



Sveriges
Kommuner
och Landsting



Swedish Labtech



AGREEMENT REGARDING RULES OF COOPERATION

CONCERNING HEALTHCARE FINANCED BY PUBLIC FUNDING, THE PHARMACEUTICAL INDUSTRY, THE MEDICAL TECHNOLOGY INDUSTRY AND THE LABORATORY TECHNOLOGY INDUSTRY

The Swedish Association of Local Authorities and Regions (Sw. *Sveriges Kommuner och Landsting*, SKL), Läkemedelsindustriföreningens Service AB, Swedish Medtech and Swedish Labtech have agreed on common rules for how employees and senior management in healthcare and industry shall cooperate and interact with each other.

It is the view of the parties that collaboration between healthcare and industry is an important part of the development of healthcare as well as industry. With these rules, the parties wish to safeguard a continued development of collaboration in a trustful manner.

The rules have been jointly developed in response to external demands for increased transparency, moderation in all collaboration, and the need for a clearer allocation of responsibilities between healthcare and industry, such as the responsibility of healthcare authorities for the training of employees.

In the agreement, the group to which these rules apply is described and certain terms and definitions are provided.

The parties shall work to ensure that the members of each party, respectively, have a properly functioning self-regulatory system for the purpose of maintaining a good level of compliance to these rules.

The parties agree to collectively reevaluate the rules once a year, in order to adjust as needed.

This agreement shall be in effect from 1 January 2014, until further notice. These rules replace the former rules of cooperation between the parties.

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1. TERMS AND DEFINITIONS

Secondary employment	Any temporary or permanent employment or assignment which is carried out as a sideline activity and not related to private life.
Senior management	Director, medical director, head of section/ division /operations, or any other official in a principal position.
Healthcare	Healthcare financed by public funding in county councils, regions or local authorities, and by private entities with healthcare agreements (Sw. <i>vårdavtal</i>) or under LOV (the Swedish System for Freedom of Choice Act [Sw. <i>Lag om valfrihetssystem</i>]).
Industry	All companies within the pharmaceutical, medical technology or laboratory technology sectors, who act on or target the Swedish market.
Employee	All healthcare professionals, such as persons employed by healthcare, students under education or training, contractors or consultants.
Medical technology product	Cf. 2 § the Swedish Act (1993:584) on Medical Technology Products.
Meeting	A meeting regarding product information, service information, therapy-oriented training, a scientific meeting, or other related types of meetings or gatherings where healthcare professionals and senior management interact with the industry.
Healthcare authority	County council, region or municipality responsible for healthcare.
Contracting authority	Governmental, regional or local authority as defined in the Swedish Act on Public Procurement (LOU) Chapter 12 Section 19.
Operations manager	Within all healthcare, an operations manager shall carry the general management responsibility and be responsible for the operations.

2. GENERAL BACKGROUND

In Sweden, healthcare and industry have had a valuable collaboration for many years, providing important developments to healthcare. A close collaboration between healthcare and industry has been a prerequisite for developing and evaluating new methods and treatments.

An efficient form of cooperation between healthcare, research, and industry creates a mutual commitment to effective gathering of knowledge, structured introduction, and evaluation of treatments. In this way, conditions required for continuous improvements of healthcare are provided, which is of great importance to patients, as well as to the healthcare and industry sectors. The basis for all efficient forms of cooperation is to provide patients with appropriate, evidence-based, cost-efficient and secure care. The industry is a knowledge-intensive sector of major importance for Sweden. To effectively develop methods and products, close and trustful cooperation is needed between companies in this sector and healthcare.

Collaboration with the industry is an important part of the training and development of skills which are necessary to enable healthcare employees to enhance methods and treatments and to ensure a high level of patient and user security. The employer is responsible for its employees' training and development of skills and carries the responsibility for related costs.

The prerequisite for a healthy collaboration is good compliance to applicable legislation, such as legislation regarding bribery and procurement. This is to ensure that tax revenue is utilized correctly, that patients and users can be assured of getting the best possible care, and that the collaboration upholds the trust of the public.

3. SCOPE OF THE COOPERATION RULES

All employees including senior management in healthcare and industry are subject to these rules.

The healthcare shall apply these rules in dealings with all companies within the industry sectors of pharmaceuticals, medical technology and laboratory technology that act on or target the Swedish market, whether or not these companies are members of an industry organization. The members of LIF, Swedish Medtech and Swedish Labtech shall apply these rules throughout on all collaboration with employees and senior management within healthcare financed by public funding.

Employees and senior management within the healthcare and the industry shall, in addition to these rules and applicable laws, apply any rules, codes or policies that their respective employers have established for their own operations regarding travel, hospitality, secondary employment, and good business and ethical conduct.

4. BASIC PRINCIPLES AND RULES

The basis for all cooperation is documentation, transparency and reasonability, and shall be of benefit to all parties.

a. The following basic principles shall always apply:

The benefit principle

The cooperation between healthcare and industry shall be based on the activities of healthcare and on the needs of

patients, and shall be clearly linked to the company's business. A mutual benefit perspective shall be applied.

The transparency principle

Cooperation between healthcare and industry shall be open and transparent and in accordance with these rules and with applicable laws, regulations, good business practice codes and ethical codes and policies.

The proportionality principle

Throughout cooperation between healthcare and industry, the obligations of each respective party shall be reasonable as seen in relation to the obligations of the other party. In addition, all kinds of remuneration shall be proportional, reasonable and shall correspond to the fair market value of the service provided.

The moderation principle

A meeting which is in any way sponsored or arranged by industry shall be permeated by moderation. The requirement for moderation means that the privilege may not appear as influencing the behavior of the recipient. Collaboration between healthcare and industry shall not constitute undue influence and may not jeopardize or be perceived as jeopardizing the independence of healthcare.

The documentation principle

All forms of cooperation between healthcare and industry where any form of remuneration or recovery of costs occurs, whether involving single employees, groups of employees or a healthcare unit, shall be documented in writing, e.g. in the case of a decision or an agreement. Relevant documentation such as agreements, related reports, invoices, etc. shall be archived.

b. The following basic rules shall always apply:

The basic rule

Companies are not permitted to offer and healthcare employees are not permitted to ask for or receive benefits or other types of remuneration, or request actions which are in breach of these rules or the intentions thereof.

Meals

At meetings arranged by or in collaboration with companies, the companies may offer a moderate meal in connection with the meeting.

Alcohol

Hospitality including alcohol in connection with a meeting shall be restrictive and only occur at meals. Spirits may never be offered. Non-alcoholic alternatives shall always be made available.

Recreational activities

Recreational activities, including various forms of entertainment, may neither be financed by industry nor requested by healthcare employees in connection with meetings or other forms of interaction.

Travel

When it is possible, travel shall be arranged in economy

class. Additionally, travel time may not exceed the length of the meeting, including potential side events.

Accompanying individuals	Only participants in the meeting may be invited. Accompanying individuals may not participate.
Selection of location and venue	Companies may arrange or sponsor meetings outside of Sweden or the Öresund region only if the majority of the participants come from countries other than Sweden or if corresponding knowledge or experience cannot be provided there. The selection of location and venue for the meeting shall be reasonable in relation to the purpose of the meeting. Leisure resorts during season and places known for their exclusivity shall be avoided, e.g. locations for winter sports during ski season. The same applies to locations at which major international events are being staged at the same time as or in connection with the meeting, e.g. sports events. Neither shall companies contribute financially to meetings held at such locations.

5. SERVICE INFORMATION

With regard to service information, the parties are referring to the obligation under the Act (1993:584) on Medical Technology Products to provide information and advice on the daily operation and management of medical technology products, which are used or will be used in the healthcare unit where the service information is provided.

Service information includes information on the operation of products used, including product updates and replacement products, service visits and follow-up of such visits, and shall benefit to the healthcare employees in their daily routines. Companies may not identify information or a visit as [service] information or a service visit, for the purpose of promoting other products.

Service information should, where relevant, be provided to a group of employees at their workplace. The information should be provided during working hours and on the basis of healthcare's requirements and demand.

In addition to what is stated in the public procurement contract, the company which provides service information may carry all relevant costs for enabling the service information to be carried out, subject to the basic principles of this agreement.

6. PRODUCT INFORMATION

A product information meeting entails a meeting where information is provided about the specific properties, functions and handling of a pharmaceutical or a medical technology product. The content shall provide the participants with current up-to-date and relevant information. For medical technology products, product information is provided in respect of products which have not been purchased in a public procurement process and which are not yet used within healthcare, i.e. an action taken for marketing purposes.

An invitation to a meeting shall always be sent to the operations manager or the person he/she has

appointed. Copies of the invitation may be sent to relevant employees, i.e. the main target group of the meeting. The operations manager shall, in such case, be informed that a copy of the invitation has been sent and the individuals or groups which are the recipients.

The invitation shall include information about content, duration and, if possible, time and venue. In the heading of the invitation, it shall be stated that the meeting is concerning product information. The invitation shall be designed to clearly indicate that the information is not product neutral.

Any healthcare professional who participates in a product information meeting is responsible for obtaining his/her employer's approval for participation.

Product information should preferably be issued to a group of employees at the recipient's workplace and during working hours.

7. OTHER MEETINGS

Meetings other than those pertaining to product information can concern various forms of training and development of skills, e.g. therapy-oriented training, seminars, scientific meeting, congresses and symposia.

a. Meetings arranged by or in cooperation with industry

Industry may independently, or in collaboration with healthcare or a third party, arrange, pay for and be the sender of invitations to meetings aimed at healthcare employees. The scientific and professional program should be the dominant element and the purpose of the meeting.

Industry may only invite to meetings where the program has a connection to the company's own business areas.

An invitation to a meeting shall always be sent to the operations manager or the person designated by him/her. "Invitation" may also refer to an advance invitation. A copy of the invitation may be sent to relevant employees, i.e. the main target group of the meeting. The operations manager shall, in such case be informed that a copy of the invitation has been sent and the individuals or groups which are the recipients.

Pharmaceutical companies shall also send a copy of the invitation for the attention of relevant pharmaceutical committees. Medical technology companies shall, if appropriate, send a copy to the medical technology managers involved.

The invitation shall specify purpose and content, the duration of the planned meeting, time and place, the costs that the company intends to finance, and any additional arrangements. It shall be clear from the program and the invitation whether product information will occur.

As a rule, the meeting shall be held at the participants' workplace, or in the vicinity of the participant's workplace, or as close to such locality as possible, unless special circumstances warrant otherwise.

Participants in meetings may not be offered a fee from pharmaceutical companies for participating in a meeting, nor may participants receive or request a fee for his/her participation.

*English translation of the Swedish Agreement "Överenskommelse om Samverkansregler".
This text is for information purposes only and is intended to convey the content of the Agreement*

The employee participating in a meeting is responsible for obtaining the employer's approval for participation.

Industry may finance the venue, speakers, study materials, meals and similar as is necessary to carry out the meeting.

Travel and accommodation for individual participants may not be paid for by companies or requested by individual participants.*

****Transitional rule during 2014***

For meetings during a limited transition period from 1 January 2014 up to and including 31 December 2014, industry may pay 50 % of costs for travel, meals and accommodation for a healthcare employee and the entire participation fee, in accordance with former agreements.

b. Meetings arranged by healthcare or a third party

At a meeting arranged by or on behalf of healthcare or an association that organizes employees in the healthcare sector, the scientific and professional program shall be the dominant element and the purpose of the meeting, to render it possible for industry to participate as sponsor.

Sponsorship entails financial or other support that includes a market-based return, such as exhibit space, the opportunity to demonstrate a product, or other forms of exposure. Sponsorship differs from a donation, where no return exists. The names of the sponsors shall be communicated well before the meeting.

Industry may only offer sponsorship to meetings that have a connection to the company's own business areas.

The income generated to healthcare or an association generated by sponsorships may only cover actual, documented, reasonable and direct costs that are necessary in order to carry out the professional parts of a meeting. Examples of such costs are expenses for speakers, venues, moderate meals in connection with the scientific part of the meeting, or the cost for training materials. Sponsorship of meetings where the meal is the only actual cost may not be requested or offered.

Upon request for sponsorship, the organizer shall provide a complete budget for the activity as a basis for decision, where e.g. the aforementioned costs are specified.

The financial outcome of the meeting shall be reported to the company within six months after the activity is completed. If the revenues from all sponsors generate a surplus to the organizer, a refund shall, as a rule, be made to the companies that have participated as sponsors.

Sponsorship of the ordinary activities and internal activities of healthcare or associations may not occur, such as training for an individual clinic, planning conferences, or staff parties, neither may such sponsorship be requested or offered.

Travel, accommodation, and participation fees may not be paid for by companies or requested by individual participants.* Booking of travel and accommodation may not be provided by industry.

****Transitional rule during 2014***

For meetings during a limited transition period from 1 January 2014 up to and including 31 December 2014, industry may pay 50 % of costs for travel, meals and accommodation for a healthcare employee and the entire participation fee, in accordance with former agreements.

8. CONSULTATION AND ASSIGNMENTS

Employees and senior management within healthcare are often an important part of various activities, such as research, training, conferences, product development, and advising bodies, referred to as advisory boards. Participation should generally entail an assignment that falls under normal work duties. If the participation is of a consulting nature, it shall be regarded as secondary employment. In such cases, the employer's rules on secondary employment shall be applied.

The assignment shall be agreed upon in writing between the employee, the employer and the company. With a public employer, the agreement constitutes a public document. Remuneration for work shall be reasonable in relation to the content of the task and the time spent. Where applicable, reimbursement of expenses shall be paid in accordance with the employer's rules for travel and expenses. No other benefits, remuneration or gifts may occur. Compensation for work carried out as a part of normal work duties shall be paid to the employer.

Industry appointment of an advisory board entails engaging and compensating healthcare employees who provide independent advice and contribute knowledge in a particular area where such knowledge cannot be obtained within the company, and where resulting information is instrumental to subsequent activities. Thus, an advisory board is a small group with a limited number of participants, and the number of employees that are engaged should not be higher than what is necessary in order to achieve the identified purpose. The selection criteria when choosing an employee shall be based on identified needs, and the individuals from the industry who are responsible for the selection shall have the experience required to evaluate if a certain individual healthcare employee satisfies these requirements. An advisory board is an activity that may not have the purpose of influencing the participants.

9. COLLABORATIVE PROJECTS

Collaboration between healthcare and the pharmaceutical industry can have various features and different aims and purposes. In respect of clinical trials, for example, separate agreements have been concluded, and the conditions for those trials are regulated separately.

Collaborative projects between pharmaceutical companies and healthcare shall be understood in these rules as cooperation in projects with the aim of improving support to patients, enhancing quality of care, or otherwise contributing to increased patient benefit.

For such projects, the following applies:

Proposals for collaborative projects shall be sent to the operations manager, who shall subsequently inform any relevant organizational levels.

An agreement regarding a collaborative project may not constitute an assignment to an individual. The agreement shall be concluded by the pharmaceutical company and a unit within healthcare. The agreement may not imply exclusivity for the pharmaceutical company to provide certain kinds of services to one or more healthcare providers.

Both the healthcare and the company shall contribute to the collaborative project with resources such as funds, materials and working time.

A project plan shall exist, which, for example, shall regulate how the project should be evaluated. The collaborative project shall be reported to the public and be available in LIF's cooperation database.

10. REFERENCE CUSTOMERS

A reference customer is a unit within healthcare through which medical technology products and services are made accessible to customers and other stakeholders in order to develop and spread knowledge about the function of products or services in daily operations.

In order for a company to refer to a healthcare unit as a reference customer, the parties shall draw up an agreement that regulates all terms applicable to the relation between the parties. In the agreement, it shall be stipulated in which manner the company may use the reference customer for marketing purposes.

11. MARKET RESEARCH

Market research comprises questionnaires, interviews and focus groups with different goals and structures, and may only have the purpose of obtaining information, opinions and attitudes. Market research must not have the purpose of influencing the respondent, or to supply sales promotional contacts. When companies subject to these cooperation rules conduct market research, the person performing the research shall abide by the ethical guidelines for market research in accordance with ICC/ESOMAR.

A request for participation in market research can only be made by e-mail, SMS, letter or fax, unless otherwise agreed upon in the particular case.

The number of respondents may not exceed the number necessary to provide reasonable assurance of the outcome. The respondents' answers shall be treated in strict confidence and in accordance with the Personal Data Act (PUL).

Compensation for participation shall not exceed what is reasonable in relation to the time committed. For market research is completed via telephone or a questionnaire in a timely manner, no payment other than a symbolic compensation shall be issued. For more time consuming market research, e.g. an in-depth interview, compensation can be paid which relates to the time committed, but no more than 2.5 % of the current base amount/KPI.

The respondent is responsible for obtaining the employer's consent, where necessary. In case of financial compensation for participation in market research that is linked to professional tasks, the employer's consent should always be obtained.

12. PUBLIC PROCUREMENT

A large part of the cooperation between healthcare and industry relates to individual products that are, or may become, subject to public procurement. In such situations, it is of particular importance that healthcare employees and the companies maintain an independent attitude towards each other and in accordance with rules under law.

Communication before, during and after the procurement between companies and the contracting authority promotes good business. It is the responsibility of the contracting authority to inform healthcare and companies that public procurement is on-going.

When a group of products is subject to a public procurement process, it is important that participants from healthcare/purchase departments and companies communicate in a manner that is consistent with the public procurement process applicable at such time.

13. GRANTS

Industry may fund grants directed towards healthcare. A grant may be awarded, following the nomination of persons, for the promotion of a certain purpose. Awarding a grant is only permitted if the grant is related to an area which is linked to the company's own areas of business.

The grant shall, in essence provide professional improvement, e.g. in regard to future education and research or similar, and shall add value to healthcare. Selection criteria, purpose, grant committee, statement of reasons for the selection of the grant candidate, and the grant donor shall be open and transparent.

Healthcare personnel shall always inform his/her employer that a grant will be received. The grant may not be used as remuneration for work performed for the employer.

A grant may not be awarded to healthcare employees for the purpose of circumventing the intentions of these collaboration rules.

14. DONATIONS

Donations may never be offered or requested to fund healthcare's internal or regular activities. Industry grants may not be requested or offered to finance of recreational activities.

Donations to healthcare are allowed only if they are made to support research and development (R&D), and under the condition that the donation is transparent, well documented, and in accordance with this agreement and its intentions.

Donations to healthcare shall not be connected to past, present or potential future use, recommendation, sale or prescription of the donor's products or services.