



Agreement on common principles between Lif and Region of Southern Denmark for collaboration between pharmaceutical companies and the Region's hospitals on continuity training and skills development for healthcare professionals.

Introduction

This agreement provides the framework for a legitimate, transparent and for all the parties, value-adding collaboration between pharma companies and Region of Southern Denmark's hospitals on continuity training and skills development events targeted at healthcare professionals employed in hospitals.

The agreement is subject to the frameworks of:

- Common regional policies for continuity training and skills development for the Regions' healthcare professionals dated 8 February 2018.
- Current legislation, especially the Medicines Act, Advertising Order and Affiliation Order.
- The ethical rules of the pharma industry regulated by the Ethical Committee for the Pharmaceutical Industry in Denmark, ENLI
- Administration Act and the Medicines Act's impartiality rules.

The agreement enters into force on 1 June 2018

The common principles of the agreement are limited to pharma companies' offer for continuity training events targeted at healthcare professionals employed in hospitals. Accordingly, the agreement does not regulate other types of meeting or collaborative relations, under the aegis of contractual agreements on affiliation between a company and healthcare professional or hospitals such as collaboration on clinical research, advisory board attendance, or where healthcare professionals provide medical teaching services by way of lectures, presentations, etc.

Purpose

Collaboration between the professional environments in hospitals and pharma companies is important for developing and quality assurance on medicine. Companies need feedback from medical environments on for example the efficacy of medicines and adverse reactions, etc., and medical environments need to be kept up-to-date professionally on scientific research and on therapeutic progress so as to be able to provide the best possible treatment to patients.

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.

At the same time, it is crucial that no doubt can be cast on the independence and impartiality of healthcare professionals when decisions are being made on the treatment of patients and on providing medical advice.

When appointing employees to advisory committees for example, it must be ensured that they do not unintentionally become ineligible as a result of the duties to which they are assigned, leaving them worse set as a result for training and education than their colleagues.

On this basis, the collaboration agreement provides that hospitals are to approve and select healthcare professionals for participation in specific continuity training events provided by pharma companies in a transparent, independent manner and clearly anchored in management.

Joint principles for continuity training collaboration

1. Pharma companies wishing to support specific continuity training and other skills development activities are to contact hospital management. Hospital management will make decisions on participation, including the selection and approval of personnel to participate in the activity. Management will notify the company as to whether they wish to accept the invitation and if so, who can participate. The Region's target is to respond within 14 days on receiving the invitation.
2. The activities concerned relate to invitations to companies' own professional events such as conferences, courses and symposia, etc. and invitations offering sponsorship for expenses associated with employees' participation in professional events arranged by a third party (such as international scientific congresses). Invitations carry with them the obligation to participate in the professional event concerned but apart from this, there must be no further obligations from participation.
3. The company's invitation may state whether the continuity training event is targeted at healthcare professionals with special competencies or (sub)specialisms. This means that professional continuity events must not be targeted (directly or indirectly) at specific individuals. A 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 with impartiality rules or the individual's lack of relevance with respect to the continuity training event being provided.
4. The invitation to and continuity training events organized by a company must clearly state the attendance fees (if the event is not covered by *de minimis* limits). No attendance fees shall be charged for ordinary meeting refreshments, materials, etc., that are regarded as coming under the *de minimis* limit. If the professional content of the event has a substantial value, this is to be included in the attendance fees. On this basis, companies are to state any attendance fees for a specific event and these must be the same for all hospitals in the Region. Any questions relating to attendance fees must be clarified in dialogue between the company and Region of Southern Denmark's hospital management. Region of Southern Denmark pays for travel and any overnight accommodation. The hospital and company can agree on the details for organisation and payment, including whether hospital management accepts the company's offer, whether the hospital should itself book and pay or whether the hospital should settle with the company which is responsible for organising things. If relevant and required, this should include details for invoicing and payment of the costs in the invitation.
5. Hospitals and pharma companies may collaborate on continuity training events held by hospitals. Agreements on this are to be made between the company and hospital at management level. The responsible hospital unit must appear as the issuer of the invitations that also should state whether

one or more pharma companies have contributed financially or in some other way in supporting the event.

6. Companies may offer to pay the hospital for healthcare professionals' access to web-based presentations from congresses (e.g. live transmissions or on-demand). Such offers are to be approved by hospital management who will decide on how many and which healthcare professionals should have access thereto.
7. Pharma companies that hold, or provide funding for, specific continuity training events targeted at the Region's hospitals are to notify them to the Ethical Committee for the Pharmaceutical Industry in Denmark (ENLI) which will check for compliance with the legislation and industry ethical rules, including whether the rules on professional relevance and the level of hospitality and location are being complied with (e.g. prohibition against entertainment and extravagance or luxuriousness). The invitations must state that the continuity training event has been notified to ENLI.
8. Hospitals and their personnel must not ask companies for funding for continuity training funds, events, etc. as this is incompatible with the legislation. One precondition for companies being able lawfully to fund continuity training events is for them to check and provide documentation that the event fully complies with legislation and industry ethical rules.
9. Hospitals, healthcare professionals and companies all have an interest in the framework for collaboration being effective and flexible. The parties therefore recognise their mutual responsibility for the conditions for collaboration being good and unbureaucratic and take into account the practicalities of planning continuity training events, including relevant timetables and deadlines. The parties to the agreement agree that constructive, trusting dialogue between hospital management and companies constitutes an important springboard for valuable collaboration on continuity training and skills development within the framework of the principles of this agreement. The parties agree that there should be joint discussions at least once a year on the current terms and conditions for collaboration, including any challenges and possible joint solutions thereto. In the first instance, the parties will also assess their shared experience of the attendance fees scheme.

Vejle, dated _____

Copenhagen, dated _____

Region of Southern Denmark

Danish Association of the Pharmaceutical Industry