical equipment businesses.

Art. 4. Notification and managerial approval of pharma companies' continuity training events

Sec. 1. Before issuing written invitations to continuity training events for a hospital's healthcare professionals, a pharma company shall always send them to department management for approval by department management (or the immediate manager if department management themselves wish to attend):

Sec. 2. Department management shall give approval for events intended to be held on-site at the hospital (e.g. in a department) and who and how many may attend. Department management shall also actively consider whether the hospital should be co-organiser or whether the company should itself be the organiser.

Sec. 3. Select and approve which healthcare professionals can attend continuity training events held by pharmaceutical companies themselves or which are held off-site from hospitals (such as conferences, after-hours meetings, courses, symposia, etc.).

a) Pharma companies may indicate the maximum number of invitations, also if as part of the events they are covering delegates' associated expenses (e.g. travel or overnight accommodation). Management shall give approval for whether delegates can have associated expenses covered by the company.
b) The company's invitation may state whether the continuity training event is targeted at healthcare professionals with special competencies or (sub)specialisms. Professional continuity events shall not be targeted (directly or indirectly) at specific individuals.
c) The pharma company may exceptionally reject management's choice of participant if this is done on the basis of applicable legislation, corporate or industry-specific compliance or impartiality rules or the individual's lack of relevance with respect to the targeted competencies/(sub)specialisms.

Art. 5. Management approval of sponsorship for healthcare professionals' attendance at international congresses arranged by a third party

Sec. 1. Pharma companies that issue invitations to attend international congresses (organised by a third party, often international scientific societies) held either in Denmark or abroad at which healthcare professionals' attendance is sponsored, shall always forward written invitations to department management. As part of such sponsorship, companies may offer to be responsible for the practical organisation and coordination of participants' travel, accommodation, etc.

Sec. 2. Department management (or the immediate manager if the head of department him/herself wishes to participate) shall select, and give approval for, the personnel to attend with corporate sponsorship.

Sec. 3. The pharma company may exceptionally reject management's choice of participant if this is done on the basis of applicable legislation, corporate or industry-specific compliance or eligibility rules or the individual's lack of relevance with respect to the targeted competencies/(sub)specialisms.

Sec. 4 Department management (or an immediate manager) shall decide whether the company should be responsible for practical organisation for participants or whether the hospital wishes to be responsible for this itself. A decision on this shall be notified to the company.

a) The company shall notify management on what is covered by sponsorship, including the number of invitations and the extent to which sponsorship covers attendance fees, travel, accommodation and/or meals in connection with the congress.
b) The company's invitation may state whether the continuity training event is targeted at healthcare professionals with special competencies or (sub)specialisms. The invitation to the congress shall not be targeted (directly or indirectly) at specific individuals.
c) Companies shall also state whether a continuity training symposium/meeting is to be held outside the official congress programme to which delegates are invited, for example before the start of the congress or in the evening.
d) Companies shall never make sponsorship of healthcare professionals conditional on their attendance in specific parts of the congress's official programme or participation in the companies' own continuity training symposia on-site.

Sec. 5. Companies may also offer to pay hospitals for healthcare professionals' access to web-based presentations from congresses (e.g. live transmissions or on-demand). Such offers shall also always be approved by management, who shall also decide, if so, who and how many should have access to this.

Art. 6. Continuity training sponsorships for hospitals

Sec. 1. Hospitals can ask companies for sponsorship for continuity training events such as:

a) Continuity training events planned by the hospital.
b) Funding for the attendance of a given number of the hospital's healthcare professionals at a specific international congress (e.g. attendance fees, travel, accommodation and/or meals).

Sec. 2. Continuity training sponsorship agreements for hospitals must always been made in writing between the hospital (at relevant managerial level) and the company.

Sec. 3. Companies shall never provide sponsorship for continuity training events at hospitals for individual healthcare professionals (or groups thereof) outside the arrangements made with the hospital (at managerial level).

Sec. 4. Corporate sponsorships for continuity training events for hospitals predicate that companies can check in advance that the event will comply with the legislation and the industry's ethical rules. Accordingly, companies shall only provide funding for specific events and on condition that the company providing the funding is fully identified to the healthcare professional. Companies shall not provide unrestricted funding for continuity training funds or the like since this is incompatible with the legislation.

Sec. 5. Responsible hospital units shall appear as the issuer of invitations, which shall further state whether a pharma company has contributed to sponsorship for the event.

Art. 7. Control and sanctions

Sec. 1. The common rules agreed between Lif and the Capital Region of Denmark have been included in the pharma industry's ethical rules, according to which the Ethical Committee for the Pharmaceutical Industry in Denmark (ENLI) undertakes control and sanctions for corporate compliance with the rules by which companies must comply.

Sec. 2. The Capital Region of Denmark has decided that pharma companies contributing to continuity training events aimed at employees at the Region's hospitals shall agree to be subject to ENLI's jurisdiction (including requirements relating to rules, control and any sanctions) and to show documentation for this when contacting Capital Region of Denmark.

Art. 8. Other agreed points

Sec. 1. The parties have agreed that in addition to the agreement, a set of FAQs shall be drawn up to answer the questions regularly asked by hospital personnel and companies about interpretation of the rules. The FAQs are to be published on ENLI's website, with access via links to relevant regional websites. The FAQs are to be regularly updated and answers are to be coordinated between the parties before publication.

Sec. 2. The parties have agreed to jointly strengthen knowledge and openness and to monitor the field on an on-going basis. This includes publication of activities between pharma companies and the Capital Region of Denmark.

Sec. 3. The agreement shall enter into force on 1 May 2018. Activities started before 1 May 2018 but not finally completed before that date (such as collaboration agreements, preparations for invitations or those sent out for upcoming events, etc.) shall comply with the practice and regulation in the area applicable hitherto.

Sec. 4. Amendments to the agreement shall require the agreement of the parties. Lif or the Capital Region may terminate the agreement at six months' notice.

Copenhagen, dated:

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Capital Region of Denmark

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Danish Association of the Pharmaceutical Industry

Appendix 1 - *Regulation, control, openness and impartiality assessment*

Continuity training activities shall be done within the framework of legislation for the time being in force and the ethical rules of the industry.

All kinds of continuity training events arranged or sponsored by pharma companies shall comply with applicable legislation in the area, cf. Medicines Act and Order on advertising medicines, etc.

In running and sponsoring continuity training events, pharma companies shall act within the ethical rules of the industry laid down by the Ethical Committee for the Pharmaceutical Industry in Denmark (ENLI).[3] In instances when regulation by both the legislation and industry ethical rules applies, the strictest rule shall apply.

ENLI systematically controls pharma company compliance with applicable rules for holding continuity training activities targeted at healthcare professionals. Control is exercised by pharma companies being obliged to notify all kinds of (their own and sponsored) continuity training activities to ENLI.

The common rules agreed between Lif and the Capital Region of Denmark have been included in the pharma industry's ethical rules, according to which the Ethical Committee for the Pharmaceutical Industry in Denmark (ENLI) undertakes control and sanctions for corporate compliance with the rules by which companies must comply.

ENLI is authorised to hear complaints against pharma companies that fail to comply with the industry's ethical rules. Complaints may be made by hospitals, hospital personnel, companies and authorities.

ENLI makes a ruling in the case and can if necessary impose sanctions on the company in accordance with ENLI's sanctions regulations. Decisions are published on the ENLI website at www.enli.dk.

Affiliation Act[4]

Healthcare professionals in receipt of financial support from a pharmaceutical or medtech company to participate in an international congress (professional event held abroad) must notify their participation to the Danish Medicines Agency, as required in law. Notification shall be done via the Danish Medicines Agency's website. Doctors, pharmacists and dentists shall make arrangements with pharmaceutical companies on professional affiliation (such as with respect to clinical research, lecturing/teaching, advisory boards, etc.) and shall notify or apply to the Danish Medicines Agency for consent thereto.

Especially with respect to advisory boards, applications for consent shall be made to the Danish Medicines Agency prior to the doctor's participation. The Danish Medicines Agency will make a specific assessment thereof, also on the basis of whether the advisory board has relevant scientific, research or similar professional purposes.

Advisory boards intended to contribute to corporate marketing activities, etc., shall not be permitted.

[3] This shall apply to pharma companies that have acceded to ENLI's authority. All members of Lif automatically accede to ENLI. A schedule of affiliated pharma companies is available on ENLI's website at www.enli.dk

[4] Order No. 1154 of 22/10/2014 on the affiliation of healthcare professionals to pharmaceutical and medtech companies and special medical equipment businesses.

There shall be full transparency about healthcare professionals' affiliation with pharma companies since (individual) data thereon is published on the Danish Medicines Agency's website.

Administration Act - impartiality rules

Healthcare professionals shall not participate in continuity training events arranged or sponsored by pharma companies if this should give rise to ineligibility with respect to a specific case, cf. Administration Act. The question of impartiality shall always be addressed on the basis of a specific assessment of the present circumstances.

Healthcare professionals shall themselves be responsible ensuring there is no risk of ineligibility in their participation in accordance with the provisions on impartiality in the Administration Act (Chap 2)[5]. In the event of doubt about participation of a healthcare professional, their immediate manager shall decide. Decisions shall be submitted in writing to the healthcare professional.

Healthcare professionals' and pharma companies' responsibilities

Healthcare professionals shall be jointly responsible for ensuring that attendance at conferences and in continuity training is done within the framework of the impartiality rules.

Healthcare professionals shall be responsible for having documentation before the start of continuity training events to show that participation in continuity training activities funded by pharma companies has managerial approval.

Pharma companies shall be responsible for acting within the framework of the legislation and the ethical rules for the area, cf. ENLI's rules. Companies must be able to show documentation that agreements have been made lawfully and that invitations to continuity training events have been submitted in advance to the relevant managerial level, cf. provisions of the collaboration agreement thereon.

[5] Chapter 2 Administration Act - ineligibility

Art. 3 Persons engaged in public administration shall be ineligible in a particular case if:

1) They themselves have a special personal or financial interest in the outcome of the case and either are or have previously been a representative of a party in the same case that has such an interest,

2) Their spouse, relative or relation by marriage in an upward or downward line or sideways such as the children of brothers or sisters or other closely related individuals have a special personal or financial interest in the outcome of the case or represent somebody with such an interest,

3)They participate in management or are otherwise closely associated with a company, association or another private legal person with a special interest in the outcome of the case,

4) There are other circumstances which serve to create doubt about the impartiality of the person concerned.

Sec. 2. Ineligibility shall not however pertain if it cannot be assumed as a result of the nature or level of interest, its nature or the duties of the person concerned with case processing that there is a danger that a decision in the case could be influenced by inappropriate considerations.

Sec. 3. A person declared ineligible in a case shall not make decisions, participate in decisions or otherwise participate in considering the case concerned.

Art. 4 The provisions of Art. 3 shall not apply if it would be impossible for, or if there are very significant difficulties or misgivings about allowing, another person to take the place of the person concerned while the issue is being investigated.

Art. 6 A person aware of issues as set forth in Art. 3 (1) relating to the person concerned shall immediately notify their superior unless it is obvious that the issue is unimportant.

Appendix 2 – *Purpose of advisory boards.*

The aim of the participation of healthcare professionals on pharmaceutical company-initiated advisory boards is to establish professional forums in which healthcare professionals can provide medical advisory services and expertise to pharma companies. Advisory boards constitute a significant precondition for pharma companies' medical knowledge and understanding of new research paradigms and results, medical assessments of relevant clinical studies, the opportunity to be able to plan clinical trials in the best way possible and to develop medicinal products that provide patients with the greatest possible quality, efficacy and safety.

Doctors' participation in advisory boards is regulated, approved and published by the Danish Medicines Agency, cf. Provisions of the Affiliation Act, section on the 'Affiliation Act' in Appendix 1.

Primary examples of the purpose of advisory boards are given below. Advisory boards may include a combination of several of the medical purposes below.

Preparations for clinical trials	• Clinical trial design • Ideas for new trials • Define patient groups and number of clinical trials
Clinical trials	• Understand and interpret clinical data from phases 1, 2, 3 and 4 • Assess the need for new/supplementary data and trials • Interpret and understand data on adverse drug reactions
Scientific data and assessment	• Discuss new scientific progress and data on products and diseases • Both for own and external investigations/trials/data, etc.
Analyses	• Interpret and understand Real World Evidence • Meta analyses
Patient treatment	• Discuss clinical practice and guidelines • Resolve problems re. diagnosis, examination, treatment, follow-up, etc.
Research and therapeutic paradigm shift	• Understand new scientific breakthroughs and the opportunities these create • New forms of treatment, technology and health data for the future • Personalised medicine, mapping the human genome, artificial intelligence
Health plans in the health service	• Discuss implications, options and challenges relating to new national (or regional) disease plans/actions/packages, etc. • E.g. cancer packages, cardiac/diabetes/prevention plans, etc.