

FAQ – for Collaboration Agreement between Lif and the Capital Region of Denmark

(The FAQs have been jointly drawn up by Lif and the Capital Region of Denmark)

1. Questions on scope and definitions

Q: When does the agreement enter into force?

(Asked by a company and a healthcare professional)

A: The agreement entered 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.) must comply with the practice and regulation in the area applicable hitherto. It is emphasised that reminder letters such as "save-the-dates" sent before 1 May 2018 are not regarded as being the same as an invitation. Subsequent events are covered by the new agreement.

Q: Does the collaboration agreement cover collaboration on clinical research?

(Asked by a company and a healthcare professional)

A: No, the collaboration agreement does not cover collaboration on clinical research. This also means that meetings limited to collaboration on clinical research are not subject to the agreement.

Q: Are all kinds of contractual forms of collaborations covered by the collaboration agreement?

(Asked by a company)

A: No, the collaboration agreement does not cover all kinds of contractual forms of collaborations. The agreement specifically includes advisory boards. Forms of collaborations as e.g. collaboration on clinical research, recruitment of speakers/instructors or the like are not regulated by the agreement, but are regulated within the framework of legislation, ENLI's ethical rules and the region's rules of sideline occupations.

Q: How does the agreement defines "healthcare professionals"?

(Asked by a company)

A: The definition follows from the provisions on this in the Medicines Act: Healthcare professionals shall be taken to mean doctors, dentists, veterinarians, pharmacists, nurses, veterinary nurses, pharmaconomist, midwives, bioanalysts, clinical dietitians, radiographers, social and healthcare assistants and students of these professions.

Q: Does the agreement apply to healthcare professionals employed at hospitals who have a private practice in parallel with their hospital employment or some other form of contemporary private business – if relations with the company (agreements or invitations) are held within the framework of their private business unit /role?

(Asked by a company and a healthcare professional)

A: It depends on a specific assessment. Fundamentally, secondary employment must not conflict with main employment which the employment by the Capital Region of Denmark is assumed to be. It follows from this that the exemption from the agreement is only permitted if it involves a clear delimitation of an individual's employment at the hospital. Exemption can only occur if the relation has no significance for an individual's responsibilities, duties, presence, impartiality status, etc. in their employment at the hospital. In the event of doubt, healthcare professionals should clarify the issue with their immediate manager.

Q: Is the collaboration agreement for medicinal products exclusively?

(Asked by a company)

A: Yes, the collaboration agreement covers companies' activities regarding medicinal products exclusively. Activities that only concerns products that cannot be characterised as a medicinal product (either wholly or partly) e.g. medical equipment, skincare products or similar products are not covered by the collaboration agreement with Lif. The scope also follows the corresponding definition of field of application in ENLI's code on advertising.

Q: How long should pharma companies save documentation for compliance with the requirements of the collaboration agreement?

(Asked by a company)

A: The agreement does not set any specific requirements. However, it is recommended that companies should keep relevant internal documentation for at least 12 months.

2. Questions about invitations

Q: Is a company obliged to pay for delegates' travel and accommodation if the head of department rejects a company's offer to be responsible for practical organisation and coordination of delegates' travel, accommodation, etc. in connection with the invitation to a congress?

(Asked by a company)

A: No, if management reject an offer made by a company, it follows that the company is not subsequently required to pay. It also follows that the company is always responsible for compliance with the industry's ethical rules on travel and accommodation if it is providing sponsorship. In such cases, the parties are free to agree the precise details of organisation and sponsorship.

Q: Is it permitted for companies to provide a copy programme for information purposes for a continuity training event to healthcare professionals?

(Asked by a company)

A: It is not permitted to send copy programmes for continuity training events for information purposes to one or more specific healthcare professionals before the relevant head of department has received the invitation and decided who should attend. If the copy information is not targeted at specific healthcare professionals but at the Capital Region of Denmark in general for all relevant healthcare professionals for the invitation and so as to provide information about holding the event and its content, this would not be seen as conflicting with the agreement.

Q: Should companies have the consent from the head of department before they can send them invitations by e-mail?

(Asked by a company)

A: No, the agreement establishes the basis for consent to send invitations because department management prioritise participation. E-mail addresses are listed on hospital websites.

Q: How can companies send "save-the-date" reminders under the agreement?

(Asked by a company)

A: "Save-the-date" reminders relevant for an upcoming event must always be sent to the department management. When management has been notified, "save-the-date" information can be circulated more widely if 1) it does not appear to be an invitation and 2) is not targeted at specific healthcare professionals but the Capital Region of Denmark in general for all relevant healthcare professionals for the upcoming event.

Q: May companies provide information about upcoming continuity training events, for example on their websites or newsletters which can be accessed and read by the Regions' healthcare professionals?

(Asked by a company)

A: Yes, pharma companies are free to circulate information about continuity training events, for example about the event's programme, time and place. The key issue is that such general information about the event: 1) must not be characterised as an invitation and also that 2) there must not for example be access to an registration module /link or the like on the website for healthcare professionals. It is however permitted to send newsletters containing invitations if these are only targeted at and restricted to managerial hospital personnel (or other healthcare professionals NOT employed at the region's hospitals).

Unauthorised translation. In case of doubt the Danish version is always applicable and official

3. Questions about the requirement to have signed up to ENLI

Q: Why has the Capital Region of Denmark decided that pharma companies wishing to target their activities to the regions' personnel must have joined ENLI (the Ethical Committee for the Pharmaceutical Industry in Denmark)?

(Asked by a company)

A: The Capital Region of Denmark wishes to ensure that all providers act according to the same ethical standards and are subject to the same controls. All pharma companies are entitled to join ENLI.

Q: Is it permitted for non-members of ENLI to visit the Capital Region of Denmark's hospital clinics to provide product information?

(Asked by a company)

A: No, it is not permitted for non-members of ENLI to provide product information to hospitals in the Capital Region of Denmark. The Capital Region of Denmark only allows companies listed on ENLI's member's site at www.enli.dk to contact its hospitals. This is the result of the Region's decision that companies must provide documentation for this when contacting the Capital Region of Denmark.

Q: Is it permitted for non-members of ENLI to make agreements with healthcare professionals at the Region's hospitals for participation on advisory boards?

(Asked by a company)

A: No, it is not permitted for non-members of ENLI to make agreements with healthcare professionals at the Regions' hospitals for participation on advisory boards. See also the answers above.

Q: Is it permitted for non-members of ENLI to invite healthcare professionals employed by the Region's hospitals to continuity training events held by companies or to provide sponsorship for invitations to international congresses?

(Asked by a company)

A: No, it is not permitted for non-members of ENLI to invite healthcare professionals employed by the Region's hospitals to continuity training events held by companies or to provide sponsorship for invitations to international congresses. See also the answers above.

Q: How shall pharma companies relate to the situation, if it is another unit in the group that facilitates the activity (e.g. enters into an advisory board contract) than the Danish unit that has joined ENLI.

(Asked by a company)

A: The central demand is that the pharma company has joined ENLI – and that the company ensures that the rules are met no matter which of the company's unites (e.g. headquarter or foreign subsidiary companies) carrying out the activity (e.g. entering into a contract or sending an invitation). The pharma company is free to organise such processes internally in the group as long as the company associated with ENLI takes the responsibility that the collaboration agreement in every case is complied with – and in case of breaches can be sanctioned by ENLI.

Q: Where can I read about the pharma companies that have joined ENLI and have permission to carry out activities aimed at the region's hospitals?

(Asked by a healthcare professional)

An updated list of the pharma companies that have joined the ethical rules and associated control under the auspices of ENLI is available on ENLI's web site <http://www.enli.dk/om-etisk-naevn-for-laeqemiddelindustrien/> under the item "Joined companies".
