

AGREEMENT ON COLLABORATION REGULATIONS

FOR PUBLICLY FINANCED HEALTHCARE, THE PHARMACEUTICAL INDUSTRY, THE MEDICAL DEVICES INDUSTRY AND THE LABORATORY DEVICES INDUSTRY

The Swedish Association of Local Authorities and Regions, Läkemedelsindustriföreningens Service AB, Swedish Medtech and Swedish Labtech have agreed on common regulations for how employees and managers in healthcare and industry should collaborate and interact with each other.

The parties deem that collaboration between healthcare and industry is an important part of the development of both healthcare and business and want the regulations to ensure that the collaboration can continue to develop in a confident and trusting manner.

The collaboration regulations have been jointly developed based on the world's demand for increased transparency, moderation in collaboration and the need for a clear division of responsibilities between healthcare and industry, e.g. regarding the healthcare principal's responsibility for continuing education.

The regulations consist of two parts: A jointly agreed policy with basic principles and regulations of a long-term nature, which constitute the basic pre-conditions for collaboration. Wise and insightful application of these can be fully sufficient for trust in the collaboration. To support the collaboration, a specification with concrete collaboration situations is also appended, which the parties update continuously for the greatest possible relevance. Both the agreement and the appendix govern the collaboration.

It is the responsibility of the parties to work to ensure that each party's members have a well-functioning self-regulatory system in order to maintain good compliance with the collaboration regulations and that their employees and managers have knowledge of them.

The parties agree to jointly follow-up the regulations once annually.

This agreement applies from and including the 1st January 2020 until further notice and replaces previously agreed collaboration regulations.

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Applicable from and including the 1st January 2020 until further notice

General conditions

In Sweden, there has long been a valuable collaboration between healthcare, research and industry that has led to a significant development. For many years the collaboration has been a prerequisite for the development and evaluation of new methods and treatments.

The industry is a knowledge-intensive industry that is of great importance to Sweden, but in order to be able to effectively develop methods and products, a close and trusting collaboration is needed between the companies within the sector and healthcare. Good collaboration between healthcare, research and industry creates mutual commitment for faster knowledge collection, evaluation and introduction of new treatment methods and the phasing out of older treatment methods. This gives the conditions for constantly improving healthcare which is very important to society.

The starting point for all good collaboration is to provide patients with appropriate, evidence-based, cost-effective and safe care.

Collaboration with industry can be an important part of healthcare staff's continuing training and skills development, which in itself is necessary to be able to improve methods and treatment and to ensure a high level of patient and user safety.

Healthcare is constantly changing, while the demand for safer and more effective treatments is increasing. The parties must therefore update the regulations regularly so that they are adapted in-line with the times.

Care should be closer to patients, which means that it must, to a greater extent, be conducted in primary care, at home or remotely. Healthcare is also becoming digitalised rapidly. New ways of meeting or monitoring the patient are being developed. Pharmaceutical, medical and laboratory technologies are also becoming increasingly integrated, including through the development of new diagnostic methods, software and apps to support medical treatment.

Healthcare's need for competence supply and knowledge support places demands on new working methods where digitalisation and knowledge management provide opportunities for other types of meeting places. Travel-free meetings held remotely can enable knowledge acquisition or dialogue, where time or finances have been obstacles. Regions and municipalities' common systems for knowledge management can contribute to the dissemination of knowledge.

In all situations, it is important that healthcare employees and companies maintain an independent attitude towards each other and in accordance with the regulations contained in the legislation, this applies in particular to procurement.

Scope of the collaboration regulations

All employees and managers in healthcare and industry are covered by these regulations.

Regardless of whether a company belongs to an industry organisation or not, healthcare must apply these regulations to all companies within the pharmaceutical, medical device and laboratory device industries that act in or target the Swedish market.

Members of the Swedish Association of the Pharmaceutical Industry, Swedish Medtech and Swedish Labtech including parent companies and sister companies, shall apply the regulations in collaboration with all employees and managers in publicly funded healthcare.

In addition to these regulations and current legislation, employees and managers within healthcare and industry must also follow the regulations for travel, representation, secondary

occupations and other policies and business codes of conduct that each employer has established for their own operation.

Supporting principles and regulations

The starting point is that all collaboration must be documented, open to review, reasonable and must benefit all collaborating parties.

The following principles apply to all forms of collaboration

<i>The Trust principle</i>	Collaboration between healthcare and industry shall not entail undue influence and shall not jeopardise or be perceived to jeopardise, the independence of healthcare.
	The prerequisite for a healthy collaboration is good compliance with current legislation, for example regarding bribes, procurement and taxation. This is to ensure that the tax funds are used correctly, that patients and users can be assured of the best possible healthcare, and that the collaboration maintains the trust of the public. The collaboration shall withstand scrutiny and review based on the risk of jeopardising trust.
<i>The Benefit principle</i>	The collaboration between healthcare and industry must be based on healthcare operations and the patient's needs and be clearly linked to the company's operations. There must therefore be a mutual benefit perspective.
<i>The Transparency principle</i>	Collaboration between healthcare and industry must be open and transparent and in accordance with these regulations, statutes, business and codes of conduct and policies.
	For pharmaceutical companies, there are additional requirements for transparency via the European Federation of Pharmaceutical Industries and Associations. Value transfers to both individual employees and healthcare operations must be annually reported openly in the collaboration database of the European Federation of Pharmaceutical Industries and Associations.
<i>The Proportionality principle</i>	In collaborations between healthcare and industry, each party's obligations must be in reasonable proportion to the other's. Furthermore, all forms of remuneration must be proportionate, reasonable and correspond to the market value of the service carried out.
<i>The Moderation principle</i>	Moderation must be observed at events that are in any way supported or arranged by industry. The requirement for moderation means that the benefit must not appear to influence the recipient's behaviour.
<i>The Documentation principle</i>	All forms of collaboration between healthcare and industry where some form of compensation or cost coverage occurs must be documented in writing, e.g. via decision, contract or agreement. Relevant documentation such as the contract, related reports, invoices etc. must be stored for a minimum of 2 years from the end of the project. This applies whether it

concerns individuals or groups of employees or is at operational level.

The following regulations apply to all forms of collaboration

<i>Basic regulations</i>	Industry may not offer, and employees and managers within healthcare may not request or receive, benefits or other compensation, or demand measures that are contrary to these regulations or their intentions.
<i>Approval of participation</i>	The participant in a meeting is responsible for obtaining the employer's approval for participation.
<i>Meals</i>	The industry may offer a modest meal in connection with a meeting arranged by or in collaboration with the industry. For remote participation, meals may not be offered. Free meals can, depending on the type of meeting and frequency, entail a taxable benefit.
<i>Alcohol</i>	Alcohol consumption in connection with meetings must be restricted and only in connection with meals. Spirits must never be offered. Non-alcoholic alternatives must be available.
<i>Social activities</i>	Social activities or leisure activities may not be financed by industry or requested by employees within healthcare, neither in connection with meetings nor in socialising in general.
<i>Travel</i>	Travel must be planned so that arrival and departure take place as close to the assignment as practically possible. For air travel, economy class must be chosen. Well-justified exceptions can be made for travel (> 6h) outside Europe.
<i>Accompanying persons</i>	Only event participants may be invited. Accompanying persons may not participate.
<i>Sponsorship</i>	Industry can sponsor professional parts of specific activities or meetings that have a connection to their own operational area, for a reasonable return. Connection means that the company has products or conducts research in a certain area of therapy. Sponsorship may only refer to actual costs for single clearly defined activity/meetings. Sponsorship of normal operations, participation fees as well as travel and accommodation may not be provided by the companies or requested by healthcare.
<i>Choice of location and venue</i>	Industry may only arrange or sponsor meetings outside Sweden or the Öresund region if the majority of the participants are not from Sweden or if corresponding knowledge or experience cannot be obtained here. The choice of location and venue for the implementation of the event must be reasonable in relation to the purpose of the event. Seasonal resorts and locations known for their

exclusivity, such as winter sports during the ski season, should be avoided. The same applies to locations where major international events take place at the same time or in connection with the event - for example sports competitions.

Definitions

<i>Secondary occupations</i>	Each secondary occupation, temporary or permanent, which is carried out in addition to the position and which is not attributable to private life.
<i>Healthcare</i>	All publicly funded healthcare in county councils, regions and municipalities as well as private operations with care agreements or according to the Act on System of Choice in the Public Sector.
<i>Industry</i>	All companies within the pharmaceuticals, medical device and laboratory device industries that operate in or target the Swedish market.
<i>Employee</i>	Hired person, student in training or internship, contractor or consultant.
<i>Normal operations</i>	Normal operations in these regulations refers to activities within the day-to-day operations that a unit within healthcare has decided that it shall perform, in addition to statutory work tasks.
<i>Healthcare principal</i>	Region or municipality responsible for healthcare.
<i>Operations Manager</i>	In all healthcare, there must be an operations manager who is responsible for operations and who has overall management responsibility.
<i>Product information</i>	Product information refers to meetings with the aim of giving information about a product's specific properties or use for marketing purposes.
<i>Sponsorship</i>	Sponsorship means financial or other support and it includes a market-based return such as e.g. exhibition space, opportunity for product demonstration or other forms of exposure. Sponsorship differs from a donation, when there is no return.
<i>Meeting</i>	All forms of meetings where healthcare employees and managers and industry interact with each other. Meetings can also be held remotely.
<i>Consultation</i>	Employees and managers in healthcare who perform assignments for companies. Consultations can for example refer to assignments within research, training, conferences, product development and advisory boards.